# Historical Relationship Between Performance Assessment for Radioactive Waste Disposal and Other Types of Risk Assessment

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This article describes the evolution of the process for assessing the hazards of a geologic disposal system for radioactive waste and, similarly, nuclear power reactors, and the relationship of this process with other assessments of risk, particularly assessments of hazards from manufactured carcinogenic chemicals during use and disposal. This perspective reviews the common history of scientific concepts for risk assessment developed until the 1950s. Computational tools and techniques developed in the late 1950s and early 1960s to analyze the reliability of nuclear weapon delivery systems were adopted in the early 1970s for probabilistic risk assessment of nuclear power reactors, a technology for which behavior was unknown. In turn, these analyses became an important foundation for performance assessment of nuclear waste disposal in the late 1970s. The evaluation of risk to human health and the environment from chemical hazards is built on methods for assessing the dose response of radionuclides in the 1950s. Despite a shared background, however, societal events, often in the form of legislation, have affected the development path for risk assessment for human health, producing dissimilarities between these risk assessments and those for nuclear facilities. An important difference is the regulator's interest in accounting for uncertainty.

**KEY WORDS:** Risk assessment; probabilistic risk assessment; performance assessment; policy analysis; history of technology.

## 1. INTRODUCTION

> *Fear of harm ought to be proportional not merely to the gravity of the harm, but also to the probability of the event. . . .*

So wrote Antoine Arnauld and others residing in the Port Royal Monastery, France, in about 1660.[1,2] More than 300 years later, the U.S. Environmental Protection Agency (EPA) mandated an examination of the relationship between the "gravity of harm" and the "probability of the event" in the regulatory standard for disposal of radioactive wastes. This article compiles and summarizes events leading up to and following this EPA-mandated assessment in 40 CFR 191 (Title 40, Code of Federal Regulations, Part 191) that have influenced risk assessments of geologic disposal.

### 1.1. Selection of Historical Material

This article is intended to provide a historical context for the issues presented on disposal of radioactive waste in this special issue of *Risk Analysis* by compiling and summarizing information concerning historical events that have influenced risk assess-

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ments of geologic disposal. This compendium focuses heavily on events at Sandia National Laboratories (Sandia or SNL) because of its extensive role in risk assessments for nuclear facilities, with significant international events presented in some cases. To broaden this context, however, events and their effects on other large-scale policy analyses of risk, particularly chemical carcinogens, are also presented. For example, legislation and select judicial decisions that have helped to mold risk assessments for hazardous chemicals are included. Although policy analysis in general and risk assessment in particular have received, and continue to receive, criticism, the historical aspects of the criticism are not included in this article. Ewing *et al.* (this issue) discusses current criticisms of performance assessments (PAs). Herein, risk assessment is presumed to be an important contributor to risk management decisions, but only one of several possible inputs.

The material is presented chronologically, within five sections that cover four major time periods. Section 2 of this article reviews risk management responses of ancient civilizations to hazards and the development of risk concepts (antiquity–1940; e.g., probability theory). Computational methods, along with limited application of reliability techniques, are discussed in Section 3 (1940–1970). Section 4 focuses on risk assessment for nuclear power reactors and its rudimentary application to geologic disposal systems (1970–1985); Section 5 focuses on the many differing legislative and judicial events that have influenced the use of risk assessments for hazardous chemicals (1970–present). During this period, government policy decisions based on risk assessments have been encouraged, and many diverse applications of risk assessment on different physical systems have been implemented. Section 6 serves as an introduction to this special issue by providing the historical context for the risk assessments of two prominent radioactive waste disposal programs in the United States, the Waste Isolation Pilot Plant (WIPP) for transuranic waste, and the Yucca Mountain Project (YMP), primarily for commercial spent nuclear fuel.

### 1.2. Risk Assessment Process

Although risk has several connotations (if not denotations) inside and outside the profession of risk analysis, *risk* is generally used in this article to express some measure that combines "the gravity of harm" to something valued by society and "the probability of the event." Frequently, within the risk profession, the measure of risk is the expected value of the consequence (e.g., probability times consequence based on average values) as used in simple annuity analysis as far back as 1660. For financial investments, where the word "risk" was used as early as 1776, the measure is often the variance of the return on investment. For situations with large uncertainty, such as disposal of radioactive wastes, the measure of risk is the entire distribution of the possible consequences as required by the EPA in 1985 in 40 CFR 191.

Similar to its use by the National Academy of Sciences (NAS) in 1983,[3] *risk management* is used to describe any means whereby an individual or society attempts to decide whether an activity is safe and, if not, how to reduce the risks of that activity, select options, and prioritize among options. It is an activity that has been performed for thousands of years. Safe is used herein as defined by Lowrance in 1976, that is, having risks that are judged acceptable by an individual or a society (through a political process in the latter case).[4,5] As used in this journal since 1980, *risk analysis* describes all facets of the risk topic such as management and risk assessment.

In the late 1970s and early 1980s, risk assessments that "quantified" risk through the use of mathematical models were called quantitative risk assessments, but the term is not often used now because modeling is so pervasive. Instead, *risk assessment* is used here to denote all systematic processes that estimate a measure of risk. Risk assessment is not a distinct branch of science.[6] Instead, it is a type of policy analysis of what can go wrong in human affairs, a "hybrid discipline,"[7] in which the current state of scientific and technological knowledge is made accessible to society as input to risk management decisions, with time and resource constraints specified by the policy decision makers (or tolerated by society). Important components of risk assessment were not performed until after the late 1950s, yet the development of ideas and tools within several branches of science before and after this time furthered risk assessment as a tool for decision making (Fig. 1).

Because of a common foundation with system analysis, the process of assessing the risk from various hazards is similar. Indeed, the founders of the Society for Risk Analysis recognized these shared ideas and brought practitioners together in 1980 to encourage and enhance the usefulness of risk concepts to society. In general, risk assessment is comprised of up to seven steps[9]: (0) identify appropriate measures of

