# A Practical Guide to Understanding, Managing, and Reviewing Environmental Risk Assessment Reports

Edited by Sally L. Benjamin and David A. Belluck

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# Dedication

To our fathers, Louis Belluck and Norton James Benjamin, for their love of books.

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We wish to thank the 31 other professionals, who shared our vision of a comprehensive, general guide to environmental risk assessment, for their dedication to the idea and for their patience as our manuscript went through several iterations. We owe special thanks to Ruth Hull, who gave freely of her ideas, professional contacts, and support. Without her, this book would not have been possible. We thank our peer-reviewers and readers, most especially Dr. Hiai Rothmann. We also acknowledge the contribution of Steven David, who has successfully implemented many of the ideas in this book.

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# PART I

# The Risk Assessment Process

CHAPTER 1

# Introduction

**David A. Belluck and Sally L. Benjamin**

## CONTENTS



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## I. INTRODUCTORY REMARKS

This is a very different risk assessment book. Many risk assessment books target risk assessment practitioners exclusively, providing them with greater technical insights and complex methodologies to aid in professional practice. Other risk assessment books provide brief overviews of the risk assessment process and technical inputs for a lay audience.

In contrast, this book is intended to introduce environmental risk assessment and to also provide sufficient technical, procedural, and methodological knowledge to empower every reader with tools and information to participate in a risk assessment team, communicate effectively with colleagues, manage a risk assessment report, direct work of expert consultants, and critically review a completed risk assessment report. How is this done?

This book is essentially divided into two functional parts. Part One begins by introducing risk assessment as a process. Next, it discusses team building to plan a risk assessment report and hire a consultant to perform risk assessment work. Then, it discusses managing a consultant to prepare a risk assessment report. Finally, Part One concludes by discussing how to formally complete a risk assessment project. Part Two, presents a series of primers, succinct treatments of key risk assessment topics, to assist readers in conversing knowledgeably with risk assessment team members. Reviewing the risk assessment, in its parts and as a whole, is discussed throughout this book.

## II. YOU NEED THIS BOOK

You need this book if you are not an expert in every facet of risk assessment generation and review. While you may be expert in certain fields, you are likely to still need to understand, communicate, and work with other disciplines to complete a successful risk assessment. One of the great weaknesses of risk assessment is the lack of interdisciplinary linkage among its components.

It is common when preparing risk assessment reports for one expert to hand off a work product to another expert in a different field. Since each part of a risk assessment hinges on earlier parts, this is logical. Unfortunately, one great weakness of risk assessment originates when work products of one discipline are used by another, without the technical result of the exchange being checked. For example, an emissions expert produces a table listing those chemicals the emissions expert believes to be important, based solely on emission rates. However, a toxicologist might add or delete chemicals from the list, based solely on toxicity. The end-product of each discipline's independent view of important chemicals for the risk assessment is insufficient. A better approach, is for these experts to collaborate and arrive at a joint, shared vision of the important chemicals list.

It is, therefore, critical for all experts involved in a risk assessment to understand each other's decision logic, so where work intersects, they can collaborate successfully. When collaboration does not occur at the borders of disciplines involved in a risk assessment, erroneous results can propagate throughout a report, producing false

risk findings. This book is intended for persons who want to better collaborate on a risk assessment process to reduce preventable errors.

It is also intended for persons who want an introduction to risk assessment. Risk assessment literature is extensive. Excellent technical papers, guidance documents, and treatises exist for each scientific discipline involved in environmental risk assessment. Nevertheless, a gap exists. No single book presents a comprehensive treatment of practical issues routinely encountered by people who develop, review, or use environmental risk assessment reports.

Why was this book written? It is intended as a plain English discussion of what it takes to prepare a risk assessment report on time, within budget, and with sufficient technical credibility to be defensible. It provides step-by-step instructions on how to push through technical "smoke-and-mirrors" to determine whether risk assessors make a technically defensible case for their risk findings.

We intend this book to fill a gap in environmental risk assessment literature by presenting a comprehensive discussion of this important process and offering strategies for developing credible risk assessment reports on-time and within budget. Toward this end, we attempt to explain the risk assessment process in simple terms, introduce basic tools of project management, and offer concepts and techniques for managing many problems routinely encountered on risk assessment projects. This book is no substitute for technical risk assessment publications. It provides guidance on how to integrate documents on technical guidance, management and review, in order to develop a high quality risk assessment report.

This book is written by risk assessment practitioners for anyone who wants to understand, manage, or review a human health or ecological risk assessment report. While certain information in this book might be found in other documents, no book brings it all together as a single publication aimed at making every reader conversant in risk assessment.

As noted earlier, literature on the risk assessment process, and its component technical disciplines, is voluminous. Scattered across government publications (including websites, formal and informal guidance documents, library catalogues, and microfiche collections), academic writing (journals, books, theses, and conference publications), practical handbooks and field references, and trade publications, all this information cannot possibly be collated into a single source. However, we have compiled one of the most extensive collections of reference materials to be found in one book. Specifically, practitioners and general readers alike should refer to the Appendix (additional resources include Chapter 23, Scientific Library Risk Research for Risk Assessment, and the end of each chapter for a collection covering both recent materials and seminal works in risk assessment-related disciplines). Use of these book sections should save a reader enormous amounts of time, may lead to resources rarely listed by other finding tools, and will provide some indication of the vast reach of the risk assessment field, with all its multifaceted parts.

A novice risk assessor and risk assessment reviewer may encounter certain technical areas that they are uncertain how to even start researching. This book eases the learning curve by providing the process, discipline, and data categories necessary to consider when performing, understanding, managing, or reviewing a risk assessment report and indicating where essential information can be found.

As you will see repeated again and again throughout our book, it is our intention to help our readers understand how to start from zero and build and manage development of an acceptable risk assessment report or review a completed report. We do not hope to supplant or compete with the numerous technical risk assessment volumes currently in print. First, we will introduce the concepts of environmental risk assessment.

## III. INTRODUCTION TO ENVIRONMENTAL RISK ASSESSMENT

### A. Common Terms

The term "risk assessment" refers to both the risk assessment process and documents that result from that process. Procedurally, risk assessment is "an organized process used to describe and estimate the likelihood of adverse health outcomes from environmental exposures to chemicals. The four steps of risk assessment are hazard identification, dose-response assessment, exposure assessment, and risk characterization."* In risk assessment, risk assessors use data of known quality in a standardized analytical framework to estimate type and degree of risks posed by environmental contaminants. These estimates are referred to as "risk estimates" or "risk findings." The result of the risk assessment process is a document, also termed a risk assessment, which presents risk findings and describes how they were generated (see Chapters 2 and 3).

"Risk assessors," usually experts in toxicology or a related scientific discipline, are responsible for technical aspects of producing risk assessments. Risk assessors work closely with a project manager to ensure that data, assumptions, methods, and analytical framework used to generate environmental risk estimates meet current technical and regulatory standards. "Project managers" are responsible for managing a risk assessment project. They may have a science background, but need not be technical specialists. Instead, good project managers understand leadership, politics, and negotiation. They can work with a diverse set of technical and scientific experts, as well as with parties with opposing interests.

The primary purpose of environmental risk assessment is to provide risk managers with all available information in a form that facilitates scientifically informed decisions. "Risk managers" are those persons responsible for making a decision regarding environmental risk. "Risk management is the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risks, while taking into account social, cultural, ethical, political, and legal considerations."** Risk managers use risk estimates, derived through risk assessment, to determine whether a process, activity, or site poses significant risks to human health or the environment. Risk managers may

* From the Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997, Framework for Environmental Health Risk Management, Final Report, vol. 1, p. 61.
** From the Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997, Framework for Environmental Health Risk Management, Final Report, vol. 1, p. 61.

decide, for example, that estimated risks are acceptable, and no action is required, or that risks are too high and require remediation, mitigation, regulation, reduction, or prohibition. Risk managers tend to be non-scientists and may view risk estimates as indicators of "real risks," rather than mere estimates of risk. Risk managers should understand that risk estimates are one component in a multi-faceted decision making process.

Ideally, risk managers use "risk communication" as part of environmental risk decision-making. Risk communication is a means of establishing meaningful two-way communication with people concerned about risk estimates and risk management decisions that use these estimates. Two-way communication provides a risk manager with information about important social factors (such as economics, law, ethics, cultural norms, and politics) and better informs the risk management decision. It also provides information about a risk assessment process, risk estimates, risk decisions, and reasons for the decision to people concerned about risk management decisions (see Chapters 21 and 22).

Environmental risk assessment can come into play at every level of environmental decisionmaking. It has been used by lawmakers to develop statutes and by regulators to write rules, to formulate regulatory guidance, and to grant or deny permit applications (see Chapter 7). Private companies, as well as government agencies and other public entities, may use risk assessment to evaluate environmental effects of projects, both to assess potential liability and to demonstrate project safety to regulators.

Risk assessments can become controversial because of concerns for health, financial, legal, or other impacts. These concerns can create high degrees of controversy, the subject of the next section.

## B. Risk Assessment Controversy

Environmental risk assessment reports often generate controversy. Controversy stems from three sources:

- Important issues at stake
- Conflicting expectations for risk assessment reports
- Pressure to perform

### *1. Important Issues at Stake*

Risk assessment deals with a contentious subject: how society balances potential dangers posed by environmental contaminants (some with potential to cause cancer, birth defects, neurological damage, or species extinction) against our appetite for raw materials and saleable products, and inexpensive waste disposal. Risk assessment reports play a central role in risk management decisions on whether to require risk reduction activities to reduce human or ecological risks or to allow a site, activity, or facility to remain unchanged. Thus, environmental risk assessment occurs within a highly political realm with potential for serious outcomes affecting human health and environmental quality, on one hand, and affecting financial well-being of a

corporation or community and imposing legal liability or regulatory enforcement, on the other.

## 2. Conflicting Expectations for Risk Assessment Reports

Controversy is heightened by certain characteristics of risk assessment. In addition to being highly technical, and, thus, difficult to discuss, risk assessments often fail to meet commonly-held, but erroneous, expectations. Some citizen activists, for example, hope a risk assessment process will present an opportunity to kill a project. In contrast, project proponents may expect the report to provide irrefutable proof of the safety of a proposed project. The next sections will attempt to disabuse readers of some common misconceptions that result in conflicting expectations for risk assessment reports.

### *a. Risk Assessment Provides True Risk Levels*

Many persons expect the results of a risk assessment to provide true estimates of risk. This is a false expectation. Risk assessment can provide an estimate of risks within the framework and limitations of the risk assessment process, no more. Risk assessment is not a crystal ball. It cannot be used to predict exact risks. It cannot say that you will or will not be the person to have their health effected by a chemical, process, activity, or site. It can give risk estimates with associated limitations and uncertainties.

### *b. Risk Decisions are Based Solely on Scientific Facts and Risk Certainties*

Many persons, including some risk managers, believe that risk management decisions are dictated solely by risk findings. While many regulators choose to make risk management decisions strictly in line with risk findings, because of political considerations, this is not necessarily how risk assessment findings are supposed to be used. Risk findings are intended to be combined with nonrisk considerations, including economics and political factors, to determine whether a risk estimate will lead to some type of risk reduction action or prevent some type of action from occurring (e.g., issuance of a facility permit to emit air pollutants).

### *c. Risk Assessment Is a Research Activity*

Neither pure science nor pure policy, risk assessment does not entirely conform to either world. Environmental risk assessors bring science to bear in the world of environmental regulation, a world governed by both scientific principles and social values, as expressed in laws, rules, policies, and personal ideals. The result is an irksome alloy, guaranteed to leave everyone involved less than fully satisfied with the outcome.

