1 Introduction

Environmental risk analysis for human health is a systematic analytical process for assessing, managing, and communicating the risk to human health from contaminants released to or contained in the environment in which humans live. Environmental risk analysis encompasses a broad variety of disciplines and endeavors, including natural sciences such as geology, meteorology, hydrology, and ecology, which describe the natural environment in which contaminants migrate; biological sciences such as physiology, toxicology, anatomy, and cell biology, which describe the interaction and response of humans to environmental toxins; physical sciences such as physics and chemistry, which describe how contaminants migrate in natural systems; and decision and social sciences, which provide methods for making rational decisions and for communicating with stakeholders throughout the risk analysis process.

A well-established paradigm for risk analysis is that it is comprised of (1) risk assessment, (2) risk management, and (3) risk communication (ACS 1998). Most of this book addresses the environmental risk assessment component of environmental risk analysis. However, most environmental risk assessments are performed to answer a question or resolve an issue, such as: Is it safe for a proposed chemical plant to operate in this location? Because the *issue* drives the scope, depth, technical content, cost, and schedule of the risk assessment, we also address the risk management and risk communication components of environmental risk analysis.

Much of the material presented in Chapters 2 through 11 is in the form of deterministic quantitative relationships. There are exceptions to this practice; for example, Chapter 3 (release assessment) contains an abbreviated treatment of probabilistic methods used for analyzing releases. Probabilistic methods are not introduced until Chapter 12 (uncertainty analysis). There are historical, pedagogical, and practical reasons for this approach. Historically, environmental risk assessment has used deterministic methods to estimate impacts on (i.e., "risks" to) exposed persons. Currently, many regulatory compliance requirements are of a deterministic nature. Because environmental risk analysis involves a blend of so many separate disciplines, an introductory textbook such as this best treats these disciplines in a simplified, largely deterministic fashion. To keep the book to a reasonable size, it is virtually impossible to treat each discipline probabilistically. Also, many probabilistic risk assessments are conducted using a probabilistic driver to repeat a deterministic calculation using different input parameter values.

Quantitative Environmental Risk Analysis for Human Health, by Robert A. Fjeld, Norman A. Eisenberg, and Keith L. Compton

1.1 RISK ANALYSIS

According to the Society for Risk Analysis (SRA 2003), **risk analysis** is

> a detailed examination including risk assessment, risk evaluation, and risk management alternatives, performed to understand the nature of unwanted, negative consequences to human life, health, property, or the environment. . . .

The Food and Drug Administration (FDA 2002) definition of risk analysis focuses on activities accomplished by its components:

> Risk analysis is a tool to enhance the scientific basis of regulatory decisions. It includes risk assessment, risk management and risk communication activities. Each component has unique responsibilities: Risk assessment provides information on the extent and characteristics of the risk attributed to a hazard. Risk management includes the activities undertaken to control the hazard. Risk communication involves an exchange of information and opinion concerning risk and risk-related factors among the risk assessors, risk managers, and other interested parties.

Given that the three-part paradigm for risk analysis is chosen from the very large universe of risk analysis paradigms, it is important to clarify the functions of the three components (shown schematically in Figure 1.1). Risk analysis is the overall

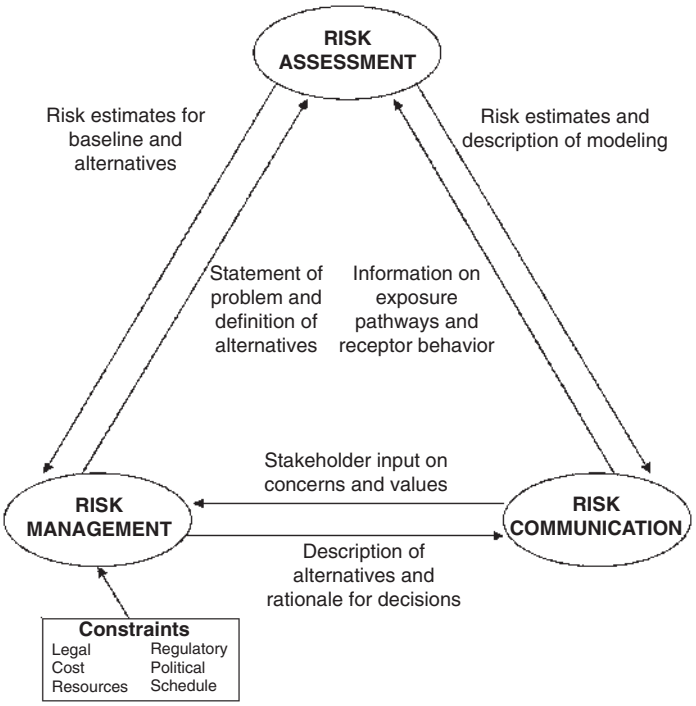


Figure 1.1 Relationships among the three components of risk analysis: risk assessment, risk management, and risk communication.

activity and each component—risk assessment, risk management, and risk communication—is a subsidiary activity required to accomplish the overall goal. It should be recognized that an environmental risk analysis is most often conducted by an entity with the responsibility and authority to make a decision; most frequently, the entity (i.e., the risk manager) is a government agency. The distinction between risk assessment and risk management has been stated succinctly as follows: "Risk assessment is the use of the factual base to define health effects of exposure of individuals or populations to hazardous materials and situations. Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and social, economic, and political concerns to reach a decision" (NAS–NRC 1983). More recently, the Presidential/Congressional Commission on Risk Assessment and Risk Management (1997) defined risk management as "the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and ecosystems," and risk assessment as the process of "considering the nature, likelihood, and severity of adverse effects on human health or the environment." In both of these documents, environmental risk assessment refers to the technical process through which quantitative estimates of risk are obtained, whereas **environmental risk management** refers to the broader process of balancing risks, costs, and social values. In this book, **environmental risk assessment** is defined as the process of making a quantitative estimate of the human health risks resulting from the release or potential release of contaminants to the environment. Environmental risk management considers both the technical results of an environmental risk assessment and the economic, social, legal, cultural, ethical, and political considerations that must be taken into account when making decisions in a broad societal context.

Risk communication refers to interactions among stakeholders, risk assessors, and risk managers. The objectives, often mandated by law, procedures, or good practices, are to assure that important issues are identified for analysis and to facilitate stakeholder understanding of the risk management decisions. Effective risk communication enhances the acceptance of risk analysis by inviting stakeholders to become involved in the analysis process and by assuring that stakeholder concerns are considered. Good risk communication requires both effective transmission and reception of information; it is not merely a means for presenting the results of a risk analysis to stakeholders.