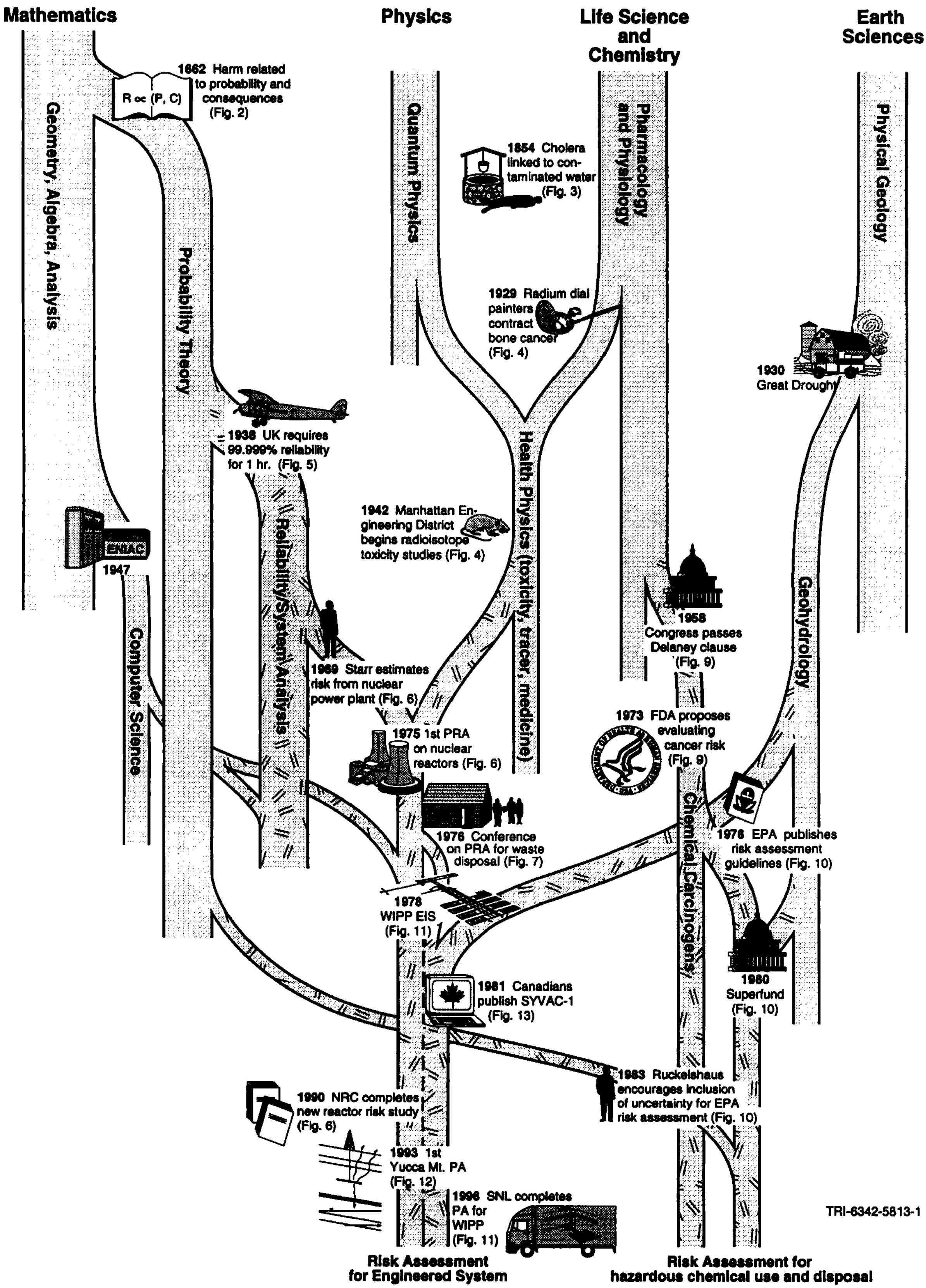



**Fig. 1.** Developments from various branches of science that contribute to risk assessments of nuclear facilities and hazardous chemical use and disposal.

risk and corresponding risk limits; (1) define and characterize the system and agents acting on the system; (2) identify sources of hazards and, if desired, form scenarios; (3) quantify uncertainty of factors or parameters and evaluate probability of scenarios (if formed); (4) evaluate the consequences by determining the response to exposure and, possibly, the pathway to exposure; (5) combine the evaluated consequences and probabilities and compare them with risk limits; and (6) evaluate sensitivity of results to changes in parameters to gain further understanding. As defined here, these steps include the four steps proposed by Lowrance in 1976[3,4] and refined by the NAS in 1983.[3]

The seven steps provide answers to three fundamental questions of risk assessment by Kaplan and Garrick in 1981[9–12]: What hazards can occur? What is the probability of these hazards? What are the consequences potentially caused by these hazards? As with any scientific modeling or policy process, the boundaries between steps may overlap. More important, an analyst may need to cycle through several steps[13] during an activity such as model building or defining risk goals, for example. Hence, the steps are not always truly sequential.

Although the general process of performing a risk assessment for hazards is similar, societal and legislative events during the mid-1970s produced dissimilarities in the emphasis and use of these concepts. In the assessment process, these dissimilarities are reflected in the use of specific terms used in this article. For risk assessments of nuclear facilities, two specific terms are used: probabilistic risk assessment (PRA) and performance assessment (PA).

*Probabilistic risk assessment* (*PRA*) denotes a risk assessment that specifically evaluates the uncertainty of knowledge from various sources in the analysis. Although not limited to such usage in this article, the term also frequently connotes (based on the use in the *Reactor Safety Study* in 1975[14]) a risk assessment of risk to health over a human lifetime from an engineered system such as a nuclear power plant, where failures are short-term events (in relation to the life of the system).

In 1991, the Nuclear Energy Agency of the European Organisation for Economic Co-Operation and Development (OECD/NEA) defined *performance assessment* (*PA*) as "an analysis to predict the performance of a system or subsystem, followed by a comparison of the results of such analysis with appropriate standards and criteria."[15] Given this definition and assuming the performance criteria are risk based and uncertainties are evaluated, PA and PRA are synonymous within the United States. (A possible exception is the implied comparison with established criteria.) However, outside the United States, PA does not always imply an evaluation of uncertainties[16]; hence, a distinction between PA and PRA is maintained. Herein, a PA is used during discussions of a risk assessment, with or without inclusion of uncertainties, to illustrate possible behavior over geologic time scales of a radioactive waste disposal system composed of both engineered and natural components and including a comparison of the results to regulatory criteria (e.g., 40 CFR 191). In such a system, the natural components evolve rather than "fail," as in a nuclear power plant.

Risk assessment is used generically during discussions of risk assessment of hazardous chemicals, despite a subtle difference between risk assessments for hazardous chemicals and those of nuclear facilities in that assessments for hazardous chemicals have a less intimate connection to systems (engineering) analysis (Fig. 1). However, a distinct and important branch of risk assessment of hazardous chemicals identified since 1976 by the EPA is carcinogenic risk assessment (Fig. 1), as noted in Volume 41 of the *Federal Register*, page 21402 (41 FR 21402). Carcinogenic risk assessment is conditional on the occurrence of external exposure to the carcinogen (i.e., the assessment omits the pathway analysis of exposure external to the human and the probability of exposure occurring). This type of assessment has also frequently omitted analysis of uncertainty in model parameters, uncertainty from alternative conceptual models, and parameter sensitivity. Because the assessment focuses on the response of the human receptor, carcinogenic risk assessment is termed a dose–response assessment herein to avoid confusion during discussion of other risk assessments for chemical disposal or ecological evaluations that encompass more steps.

## 2. CONTRIBUTORS TO RISK CONCEPTS

### 2.1. Rudimentary Hazard Identification and Risk Management

Occasional, rudimentary risk management was applied by society prior to 1600, as noted by several authors.[2,17–20] In these cases, society identified a hazard (step 2 of a risk assessment) and then pragmatically adopted risk management controls (i.e., insurance or government controls). Hazard identification, directly followed by risk management controls, is still in use today.

An early response to a hazard was to spread risk among several social groups by issuing insurance, such as bottomry contracts in the Mediterranean in the 1600s BC. This method had been formalized by Hammurabi, King of Babylon, in 1758 BC, whereby risk of maritime loss was borne by money lenders in exchange for interest. Also, by AD 230, the Romans had rudimentary life insurance through societies (collegia) formed to pay burial expenses of its members[2,19] (Fig. 2).