### *d. Risk Assessment Findings are Unimpeachable, as Pure Science*

Although technical in nature, risk assessment is not pure science. This simple fact is often overlooked by risk managers and scientists alike.

On one hand, risk managers prefer an unassailable basis for their decisions and, therefore, they press for "scientifically defensible" risk assessments, reports that are sure to withstand all technical, political, and legal challenges because they have undergone the highest level of peer review and employ testable hypotheses. This is natural because they rely on risk assessment reports to make decisions with highly political and emotional consequences, as well as significant legal and regulatory ramifications.

On the other hand, environmental scientists also forget that risk assessment is not pure research science, especially when defending their professional work. Early in the education of environmental scientists, they learn to value technical rigor and the formal scientific process (hypothesis testing, peer review, and control of variables). When challenged, an honest scientist must agree that risk assessments fail to achieve the rigor of pure science. Many scientists face criticisms of risk assessment rigor by redoubling their efforts to perform a scientifically defensible assessment, but such efforts are doomed.

The problem does not stem from inherent flaws in risk assessment, but from a failure to recognize the difference between environmental risk assessment and research science. Whereas a research scientist articulates a hypothesis and then conducts tests under controlled conditions to learn about the natural world, risk assessment functions within a totally different process with a different purpose. The environmental risk assessment process does not control variables or test (or even articulate) a null hypothesis. Risk assessment acquires specific types of data for use in a standardized analysis in order to generate a risk estimate and discuss the uncertainties surrounding that estimate. Once this distinction is made, risk professionals can view challenges to risk assessment rigor in a new way. Specifically, they will see that, while it is appropriate to improve environmental risk assessment, if possible, it is inappropriate to hamstring the environmental decision-making process in a quixotic quest for scientific rigor equal to that demanded of research science. However, where science is employed, it must be current, applicable, and technically correct.

### *e. Risk Assessment is Junk Science*

Risk assessment is not junk science. It is not intended to meet academic levels of research and analysis because a risk assessment cannot be evaluated using common scientific hypothesis testing techniques. It is simply a regulatory and governmental analysis scheme to evaluate potential risks in a systematic and reviewable manner. Thus, although components within a risk assessment may achieve research levels of rigor, the whole report cannot. Expectations that risk assessments should meet hypothesis testing levels of performance are at best disingenuous and at worst junk logic.

### *f. Risk Management Decisions can Ignore Risk Assessment Findings*

Risk management decisions cannot ignore risk assessment findings in order to achieve a predetermined decision based on hidden agendas or political expediency. Court cases have shown that risk management decisions by administrative agencies not based in risk assessment findings cannot withstand judicial scrutiny.

### *g. Risk Assessment Guidance and Methods can be Ignored and Still Produce a Credible Risk Assessment*

International, national, and local risk assessment guidance, methods, data, techniques, and court decisions cannot be ignored. To do so jeopardizes institutional and risk assessment credibility as well as professional reputations. Risk assessment reports must meet generally accepted standards of risk assessment or fail critical review, with all its consequences.

### *h. Citizens Cannot Understand, Review, or Contribute to a Risk Assessment Report*

Given the chance and the information provided in this book, anybody can participate in a risk assessment in a meaningful capacity. The input-output analysis presented in this report allows the reader to critically evaluate all data put into a report to determine if it is properly generated, used, and interpreted.

### *i. All Data Used in a Risk Assessment are Equal*

All data are not created equal. Some are better than others. Data from a peer reviewed report can be of much better quality and, therefore, more reliable, than data generated by a party directly affected by a risk assessment report, especially since such data sets are unlikely to have been peer reviewed. Thus, reviewers must check that data of the highest available quality have been used in a risk assessment report. Where lesser quality data are used, the reviewer must ensure that their limitations for use in the risk assessment, and all uncertainties associated with their use, are fully articulated.

### *j. All Models to be Used in a Risk Assessment are Equal*

All models are not created equal. Some are useful for some situations and may not be suitable for others. Many models have never been fully evaluated to ensure that their outputs reasonably reflect reality. Any model used in a risk assessment should have a proven technical track record before it is accepted for a specific use. Reviewers must determine that this evaluation process has occurred for every model used in a risk assessment report.

### k. *Much of the Information and Data Presented in a Risk Assessment is too Complicated to Explain*

All information and data should be presented in a risk assessment in such a way that an educated lay person can understand the technical process, determine the source and validity of data inputs, and check the math. If this cannot be done, with a few notable exceptions (e.g., all the calculations done by a computer modeling program — however, the validity of the model, its inputs and outputs can be reviewed), then the risk assessment is not complete. Good science does not excuse bad writing or weak logic. All information, data, inputs, and outputs in a risk assessment should be presented in such a manner that it can be readily reviewed.

## 3. Pressure to Perform

Risk assessment functions under tight timelines, with limited budgets, and under constant pressure to produce results that are relevant to nonscientists. Pressure to be timely and cost-effective, and to still create a high quality report, invariably causes friction.

In the recent past there has been persistent pressure to make risk assessment less expensive and time-consuming. This consistent pressure occurs, despite the fact that risk assessments often represent a fairly small part of the total time spent in reaching a risk management solution.

### a. *Conflicting Demands*

Conflicting demands to reduce costs, shorten production time, and improve technical rigor, place those who produce risk assessments in a thankless situation. The result has been greater use of generic data, models, canned "risk assessment" software, or default assumptions. This can result in criticism that risk findings are unrealistic. Selecting the proper level of technical rigor in a risk assessment (and commitment to the resulting time lines, costs, and confidence in risk findings), often turns on the need for stringent analysis against the need for cost savings and efficient use of time. In practical terms, this balance of rigor against cost is usually based on a sense of the project's likely political or legal consequences, not on a scientist's need to prepare a technically defensible report capable of withstanding peer review, litigation, or public scrutiny.

### b. *Why Bother?*

So, why bother with risk assessment? For one thing, risk assessment is a process embraced by regulatory agencies, legislative bodies, and courts. For another, although environmental risk assessment will never achieve the rigor of pure science, it is a valuable and essential tool to lead to informed risk management decisions as society seeks to balance environmental safety against industrial growth and economic development. Risk assessment forms the technical underpinnings for risk management, a decision-making process by which society decides whether to accept or

reject risks posed by a site, activity, or facility. It is a key component of environmental decision-making and regulation in technologically advanced nations, including the U.S. When those involved in risk assessment recognize that a legitimate purpose of risk assessment is to bring science into public policy-making, they will be prepared to meet its challenges and may take pride in their ability to work with limited data, limited time, and limited budgets to create reasonable, clear, and honest appraisals of environmental risk.

## IV. WHO IS TECHNICALLY QUALIFIED TO PRODUCE A RISK ASSESSMENT?

### A. Different Risk Assessments Need Different Experts

Environmental risk assessments address risk to either human health (Human Health Risk Assessments, termed HHRAs) or ecological systems (Ecological Risk Assessments, termed ERAs). HHRAs characterize the nature and magnitude of risks to human health from exposure to hazardous substances, pollutants, or contaminants. Risk characterization can be quantitative (describing risk as a number) or qualitative (describing risk in relative terms, such as high or low). ERAs estimate impacts or potential risks to living things other than humans. An ERA may consider stress from habitat alterations and ecosystem disruption, as well as exposure to potentially toxic substances. Since ERAs might deal with potential risk to entire populations or ecosystems, as well as to individual organisms, they may require far more complex analysis than HHRAs, which typically deal with risks to individuals. Each risk assessment type requires different experts who are trained and experienced to perform the specialized and different tasks in an HHRA or ERA.

### B. Technical Credentials Needed to Perform Expert Tasks

Technical training and experience required to conduct HHRAs and ERAs differ. HHRAs require expertise in human health-related disciplines. ERAs require expertise in wildlife biology, ecology, botany, or other disciplines focused on health and interrelationships of nonhuman organisms. Although professionals probably exist with adequate cross-training to handle both HHRAs and ERAs, most risk assessment professionals specialize in one area. In fact, demand for sophisticated analysis in risk assessment may limit a professional's expertise to certain narrow aspects of a human health or ecological risk assessment.

An essential step in obtaining a quality analysis is to match professional credentials and experience to the type of risk assessment to be performed. Significant problems occur when unqualified individuals conduct risk analyses. There is an unfortunate trend for professionals without biological training, such as engineers and hydrologists, to treat health risk assessment as a type of physical science where a correct answer can be generated simply by plugging data into equations and calculating a result. Unfortunately, such simplistic analyses disregard the complexity and subtlety of the biological world and result in questionable risk estimates.

## V. RISK ASSESSMENT AS A MULTIDISCIPLINARY ENDEAVOR

The following discussion emphasizes HHRA, an emphasis that reflects the history of environmental risk assessment. HHRA has enjoyed a longer and more in-depth technical treatment, although an ERA paradigm was recently developed by the U.S. Environmental Protection Agency (U.S. EPA). Compared to HHRAs, a generally accepted technical guidance on ERAs is recent, and somewhat limited.

A risk assessment project is a multidisciplinary endeavor. A project manager leads a project, coordinating a team of experts from technical disciplines and non-technical professions. The precise mix reflects project needs. The core of a risk assessment project is typically analysis of environmental movement of chemicals and of their toxic effects on human or ecological health. This analysis requires environmental modeling, sampling, and data quality assurance and quality control (QA/QC), and involves toxicologists, ecologists, environmental chemists, modelers, statisticians, and experts in chemical procedures and analytics. A project may also benefit from involvement of a variety of other professionals. Attorneys, for example, may contribute to a project by drafting contracts that define and enforce project performance standards. Technical writers and editors help a team write a report that is both accurate and understandable. Risk communicators help a team explain risk estimates in meaningful ways to risk managers, political leaders, and concerned citizens. Planning, accounting, team-facilitation, and dispute resolution skills may also be required to produce a quality risk assessment report, on-time, within-budget, and in a useable form.

### A. Mandated Science

Risk assessment is a mandated science (see Figure 1). Neither pure science nor pure public policy, risk assessment reports are a hybrid of both. A risk assessor usually works on a multidisciplinary team of regulatory scientists under direction of a project manager. The goal is to generate a risk assessment report that provides credible risk estimates (see Figure 2).

### B. Team Work in Risk Assessment

A project manager must appreciate the importance of teams to successfully manage a complex environmental risk assessment project. This is true because risk assessments pose particular challenges to teamwork.

First, success of the project hinges on full participation by experts from a variety of disciplines. Each discipline brings its own paradigm, language, assumptions, and skills to the project, as does each individual. Such diverse views can lead to confusion and friction in a team setting. If a team is to generate a truly acceptable* final risk assessment report, a project manager must send a clear message that, although credentials and disciplines differ on a team, all team members have an equal duty

* An "acceptable" risk assessment report is more than "merely acceptable" in the common sense of the term. Here, "acceptable" requires a risk assessment report to meet or exceed all performance standards (e.g., all math and science is correct and can be verified by critical reviewers).