Although in this book we adopt the idea that risk analysis is comprised of risk assessment, risk management, and risk communication, there has been a trend to blur the boundaries between these activities. For example, the American Society of Mechanical Engineers recently stated (ASME 2002): "It has been common practice among practitioners of risk analysis to make distinctions among the various 'phases' of risk analysis (e.g., risk assessment, management, communication). These distinctions are not useful in the overall debate. In attempting to develop a broad consensus on methodology, all aspects of the process should be integrated." Another view essentially incorporates risk assessment and risk communication into risk management. The Presidential/Congressional Commission on Risk Assessment and Risk Management (1997) articulates a six-stage risk management framework: "(1) Define the problem and put it in context; (2) analyze the risks associated with the problem in context; (3) examine options for addressing the risks; (4) make

decisions about which options to implement; (5) take actions to implement the decisions; (6) conduct an evaluation of the actions."

Furthermore, all stages are to engage stakeholders, and iterations are to be performed as warranted by new information. Nevertheless, other approaches recognize that close association of risk management and risk assessment has the potential for undermining the objectivity of the risk assessment. For example, the U.N. Food and Agriculture Organization states (FAO 2003): "There should be a functional separation of risk assessment and risk management in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers, and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application." The three-component paradigm for risk analysis is adopted in this book in part to make the explanation and understanding of these components easier. Even though a linear, one-pass approach is presented here, in practice, risk analysis usually requires significant communication and feedback among components (some are indicated in Figure 1.1) and multiple iterations within each component and for the entire process.

For brevity, in this book the terms environmental risk analysis, environmental risk assessment, environmental risk management, and environmental risk communication are often shortened to risk analysis, risk assessment, risk management, and risk communication, respectively. In so doing, the possibility of confusion is recognized, as there are other types of risk (e.g., financial, political, technological, programmatic) that have nothing to do with human health or environmental contaminants. The reader is cautioned to use these abbreviated forms with care whenever there may be ambiguity about the meaning.

1.2 RISK

Defining risk is a challenging problem. Physical scientists may tend to prefer a quantitative view of risk, and social scientists may favor inclusion of qualitative social and psychological elements in defining risk. Psychological and sociological studies have shown that a person's perception of risk can be affected by a myriad of objective and subjective factors. A quantitative approach to defining risk as appropriate for quantitative analysis has been adopted. However, as discussed in Chapters 13 and 14, the subjective and qualitative elements of risk are of great importance in the broader context of risk communication and risk management. Thus, it is appropriate to recognize the practical limitation of any particular quantitative definition that an analyst may use in performing an assessment.

A general definition of **risk** is: "the probability that a substance or situation will produce harm under specified conditions" (Presidential/Congressional Commission on Risk Assessment and Risk Management 1997). Under this definition, risk is a combination of (1) the probability that an adverse event will occur (such as a specific disease or type of injury) and (2) the consequences of the adverse event. Another definition of risk is "the potential for realization of unwanted, adverse consequences to human life, health, property, or the environment; estimation of risk is usually based on the expected value of the conditional probability of the

event occurring times the consequence of the event given that it has occurred" (SRA 2003).

The definitions above imply a two-dimensional construct that includes (1) the probability of an adverse event (i.e., a hazard) and (2) the consequences of the event. A **hazard** is a potential source of danger; and hazards are a normal part of everyday experience, ranging from the familiar (the electrical energy in household outlets or an automobile accident) to the exotic (the existence of undiscovered viruses or a meteorite falling from the sky). The distinction between hazard and risk is stated succinctly by the Presidential/Congressional Commission on Risk Assessment and Risk Management (1997) as: "Risk encompasses impacts on public health and on the environment, and arises from exposure and hazard. Risk does not exist if exposure to a harmful substance or situation does not or will not occur. Hazard is determined by whether a particular substance or situation has the potential to cause harmful effects."

For each hazard, there is a chance or likelihood, which is expressed as a probability, of contacting or experiencing the hazard. For example, earthquakes are a natural hazard that may cause injury, death, and property damage. The consequence for human health can range from no injury to death, depending on the severity of the earthquake, distance from the epicenter, and other factors. Quantification of risks such as this are expressed through a risk curve. The ordinate (y-axis) of a risk curve is exceedance probability or exceedance frequency, which is the probability or frequency that the severity of the effect exceeds the corresponding value on the abscissa (x-axis). A risk curve for earthquake-caused fatalities is presented in Figure 1.2. The ordinate is the number of earthquakes per year that cause the number of deaths exceeding the value given on the abscissa. For example,

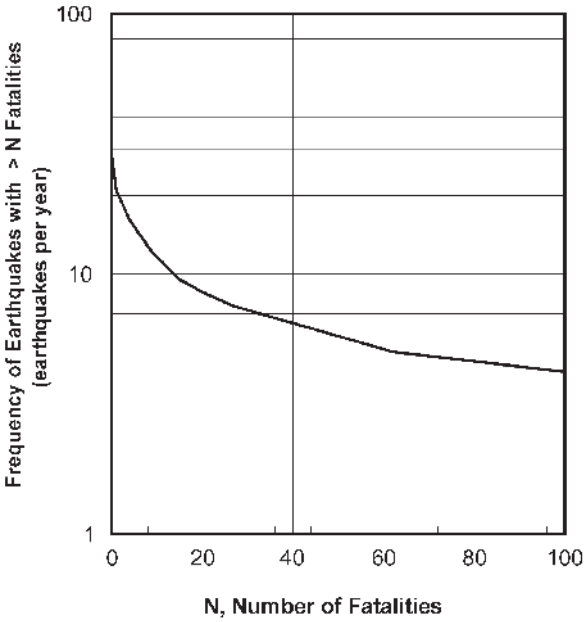


Figure 1.2 Risk curve for earthquake-caused fatalities. (From USGS 1997.)

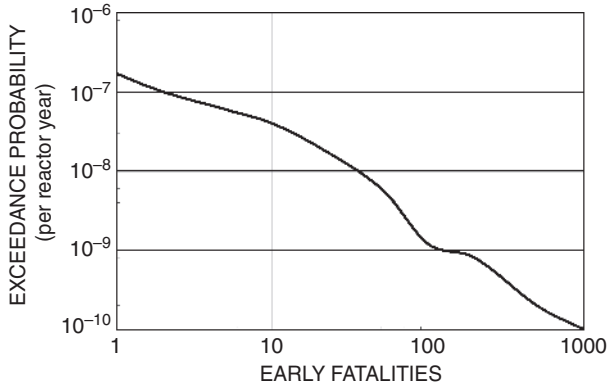


Figure 1.3 Risk curve for early fatalities as a result of a nuclear reactor accident. Results are for Unit 1 of the Surrey Power Station near Williamsburg, Virginia. (From NRC 1991.)

the number of earthquakes causing more than 100 deaths is approximately 4 per year. Another exceedance curve is shown in Figure 1.3 for nuclear reactor accidents. The abscissa is the number of fatalities occurring as a result of a reactor accident, and the ordinate is the corresponding exceedance probability. For example, the probability per year of an accident occurring and causing more than 100 fatalities is approximately 10^{-9}. Thus, the probability of an accident occurring and causing more than 100 fatalities during 40 years of operation would be approximately 4×10^{-8}.