Government intervention to control risk was another technique adopted by ancient civilizations. In 1758 BC, Hammurabi mandated dam maintenance with strict liability for property destroyed when the owner failed to maintain his dam.[21] The enforcement of strict liability presumably encouraged wise building practices, which have continued throughout the centuries and been reinforced by canons of ethics. For example, engineers in the 1930s and 1940s developed procedures for determining plausible upper bounds on floods (plausible maximum flood) for the emergency spillway design on dams.

In the United States, an early attempt at risk management of new technology was performed via the mandated tests and inspections by U.S. Congress to prevent deaths from boiler explosions on steamboats in 1838. Although this legislation failed to reduce explosions because no data or experience existed on necessary tests and useful inspections, a report prepared at personal expense by Guthrie, an Illinois engineer, provided the knowledge for Congress to pass a more effective law in 1852 and establish a regulatory agency, with Guthrie as its first administrator.[19]

These risk management controls were government intervention after the fact. Government intervention *before* an incident, which required the ability to recognize and differentiate among certain types of behavior or actions as hazardous and nonhazardous, and an ability to predict consequences, was not practiced until the 20th century. As described later in this article, it was employed first in the early 1900s for health hazards causing immediate harm, and then in the mid-1900s for hazards causing harm over the long term.

## 2.2. Probability Foundation and Application to Annuities

Probability theory, of which a rudimentary form had emerged by 1660, spread relatively quickly as its

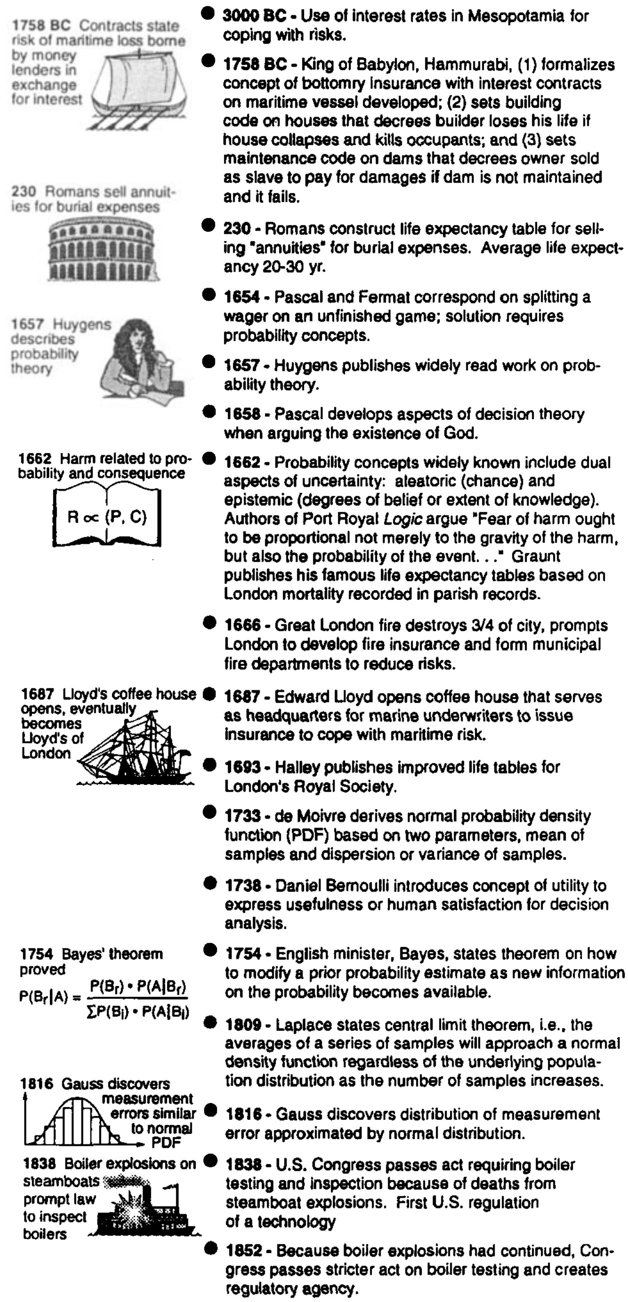



**Fig. 2.** Early events prompting mitigation and development of probability theory (antiquity to 1940).

usefulness was recognized.[1] For example, the Dutch government benefited from this theory because, unlike the Romans of early times, the Dutch often lost money when selling life annuities to finance public works. The use of probability theory, as well as tracking frequencies of disaster and death (e.g., Graunt's tables of life expectancy in 1662 for

London[22]) eventually placed life annuities on a firm foundation.[1,2]

A rudimentary application of probability theory was determining the minimum premium to charge for a death benefit in relation to the expected cost: frequency of death for a person of a certain age or older multiplied by the expected benefit (i.e., "average" cost or consequence to insurance company). Thus, the concept of risk as the expected (mean) consequence was rapidly developed and applied to insurance.[2] However, the steps for performing a formal risk assessment were far from fully developed, and determining the distribution of the consequence, as a more complete characterization of risk, would not occur until the 20th century.

### 2.3. Assessing Human Health

*Health and Hazardous Substances*

As early as 500 BC, a relationship was observed between swamps and diseases such as malaria. In his writings, Hippocrates (460–377 BC) advised that rainwater should be strained and boiled to maintain health.[25] The Romans noted health hazards from mining (beyond those incurred by a mine collapse) and metal use, as did German physicians in the 1400s at two mines in Saxony.[3] With the increased concentration of people in towns during the Industrial Revolution in the 1700s and 1800s, relationships between occupations, personal habits, living conditions, and overall health were more widely observed. Examples include observations by Dr. John Snow who, in 1854, graphically linked cholera outbreaks to contaminated water from one well by means of a map of central London (Fig. 3).[25,26]

Hazard identification followed by increased sanitation, better working conditions, and improved medical services had increased life expectancy in the United States to approximately 50 years by 1900, a doubling of the life expectancy of the Romans; however, the leading cause of death was still infectious diseases (e.g., pneumonia, influenza, tuberculosis).

*Control of Health Risks*

From observations about relationships between living conditions and health came efforts to protect the public from impure or untested chemicals in food and drugs. An early attempt to mitigate health risks was an English law, Assize of Bread, passed in 1263, making it unlawful to sell food "unwholesome to man's body."[17,27] The first large-scale attempt to mitigate health risks of society in the United States occurred in 1813, when Congress passed the Federal Vaccine Act (2 Stat. 806) to test the smallpox vaccine developed by E. Jenner, a British physician in 1796.[27] Prior to this time, some private doctors had inoculated individuals at their request (e.g., Thomas Jefferson in 1766) using pus from smallpox victims in the hope of causing a "light" case of smallpox. The value of this procedure, which carried a moderate probability of inducing a deadly case of smallpox, was examined by Laplace in 1792.[19] Further attempts to control health risks included the 1906 passage of the Pure Food and Drug Act (Public Law 59-384 [34 Stat. 768]), whose main impetus was widespread fraud in packaging, and the more stringent Federal Food, Drug, and Cosmetic Act in 1938 (Public Law 75-717 [52 Stat. 1040]).