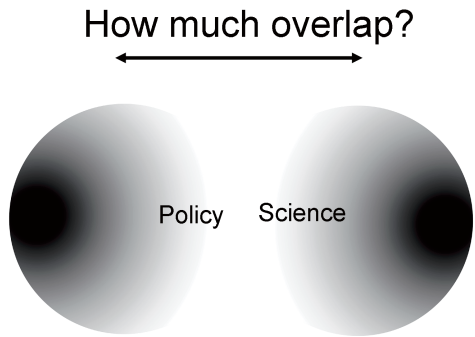


**Figure 1** Mandated science at the intersection of policy and science. (Adapted from Mandated Science, 1988.)

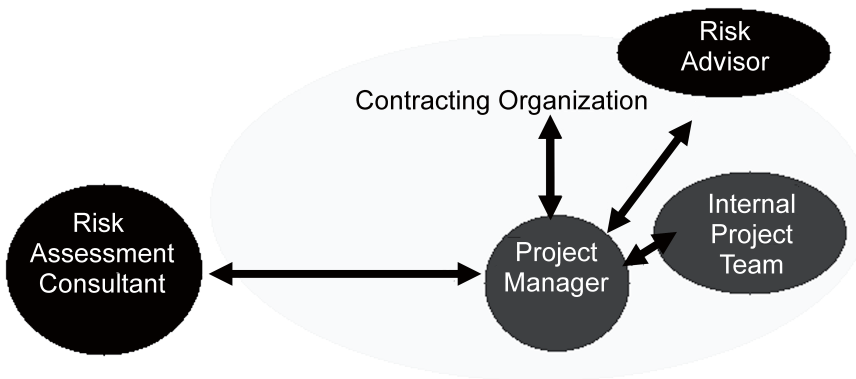


**Figure 2** Risk assessment teams.

to voice concerns, and to respond to concerns with respect. All team members must employ methods that allow all technical work to be verified and reviewed.

Some experts may resist teamwork, believing that there is one right answer and that their only task as a scientific expert is to determine that answer, not to explain how they perform tasks, and why, nor to debate ideas or consider alternate views. No matter what their credentials, such people will make poor team members. Arrogance will prevent them from helping a team to integrate their expertise into a project. This attitude can destroy teamwork and must be curtailed by a project manager. Otherwise, the power of teamwork will be lost.

Second, mixed loyalties arise when people involved serve two masters — an organization that pays them and a risk assessment team. Environmental risk assessment participants usually have differing goals. For example, an environmental risk assessment normally draws experts from several divisions of an organization, especially in large organizations, each division with a slightly different view of the project. Also, outsiders are sometimes involved, such as regulators or other government officials, citizen activists, or community leaders, or even industrial competitors.

Organizations may hire environmental consultants to provide specialized technical expertise. When team goals conflict with goals of their principal employer, team members will feel a degree of stress. A project manager, who typically lacks direct authority over team members, must acknowledge the stress, attempt to reconcile conflicting goals and, thus, win team member cooperation and support for the risk assessment process.

A third challenge to teamwork on a risk assessment project results from prior relationships among participants. People involved in an environmental risk assessment project — as project sponsors, affected parties, or reviewing authorities of a final product — are likely to know one another from involvement on other projects. Naturally, prior relationships affect expectations about roles, tactics, and agendas. If previous interactions were productive, a project manager is lucky. However, more often, prior interactions occurred in a win-lose setting. If so, a project manager must establish a new way for people to interact with each other. This requires a project manager to address assumptions and make explicit every aspect of how a report will be developed — including the basis of team work: team roles, project priorities, and working rules.

Although most professionals have experience with meetings, it takes more than meeting etiquette to create a team environment that allows members to contribute fully to the process. A project manager must help team members agree upon a legitimate purpose for a team. Then, based on its purpose, a team can identify roles team members should fill. Rules for working together must be developed, agreed upon, and enforced. Finally, a team should consider potential project outcomes and establish realistic project expectations that achieve a team's purpose.

Although much of how a team works is negotiable, there are issues not open to negotiation. Laws, rules, guidance documents, and generally accepted technical and scientific principles are clear examples of items not open to a group consensus-building process. Negotiating items that a professional and general populace accept as "given," wastes time and resources. It also endangers success of a project and undermines morale and professional credibility of those associated with the risk assessment. Negotiation of nonissues is a signal that certain players controlling a project are either not technically qualified or hope to kill the project.

Consensus-building in a team setting must never be used as a means to squelch expert input and determinations. Teams must recognize and respect expert opinions. Teamwork is a process to smooth the development of complex tasks, such as preparation of a risk assessment report. Consensus-building must not be used as a bludgeon to silence or marginalize an expert working within their field of expertise. For example, the opinions of four hydrologists do not outweigh the views of one toxicologist if the issue is toxicology.

## C. Roles in Risk Assessment Teams

Although team members may be equals within a team, a project manager must recognize that different team members play different roles in a risk assessment process. Certain roles will be assigned with specific responsibilities. For example, a project manager and risk advisor play unique vital roles on a project. These roles

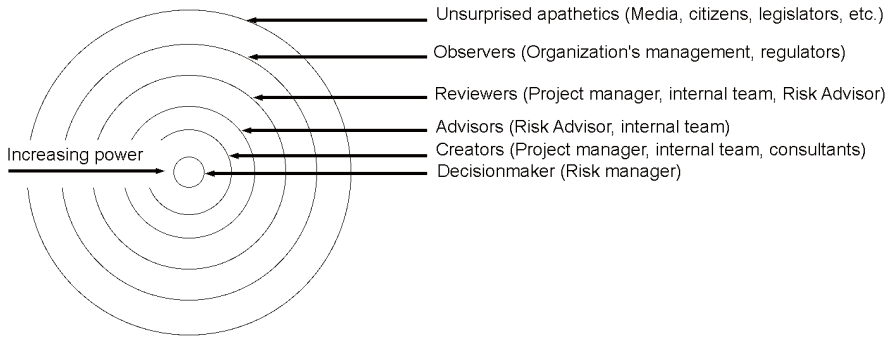


**Figure 3** Roles in risk assessment project development. (Adapted from Synergy, 1986.)

are discussed below. A project manager might work differently with internal team members versus outside experts. Staff, project proposers, and other paid participants will typically fill different roles than volunteers. Team members who are on loan may be less involved than team members who work for a project manager.

Certain generic roles can be identified for any project. It is useful to identify which role each participant may occupy on a risk assessment project (see Figure 3). As this figure indicates, most active participants occupy roles close to the center. Roles introduced below are discussed in more detail in Chapters 4 through 6.

### *1. Project Manager*

Project managers manage a risk assessment project. They oversee project communications, administer a work schedule, and budget for contractors and a project team, and ensure that resulting work meets performance standards.

### *2. Internal Experts*

In-house expertise is a tremendous asset to a risk assessment project. Depending on the nature and degree of internal expertise, an internal team may either perform risk assessment work, or oversee work performed by a contractor with specialized risk assessment expertise.

Even when a consultant is employed, internal experts play a vital technical role on a risk assessment project. As members of an internal project team, they help formulate a scope of work, review work plan adequacy, and set project performance standards. An internal project team can help a project manager anticipate and solve problems. A team can also provide oversight by reviewing interim and final deliverables to assure that consultant work meets process and product standards, as required under a project contract.

Support of internal experts can greatly enhance project credibility and speed internal acceptance of a risk assessment report; opposition can defeat a project. Internal experts bring technical expertise and organizational savvy to a project team.

They serve as both trustworthy sources of technical knowledge and as internal reality checks on outside consultants' views of a project. Therefore, a risk assessment project manager must make every effort to recruit and earn support from internal technical experts.

### *3. Risk Advisor*

A risk advisor is a person who has mastered the risk assessment process through experience on several successful projects. The exact role of a risk advisor is defined by an organization's needs. A risk advisor serves as mentor to a novice project manager, as a sounding board to an experienced project manager, and as a watchdog over outside consultants in areas where internal expertise is lacking. A risk advisor can also function as a technical liaison between internal-project staff, who may lack in-depth understanding of risk assessment techniques, and technical consultants. A risk advisor may be found within an organization, but often is hired from an environmental consulting firm. A risk advisor's first duty is to advance the contracting organization's interests. Due to an adversarial relationship between a Risk Advisor and external consultants, a Risk Advisor should not be an employee of a consulting firm hired to conduct a project (see Chapters 4, 5, and 6).

### *4. Consultants*

Since few organizations possess internal technical capacity required to conduct a credible risk assessment project, organizations in need of an environmental risk assessment hire consultants to perform technical risk assessment services. Consultants typically work under the guidance of a contracting organization's project manager with review by an internal-project team and risk advisor, discussed above.

The precise role of a consultant will vary somewhat depending on performance standards established for a project. However, in order to fulfill the basic role, a firm and individuals assigned to a project must be technically and ethically credible. Specifically, a consulting firm must either have technical experts on staff who are capable of performing required work or it must demonstrate professional affiliations sufficient to cover any gaps in expertise through subcontracting. A credible consultant will be prepared to prove technical expertise through statements of staff credentials and prior project descriptions. A reputation for honest dealing should be required of any consultant. An experienced firm will be able to provide names of satisfied clients. Individuals assigned to a project must also be trustworthy. Although this is more difficult to determine, it is important. Any ethical or legal breach will reflect badly on a project and on an organization represented by the consultant and its staff.

## D. Teams Establish Performance Standards

The purpose of an environmental risk assessment project is to define and generate an acceptable risk assessment report. An "acceptable" risk assessment report is defined as a report that meets all performance standards for a project, discussed in the following section. A team will define a complete set of performance standards

that articulates needs of the organization. A team will also ensure that the project adheres to these standards, as it proceeds.

### 1. Performance Standards

A team's first, most important, task is to establish "performance standards." Performance standards articulate a process a risk assessment project will follow, termed "process standards," and attributes of interim and final work products, termed "product standards." Every project has a timeline and a budget, for example. A precise project schedule and details of the budget should reflect specific project demands. A project schedule and budget are two basic performance standards. A team's analysis must typically go far beyond basic performance standards of schedule and budget. This is accomplished by articulating the purpose of environmental risk assessment and then, keeping that purpose firmly in mind, identifying all decisions necessary to accomplish that purpose.

For example, what degree of technical accuracy is required? An appropriate degree of accuracy depends on the expected use of a risk assessment. Is it for litigation and, thus, must it be highly defensible? Or, is it for planning, and will estimates and qualitative analyses be acceptable? Most risk assessment reports fall somewhere between these extremes. If litigation is a purpose of a risk assessment, it is realistic to expect aggressive scrutiny in court. A risk assessment report will need to be scientifically accurate and technically defensible to survive: models must be current and must be generally accepted, default values and assumptions must be realistic (or their use must be minimized), and data must be of the best quality. On the other hand, a high level of technical rigor may not be required, or appropriate, in a risk assessment report intended merely to aid internal planning. High levels of technical rigor, where it is not needed, may be a waste of resources (see Chapters 2 through 6).

### 2. Process Standards

Process standards address "how" questions. They define how a risk assessment will be conducted and managed and they define acceptable behaviors of project participants.

One fundamental process standard establishes how a contractor will be managed, by a proactive or reactive management approach. If a "proactive" contract management strategy is used, project work will undergo iterative review, comment, and approval throughout a project. "Iterative review" requires a consultant to submit each interim work product for team review as soon as a deliverable is completed. Each interim work product must meet all relevant standards before a product is accepted and a consultant is allowed to begin work on the next deliverable. If project management is reactive, product review starts only after delivery of a draft final report (see Figure 4).

A second important set of process standards will govern how communication will occur on a project. Specifically, how will communication occur within a project team,* between a consultant and project manager, and with outsiders (such as

* Throughout this book, use of the term "project team" always refers to staff of an organization that hires a risk assessment contractor. Contractor staff may, in actuality, also constitute a separate project team, but we refer to contractor staff collectively as "contractors" to avoid confusion.