► **Example 1.1**

Use Figure 1.3 to find the following:

(a) The probability of more than 10 fatalities in one year of reactor operation.
(b) The probability of more than 10 fatalities in 40 years of reactor operation.
(c) The probability of one or fewer fatalities in 40 years of reactor operation.

Solution

(a) Reading from the graph, the exceedance probability per year corresponding to more than 10 deaths is approximately 4×10^{-8}.
(b) As stated, the probability of more than 10 deaths per year of operation is 4×10^{-8}. Thus, the probability for 40 years of reactor operation is approximately $(40\,\text{yr})(4 \times 10^{-8}\,\text{yr}^{-1}) = 1.6 \times 10^{-6}$.
(c) From the graph, the probability of more than one fatalities is approximately $1.6 \times 10^{-7}\,\text{yr}^{-1}$. Thus, the probability of one or more fatalities for 40 years of reactor operation is $(40\,\text{yr})(1.6 \times 10^{-7}\,\text{yr}^{-1}) = 6.4 \times 10^{-6}$. The probability of less than one fatality is then $1 - 0.0000064 = 0.9999936$.

The two-dimensional definition of risk clearly articulates that risk may be thought of as a particular *un*desirable outcome and the probability of that outcome. Clearly, any particular outcome is uncertain; however, low-consequence outcomes typically have a probability of occurrence close to 1. In the context of environmental risk analysis for human health, the probability represented in the risk curve may reflect uncertainty due to a variety of factors, either individually or together: (1) the occurrence of some event that could initiate an environmental release, (2) the probability of a release given an initiating event, (3) the likelihood that a contaminant would migrate to a particular location, (4) the likelihood that a person would be exposed at that location, and (5) the probability, given an exposure, that a person would respond with a particular level of injury. Variability of risk in space, time, and across a population is considered in Chapter 12. For some problems in environmental risk analysis, either the health impact or its probability of occurrence may be "degenerate" or "trivial"; that is, probabilities may be zero or one and health impacts may be zero. However, even in these degenerate cases, the risk paradigm may be used.

Another approach (Kaplan and Garrick 1981) defines risk as a triple (sometimes called the Kaplan–Garrick **risk triple**):

$$R_i = \langle S_i, P_i, C_i \rangle \tag{1.1}$$

where S_i is the scenario i, P_i the probability of scenario i, and C_i the consequence of scenario i. In this construct the scenario represents what can happen (or the set of conditions), the probability represents how likely it is, and the consequence represents the impacts. This mathematically robust definition of risk has the advantage of directly representing a commonsense understanding of the concept; for example, the definition promulgated by the Presidential/Congressional Commission on Risk Assessment and Risk Management (1997) of risk as the "probability that a substance or situation will produce harm under specified conditions" reflects the quantitative definition succinctly.

Although Eq. 1.1 represents the consequence C_i as a scalar quantity, it is sometimes useful to consider it to be a vector with various components. For example, the accidental release of a contaminant from an industrial facility could cause different classes of consequences, such as injury, prompt death, latent cancer fatality, and genetic damage. Although each of these is a human health impact, they are qualitatively different. Different scenarios may produce a different distribution of consequences among these categories. Another common partitioning of consequences is to separate health effects among the general public from those among workers at a facility. The distribution of consequences among categories can become especially important when evaluating alternative risk management strategies. For example, some strategies for reducing public consequences may produce unacceptably high consequences for workers. This type of trade-off is discussed in more depth in Chapter 14.

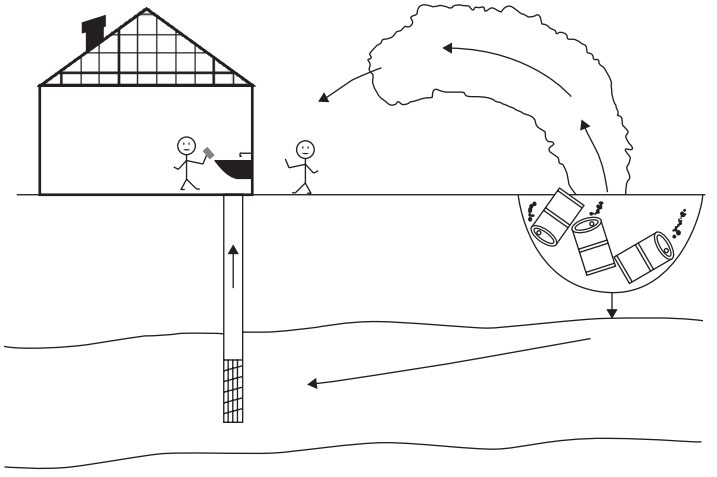
Based on the above, environmental risk as used in this book is the risk triple. The scenario represents the conditions of contaminant release, contaminant transport, and human exposure; the probability is the probability of the scenario; and the consequence is the health effect (more generally, the consequence would include impacts on human health, ecological effects, and aesthetic effects).