By 1940, life expectancy in the United States had increased to 63 years. Knowledge of the sources of infectious diseases (Pasteur in 1864), and introduction of coagulation (1884), filtration (1892), and chlorination (1908) of water supplies,[25] had so greatly reduced incidence of deadly infections that degenerative diseases, such as heart disease and cancer, became the leading cause of death.

*Dose–Response Assessment*

The opinion that effects of a chemical substance could range from beneficial to harmful, based on dose, was expressed as early as 1567.[17,27] Similar observations in this century engendered the field of public health and the need to evaluate a safe level of exposure to such chemicals.[17] Initially, this was accomplished by assessing the threshold dose

[2] The close association of the word "risk" with "insurance" is possible because the word "risk" entered the English language around 1660, just as probability theory emerged, from the French word "risque," which means to expose to hazard.[23] *The Oxford English Dictionary* noted a usage apart from insurance or uncertainty, beginning in the 1900s, in relation to finances ("whether the capital owned . . . was not in risk . . .").[24]

[3] The cause of the high death rates in German mines was later discovered to be from silicosis, tuberculosis, and lung cancer caused by high concentrations of radon gas.[20]

- 500 BC ca - Relationship between swamps and malaria noted.
- 400 BC ca - Hippocrates admonishes that rain water should be boiled and strained to maintain health.
- 100 BC - Romans note exposure to lead fumes injures health.
- 1263 - English pass law, Assize of Bread, making it unlawful to sell food "unwholesome for man's body."
- 1300 ca - Edward I bans use of "sea coal" and requires use of wood in kilns around London.
- 1390 ca - Richard II sleeks to restrict use of coal in London through taxation.
- 1472 - German booklet tells goldsmiths how to avoid poisoning by lead and mercury.
- 1500 ca - Wood around London depleted and use of coal a necessity.
- 1556 - German mineralogist, Agricola, describes miner health problems in Saxony.

1567 The right dose differentiates a poison from a remedy

- 1567 - Physician-alchemist Paracelsus writes: "All substances are poisons. There is none which is not a poison. The right dose differentiates a poison from a remedy."
- 1661 - In London, smoke from coal fires is linked to acute and chronic respiratory problems.
- 1718 - Lady Montagu of Britain proposes inoculation with pus from victims of smallpox to get "light" case of smallpox.
- 1775 - Data suggests juvenile chimney sweeps susceptible to scrotal cancer at puberty.
- 1781 - Tobacco snuff linked to cancer of nasal passage.
- 1792 - Laplace examines the probability of death with and without small pox inoculation.
- 1796 - British physician E. Jenner inoculated 8 yr old boy with cowpox pus from hand of milk maid to vaccinate against human smallpox - human experiment successful.
- 1798 - The United States begins health service for merchant sailors.

1800's Actual deaths compared to predicted deaths from horse kicks

- 1800's - Von Bortkiewicz estimates average number of Prussian soldiers killed from horse kicks based on Poisson distribution and compares with actual deaths.
- 1813 - U.S. Congress passes Federal Vaccine Act to test smallpox vaccine.
- 1822 - Cancer linked to occupational and medicinal exposures of arsenic.
- 1842 - Chadwick reports on link between health problems and lack of nutrition and sanitation in English slums.

1854 Cholera linked to contaminated water

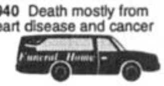
- 1854 - Dr. John Snow links cholera outbreaks to contaminated water.
- 1864 - Pasteur invents pasteurization and establishes link between microbes and infectious disease.
- 1870 - U.S. Congress forms Marine Hospital Service for merchant sailors.
- 1884 - Chemical-coagulation filtration patented.
- 1890 - Ohio starts regulating coal-fired industrial boilers.
- 1892 - German professor observes the value of sand filtration in protection against cholera bacteria when comparing Hamburg to Atone, Germany.
- 1894 - Physicians observe that skin cancer is only on exposed skin.

1900 Death mostly from pneumonia, influenza, and tuberculosis

- 1900 - Life expectancy 50 yr and leading cause of death in the United States is infectious disease (pneumonia, influenza, and tuberculosis).
- 1906 - Jun: Prompted by public concern from press reports of harmful substances in food and drugs in late 1800's, U.S. Congress passes Pure Food and Drugs Act to curb fraud.
- 1908 - Chlorination of water supply adopted at Jersey City, NJ.
- 1912 - U.S. Congress establishes public health service from Marine Hospital Service.

1938 Congress passes Food, Drug, and Cosmetic Act to curb fraud

1940 Death mostly from heart disease and cancer




- 1938 - Jun: U.S. Congress passes stronger Food, Drug, and Cosmetic Act of 1938 to replace law of 1906.
- 1940 - Life expectancy 63 yr and leading cause of death in U.S. are degenerative diseases: heart disease and cancer.
- 1954 - The U.S. Food and Drug Administration (FDA) adopts a "factor of safety of 100" for the threshold measured in the laboratory for hazardous chemicals (no observed adverse effects level [NOAEL]) – factor of 10 for variability in humans and factor of 10 for variability between species.

**Fig. 3.** Early observations of ill health and subsequent risk management (antiquity to 1950).

below which no ill effects could be observed (no observed adverse effects level [NOAEL]). The Food and Drug Administration (FDA)—formed through 1938 legislation (Public Law 75-717 [52 Stat. 1040])—established in 1954 a factor of safety ("uncertainty" factor[28] or factor of protection[29]) of 100 to determine the allowable daily intake (ADI). That is, the safe dose (ADI) used the estimated threshold of a chemical substance obtained from an animal study that used "small doses" over "long-times" divided by 100: a factor of 10 for variability in humans and another factor of 10 for variability between humans and the species with which the chemical response was measured (i.e., ADI = NOAEL/100).[17,28]

## 2.4. Radiation Health Effects and Development of Consequence Evaluation

### *Health Effects of Radiation*

Within a year of the discovery of X rays in 1895, X-ray "burns" were reported in the medical literature. By 1910, it was known that radioactive material such as radium (discovered by the Curies in 1898) could produce similar burns.[30] Furthermore, cancers of the jaw bone reported in the 1920s in watch dial painters who used luminous paint containing radium revealed the hazard of internal ingestion of alpha-emitting radium[20] (Fig. 1). In 1927, Müller discovered that X rays could damage chromosomes in fruit flies.[4] Consequently, in 1928, the International X-Ray and Radium Protection Commission (later named the International Commission on Radiation Protection [ICRP]) was created to set criteria to protect humans from radium and X rays. In setting up the commission, the International Congress of Radiology recommended that each nation form a national advisory commission. Furthermore, medical risks associated with radioactive elements became of interest with the availability of manufactured isotopes in the late 1920s. Hence, in 1929, the U.S. radiological societies voluntarily established the U.S. Advisory Committee on X-Ray and Radium Protection, which was the predecessor of the National Council of Radiation Protection (NCRP) chartered by Congress in 1964 (Public Law 88-376). The NCRP Advisory Committee initially recommended an occupational "tolerance dose" of ~25 rem/yr (actually expressed as 0.2 roentgen/day) for X rays and gamma rays (Fig. 4).[20] The tolerance dose was similar in concept to ADI for hazardous chemicals.