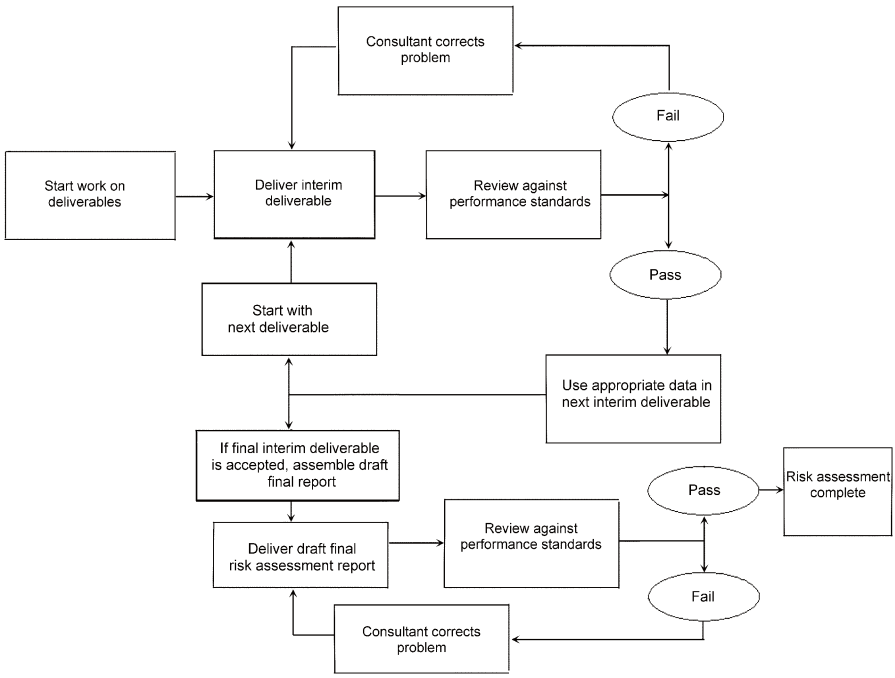


**Figure 4** Iterative review of consultant deliverables.

interested staff and managers within the organization, political leaders, citizens, and the media). In order to develop process standards for communication, a team first articulates internal and external communication needs, then selects appropriate techniques and, finally, assigns responsibility for maintaining communications channels (see Chapter 21).

Project review and communications are just two examples of many procedural matters a risk assessment team will address through process standards. Each decision on process standards affects how a project will proceed and how it will be judged.

### *3. Product Standards*

Product standards address "what" questions and, thus, articulate characteristics required from an acceptable work product. Product standards define the quality of a final product. They may also define quality of interim work products. Product standards establish the scope of a risk assessment — human health, ecological risk, or both? They also address the type of assessment to be performed — a quantitative or qualitative assessment — and a level of scientific rigor. They mandate rigor of technical review; they set the clarity and style of writing and editing; and they may specify a style and consistency of document layout, as well as myriad other nonprocedural aspects of a risk assessment.

### *4. Teams Apply Performance Standards*

After performance standards are established, the main work of a project manager and project team will be to ensure that a project meets these standards (see Part I). During the course of a project, however, certain performance standards may require modification. A consultant might identify unmet standards, for example. If so, a project manager should require a consultant to document reasons for failing to meet each standard and, based on justification, determine whether to drop, amend, or enforce a requirement. Unmet standards will also be discovered when a project manager and team review work products. Again, the issue is why a failure occurred and whether it matters.

## VI. AN OVERVIEW OF THE RISK ASSESSMENT PROCESS

Now that you understand the basics of environmental risk assessment and the role of teams and experts, we will integrate this information into practical methods to produce a risk assessment report.

There are four phases in risk assessment report development: planning, managing, accepting, and dealing with results. Chapters 4 through 6 discuss major steps in developing a risk assessment report. The process is capsulized in Table 1. This table can be used as it is presented, but it will function best if it is expanded or simplified to reflect specific project needs. Whether an expanded or simplified version of this form is used, a project manager and internal project team will need to perform, or oversee, all outlined steps.

### A. Phase One — Planning a Risk Assessment

Planning is the first phase of a risk assessment project. Planning deserves careful attention because it reduces "preventable problems." Preventable problems are those obstacles that could have been easily avoided or removed, if someone had anticipated them. After deciding to perform a risk assessment, an organization selects a project manager. The project manager then recruits a project team. A project team works with a project manager to develop a scope of work. A scope of work describes each important facet of a risk assessment project and serves as the basis for a Request for Qualifications (RFQ) or a Request for Proposals (RFP), and for project performance standards. An organization distributes or publishes an RFQ/RFP to notify contractors that it seeks services they may offer. Contractors respond by submitting bids, which a project manager reviews with an internal project team. A project manager selects a contractor, based on qualifications, project needs and cost, and then negotiates with a prospective contractor on specific contract terms and a project work plan. Parties sign a contract when they agree on a contract and work plan. If negotiations break down, a project manager may decide to negotiate with another qualified contractor.

**Table 1 Generic Risk Assessment Planning Form**

| Step | Actions |
|---|---|
| **Phase One — Planning a Risk Assessment** | |
| Is risk assessment needed? | Consider why the risk assessment is being done. Is it required, requested, or voluntary? Identify the site, activity, or facility to be assessed. |
| Staff the risk assessment | Build a project team. Assign staff to serve as project manager and project team members. Determine your role in the process. Assess skills and technical specialties needed to generate a risk assessment report and determine which skills are available in-house. Consider using a risk advisor to supplement team and project manager skills. Consider need for consultants to perform part/all of the risk assessment. |
| Fund risk assessment | Estimate required funding needed for the project. Determine actual/likely funding available. Encumber the financial resources (or develop alternate strategies for obtaining support, personnel, resources). |
| Determine report end-user needs | Set appropriate project goals and expectations. Establish clear performance standards to evaluate and demonstrate project success and failure. |
| Scope the risk assessment | Develop a risk assessment scope of work that includes project performance standards, including timelines and budget. |
| Distribute RFQ/RFP | Write, issue, publish, and distribute the Request for Qualifications (RFQ)/Request for Proposals (RFP) (if contractors are needed). |
| Hold a project kick-off meeting | Invite interested contractors and other interested parties to attend a project overview and ask questions. |
| Evaluate proposals | Evaluate submissions based on criteria outlined in the scope of work, especially project performance standards. |
| Select contractor | Select contractor(s)with skills to produce an HHRA or ERA and notify the firm of their opportunity to negotiate a contract. |
| Negotiate contract and contractor work plan | Negotiate a contract that includes a contractor work plan. Base acceptability of both documents on project performance standards. |
| **Phase Two — Managing a Risk Assessment (Including Iterative Review)** | |
| Mobilization | Initiate work. This assumes use of proactive development process illustrated in Figure 4 above to generate five deliverables. |
| Hazard evaluation | Collect and evaluate data. Produce a draft Chemicals of Potential Concern (COPC) and a final Chemicals of Concern (COC) list. For each COC, produce a source concentration or emission rate for use in the exposure assessment. Iteractive review requires submission of a draft hazard evaluation for review by the internal risk assessment review team. Failures to meet performance standards are identified and the contractor is notified of insufficiencies requiring correction. A deliverable that meets all performance standards is accepted and the contractor receives approval to initiate work on the next step. |

**Table 1 continued**

| | |
|---|---|
| Exposure assessment | Chemical-specific source concentrations or emission rates are used in fate and transport models, or environmental monitoring data are used, to calculate the concentration of each chemical in a given environmental medium at a location where organisms will be exposed. Exposure equations are used to calculate chemical specific uptakes or intakes. The draft Exposure Assessment is submitted an interim deliv-erable for iterative review and approval, as described above. |
| Toxicity assessment | Chemical-specific and chemical-mixture toxicology information is gathered. Chemical-specific toxicity values are obtained or derived from data found in the open literature. This information is used with exposure levels from the exposure assessment to characterize risks. The draft toxicity assessment is submitted as an interim deliverable for iterative review and approval, as described above. |
| Risk characterization | Exposure levels and toxicity values are coupled to calculate risks and impacts. The draft risk characterization is submitted as an interim deliverable for iterative review and approval, as described above. |
| Review draft report | Review of the report should be minimal if iterative review by the internal risk assessment team was thorough. |
| **Phase Three — Accepting a Risk Assessment (Including Iterative Review)** | |
| Accept final draft | Final review should focus on report clarity, completeness of explanatory materials, and integration of the interim deliverables into a coherent report. The conclusions, uncertainty analysis, and executive summary bear special scrutiny because they will not yet have been reviewed and they synthesize the reports various pieces. When using reactive risk assessment development process, all aspects of report must be evaluated. Any problems identified by reviews must be corrected prior to acceptance of report. This may require several iterations and considerable time. |
| Close contract | Bring closure to the contract and the professional relationships developed on the project by hosting a formal meeting where report findings are presented to the group that generated the report, to those who will accept the report and those who will use the results. Conduct a series of private exit interviews with both internal team members and contractors to learn how the process can be improved. Final copies of the report are deliv-ered to the contracting organization. The contractor is paid. |
| **Phase Four — After a Risk Assessment** | |
| Risk communication | Use formal acceptance of the report as a transition into the risk management and risk communication phase. Emphasize rigorous process of review and clear performance standards used to generate the report to highlight its technical credibility. For most projects, it is best to conduct risk communication throughout the risk assessment project, as well, using citizen input to provide information on the type of land use, exposure routes, and other aspects of the project. Use of such information can improve report assumptions and credibility, as well as public acceptance. |

**Table 1 continued**

| | |
|---|---|
| Risk management | Use a formal evaluation methodology to generate and support risk management options. Generate a risk management decision document that provides all risk management decisions with their associated data and logic, including uncertainties and limitations. Coordinate this activity with participants in the production of the risk assessment and other appropriate interested parties. |
| Defending the risk assessment report | Present and defend risk estimates at public meetings, public hearings, administrative actions, and court proceedings, as required. |
| *Note:* An actual risk assessment project can have greater or fewer steps, depending on project needs. | |

## B. Phase Two — Managing a Risk Assessment (Including Iterative Review)

A second phase of a risk assessment project involves technical work; a project manager must oversee work of a contractor, facilitate review by a project team, and manage communication and disputes on a project. Work planning and scoping processes that occurred in Phase One will have delineated process and product standards that come into play in Phase Two. Therefore, a project manager will have developed a grasp of major aspects of a project, such as what work products are to be produced (interim and final products); how they will be produced (who will do the work, what resources will be used, when each work product will be delivered); how progress will be tracked, and how work will be reviewed and evaluated for sufficiency. We recommend using a proactive approach. This calls for a series of discrete interim deliverables. Each deliverable must pass review before work begins on subsequent deliverables.

After a contract is signed, a contractor starts work, guided by performance standards set forth in the project contract and work plan. A formal risk assessment process begins with data collection and evaluation (also known as hazard assessment). Contractors accumulate all existing data relevant to a site, activity, or facility and then determine whether sufficient information exists to develop a risk assessment report. If time or funding is limited, risk assessors may evaluate quality and quantity of available data to determine what level of risk evaluation can be done. Data quality must be properly matched to the level of risk analysis rigor (e.g., qualitative, semi-quantitative, and quantitative). If available data is of suitable quality for required risk analysis, no additional data are gathered. If not, additional data must be collected and analyzed. Project managers decide how to collect and analyze additional data in consultation with other team professionals.