1.3 CONTAMINANTS IN THE ENVIRONMENT

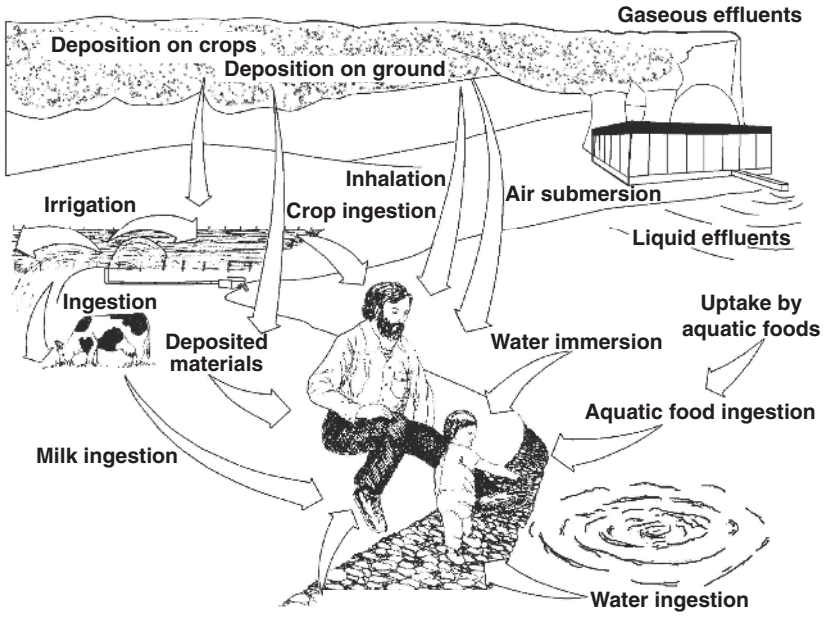
In the context of environmental risk assessment, a contaminant can be defined as a substance in the environment that is capable of causing adverse human health, ecological, or aesthetic effects. Recognizing that virtually any element or compound in sufficient quantity is capable of causing harm, identification of specific substances as contaminants requires the exercise of judgment. The Environmental Protection Agency (EPA) defines a **contaminant** as "any physical, chemical, biological, or radiological substance or matter that has an adverse effect on air, water, or soil" (EPA 2005). Environmental contaminants can be the result of either natural processes or human activities. Examples of naturally occurring contaminants include airborne particulate matter and gases from volcanic activity or forest fires; waterborne metals such as arsenic, mercury, or uranium decay products due to leaching from soil; and aflatoxin B1 in grains due to mycotoxin-producing molds. Examples of anthropogenic contaminants include ozone and related photochemical oxidants in air due to emissions from internal combustion engines, chlorinated hydrocarbons in air and water from the use of pesticides and herbicides, and radionuclides such as hydrogen-3, cesium-137, and plutonium-239 from nuclear reactors.

Many anthropogenic contaminants are routinely released to the environment because they either serve some useful purpose (such as protecting crops against insects or disease) or they are the by-products of an activity (such as the generation of electricity) that society considers to be beneficial. Others are released accidentally as a result of equipment failure, human error, or a natural phenomenon (such as a flood or earthquake). The conceptualizations in Figure 1.4 illustrate the release, transport, and human exposure of contaminants from (a) buried wastes and (b) an operating facility, both of which are typical scenarios encountered in environmental risk assessment. Risk assessment scenarios generally have the following elements: an actual or potential source of a contaminant, mechanisms for the release of the contaminant to the environment, environmental pathways through which the contaminant is transported and transformed, routes or mechanisms of exposure to humans or other receptors, and the possibility of an adverse human health, ecological, or aesthetic effect.

There exist plentiful historical examples for which contaminant releases resulted in documented adverse human health or ecological effects (Table 1.1). These range from the classic water pollution example in which John Snow traced cholera to a contaminated well in nineteenth-century London (Snow 1855) to the induction of thyroid cancer in children in Belarus and the Ukraine as a result of radionuclides released in the Chernobyl accident in 1986 (UNSCEAR 2000). With examples such as those in Table 1.1 in mind, questions then arise when contaminants are found in environmental media (e.g., pharmaceuticals and endocrine-disrupting chemicals in water, fine particles in urban atmospheres, or pesticides and herbicides in food) or when permits are sought for certain types of facilities (e.g., for hazardous waste incinerators, radioactive waste disposal sites, or chemical manufacturing facilities). Do these pose a threat? The intuitive answer can range from alarm to indifference, either of which may be appropriate but neither of which is defensible without a systematic informed evaluation. Such an evaluation is achieved by an environmental risk assessment, which may generally be defined as the process of making a



(*a*)



(*b*)

Figure 1.4 Human exposures due to routine releases of environmental contaminants: (*a*) buried waste (adapted from EPA 1989); (*b*) facility release (adapted from DOE 1978).

quantitative estimate of the human health, ecological, or aesthetic effects of the release or potential release of contaminants to the environment. It is a systematic process for obtaining an objective estimate of the risk posed by environmental contaminants. Contaminant effects may be considered to be in three broad classes: effects on human health, such as cancer or systemic disease; impacts on ecosystems, such as loss of species or decreased species diversity; and adverse impacts on

TABLE 1.1 Examples of Contaminant Releases Resulting in Adverse Human Health or Ecological Impacts

Location	Date	Contaminant	Effect	Reference
London	1852	Human waste	Cholera	Snow 1855
Ducktown, TN	1900s	SO_2 from a smelter	Death of vegetation	Wagner 1971
Donora, PA	1948	SO_2 and particulate matter from various industries	20 immediate deaths; 5910 cases of respiratory distress in a population of 14,000	Waldbott 1978
Minimata, Japan	1950s	Methyl mercury	Dead fish, birds, and cats; nervous disorders and birth defects in humans	CERHR 2006
Seveso, Italy	1976	Dioxin	Chloracne, death of farm animals, high female/male birth ratio	CDC 2006
Bhopal, India	1984	Methyl isocyanate released in an accident at a chemical plant	3800 immediate deaths; other effects (lungs, eyes, stillbirths) in 170,000 survivors	EPA 1986
Ukraine and Belarus	1986	Radioactivity released from the Chernobyl accident	31 immediate deaths; increased thyroid cancer in children	UNSCEAR 2000
Sweden and northeastern United States	Present	Acid rain due to oxides of nitrogen and sulfur in the atmosphere from combustion of fossil fuels	Widespread damage to forest ecosystems and freshwater fish habitats	Lloyd 2001

aesthetic qualities of the natural environment, such as reduced visibility due to air pollution or odors from industrial operations. Conceptually, the risk assessment framework presented in this book for human health effects could be extended to ecological and aesthetic effects, but a description of the implementation of such an approach is beyond our scope.

1.4 USES OF ENVIRONMENTAL RISK ASSESSMENT

There are various reasons for performing environmental risk assessments, most of which serve one of the following generic purposes: risk management for an existing or proposed facility, development of regulations, demonstration of compliance with regulations, litigation, or scientific inquiry. In practice, most risk assessments are performed for the purpose of risk management or to demonstrate regulatory compliance. As introduced in Section 1.1 and covered in detail in Chapter 14, risk assessment is only one component of a larger risk management process, which is usually conducted in a regulatory context. At both the federal and state levels, there is an abundance of environmental regulation with broad policy goals (e.g., protection of human health or the environment) which either implies or is interpreted by

regulators to imply that risk assessment is required. For example, the Comprehensive Environmental Response, Compensation and Liability Act (42 U.S.C. 9601 et seq.; CERCLA or "Superfund") stipulates that hazardous waste cleanup levels must assure "protection of human health and the environment" against contaminants that "will, or may reasonably be anticipated to cause" certain adverse effects. Another risk management context in which risk assessments are needed is to support remediation programs for complex contaminated sites. For example, the Department of Energy's environmental management program lists the elimination of urgent risks and risk reduction as two of its objectives. Risk assessments are used to evaluate the level of risk posed by contaminated sites, to identify sites that pose urgent risks, to establish cleanup priorities, and to determine the reduction of risk that can be obtained through remediation. Another practical application of risk assessment is in regulatory compliance. The operator of a proposed facility might be required to perform a risk assessment either to show compliance with numerical regulatory requirements or to provide a regulatory agency with evidence that the facility will not result in harm to public health or the environment. On a smaller scale, a person might want to estimate the risk to herself or to a family member, due to lead in drinking water, mercury in fish, or fine particles in the atmosphere.