As the United States prepared for World War II, the U.S. Navy asked the NCRP to develop standards for radium to avoid the problems experienced by the young female dial painters in World War I. In May 1941, based on studies of 27 dial painters and radon exposure of numerous German miners in Saxony, a fruitful collaboration of a physicist (R. Evans), a chemist (Gettler), and physicians (Martland and Hoffman) was able to set the maximum allowable activity within the body[4] at 0.1 $\mu$Ci for radium and a maximum allowable gas concentration of 10 pCi/liter in the work place for radon, the latter standard being set for the insurance industry.[20] The allowable dose was about a factor of 10 below the lowest value of 1.2 $\mu$Ci residual body burden where effects had been observed. Because this low value at 1.2 $\mu$Ci was residual body burden and the initial dose was between 10 and 100 times greater, the limit also had an additional factor of 10 to 100 protection.[33] In an interesting cross-over between carcinogenic and noncarcinogenic dose work, a study that compared bone sarcoma in rats that had ingested radium and surmised doses in the female dial painters of World War I was eventually used to justify 100 as a factor of protection for evaluating noncarcinogenic doses.[28,34]

[4] The concept of a maximum allowable body burden, which was adopted in 1959,[31] was modified by the ICRP in 1979[32] to a scheme weighting organ dose to obtain an effective dose equivalent.

The first atmospheric test near Alamogordo, New Mexico, in 1945, generated scientific interest and monitoring of fallout and effects on nearby cattle. Experiments were performed on effects of radiation on Columbia River fish near Hanford, Washington, and monitoring of weapons production facilities began in the late 1940s.[20] Results of the experiments and epidemiological observations in the 1950s led to the hypothesis of potential harm from chronic exposure to low levels of radiation (e.g., radiation-induced leukemia).[35] As a result of this possibility, the NCRP lowered the maximum permissible dose from ~25 rem/yr to 15 rem/yr (40% reduction) in 1948 and recommended the adoption of a policy of limiting radiation doses to as low as reasonably achievable (ALARA). (ALARA was introduced in the general Environmental Impact Statement [EIS] for light water reactors 25 years later, becoming official U.S. policy in 1975 [40 FR 19442].) In 1956, the NAS recommended a maximum dose of 10 rem/yr with 5 rem/yr be allocated to medical diagnosis procedures. In 1959, the ICRP recommended that the maximum occupational dose be lowered to 5 rem/yr (a reduction by a factor of 3) and suggested a maximum dose to the public of 0.5 rem/yr (an order of magnitude lower).[20,30] In 1960, the first Biologic Effects of Atomic Radiation (BEAR) panel was convened by the NAS to estimate the relationship of radiation dose to observed cancer. The BEAR panel reported on a notable epidemiological study of the incidence of cancer in Japanese survivors of the atomic bomb[20] in developing a model of the response of the biological organism to the input stressor.

*Exposure Pathway Assessment*

Several events engendered a need for developing exposure pathway model external to the receptor. In 1954, fallout from an atmospheric test on Bikini Atoll in the Pacific contaminated 43 Marshall Islanders and 14 Japanese fishermen aboard the Lucky Dragon, which prompted a public outcry to stop atmospheric tests.[20,36] In 1957, the fire in the Windscale graphite reactor in the United Kingdom released $^{131}$I, and milk consumption was temporarily curtailed.[5,36] In 1961, the Atomic Energy Commission (AEC) used the bedded salt in southwestern New Mexico (Project Gnome) to evaluate the peaceful uses of nuclear explosives (Plowshare Program).[20,37] Hence, by the 1960s, Oak Ridge National Laboratory (ORNL) began predicting the movement and attendant health

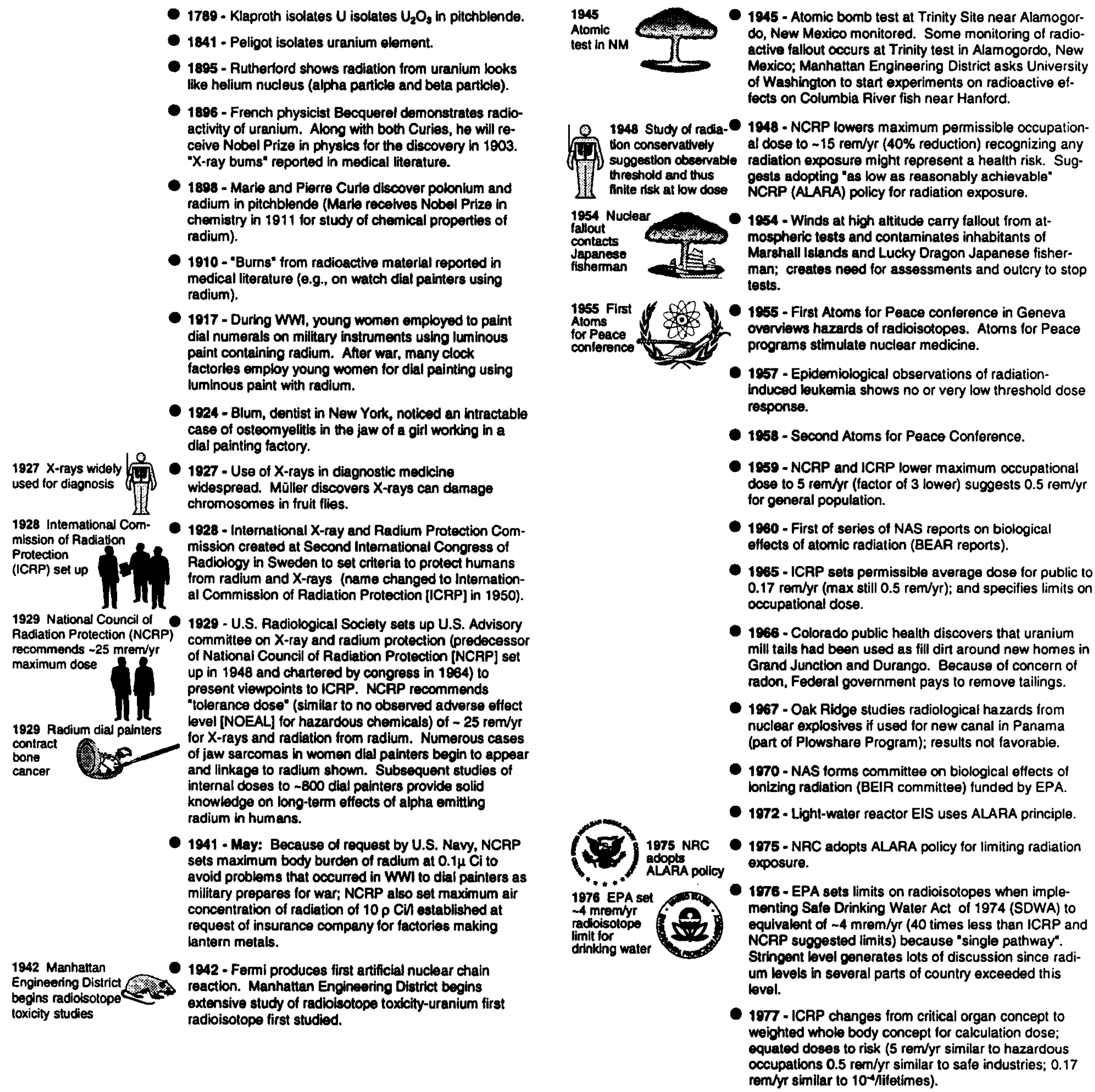



**Fig. 4.** Studies and guidance on health effects of radiation.

risks of radionuclides that might enter either the atmosphere or the groundwater: The use of different models internal and external to the receptor remains. However, the strict use of conservative assumptions for the response model of humans[5] has remained, whereas probabilistic models have since been used in PRA and PA exposure pathway models.