After a contractor gathers all relevant and acceptable data, data are statistically evaluated to generate source concentrations (e.g., for each water or soil contaminant, and emission rates for each air contaminant). Environmental contaminants pose no risk unless they move to a point where an organism will be exposed. If there is no exposure, there is no risk. While it is possible to measure environmental contaminant concentrations at an exposure point some distance from its source, risk assessments

generally rely on mathematical environmental fate and transport models and calculate exposure point concentrations in environmental media (e.g., soil, air, water, food), rather than collecting data. This makes sense when using "potential to emit" estimations for proposed facilities.

Next, movement from environmental media at a given location into an exposed organism is considered. All relevant exposure pathways are evaluated. Standardized exposure equations are used to calculate exposure levels, i.e., intake and uptake (see Chapter 2 IV. C). Chemical intakes and uptakes are compared to toxicological values to calculate chemical-specific risks. Risks are then considered by grouping chemicals with similar toxic effects. For example, all risks are summed for all carcinogen exposures; this value is compared to an acceptable cancer-risk yardstick. For noncarcinogens, all risks are summed for all pathways for chemicals with similar toxic effects and exposure duration; this value is compared to acceptable noncancer risk yardsticks.

After completing these steps, a contractor organizes numerical findings into a series of summary tables. A quantitative or qualitative uncertainty analysis is also provided in narrative form. If the risk assessment was financed by the interested party, or their contractor, they might wish to include a chapter that presents their editorial comments on their mandated risk assessment.

Summary tables provide a better understanding of the basis of a report's risk estimates, and uncertainty analysis clarifies a risk assessment project's rigor and points out limitations of its findings.

## C. Phase Three — Accepting a Risk Assessment (Including Iterative Review)

In the third phase of a risk assessment report development process, a final report is critically reviewed by the project manager and risk assessment project team. It is corrected as necessary. When it meets all performance standards, work is accepted.

If a proactive contract management strategy was used, Phase Three is relatively simple. As discussed above, previous project work will have already undergone iterative review and final review requires detailed examination of only the last set of interim deliverables, and of integration of all interim deliverables into a consistent, cogent final report.

If project review was reactive, review is delayed until all work is completed and delivered as a draft final report. This will undoubtedly make Phase Three more difficult.

Reactive review is a favorable situation for consultants. It allows them to maximize use of consulting staff because there is no predetermined order in which work is done. As consultant staff finds time, work is performed on a risk assessment. Eventually, all pieces are integrated into a draft report for review. A project manager and project team are, however, disadvantaged by a consultant's use of reactive management. First, problems with interim work are not remedied before they are integrated into other work. Second, serious problems can lead to serious delays toward the end of a project, when time is running out. Third, a project manager is at a disadvantage when negotiating with a consultant to fix problems near the end of a project. A contractor will have scheduled other projects to begin as a risk

assessment concludes. New project demands will make a contractor far less likely to cooperate at the end of a risk assessment project than at the beginning.

In most cases, passing final review concludes a contract, unless public comment requirements are required, precipitating additional changes to a report. Contract provisions should delineate this work and make clear that contractual obligations are not concluded until public comments have been incorporated into a final risk assessment report.

### D. Phase Four — After a Risk Assessment

In the fourth phase of the process, risk managers receive risk report findings and use them, along with nonrisk factors (e.g., technical feasibility of risk reduction measures, economics, politics, and cost/benefit analyses) to arrive at a risk management decision. Risk management options are evaluated and risk communication strategies are determined. Risk management decisions are explained to interested parties through risk communication.

### E. Risk Assessment Planning Form

A Risk Assessment Planning Form, presented in Table 1, provides a detailed treatment of the risk assessment process. A project manager may use this form to quickly establish time lines, interim and final deliverables, and other routine scheduling and budgeting items. This table combines elements of a risk assessment performed using resources within an organization and one where consultants are hired to perform a risk assessment. Depending on the specific situation, sections of this table may be omitted or supplemented. This abbreviated approach cannot replace in-depth risk assessment report planning. If there is absolutely no other way to meet a mandate to initiate a risk assessment, however, abbreviated planning is better than no plan.

## VII. CONCLUSION

Risk assessment is a standardized method for evaluating and presenting potential health risks and environmental impacts from potentially toxic substances released to the environment. It serves as a framework to force science into constraints of societal needs, and of political and legal mandates. Risk assessments follow procedural rules established by regulatory and scientific organizations. An extensive body of federal and state guidance outlines risk assessment requirements and standard methods. Guidance documents are also being produced by international organizations. In practice, however, implementation of this generally accepted risk assessment paradigm varies greatly.

Unfortunately, although detailed guidance exists on technical aspects of assessing environmental risk, little heed has been paid to improving day-to-day development of risk assessment reports and how environmental risk estimates are communicated. Reports are often confusing, logic is muddled, math and modeling can not be

checked, and terms are obtuse and undefined. As a result, even people well-versed in environmental risk assessment find it difficult to understand the basis for risk estimates, to review adequacy of their supportive reports, or to judge the validity of science and assumptions used in an environmental risk assessment. Thus, an important aspect of the scientific method, the ability to check and verify technical work, becomes impossible. This has resulted in a perception that risk assessment is "smoke and mirrors" and, thus, unreliable. This is, arguably, the fault of risk assessment practitioners, not an inherent flaw in the discipline.

A risk assessment cannot be quick, comprehensive, and cheap. Every risk assessment project manager is probably asked, at some time, to produce a high-quality, low-budget, scientifically-rigorous risk assessment using a contractor. In such circumstances, at least one of three ideal attributes — speed, thoroughness, or cost effectiveness — will be sacrificed. If an organization requires a risk assessment that is both fast and cheap, it must recognize that thoroughness will suffer.

While limitations inherent in risk assessment will probably not be completely eliminated, they can be minimized through use of procedures presented in this book. Our following chapters provide methods to control quality of risk assessment reports, to manage the process, and to critically evaluate risk assessment work products. Understanding gained from this book will prepare a reader to make better use of information from a wealth of technical documents relating to environmental risk assessment and to build a common understanding of risk assessment. Techniques offered in this book can help a project manager keep report development on track, manage and control consultants, and create a report that people can understand, review, use, and trust. Finally, methods discussed in this book can allow effective critical review of risk assessment reports.

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CHAPTER 2

# Human Health Risk Assessment

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## CONTENTS



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## I. INTRODUCTION TO HUMAN HEALTH RISK ASSESSMENT

HHRA reports provide risk findings, estimates of human health risks associated with a site, activity or facility. Risk managers use HHRA risk findings for many purposes. Risk findings guide risk reduction measures. For example, they help determine a need for site cleanup, define cleanup levels, and aid in establishing facility permit conditions to limit environmental releases and, thus, limit risks.

HHRA risk findings are often numerical* and are compared to numerical regulatory criteria (e.g., bright lines), official or informal yardsticks of acceptable and unacceptable risk. If HHRA numerical risk findings do not exceed numerical criteria, risks are typically deemed "acceptable" or "insignificant." Risk findings that exceed applicable risk criteria are typically considered "unacceptable" or "significant." Exceeding risk criteria may pose serious legal and economic results for a regulated entity because these numbers serve as triggers for regulatory action. Exceeding them may trigger remediation, denial of a permit, or enforcement action.

Government agency use of terms discussed in previous paragraphs are often confusing and inconsistently applied. For example, some regulatory and health protection programs may use different bright line values (e.g., cancer risks from one-in-ten thousand to one-in-one million) to determine when risks are too high. When using these bright line values for carcinogens, it is reasonable to expect that exceedance of a bright line will result in cancer health risk concerns, whereas risks at, or below, a bright line value will not result in cancer health risk concerns. In practice, however, application of bright lines is highly variable; there is no uniform black or white, unsafe, or safe application of a bright line concept. Determining when a risk estimate moves from acceptable to unacceptable is merely a value judgment made by risk managers (e.g., government regulatory agency senior- or middle-management), not by risk assessors. Risk managers use risk findings as a single input into a complex decision-making process that balances calculated risks with broader considerations, including economics, social impacts, and politics. Thus, a purely technical finding of unacceptable risks from a risk assessment report (e.g., risk estimate exceeds a bright line) can still be negated, resulting in a risk management

* Quantitative risk assessment reports yield numerical risk estimates, whereas qualitative risk assessment reports characterize risk in relative terms, such as "high," "medium," and "low."

finding of acceptable risks. Risk findings and risk management decisions of health concerns make legal implications of a risk assessment difficult to predict.

Risk assessment involves four formal steps: Hazard Assessment (also referred to as Data Collection and Evaluation, Hazard Evaluation, or Hazard Identification), Exposure Assessment, Toxicity Assessment (e.g., quantitative dose-response relationships) and, ultimately, Risk Characterization. The following discussion will provide a thumbnail sketch of a generic HHRA development process and is not designed to duplicate or replace the voluminous library of government guidance documents and technical reports on risk assessment. This information provides readers with context for the remainder of our book.

The first step in HHRA process is hazard assessment. Hazard assessment begins with collecting existing data on a site, activity, or facility of concern. This analysis may reveal a need for additional data collection prior to initiating risk assessment calculations. When sufficient data of known quality have been collected, a list is produced of all potentially toxic chemical substances that may result from a site, facility, or activity, termed COPCs.* A list is narrowed to a final list of COCs, those chemicals slated for quantitative evaluation in the next three steps of an HHRA (some authors use COPC and COC interchangeably).** A concentration term (or emission rate***) is calculated (or obtained) for each COC at its source. Source concentrations (or emission rates) are used in fate and transport mathematical models in the next step, exposure assessment.

Exposure assessment, the second step in an HHRA process, determines chemical concentration in soil, air, or water at locations where humans may be exposed, termed receptor points. In some cases, actual chemical residue data can be collected at a receptor point. Since it may be difficult or impossible to obtain field collected media-specific (e.g., soil, water, air, food) chemical contaminant concentrations, especially for proposed facilities, mathematical models are used to calculate chemical-specific exposure levels. Chemical source concentration terms (or emission rates) are used in environmental fate and transport equations or computer models to calculate chemical concentrations at receptor points by calculating decrease in a chemical's concentration from its source to potential human receptors at a given location. This step in HHRA is very complex and typically relies heavily on data derived from literature or generated using models. This step in the process produces numerical exposure levels.

Toxicity assessment is the third step in HHRA. It may be conducted concurrently with exposure assessment. Toxicity data are collected on each COC in this step. Chemicals are classified as either carcinogens or noncarcinogens and their toxic properties and numerical toxicity values are determined.

Risk characterization, the fourth and final step of HHRA, generates risk levels based on exposure levels and toxicity data. Although methods of calculating carcinogenic and noncarcinogenic risk differ, numerical expressions of both types of risk

* A chemical of potential concern (COPC) is a chemical known or suspected to be associated with a site, activity, or facility under review. A chemical of concern (COC) is a chemical that will be evaluated in the next three steps of a risk assessment.

** Chemicals not evaluated quantitatively, for example because they lack a toxicity value, still should undergo qualitative evaluation in the uncertainty analysis.

*** "Emission rate" refers to an air concentration of a COPC or COC.

are compared to appropriate risk criteria to determine whether calculated risks exceed an acceptable risk threshold.