▶ Example 1.2

In 1985, the EPA established the first set of risk-based standards for volatile organic compounds in drinking water. These standards were applied to eight compounds, five of which were considered to be carcinogens. The concentration limits that were established at that time yielded lifetime cancer probabilities that ranged from 2×10^{-6} (for TCE) to 1×10^{-4} (for 1,1-dichlorobenzene). These risk estimates were based on the consumption of 2 L of water per day for 70 years.

Sometimes, risk assessments are undertaken to determine if a problem exists that requires a response. Such risk assessments are usually conducted as part of a risk analysis that includes risk management and risk communication. Such studies may be conducted or sponsored by regulatory agencies to determine if some sort of regulatory action is required. Examples include those above, in which there is concern over the impact of a given instance of environmental contamination or the potential impact of an industrial plant or waste disposal facility. This also includes retrospective risk assessments in which an attempt is made to estimate the risks posed by historical contaminant releases from a facility. If a reasonable case is made that historical releases caused significant harm, compensation may then be paid to those affected.

■ Fernald Risk Assessment

The Fernald Feed Materials Production Center (FMPC), part of the U.S. Department of Energy's nuclear weapons production complex, operated from 1951 to

1988. The FMPC mainly produced uranium metal at a 1000-acre site located about 15 miles northwest of Cincinnati, Ohio. During operations, radioactive material was released from the site into the air from waste material stored in two large silos and from waste burned or buried in pits and incinerators. Increased risks of cancer in the population near the facility resulting from radioactive material releases from the FMPC were estimated by two risk assessments; phase I (CDC 1998) addressed lung cancer and phase II (CDC 1999) addressed kidney cancer, female breast cancer, bone cancer, and leukemia. The phase I study estimated a median lifetime dose of 0.45 Sv (sievert), principally from inhalation of radon decay products, which was estimated to produce an excess of 85 lung cancer deaths in an exposed population of about 50,000. When some types of uncertainties are considered, the estimated doses ranged from 0.12 to 1.74 Sv, corresponding to an estimated number of excess lung cancer deaths of 25 to 309. This implies an increase of 1 to 12% in cancer incidence from 1951 to 2088 in the exposed population. The phase II study estimated upper bound incidences of various cancer types resulting from exposure to releases from the FMPC. Radiation doses were estimated for hypothetical individuals who ate contaminated foodstuffs (vegetables, fish, milk, eggs), breathed contaminated air, and resided on contaminated soil. The upper bound cancer estimates were 23 for leukemia, 4 for kidney cancer, 3 for female breast cancer, and 4 for bone cancer in a population estimated at 46,000.

In implementing legislative initiatives, regulatory agencies frequently use risk assessment to develop limits on contaminant concentrations in air or water that meet a numerical risk goal. For example, the Clean Air Act (42 U.S.C. 7401 et seq.) requires the EPA to issue ambient standards sufficient to "protect the public health with an adequate margin of safety," issue standards for sources of hazardous pollutants which are "known or anticipated to cause adverse effects," and set supplemental emission standards if it is found that the standards do not provide an "ample margin of safety" (for known and potential carcinogens, generally defined as a 1 in 10,000 to 1 in 1 million lifetime chance of cancer). Similarly, the Atomic Energy Act (42 U.S.C. 2011 et seq.) stipulates the formulation of standards for the "protection of the public health, safety, and the environment" from radiation hazards.

Suits ("toxic torts") may be brought alleging that a given effect (e.g., cancer, birth defect, mental disorder) occurred as a result of exposure to a given substance. Risk assessments can be used by either defendants or plaintiffs to support their side of a case. Risk assessments have been used in cases involving radiation hazards, dioxin, Agent Orange, and volatile organic compounds, to name a few. Risk assessments can be used to provide weight of evidence that a toxic response may or may not be due to the exposure in question and thus may or may not be eligible for redress under the law. The scientific inquiry purpose of risk assessment is frequently tied to an investigation of new or alternative methods of analysis. Another issue for scientific inquiry is the investigation of contaminants or impacts not previously considered in a regulatory context, which could be significant.

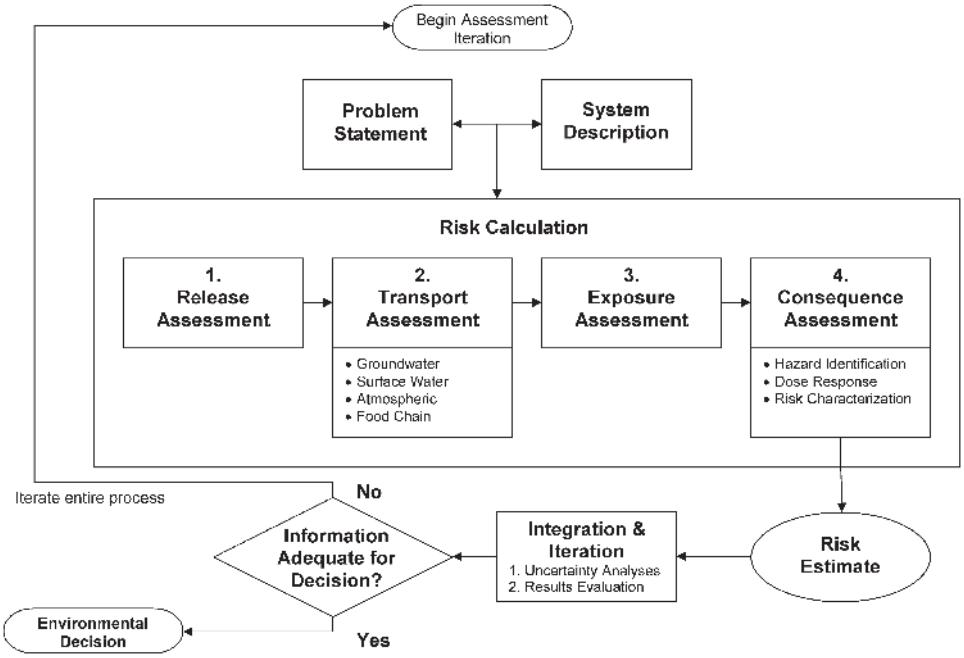


Figure 1.5 Risk assessment process.