[5] Occasionally, average response models may be used for other receptors in ecological risk assessments (61 FR 47552; 63 FR 26846). Recent evaluations of human dose–response uncertainty are noted in Section 5.2.

## 3. INFLUENCE OF COMPUTATIONAL TOOLS AND RELIABILITY ANALYSIS

The lack of experience with new technologies and their mode of failure, along with the potential for physical harm and economic loss from such failures (or "accidents"), motivated reliability and system analysis in the 20th century.

### 3.1. Development and Application of Reliability Analysis to Aircraft

With the development of commercial aviation in the 1930s, the ability to predict the reliability of equipment was increasingly emphasized. Although the aircraft industry primarily relied on a build-and-test learning process, it began to explore ways to improve reliability beyond those gained from direct experience. In 1939, regulations in England specified 99.999% reliability (i.e., probability of success at 0.99999) for 1 hour of flying time for commercial aircraft[38] (Fig. 1). Although the regulation was relatively lenient in that it meant that the probability of failure could be as high as $10^{-5}$/hr, it is possibly the world's first probabilistic regulation. This type of regulation required that the entire aircraft system be examined, along with the influence of its components on reliability. The regulation resulted in the development of safe but slow aircraft (1 million miles for the British Handley-Page biplane without a fatality).

### 3.2. Application of Reliability Analysis to Missiles

During the 1940s, the advent of computers allowed new problem-solving techniques to address issues of nuclear weapon design. An important practical tool developed at this time—Monte Carlo simulation—was used by the Manhattan Project for its work on the physics of weapons, specifically diffusion of neutrons through fissile material, as first reported in 1949.[39] Computers and Monte Carlo contributed to the design of the fusion nuclear bomb, which was detonated in a 1952 atmospheric test in the Marshall Islands at the Pacific Ocean proving grounds.

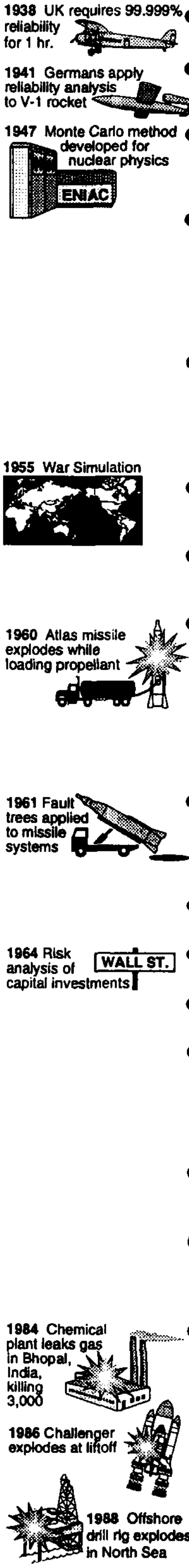
Development of a fusion explosive made feasible the delivery of a nuclear weapon by missiles—its size was small enough to fit into a missile warhead, whereas the explosive energy was large enough to compensate for the missile's inaccuracy at that time. In 1957, when the Soviet Union launched Sputnik, Congress allowed the Air Force to accelerate missile development.[40] But several missile failures during fueling in 1960 prompted the military to seriously examine reliability problems. The United States adopted reliability analysis, as practiced by the Germans in World War II to improve the reliability of their V-1 rockets, and greatly expanded the use of practical tools to improve the reliability of missiles (Fig. 5).[38,40] An important starting point of determining the reliability of a missile was examining the system as a whole, which engendered the field of systems engineering.[41]

Reliability analysis used block diagrams to describe how components in a large system were connected. From these block diagrams, Watson at Bell Laboratories developed the fault-tree technique, which he applied to the Minuteman Missile launch control system, and which Boeing later adopted and also computerized.[38,42] Reliability analysis required the first three steps of risk assessment: (1) characterization of the system, (2) evaluation of potential pathways to failure (i.e., hazard identification and scenario development), and (3) evaluation of the probability of failure through the measurement of component failure rates.

### 3.3. Development of Related Techniques in Policy Analysis

*Cost–Benefit Analysis*

A noteworthy attempt at large-scale policy analysis of a government project or action *before* initiation of the project occurred in 1936, when Congress mandated that the benefits and costs of flood control projects would be assessed prior to construction (Public Law 74-738). In response, the U.S. Army Corps of Engineers developed procedures for a cost–benefit analysis, which were later required for all water resource projects and some transportation projects. Only financial costs and benefits were assessed—not health risks—but the concept of collecting and analyzing data to assist in general policy analysis was developed and accepted. Furthermore, the cost–benefit analysis grew to include sociological factors in the 1960s. In the 1980s, both ecological and sociological risks were taken into account, although they could not always be clearly defined and quantified. Prompted by the requirements of National Environment Policy Act (NEPA; Public Law 91-190 [83 Stat. 852]), federal agencies began to include health risks in their analysis, as discussed in Section 4.2. Policy analysis and, specifically, risk–cost–benefit analyses can be abused when used to substantiate a preconceived view or justify actions already taken,[43]