The next four sections discuss each of the four HHRA steps in detail. Information presented in these sections is a broad overview of each subject, intended to familiarize readers with the HHRA process, and assist in day-to-day work with other members of a risk assessment team and in reviewing a risk assessment report. It does not replace a need to rely on qualified risk assessment professionals or source materials that risk assessment practitioners use to conduct and review a risk assessment.*

In order to avoid later confusion, readers should note that risk assessment guidance documents and books differ in where they place a given activity. Thus, for a given risk assessment process, scoping document, or report, an exact location of a specific risk assessment task may vary. In final analysis, it is inclusion of all required parts of a risk assessment that is crucial, not necessarily their precise order.

## II. HAZARD ASSESSMENT

Hazard assessment is the first step in a formal evaluation of potential risks posed by environmental releases of chemicals. To conduct an HHRA, the names and concentrations of chemicals known, or expected to be released to the environment, must be determined. Data used to generate chemical release levels must either meet minimal data-quality requirements, or be of known quality (e.g., acceptable, marginal, unacceptable). All existing data relating to identity of COPCs and their source concentrations is collected for a site, activity, or facility that is subject to risk assessment. Existing data sets are then evaluated or grouped as to their adequacy for determining identities of COPCs. During evaluation, data quality is checked and data sets may be combined, analyzed, and statistically manipulated to yield chemical concentration terms (or emission rates) at a source of each COPC.

If existing data are inadequate, data collection is required. A sampling and analysis plan assures statistical relevance of data collection. New data sets can be used alone or combined with existing data sets. Sufficient data must be amassed to evaluate each COPC and determine whether to list it as a COC to undergo quantitative risk assessment. Various methods can be used to develop a COC list from a COPC list. These are discussed later in this chapter.

For each COC, concentrations are calculated for water, soil, or other media; emission rates are calculated for air contaminants. These environmental concentrations serve as inputs to environmental fate and transport models in Exposure assessment. Risk assessment findings are only as reliable as chemical-specific data inputs. Our following sections describe issues influencing data reliability.

### A. Defining Acceptable Data Quality

Data quality and usefulness varies. Some data points can be unusable because of sampling or laboratory analysis problems or errors. Data usefulness relates directly to its anticipated use. Data Quality Objectives (DQOs) ensure that only data of

* Many of the technical aspects discussed in this chapter are portable for use in ERAs.

quality required for HHRA purposes are used in an HHRA. The DQO process identifies risk assessment data needs, objectives, and uses. Sampling approaches and analytical options are established and a data collection program and methods are designed to obtain data acceptable for its intended use.

## B. Defining Data Needs

Several generic data types are used in an HHRA. Existing information is gathered on chemical identities and their concentrations in environmental media (e.g., soil, air, water, food, organisms). Data are gathered on environmental characteristics that could influence fate, transport, and persistence of released chemicals, probable or known exposed individuals or populations, and properties and degradation pathways of chemicals of potential concern. Comprehensive data collection, and analysis of these data sets, requires time and resources.

## C. Defining Chemical Background Concentrations

Background concentrations (sometimes also referred to as ambient concentrations), by definition, cannot be attributed to a site, activity, or facility under review. There are two different types of chemical background concentrations. Naturally occurring levels are ambient concentrations of chemicals in the environment that are not caused by human activity. In contrast, anthropogenic levels are chemical concentrations that are a result of human activities. A given background level of a chemical can have a localized spatial distribution or it can be ubiquitous. Appropriate background sampling is conducted to establish naturally occurring levels of chemicals and anthropogenic levels, to distinguish these levels from those associated with a site, activity, or facility of concern. Some professionals use "ambient concentrations" to describe actual conditions measured in the field (e.g., city air chemical concentration levels).

Background samples are collected at or near a site, activity, or facility in areas that are not contaminated from such operations or activities. Sampling areas and sample size are specific to each case. Background chemical levels cannot be defined by measuring so-called "clean areas" within a zone of impact or contamination. For example, soil concentrations at a suspected hazardous waste site may not be deemed of regulatory concern, until it is shown to exceed both background or regulatory concentrations. In other cases (e.g., air pollutant levels in cities), background levels are considered to be those that typically exist. These levels could be of regulatory concern. Unless background concentrations are exceeded, there may be no scientifically valid basis for performing a risk assessment.

A valid sample size is required, both to establish background concentration of a particular chemical and to properly differentiate it from greater concentrations. Statistics are used to set a valid sample size. An appropriate degree of statistical certainty (e.g., $\alpha = 0.01, 0.05, 0.10$) is selected on a case-specific basis. Statistical analyses of background samples may be necessary to differentiate them from non-background sites.

After background concentrations are calculated, they are compared to a "contaminated medium" to determine whether that medium is truly contaminated. If a

medium is found to have chemical concentrations significantly higher than background or regulatory concentrations, a risk assessment can be performed. In some cases, background concentrations of a chemical (such as natural arsenic levels in some midwestern aquifers) are already above levels of health concern. In such cases, a risk assessment may be used to estimate total risks from exposure to all contaminants found in the groundwater.

### *1. Regulatory Concentrations*

State, federal, and international organizations often establish different regulatory concentrations, i.e., concentration at which a chemical or substance may be of health concern. Regulatory concentrations are numerical expressions relating to risk posed by exposure to chemical- or mixture-specific concentrations. Exceeding a regulatory concentration may pose unacceptable risks to exposed organisms. Regulatory concentrations, however, are not necessarily based solely on toxicological or risk assessment factors (e.g., U.S. Environmental Protection Agency Drinking Water Standards). Social values or environmental policies, for example, may influence risk management decisions that are reflected in regulatory concentrations.

"Regulatory standards" are legally enforceable regulatory concentrations. These numbers define maximal permissible levels of single chemicals or mixtures in a given medium. Government agencies also generate guidance concentrations. Unlike standards, guidance concentrations are not legally enforceable, but are often used as if they have legal force. There are innumerable names given by government agencies for guidance concentrations (e.g., action levels, action limits, etc.).

Precisely which regulatory concentrations apply in a particular situation depends on the experience of a regulator, applicable laws, and nature of a risk assessment project. In Superfund, for example, regulatory concentrations that are considered for a site cleanup are termed "Applicable or Relevant and Appropriate Requirements" (ARARs). Three types of ARARs are recognized: chemical-specific, location-specific, and action-specific. ARARs can be selected from among many possibly applicable state and federal standards and guidance concentrations (see Table 1).

## D. Defining Acceptable Sampling and Analytical Plan

Sampling and analytical plans should be prepared before new data are collected. These plans address all relevant human exposure routes and points (see Table 2), exposure pathways, transport media mechanisms and chemical-specific factors (see Table 3), media of concern, areas of concern, contaminant types, routes of contaminant transport, environmental media characteristics, analytical chemistry requirements, and organisms of concern.

Goals of a project govern details of sampling plans. Sampling locations, for example, can be chosen with a purpose (such as to identify all contaminants), or they may be random (for unbiased sampling) or systematic. Project goals also influence choice of sample types (grab samples or composite samples*), use of field screening analytical methods, and time and resources allocated to sampling.

* Composite samples combine subsamples from different locations or times.

**Table 1 Examples of Common Regulatory Standards and Guidelines**

| Standard / Guideline | Purpose |
|---|---|
| U.S. EPA Drinking Water Health Advisory Concentrations | Maximally recommended concentrations of individual drinking water contaminants for 1-day, 10-day, longer-term (~7 years) and lifetime exposures |
| U.S. EPA Maximum Contaminant Level (MCL) | Maximum permissible level of a contaminant in water that is delivered to public water systems |
| U.S. EPA Water Quality Criteria | Recommended maximum concentrations in surface water of a pollutant consistent with protection of aquatic organisms, human health, recreational activities, and other specified uses |
| OSHA Permissible Exposure Limits (PELs) | Establish safe concentrations of air contaminants in work places. |
| National Institute for Occupational Safety and Health Recommended Exposure Limits (RELs) | Exposure to potentially hazardous airborne substances in work places |
| National Ambient Air Quality Standards (NAAQS) | Protect public health or welfare. Not directly enforceable |
| National Emission Standards for Hazardous Air Pollutants (NESHAPs) | Chemicals not covered by NAAQS |
| Food and Drug Administration Action Levels | Maximum allowable levels of poisonous and deleterious substances in food |
| U.S. EPA Tolerance Levels | Control levels of pesticide residues in raw or processed agricultural products and processed food |
| RCRA Appendix VIII and IX, Superfund Target Substances | Enforceable point source discharge limits |
| Clean Water Act Priority Pollutants | Enforceable point source discharge limits |
| State Groundwater Standards | May be enforceable concentrations |
| State Surface Water Standards | May be enforceable concentrations |
| State Air Standards | May be enforceable concentrations |
| State Medium-Specific Cleanup Standards and Guidance Concentration | May be enforceable concentrations |
| State Drinking Water Standards | May be enforceable concentrations |
| State Fish Flesh Contaminant Advisories | Designed to minimize risk from eating fish but allow sport fishing to occur |

Sampling plans also address physical factors, such as meteorology of a project area, and physical/chemical characteristics of environmental media to be sampled. Some environmental sample matrices are difficult to sample and require specialized collection. Others are easy to sample, but yield samples that are difficult to analyze in the laboratory and require special analytical chemistry procedures. Sampling plans are applied through sampling protocols which define objectives of a sampling study

**Table 2 Examples of Exposure Routes and Points by Environmental Medium**

| Environmental Medium | Exposure Points | Exposure Routes |
|---|---|---|
| Groundwater | Municipal and private water wells, swimming pools, discharge zones to surface water, irrigation, springs, sinkholes | If used as a drinking water source: direct ingestion, dermal and ocular contact, inhalation of chemicals volatilized from water |
| Surface Water | Locations where water bodies used for recreational purposes | Direct ingestion, dermal and ocular contact, inhalation of chemicals volatilized from water |
| Soil | Hazardous waste sites, residential soil surfaces, excavations, dust | Direct ingestion, dermal and ocular contact, inhalation of volatilized chemicals and dust |
| Air | Indoor or outdoor exposure to dusts, aerosols, gases, and particulates in respirable air | Inhalation of volatilized chemicals, dermal contact with aerosolized chemical droplets |
| Food | Chemical contaminants on food as a residue or in food via food chain uptake and distribution | Ingestion of food products containing chemical contaminants in their tissues or on their surfaces, dermal contact with contaminated food products |

and, in combination with QA/QC methods, govern each step in sample collection, preservation, transportation, and analysis.

## E. Defining Quality Assurance/Quality Control (QA/QC) Methods

QA/QC methods ensure data quality through proper sampling, handling, storage, and preservation. Sampling protocols define objectives of a sampling study and articulate procedures for sample collection, preservation, handling and transport, and analysis. Data collected under sampling and analysis plans should be reviewed as they become available to ensure that data meet project needs. This helps eliminate data gaps and limits problems to be addressed in the data evaluation phase.

## F. Defining Methods for Pooling Sampling Data

Available data are evaluated to determine whether they can be combined for use in an HHRA. It is important to define quality of available data sets. Analytical chemists review available data, determine its reliability, and can apply a letter data qualifier to each reported data point. Each "data indicator" indicates a chemist's degree of certainty about a chemical's reported identity and concentration. Data qualifiers can also note data problems. Risk assessors rely on data qualifiers to judge whether a data point can be used in a quantitative risk assessment and, if so, how much reliance on data is appropriate. Rigor, reliability, and credibility of numerical risk assessment findings relate directly to quality of data sets used in a risk assessment.