1.5 RISK ASSESSMENT PROCESS

The overall risk assessment process consists of four major components: problem statement, system description, risk calculation, and integration and iteration (Figure 1.5). The focus of this book is on the risk calculation component, which is the computational core of the overall process. However, this computational core depends greatly on other parts of the risk assessment process, particularly the problem statement and system description. Also, during the final step of integration and iteration a decision is made to determine whether the assessment is complete and adequate or whether certain aspects need to be revisited. In reality, the risk assessment process may be much more complicated and nonlinear, with multiple iterations (Morgan and Henrion 1990, Sec. 3.8.8).

1.5.1 Problem Statement

Virtually all risk assessments are performed to answer a question. Even risk assessments pursuing scientific inquiry have a hypothesis to be tested, consistent with the scientific method. The question asked has a great influence on the scope, level of detail, and focus of the risk assessment, including the time scale, the spatial scale, the contaminants considered, the endpoint of the assessment (the measure of risk or impact), the persons at risk, and the treatment of uncertainty. For example, retrospective assessments of doses and risks, called dose reconstructions, have been performed to determine whether previous operations at former DOE weapons

facilities were harmful to the adjacent population. Some dose reconstructions have been directed toward an entire population within broad geographical boundaries; others have been directed to populations of special concern, such as nearby Native American groups. Dose reconstructions are focused on the releases of radioactive and chemical contaminants from the site but are not concerned with releases from other sources or contaminants already present in the air, water, and soil. Dose reconstructions usually consider uncertainties, so both the average dose and risk may be reported as well as their ranges.

In addition, the statement of the problem might implicitly or explicitly mandate certain assumptions or methods. For example, the EPA uses the concept of "maximally exposed individual" in several regulatory applications. A maximally exposed individual is defined as "the single individual with the highest exposure in a given population" and is used synonymously with the worst-case or bounding estimate. The concept is found in regulations for high-level nuclear waste and Superfund sites, where an upper limit on the dose or risk to the maximally exposed individual is prescribed. In practice the analyst may limit the assessment by choosing the nearest accessible location to the site as the location for the maximally exposed individual and by using pessimistic values for variables associated with environmental transport and uptake of contaminants. In this fashion, calculations at multiple locations and for multiple values of a large number of variables are avoided.

1.5.2 System Description

The system description includes qualitative and quantitative information about physical processes in the system, the time scales of interest, and the geometry and physical configuration of the system. The system description provides key information for the risk calculation component of the risk assessment, including the release form, the temporal character of the releases, transport mechanisms and transport media, biota at the site, land-use characteristics, human activities in the vicinity, and toxicological characteristics of the contaminants of concern. From this information the analyst can formulate a conceptual model for each step of the risk calculation. For example, a dose reconstruction (CDC 2005) was performed for the Savannah River Site, a DOE facility used to manufacture material for nuclear weapons. Although several instances of groundwater contamination on the site had been documented, the dose reconstruction did not consider radionuclide migration by the groundwater pathway because the contaminated groundwater moves so slowly that it had not yet migrated past the site boundary. However, since air and surface water releases were well documented, the conceptual model included migration in the air and in the Savannah River.

1.5.3 Risk Calculation

When applied to human health effects, the objective of the risk calculation component of the risk assessment process is to produce a quantitative estimate of human health risk due to the release of a contaminant to the environment. The process for making this estimate of health effects can be formulated in different ways. In this book it is presented as four sequential steps (Figure 1.6): release

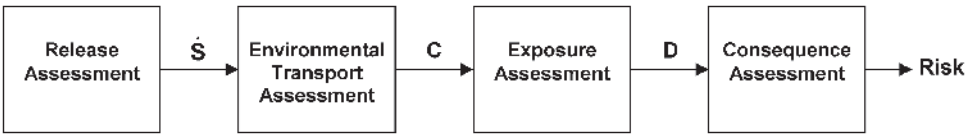


Figure 1.6 Risk calculation component of the risk assessment process.

assessment, transport assessment, exposure assessment, and consequence assessment. Each step has a qualitative component and a quantitative component. Qualitative components are those that do not result from calculations: for example, identification of contaminants or of potentially exposed populations. The quantitative output of each step is the input to a subsequent step, ultimately leading to a quantitative estimate of health risk. Each step and the quantitative results are described below.

Traditionally, the risk calculation step in the overall risk assessment process has been denoted by the term "risk assessment". However, as noted, the actual process of assessing risk involves more than just the risk calculation itself. The risk calculation component of the process can be formulated in various ways; the end result of each is a quantitative estimate of health risk. The American Association of Engineering Societies (AAES 1996) casts the risk calculation step in a fashion similar to that presented in this book. They specify the following three steps: source assessment, exposure assessment, and effects assessment. In the AAES formalism, risk characterization is a separate step that combines the results of effects assessment with risk assessment policy. In 1983, the National Academy of Sciences (NAS–NRC 1983) cast risk assessment in terms of the following four steps: hazard identification, dose–response assessment, exposure assessment, and risk characterization. The EPA has modified this slightly for the baseline risk assessments they require for the CERCLA process. The EPA baseline risk assessment (EPA 1989) consists of data collection and evaluation, exposure assessment, toxicity assessment, and risk characterization, as shown in Figure 1.7. An important perspective provided by the NAS and EPA formulations is that the dose–response assessment (NAS) or toxicity assessment (EPA) depends primarily on the contaminant, its form, and to a lesser degree the nature of the exposed population (e.g., age, gender). Therefore, generic toxicity data may be obtained independently from site investigations and may be used at a variety of sites. This is significant for organizing significant amounts of work to accomplish the baseline and other risk assessments. The linear sequence of four calculational steps adopted in this book is intended for use by the risk analyst, who will produce an estimate of health risk by executing the sequence of steps. That being said, it is important to point out again that in practice there may be iterations within or among steps or iterations with other elements of the overall risk assessment process.