- **1926** - von Neumann publishes theory of games.
- **1938** - UK requires commercial aircraft have a reliability of 99.999% for 1 hr of flight.
- **1941** - Reliability of a system in series shown to be product of reliability of each component; first applied to German V-1 rocket.
- **1947** - Monte Carlo methods developed to solve neutron diffusion in atomic bombs; one of first problems is run on digital computers invented by von Neuman. Axioms for individual decisions are developed.
- **1952** - Future Nobel laureate Markowitz uses stock price variance as a measure of risk and demonstrates value of diversity in a stock portfolio with this measure. **Nov:** The United States explodes thermonuclear bomb; the reduced size but high yield makes missile delivery practical and prompts missile development.
- **1953** - Morgenstern and von Neumann publish book (written in 1944) on Theory of Games and Economic Behavior, based on concept of utility. U.S. Department of Defense finds cost of repairing unreliable electronic equipment $2/yr for every dollar of equipment during Korean War.
- **1955** - Game theory applied to simulation of war (i.e., war games) using Monte Carlo methods to teach consequences of decisions.
- **1957** - Soviet Union launches Sputnik, 1st artificial satellite, into space. Air Force accelerates development of Atlas and Titan ballistic missiles.
- **1960** - **Mar:** Atlas missile explodes while loading propellant at Vandenberg Air Force Base. This and other missile failures from acceleration of initial development, prompts military to seriously examine reliability problems. Reliability and systems engineering matures to point that several text books are available and symposia are organized. Decision analysis used to explore decisions made by oil and gas drillers.
- **1961** - Watson at Bell Laboratories develops fault-tree methodology from reliability block diagrams for Minuteman launch control system in order to synthesize reliability of entire system; Boeing computerizes methodology.
- **1962** - Air Force mandates safety analysis for all new missiles systems.
- **1964** - Risk assessment is done for decision analysis of capital investments of a business.
- **1965** - Boeing holds symposium on safety, highlighting fault trees.
- **1966** - Apollo Program at National Aeronautics and Space Administration (NASA) abandons fault-tree analysis because estimates of failure are either too high or too low. NASA resorts to rigorous testing of parts but retains hazard identification through Failure Mode/Effects Analysis.
- **1973** - Arab oil embargo because of U.S. support for Israel causes energy crisis. Severe bear market for stocks prompts financial risk assessments.
- **1974** - **Jun:** Cyclohexane vapor from ruptured makeshift bypass pipe explodes in Flixborough, England, killing 28 workers; prompts legislation for risk studies of British chemical plants.
- **1984** - Chemical Plant in Bhopal, India, leaks poisonous gas killing 3000 and disabling 10,000, 2 years after Union Carbide relinquishes oversight of safety to local workers.

**1986** - Though warned not to, NASA launches Challenger when engineers' arguments not convincing; explodes because O-rings on solid booster are brittle from cold; subsequent review suggests adopting risk assessment.

- **1988** - Offshore oil well platform explosion in North Sea (Piper Acpua) prompts United Kingdom to require risk assessments in oil industry.

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**Fig. 5.** Diverse applications of reliability analysis and risk assessment.

but evaluating uncertainty, peer review, full documentation, and open debate can all promote diligent and honest analysis.[13] Furthermore, in 1985, a philosophical evaluation of risk–cost–benefit analysis uncovered no fundamental ethical flaw with risk–cost–benefit analysis as input to decisions.[18]

### *Development of Decision Theory and Its Applications*

Risk assessment, cost–benefit analysis, and decision theory share a similar early history and a similar purpose (i.e., aid in decision making). However, decision theory focuses on using the quantification of risk, along with other information, for management decisions, such as risk management. In 1738, Daniel Bernoulli introduced the concept of utility to express personal usefulness or satisfaction as an important concept of decision analysis. Other axioms for individual decisions were informally developed along with probability theory (Fig. 2). However, a more formal development occurred in the 1950s.[2] In 1953, economist Morgenstern and mathematician Von Neumann published the *Theory of Games and Economic Behavior,* which incorporated Bernoulli's utility concept.[2,22] Later, in the 1950s, decision theory benefited from Monte Carlo methods; for example, these methods appear in the game theory, especially the simulation of war, to teach the consequences of decisions.[44]

By 1964, a financial risk assessment was demonstrated to businesses for decision analysis of capital investment,[45] and textbooks were available by 1968.[46] In 1976, methods were proposed for making decisions with multiple, often conflicting, objectives,[47] and then applied a year later to determine the best location for nuclear reactors in Washington.[48] In 1986, this method was also applied to developing a portfolio of potential radioactive waste disposal sites for characterization.[49] Decision theory now includes concepts that attempt to logically resolve difficulties in making the optimal choice among options when (1) consequences of options are uncertain; (2) the decision has multiple, often conflicting, objectives; (3) multiple participants are involved in making the decision; and (4) there are intangible concerns. After the large stock market decline in 1973 and 1974, due in part to the Arab oil embargo, financial risk assessment began to gain more favor with investment firms. At that time investment firms began to seriously examine the academic work on portfolio selection (i.e., Markowitz's work in 1952 [Fig. 5]) to reduce investment risk, which in the investment world is associated with the second moment of the distribution of the returns or investments (variances).[6] The 1970s saw a dramatic increase in managing risk in mutual fund portfolios.[2]

## 4. EARLY RISK STUDIES FOR NUCLEAR FACILITIES

The application of reliability analysis to several components in nuclear facilities in the late 1960s led to large-scale, probabilistic risk studies for entire nuclear power plants in the 1970s. During this same period, the federal government began to investigate possibilities for disposal of nuclear wastes.

### 4.1. Adaptation of Reliability Analysis Techniques to Nuclear Power Plants

Through passage of the Atomic Energy Act of 1954 (Public Law 83-703 [68 Stat. 919]), Congress encouraged peaceful uses of atomic energy, specifically, electrical power production. An impediment to this development, however, was the inability to obtain liability insurance for public utilities, and so Congress agreed in the Price-Anderson amendments of 1957 to indemnify public utilities (Public Law 85-256). To do so, Congress and the AEC, which had been created by an earlier version of the Atomic Energy Act in 1946 (Public Law 79-585 [60 Stat. 755]), needed to know not only the reliability of a nuclear reactor but also the consequences of various types of failure. This need motivated the development of techniques for consequence evaluation, the fourth step in a risk assessment. As a result, in 1956, Pacific Northwest Laboratory (PNL) described semiquantitative effects of a major reactor accident and, in 1957, Brookhaven National Laboratory conducted a deterministic assessment of the financial risk to the federal government as part of the indemnification of the nuclear power industry[20,50] (Fig. 6).

Computational tools developed for reliability analysis were applied to assessments of nuclear reactors during the late 1960s. Specifically, in 1967, fault trees were applied to various nuclear reactor components and, in 1968, event trees were employed in the siting of those reactors.[51] Although neither fault trees nor event trees are an essential feature of risk assessment, they played an important role in improving the consistency of analyzing failure modes for nuclear reactors, similar to the block diagram's role in improving general reliability analysis. In 1969, C. Starr brought many aspects together in a risk–cost–benefit analysis to evaluate the social benefits and technological risks of nuclear power plants.[52]

### 4.2. Influence of National Environmental Policy Act

The National Environmental Policy Act of 1969 (NEPA; Public Law 91-190 [83 Stat. 852]) required federal agencies to consider the environmental consequences of any major action (such as decisions on development) and evaluate other options in an EIS. After passage of NEPA, the AEC prepared hearing rules for an EIS on the Calvert Cliffs reactor that limited the discussion of environmental impacts, but was quickly sued by the citizen group opposed to the reactor. In 1971, the U.S. Court of Appeals, District of Columbia Circuit, stated that environmental impacts must be given equal weight to economic and technical considerations in the EIS (449 F. 2d 1109). This and other court rulings established a large reservoir of case law that more clearly defined specific requirements based on the general policy statements in the legislation.[53] During the required hearings and written comment period, individual and special interest groups were able to express concerns with the adverse effects of large technological systems and a desire for more stringent analysis of all associated short- and long-term hazards to the physical environment and human health. These requests in turn stimulated many general and specific ecological studies and modeling advances. For the general EIS on lightwater reactors and especially for proposed nuclear facilities, NEPA indirectly stimulated the use by AEC of detailed mathematical modeling to predict the transport of radioisotopes in the environment, resulting population doses, and, ultimately, the risk consequences

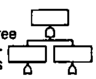
[6] Variance as a measure of risk, rather than the expected value, corresponds to the oldest usage of risk noted by *The Oxford English Dictionary* (i.e., in 1776, Adam Smith in *Wealth of Nations* associated risk with financial uncertainty) (high variance that includes potential for loss) and the source of an entrepreneur's profit; safety was associated with certainty.[24] Both usages are still common.[29]

**Fig. 6.** Events influencing early risk studies for nuclear reactors.

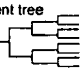
- **1946 -** Atomic Energy Act (AEA) of 1946:
  - creates Atomic Energy Commission
  - establishes government monopoly on atomic weapons and nuclear material (and eventually expectation to dispose of waste)
- **1948 -** Construction begun on nuclear reactor for Navy.
- **1951 - Dec:** Experimental Breeder Reactor produces electricity.