**Table 3 Examples of Transport Media, Transport Mechanisms, and Chemical Specific Factors that Could Affect Environment Transport of Chemical Contaminants**

| Environmental Medium | Transport Mechanisms | Chemical-Specific Factors Affecting Transport |
|---|---|---|
| Groundwater | Groundwater movement | Density, water solubility, organic carbon partition coefficient ($K_{oc}$) |
| | Volatilization | Water solubility, vapor pressure, Henry's Law Constant |
| | Adsorption to soil particles | Water solubility, octanol/water partition coefficient ($K_{ow}$), $K_{oc}$ |
| | Precipitation out of solution | Water solubility $K_{ow}$, $K_{oc}$ |
| | Biological uptake | $K_{ow}$, bioconcentration factor |
| Surface Water | Overland flow | Water solubility, $K_{oc}$ |
| | Volatilization | Water solubility, vapor pressure, Henry's Law Constant |
| | Move to groundwater | Density |
| | Adsorption to soil particles | Water solubility, $K_{ow}$, $K_{oc}$ |
| | Sedimentation of particles | Density, water solubility |
| | Biological uptake | $K_{ow}$, bioconcentration factor |
| Soil | Runoff by soil erosion | Water solubility, $K_{oc}$ |
| | Leaching | Water solubility, $K_{oc}$ |
| | Volatilization | Vapor pressure, Henry's Law Constant |
| | Suspension | Density, particle size |
| | Biological uptake | Bioconcentration factor |
| Air | Aerosolization | Water solubility |
| | Atmospheric deposition | Particle size |
| | Volatilization | Henry's Law Constant |
| Biota | Bioaccumulation | Bioconcentration factor |

Adapted from ATSDR, 1990.

## G. Defining Data Sources

Chemical identity, concentration, or emission rates can be obtained from various sources. Actual data can be collected and pooled for an existing site, activity, or facility. When this is not possible, however, surrogate data sets must be obtained from models or existing sources of environmental releases. For example, surrogate data may be used when an HHRA involves risks associated with a facility that has not yet been built; surrogate data sets will probably be comprised of data gathered at existing facilities that are identical or similar to a proposed facility. Chemical

identities and release information can be derived from Material Safety Data Sheets, published literature, monitoring data, or mathematical models, using projections for proposed facility operations. As a source of chemical identity and release information becomes less specific to a site, activity, or facility of concern, uncertainties increase in an HHRA.

When a risk assessor has collected sufficient data of acceptable quality, a list of all COPCs is developed. A concentration*, or emission term, is statistically generated for each chemical at its source using location-specific data or surrogate data sets.

In the past, qualitative or quantitative methods have been used to reduce an exhaustive list of COPCs to a shorter list of COCs. RAGs 1989, pages 5-23 to 5-24, provides a detailed discussion of this topic. One way to generate a COC list is to use a chemical concentration-toxicity screen. EPA provides the following equation for calculating Individual Chemical Scores:

$$Rij = (Cij)(Tij)$$

where Rij = Risk factor for chemical i in medium j, Cij = Concentration of chemical i in medium j and Tij = Toxicity value for chemical i in medium j (i.e., either a slope factor or 1/RfD).

Risk factors are generated for individual COPCs by multiplying a chemical's concentration in a particular medium by its toxicity value (noncarcinogenic or carcinogenic). Risk factors are summed for all COPCs to generate a total score for each medium. A percentage of total risk attributable to each chemical is then determined by dividing each chemical-specific risk factor by a total score for each medium evaluated.

Chemicals posing an insignificant percentage of a total risk may, in some cases, be eliminated from further consideration. Those representing a significant percentage undergo full analysis. Chemicals representing the lowest 1% of a risk might be eliminated from a list of chemicals of concern, for example, while those representing 99% of risk undergo complete risk analysis. Chemicals included in a COC list represent a majority of risks from a site, activity, or facility and they have readily available emission, concentrations, and numerical toxicity values. COPCs screened out of quantitative analysis, because of inadequate data, no numerical toxicity value, or because they seem to pose insignificant risk, are not included in a final COC list. These chemicals still deserve qualitative analysis and should be discussed in an uncertainty analysis section of a risk characterization.

In other cases, all identified chemicals with toxicity values are addressed throughout an entire report. No chemicals are eliminated from evaluation.

* Concentration terms can be generated using an arithmetic average concentration for a contaminant, based on a set of sampling results, and the 95% upper confidence limit (UCL) of an arithmetic mean. This approach compensates for uncertainties associated with ascertaining a true average concentration at a sampling area. Averages are used because carcinogenic and noncarcinogenic toxicity criteria are based on lifetime average exposures. An average concentration is considered most representative of a concentration that would be expected at a location over a lifetime. When chemicals are expected to be present, but are not detected, they may be assigned a numerical value other than zero, such as a percentage of a detection limit. However, defining a concentration term is often a function of which methods are preferred by those producing or reviewing a report.

## III. HAZARD ASSESSMENT CONSERVATISM

Chemical screening to reduce risk assessment production time and costs is no longer considered a routine practice and is disfavored by many regulatory agencies. Risk assessors can rapidly generate credible risk estimates as a result of significant productivity improvements in risk assessment methods, techniques, and tools during the past decade. Risk assessors, who used pencils and hand calculators in years past, now use powerful computers able to run sophisticated risk assessment and fate and transport modeling programs. They are also able to obtain environmental and toxicological data from on-line databases. Although technical means to generate risk estimates have improved, many cost- and labor-saving methods adopted in early days of risk assessment still linger. Concentration-toxicity screening, described above, is one such holdover.

Risk assessment software, commercial spreadsheets, and toxicological values readily available from U.S. EPA's internet or hard copy accessible Integrated Risk Information System (IRIS) and Health Effects Summary Table (HEAST) databases (for most common contaminants) negate a need to limit quantitative analysis to an abbreviated list of COCs. Risk assessors no longer must perform laborious calculations by hand. Instead, they use computers to perform calculations required to generate risk estimates. Thus, there is little justification to eliminate chemicals, unless a COPC lacks a concentration/release term or a toxicity value, or it is shown not to be relevant to a specific risk assessment. If data exists for all COPCs, a complete quantitative evaluation is possible. In cases where a COPC with known human health effects lacks an approved toxicity value, a risk assessor can either generate a toxicity value or evaluate a chemical qualitatively in uncertainty analysis of a risk characterization section.

### A. Problems Associated with Developing a COPC and COC List

Certain problems commonly occur during preparation of a hazard assessment section of a risk assessment report. If these problems are not addressed, a result could be a COPC or COC list that can mischaracterize environmental releases and, consequently, underestimate exposures and risks. Common problems include:

- Failure to adequately describe chemical processes occurring at a facility. When inadequate analysis of an activity, facility, or site occurs, chemical identification can suffer (e.g., large numbers of chemicals known or expected to be released from a facility are missed and not included on a COPC or COC list). Adequate description of all chemical processes helps to formulate a comprehensive list of COPCs and COCs.
- Failure to adequately review available literature. All too often an incomplete review of site records, industry literature, government literature, or peer-reviewed literature results in a hazard assessment that fails to list all chemicals known or expected to be produced at a given type of facility. A robust COPC and COC list can only be produced when a comprehensive review of relevant literature is done.
- Failure to use engineers and chemists. Chemists and engineers working at a site, facility, or activity have special knowledge about the chemicals that go into and

out of their work location. For example, at facilities involving high-temperature processes or combustion, combustion chemists and engineers can help predict identities and estimate amounts of chemicals that may be released. Such specialists provide a valuable means for identifying chemicals that might be released directly from facility activities or that may materialize as a result of physical or chemical reactions in a waste stream (e.g., gas condensation from smoke stacks).

- Failure to review analytical chemistry methods to ensure that releases have been adequately evaluated. If erroneous methods are used (e.g., sampling, extraction, digestion, and analytical methods) or selected analytical techniques are unable to detect chemicals at levels of health concern, chemicals moving off-site could go undetected or underreported. Standard methods exist that should be followed to ensure generation of reliable data.
- Failure to evaluate all relevant operating units on a site. Some sites contain many different operating units with different chemical processes and environmental releases. If each unit is not fully evaluated, many chemicals being released to the environment could be missed in a risk assessment. All operating units should be evaluated for chemical releases by trained and experienced personnel.
- Failure to obtain certifications of work from hazard assessment preparation contractors or permittees. One common way to ensure that quality work has been performed by a contractor or permittee is to have them sign a certification statement that all work was conducted and performed to standards of relevant disciplines. Lacking such signed statements, hazard assessment reviewers may not fully understand who prepared documents and how they were prepared, bringing their credibility into question.
- Failure to adequately evaluate literature used in development of a COPC or COC list. When data on a particular site, facility, or activity are limited, a risk assessor may be forced to rely on literature of limited quality and reliability. For example, some literature does not list chemicals if they are less than a certain percentage of total mass, regardless of their presence or their toxicity. As a result, highly toxic chemicals in very small amounts may not be included in a given type of literature, whereas low toxicity, high concentration materials may be listed.
- Failure to establish environmental release criteria that are relevant to establishment of a COPC and COC list. Inclusion of chemicals in a risk assessment is sometimes linked to estimated emission rates or concentrations, on-site or off-site. Specifically, chemicals are not included in a COPC or COC list if their concentrations do not exceed some set value. If a calculation of this value is not strictly defined and related to health effects (e.g., average versus peak air concentrations), chemicals could be excluded from a COPC and COC lists for wrong reasons.
- Failure to establish performance standards for development of a COPC and COC list. Without performance standards, COPC and COC lists of various levels of quality and reliability are generated.
- Failure of toxicologists and risk assessors to design and implement rigorous chemical selection processes. In some organizations, toxicologists and risk assessors are not responsible for designing how COPC and COC lists will be generated. Results of this management decision can drastically alter risk findings.
- Failure to review hazard assessment documents provided by regulated parties for technical accuracy. Many times hazard assessments are provided to government by parties with vested interests in an outcome of a risk assessment. These hazard assessments must be rigorously reviewed before they are accepted to ensure risk assessment integrity.

- Failure to combine site-specific and generic information sources to generate a COPC and COC list. By conducting a comprehensive review of literature and conducting interviews with relevant experts, a robust COPC and COC list can be produced. Without such an effort, a COPC and COC list may be of little value in development of a credible risk assessment.
- Failure to gather extensive lists of toxicity values from state, national, and international sources. Often, chemicals are not quantitatively evaluated in a risk assessment because there is no numerical carcinogen or noncarcinogen toxicity value listed for them among a limited number of sources. Obtaining a comprehensive library of toxicity value sources ensures that all relevant chemicals with appropriate toxicity values can be evaluated quantitatively in a risk assessment.
- Failure to evaluate secondary effects. While there is no standard method to quantitatively evaluate secondary toxic effects of a chemical (i.e., primary or critical toxic effects are used to establish numerical toxicity values), cumulative secondary effects of several chemicals may pose significant, if unrecognized, health risks when their release rates and exposure levels are combined. Unfortunately, the authors are aware of no practical solution to this problem at this time.
- Failure to establish COPC and COC list criteria for use in multipathway risk assessment. In an effort to reduce risk assessment complexity, costs or eliminate generation of unacceptable risk findings, some organizations use "exclusionary" risk assessment tools. Rather than develop a robust list of COPCs and COCs, based on actual case conditions, managers mandate use of methods and techniques that reduce risk assessment scope and limit COPC and COC lists to consider only a single approach (e.g., inhalation exposure only). As a result, chemicals that might pose risks via ingestion or dermal exposure may not be evaluated at all, unless they happen to pose an inhalation risk as well. Many times exclusionary risk assessments rely on emission, concentration, or toxicity tables linked to acceptable risk levels established by a regulatory agency or other government office. Non-risk assessors compare these emission or concentration values from these tables to values provided by permittees or engineering staff. Not fully aware of complexities of risk assessment, untrained staff cannot evaluate toxic chemical interactions, environmental chemistry, or validity of values they are provided (e.g., values in such tables may be out-of-date or based on calculation methods or regulatory values for one medium that cannot legitimately be used for another medium). Thus, rejecting, by fiat, use of hazard assessment techniques to produce COPC and COC lists for a multipathway risk assessment can routinely underestimate total incremental risks from an activity, facility, or site, placing receptors at unknown risk.