1.5.3.1 Release Assessment Release assessment is identification of contaminants and quantitative estimation of release probabilities and release rates into the environment. Contaminant identification is accomplished by direct measurement of inventories or effluents, process knowledge, and an audit of facility records. For convenience, in this book contaminants are grouped into five discrete categories:

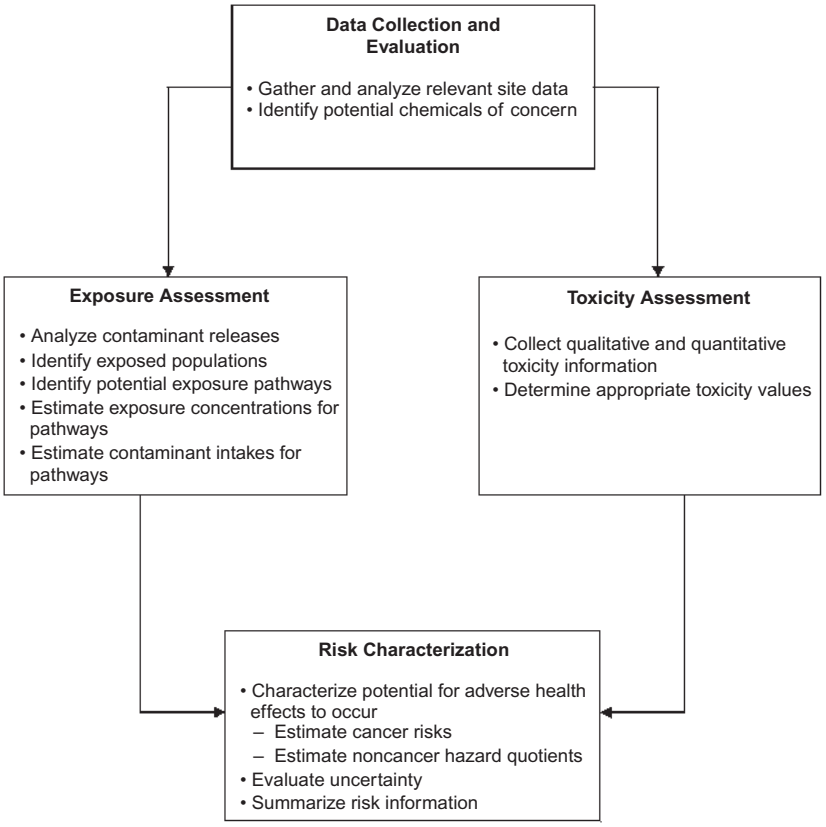


Figure 1.7 EPA and NAS formulations of the risk calculation component of the risk assessment process.

(1) organic compounds such as TCE, PCE, and CCl_4; (2) inorganic compounds such as SO_2 and NO_x; (3) metals such as lead, mercury, and chromium; (4) radionuclides such as ^{3}H, ^{90}Sr, ^{137}Cs, and ^{239}Pu; and (5) miscellaneous contaminants such as particulate matter, asbestos, and pathogens. Contaminant identification also includes the physicochemical form of the contaminants and the environmental media—atmosphere, soils, groundwater, and surface water—into which the contaminants are released.

The quantitative result of release assessment is **contaminant emission rate**, $\dot{S}$, which is the amount of contaminant released per unit time. For chemical contaminants, the emission rate is contaminant mass per unit time [M/T]; for radiological contaminants, it is the amount of radioactivity per unit time [activity/T]. The emission rate may have both a spatial and a temporal dependence, and it can result from either normal facility operation or an accident. Accidental releases occur as the result of an unlikely event (such as an earthquake, tornado, or fire) or a sequence of unlikely events (such as a series of component failures possibly combined with human error). Emission rate may be estimated either from direct measurement of emissions, from models based on process knowledge, or from a combination of the two.

1.5.3.2 Transport Assessment Transport assessment is (1) identification of the pathways (such as those illustrated in Figure 1.4) through which the contaminants move and are transformed by physical, chemical, and biological processes in the environment, and (2) estimation of **contaminant concentration**, C, in air, water, soil, and food at specific locations in time and space. As in release assessment, transport assessment may be conducted either by direct measurement or by the use of predictive models for the movement of contaminants through environmental media.

For some problems, such as a preexisting waste disposal site, it might be possible to determine contaminant concentrations through a network of field measurements. These concentration measurements could then be used to estimate exposures. More commonly, the concentrations must be based on transport models because measurements are either not practical (e.g., concentrations are below detectable limits, the area of consideration is too large) or not possible (e.g., future concentrations from existing or planned facilities are needed). The contaminant transport problem is complex because of the inherent complexity of environmental systems. In addition to the physical processes that govern transport in air and water; any of a number of chemical and biological processes may also be important. These processes are not always well understood, and they can depend on many factors. These factors, in turn, may be poorly understood or highly variable. Nonetheless, by combining and interfacing empirical data for processes that are poorly understood with mathematical theory for processes that are well understood, it is possible to develop models for predicting contaminant concentrations in air, water, and food. However, it must be remembered that a model is an idealization, so the adequacy with which the model represents the important aspects of the environmental system is usually an issue.

1.5.3.3 Exposure Assessment Human exposure assessment consists of (1) identification of exposed populations (receptors) and exposure routes, and (2) estimation of the rate at which humans are exposed to the contaminant. The quantitative result is an estimate of contaminant dose or dose rate to members of the exposed population. Human exposure can occur via a number of pathways. The most significant from an environmental contamination perspective include ingestion, inhalation, dermal absorption, and in the case of radioactivity, exposure due to contaminants located outside the human body. Ingestion can include the consumption of contaminated food or water and from the accidental ingestion of water or soil. Inhaled contaminants may be present in either gaseous form or as suspended particulate matter. Dermal absorption can arise from immersion in contaminated air or water or as a result of physical contact with contaminated soil.

For chemical contaminants, exposure is commonly quantified by the **average daily dose rate**, $\bar{D}$, which is the mass of contaminant taken into the body per unit body weight per unit time [M(c)/(M(body)/T]. The integrated dose, D [M(c)/M(body)], is used to quantify short-term exposures. For radiological contaminants, the dose measure is either **equivalent dose** or **effective dose**, and the integrated dose is used for all exposures, both short and long term.

1.5.3.4 Consequence Assessment In general, consequence assessment encompasses adverse aesthetic, ecological, and human health effects. In this book the

focus is on human health effects; and consequence assessment is identification of the types of health effects that can be caused by a contaminant and a quantitative estimate of the probability and/or severity of those effects. For purposes of contemporary human health risk assessment, it is convenient to define two broad health effect categories: deterministic and stochastic. Although these categories are addressed subsequently in some detail, they are introduced here because of their importance in the risk assessment process. **Deterministic effects** are those for which the severity is a function of dose. They typically occur only if an individual tolerance threshold is exceeded, and they display an increasing severity as the dose is increased above the threshold. Lead is a contaminant that causes deterministic effects. It affects the brain, and as the amount of lead in the brain increases, the degree of mental impairment increases. **Stochastic effect**s are those for which the probability is a function of dose. The effect is binary, that is, it either does or does not occur, and the severity is independent of the dose. The induction of cancer as a result of exposure to chemicals or radiation is the most widely analyzed stochastic effect in health risk assessments, although inherited effects also fall into the stochastic category. Benzene is known to cause leukemia in humans, but an exposure to benzene does not always result in leukemia. However, as the dose increases, the probability of contracting leukemia increases as well. Some risk agents induce both deterministic and stochastic effects. For example, in addition to the risk of leukemia, benzene reduces the number of all three types of blood cells and at very high concentrations damages the central nervous system.

The utility of the stochastic versus deterministic distinction lies in the metrics that are used to characterize health risk. The metric for stochastic effects is the **fractional response**, which is the probability of incidence of a binary effect. The metric for deterministic effects is a **margin of safety**, which is a comparison of the calculated dose to a dose that is considered to be safe. The deterministic/stochastic distinction presented here is similar to, but more general than, the noncarcinogenic/carcinogenic scheme used by the EPA. Stochastic effects are not limited to cancer but can include other binary effects, such as inherited abnormalities and some teratogenic effects (e.g., deformed or missing limbs).

1.5.4 Integration and Iteration

During the entire process of risk assessment, it is important to assure that the different parts of the analysis are integrated. For example, releases to both air and water may be important for a particular assessment. The assessment must model the transport of these releases, human exposure to contaminated media, and the response of the humans to the resulting dose. In addition, it may be important to model significant transfer from one medium to another. For example, a volatile contaminant released to water may provide a significant source of contamination for air. Another aspect of integration is the consistency of assumptions and choices for variable values. If it is assumed that all of the contamination released ends up in a small pond, it is incompatible to assume that a community of hundreds of thousands of people uses the pond for their entire water supply. If the assessment has assumed a significant annual rainfall (say, 3000 mm/yr) for purposes of

calculating deposition of sulfur dioxide onto the land surface, it would normally be incompatible to assume a high rate of irrigation from nearby surface water bodies.

When the results are obtained from the four-step risk calculation process, those results should be evaluated in the context of the problem statement. If the questions posed by the problem statement are not answered adequately, the assessment process needs to be iterated (i.e., repeated) to provide an adequate response. This usually means the scope or level of detail (or both) needs to be adjusted. For example, if doses and risks for a particular site are computed based on average adult characteristics but the problem statement asks for the risks to the entire population, including sensitive individuals, the assessment scope must be expanded to include children, the elderly, and the infirm.

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PROBLEMS

1.1 **(a)** Give an example of actual contaminant releases that have resulted in documented adverse (**i**) human health, (**ii**) ecological, and (**iii**) aesthetic effects. Give the setting and identify the following: source of the contaminant release, the environmental transport pathway(s), route of exposure, and the adverse effect.

(b) Give an example of a contaminant release in which the human health, ecological, or aesthetic effects are an open question.

1.2 Use the earthquake risk curve in Figure 1.2 to determine the following:

(a) The number of earthquakes each year that result in more than 60 fatalities.

(b) The number of earthquakes each year that result in 21 to 60 fatalities.

1.3 **(a)** Given the risk curve in Figure 1.8 for the risk per year of early fatalities as a result of an accident at a nuclear power plant, find the following: (**i**) the probability of more than 100 fatalities in a given year as a result of an accident; (**ii**) the probability of one or less than one fatality in a given year as a result of an accident.

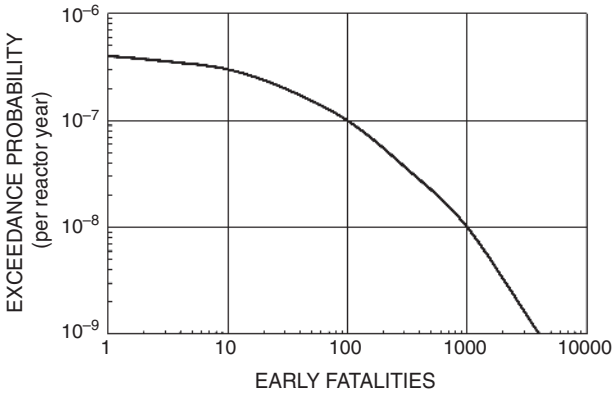

Figure 1.8 Risk curve for Problem 1.3.

(b) If the risk curve in Figure 1.8 were to apply to each of the 100 nuclear power reactors in the United States, what is the probability of one or more fatalities as a result of accidents during the 40-year operating life of the reactors?

1.4 A risk curve for fatalities as a result of train accidents in the Eurotunnel between France and England is shown in Figure 1.9. The abscissa is the number of fatalities and the ordinate is the exceedance frequency per year (i.e., the probability per year that an accident will occur that results in more than N fatalities). From this curve find the following:

(a) The probability of an accident resulting in more than one fatality.

(b) The probability of an accident resulting in more than 10 fatalities.

(c) The probability of an accident resulting in 21 to 30 fatalities (i.e., more than 20 but fewer than 31).

(d) If the exceedance frequency is constant over time, how often will there be an accident involving (**i**) more than one fatality and (**ii**) more than 10 fatalities.

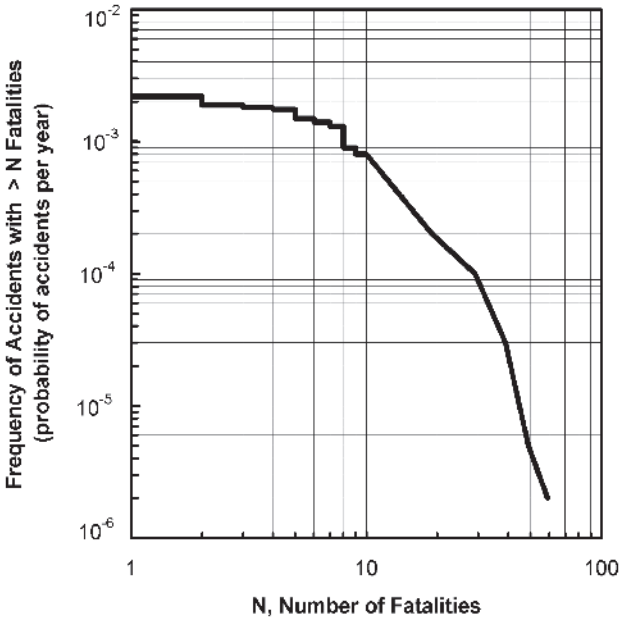

Figure 1.9 Risk curve for fatal accidents in the Eurotunnel between France and England for Problem 1.4. (Data from Evans and Verlander 1997.)