## IV. EXPOSURE ASSESSMENT

Exposure assessment, the second step in HHRA, follows hazard assessment and may be performed concurrently with a toxicity assessment. Exposure assessment produces numerical exposure levels.

Exposure occurs when a chemical of concern contacts an outer boundary of a receptor organism, either at a chemical's source or some distance from a source. Exposure assessment evaluates movement of a chemical from its source to a potential human receptor by identifying potential exposure pathways. In moving from its source to a receptor organism, a chemical concentration generally decreases by

processes of dilution, dispersion, and degradation and, as a result, a receptor typically receives less than a concentration of a chemical in an environmental medium. Degradation may increase risks, however, if breakdown product toxicity is greater. Exposure assessment quantitatively evaluates this process. This step in HHRA typically relies on data found in technical literature or generated by using models.

First, exposure setting is characterized. This requires an examination of physical setting of a site, activity, or facility: its climate, meteorology, geological setting, vegetation, soil types, groundwater hydrology, and surface water features. Potentially exposed populations are identified, including populations of special concern such as children, elderly people, pregnant women, people with chronic illnesses, and other potentially sensitive subpopulations. Current and future land uses are characterized, in part to locate and identify potentially exposed populations and to project characteristics and location of populations that may move into an area at some future time.

Next, exposure pathways are identified. Exposure pathways describe movement of a COC from its source to human receptors. As much as possible, every step is identified in potential exposure pathways. These include:

- Sources of chemical contaminants: such as a waste pile, smokestack, automobile, and leaking drum
- Mechanism of environmental release: such as volatilization, fugitive dust generation, surface runoff, overland flow, leaching, and groundwater seepage
- Environmental medium to hold or transport chemicals: such as air, surface water, soil, groundwater, sediment, and biota
- Human exposure point: such as on- or off-site, backyard, and shower
- Exposure routes: ingestion, inhalation, or dermal exposure — "direct exposure" or "indirect exposure." (Direct exposure might occur by ingestion of contaminated water, whereas, indirect exposure might occur through consumption of contaminated fish)

After identifying potential exposure pathways, a risk assessor evaluates likelihood that a pathway will be completed. Usually, only those exposure pathways likely to be completed undergo further analysis; others are eliminated from consideration. In special circumstances, risk assessment may go farther and address potential future pathways.

## A. Fate and Transport Analysis*

Environmental fate and transport models** simulate environmental behavior of a chemical when monitoring is not possible or practical. A concentration of a COC at its source, termed chemical source concentration, is a starting point. A modeler uses a series of equations to project change in concentration for each COC as it moves from its source along likely exposure pathways. This analysis yields a plausible estimate of each COC concentration, termed an exposure level, likely to reach a location where human exposure is expected, termed a receptor point (see Figure 1).

* Risk assessment treatises vary in their treatment of chemical fate and transport. It may be discussed either in hazard evaluation or exposure assessment. We deal with it as part of exposure assessment.
** "Model" signifies both mathematical equations and computer models, unless otherwise noted.

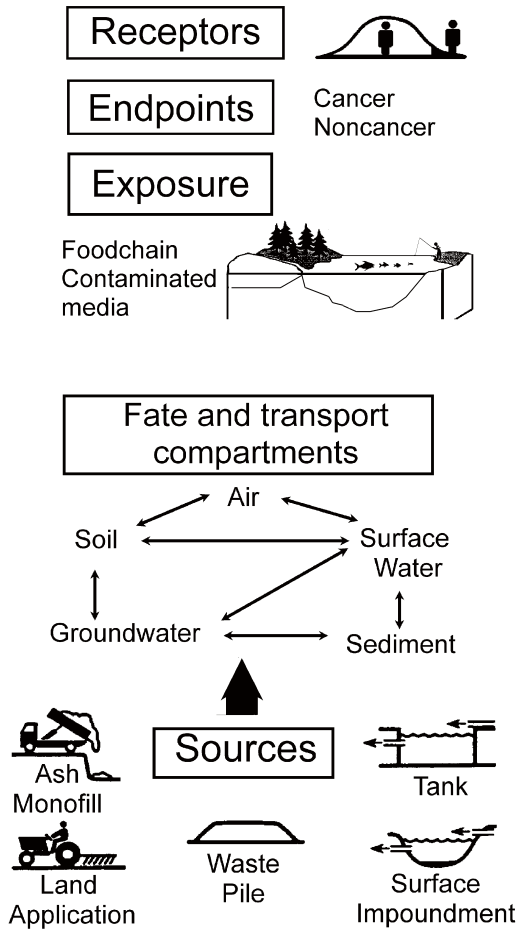


**Figure 1** Human health risk assessment multipathway analysis. (Adapted from U.S. EPA, 1995, Development of Human Health Based and Ecologically Based Exit Criteria for the Hazardous Waste Identification Project, Figure 1-1, pages 1–6.)

### *1. Chemical Movement Depends on Physical and Chemical Properties*

Chemicals released move within and between environmental compartments (such as water to air and back, water to soil/sediment and back, and soil to air and back) and from the physical environment into living organisms and back into the environment.

Chemicals can exist in three physical states, as solids, liquids, and gases. Chemicals can shift physical state by undergoing a "phase change." For example, water is solid at 32°F; it is liquid between 32°F–212°F, and at 212°F it starts to boil and enters a gaseous phase. Some chemicals, such as carbon dioxide, can move directly from solid (dry ice) to gas phase without going through a liquid phase. This is called "sublimation."

Chemical movement in the environment is also related to a chemical's affinity to a media in which it is found. For example, chemicals that bind strongly to a medium tend to stay in that medium (such as dioxin in soils). Chemicals weakly bound to a medium tend to move out of that medium into other media (such as volatile chemicals moving from soil particles or water to air). Chemicals that are released to air can disperse in air or they can enter other environmental media where they can concentrate.

Chemicals in the environment can be altered through "abiotic" (no organisms involved) or "biotic" (living organisms involved) processes. These processes include chemical hydrolysis; oxidation, reduction, and conjugation; photolysis or photooxidation; and biological degradation reactions. These general principles apply to movement of environmental contaminants.

A study of distribution of chemicals in the environment based on their chemical properties is called "chemodynamics." Knowledge about environmental fate chemistry of a contaminant is important, since environmental fate can change as chemical structure is altered. Thus, a chemical of moderate potential to bioaccumulate/biomagnify can be altered by biotic or abiotic processes into a chemical with very high potential to bioaccumulate/biomagnify. Toxicity can also change through even seemingly minor alterations in chemical structure. Environmental contaminants have numerous chemical and physical properties that dictate their environmental fate and how they are transported in the environment (see Table 4).

Knowledge of how a chemical moves in the environment is acquired through "fate and transport" analysis. Physical and chemical data for environmental contaminants directly affects their fate and transport in the environment and such data are used in fate and transport models. Models are a mathematical abstraction of a physical system used to predict concentration of specific chemicals, as a function of space and time subject to transport, inter-media transfer, storage, and degradation in the environment. Computer simulations, such as a Fugacity Model, are used to predict how a chemical will move in the environment, to which compartment or medium it will move, and what percent of released chemicals will enter and be found in each environmental compartment or medium.

### *2. Steps in Fate and Transport Analysis*

At each step in the analysis, a fate and transport model must account for environmental factors capable of influencing COC movement. Environmental interactions may transform a COC physically, chemically or biologically, affecting how and where it travels. If a COC changes physical state, it will exhibit different characteristics. As a result, it may move through an entirely different series of environmental compartments. Transformations due to chemical reactions or biological interactions can convert COCs into new substances with distinct physical, chemical, and toxicological properties.

Chemical transformations may also occur as a COC interacts with the environment. For example, as a chemical is discharged to air from a stack, do chemical reactions occur? If so, what new substances are created? What are their chemical properties? How much of a COC transforms by chemical reaction? Does any remain?

**Table 4 Examples of Physical Properties Affecting Chemical Environmental Fate and Transport.**

| | |
|---|---|
| Boilng point | Definition: Temperature in degrees Celsius at which vapor pressure of a constituent in aqueous form is equal to atmospheric pressure. |
| | Effect: Some chemicals have boiling points far below ambient temperatures. Boiling points provide information on how a chemical will behave in the environment at a given temperature. Inhalation exposure is most common route of exposure for low-boiling liquid, in contrast to high-boiling liquids which enter a body via direct contact. |
| Chemical structure | Definition: Chemical formula drawn to show relative arrangement of molecules. |
| | Effect: Chemical structures provide important clues to toxicity and environmental fate characteristics of a chemical. |
| Cosolvency | Definition: Ability of one chemical to enhance solubility of another in water. |
| | Effect: Change fate and transport of chemicals in soils, sediment, and ground water. |
| Degradation rates | Definition: Expressed in terms of half-lives, time required for a chemical, under defined conditions, to reach half of its initial concentration. |
| Density | Definition: Weight of a substance divided by its volume. |
| | Effect: Density measurements provide clues to a chemical's environmental behavior. Very dense liquids (DNAPLs or Dense Nonaqueous Phase Liquids) move to deepest confining layer of an aquifer. Materials of lesser density dissolve in water (LNAPLs) or form layers on top of an aquifer (Light Nonaqueous Phase Liquids). |
| Empirical formula | Definition: States number of each type of atom in a molecule. |
| Henry's Law Constant | Definition: Ratio of equilibrium concentration (in atmospheres) of a constituent in air relative to its concentration (in moles/cubic meter) in water at referenced temperature. |
| | Effect: Often termed "air-water partition coefficient," it describes relative volatility of chemicals. Henry's Law Constant less than $10^{-7}$ atm-$m^3$/mol indicates a chemical of low volatility, greater than $10^{-7}$ atm-$m^3$/mol, but less than $10^{-5}$ atm-$m^3$/mol, indicates slow volatilization into air, values greater than $10^{-5}$ atm-$m^3$/mol but less than $10^{-3}$ atm-$m^3$/mol indicate volatilization is an important mechanism of loss to air. Values exceeding $10^{-3}$ atm-$m^3$/mol indicate rapid volatilization. |
| Log $K_{oc}$ | Definition: Ratio of absorbed chemical in soil/sediment to an aqueous solution concentration. |
| | Effect: Also called "soil/sediment partition coefficient," it provides information on relative attraction of a chemical for soil/sediment in comparison to water. Chemicals with high values typically have low water solubilities while chemicals with low values have high water solubilities. |
| Log $K_{ow}$ | Definition: Log of ratio of equilibrium concentration of constituent in octanol relative to its concentration in water. |
| | Effect: This metric is also known as "n-octanol/water partition coefficient." Chemicals with higher Log $K_{ow}$ values tend to partition into fatty tissue, compared to those with lower values and also have a higher tendency to bioaccumulate/biomagnify than those with lower values. This is a key parameter to predict environmental fate of organic chemicals. |