- **1954 - Jan:** First nuclear submarine, Nautilus, launched. **Aug:** In AEA of 1954, Congress seeks peaceful uses of atomic energy; thus allows private but regulated atomic energy development.
- **1956 -** Hanford reports on semi-quantitative effects of major reactor accident.


- **1957 -** Windscale graphite reactor fire burns for 42 hr in United Kingdom (UK) and releases $^{131}I$; milk consumption curtailed. Brookhaven National Laboratory (BNL) worst-case, deterministic risk assessment using expert opinion, is done to determine indemnification of nuclear industry (study similar to typical safety analysis). **Oct:** International Atomic Energy Agency (IAEA) formed to promote peaceful uses of nuclear energy. **Dec:** First large U.S. nuclear power plant operates at Shippingport, PA. To further encourage atomic energy use, Atomic Energy Damages Act ("Price-Anderson Act") sets up 2-tier insurance system for liability from accidents. First tier insurance purchased by each individual facility from private companies second tier insurance funded by premium on all facilities. (If claims exceed second tier then U.S. Congress would pay from public funds).




- **1967 -** Fault trees applied to various components of nuclear reactors.

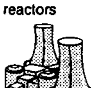



- **1968 -** Event trees applied to siting of nuclear reactors. Decision analysis advances such that text books available.



- **1969 -** Social benefits and technological risk of nuclear power plant estimated. Starr notes 1000-fold difference between voluntary and involuntary risks is accepted by the public and that voluntary risk is about equal to disease risk. National Environmental Policy Act (NEPA):
  - requires federal agencies to consider environmental consequences of any major action through an environmental impact statement (EIS)
  - one impetus for passage was proposed Calvert Cliffs reactor
  - requires public comment – avenue for citizen groups to push for stringent regulations for nuclear power
  - leads to citizens voicing expectation that government should protect against all long-term technological hazards (not just food and drug)
  - leads to assessing social benefits versus risks of technology
- **1971 -** Appeals court requires AEC to look at *all* impacts in EIS on Calvert Cliffs reactor.

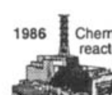

- **1972 -** AEC Chairman Schlesinger asks for a probabilistic risk assessment (PRA) of severe accidents in nuclear reactors.




- **1973 -** EIS for lightwater-cooled reactor is published (WASH-1258).
- **1974 -** Congress splits AEC into Nuclear Regulatory Commission and Energy Research and Development Agency (ERDA). **Aug:** Draft of first major PRA published on two plants (Slurry and Peach Bottom) by 60-member team led by Rasmussen, MIT professor, for the Nuclear Regulatory Commission (NRC) *(Reactor Safety Study)*; method uses fault trees and event trees to synthesize probability of total system failure from estimates of component failure rates. American Physical Society (APS) begins review.


- **1975 - Mar:** Electrician sets cables on fire when using candle to check for air leaks below control room of Browns Ferry reactor in Alabama. **Apr:** Lewis publishes review of Reactor Safety Study draft for NRC: criticizes treatment of multiple failures, criticizes treatment of epistemic (degree of knowledge) uncertainties, but general approach applauded. **Oct:** Final of Reactor Safety Study released: probability of accidents (aleatoric uncertainty)
- **1975 (con't) -** higher than initially thought, consequences of accidents lower than initially thought, and suggests human errors could cause accident (Three Mile Island accident). APS review calls for more study of unknowns to correct potential errors in consequences and their probability and requests NRC to promulgate safety goals for reactors based on risk. **Jul:** Conover at Texas Tech develops Latin Hypercube Sampling (LHS) scheme for reactor pipe-break code at Los Alamos National Laboratory (helps make detailed modeling in stochastic simulations feasible).
- **1976 -** NRC funds Sandia National Laboratories to apply event tree method to more plants (Calvert Cliffs-2, Grand Gulf-1, Sequoyan-1, and Oconee-3) but omits funding for new consequence modeling (Reactor Safety Study Method Application Program). SNL connects events from both loss-of-coolant and transient trees.
- **1977 -** Decision analysis applied to siting nuclear power plants in Washington state. NRC funds SNL to evaluate risks of transporting nuclear waste — SNL develops radioactive material transportation model (RADTRAN) using event trees.


- **1979 - Mar:** Accident at Three-Mile Island Reactor occurs and partially melts fuel rods when valves fail (similar to failures in other reactors) and poorly trained operators misinterpret conditions on poorly designed readouts. In response to Three-Mile Island, NRC funds SNL to improve treatment of human actions in event trees and more detailed logic models for five plants (Crystal River-3, Browns Ferry-1, Arkansas Nuclear One-1, Calvert Cliffs-1, and Millstone-1) (Interim Reliability Evaluation Report). SNL finds support systems both contribute to and mitigate accidents. SNL issues RADTRAN II, generalized version for transportation risks of nuclear waste.
- **1980 -** NRC begins to develop safety goals for nuclear power plants.
- **1981 -** Zion Station probabilistic risk assessment includes external seismic and fire events, and site-specific meteorology, terrain, and evaluation routes. Kaplan and Garrick define risk using three components: scenarios, probability, and consequence ($R = \{S, P, C\}$).
- **1982 -** State of New York funds PRA for Indian Point reactor.
- **1983 -** NRC asks SNL to add external events, sabotage, cost/benefit analysis in PRA.




- **1986 - Apr:** Major accident at Soviet's Chernobyl reactor occurs during shut-down test; however, many emergency controls turned off by poorly trained operators. **Aug:** NRC promulgates safety goals for nuclear reactors similar to 40 CFR 191:
  - risk of prompt facilities < 0.1% of other accidents
  - risk of cancer death < 0.1% of other cancer deaths
  - suggests frequency of large release of radionuclides < $10^{-6}$/yr
  - requires inclusion of uncertainty

  State of New Hampshire funds PRA for Seabrook Station. SNL issues RADTRAN III with several model changes to improve calculation of transportation risks.
- **1987 -** NRC funds new study (NUREG-1150) to repeat and improve *Reactor Safety Study* "PRA".
- **1988 - Sep:** U.S. Congress amended AEA to set up Defense Nuclear Facilities Safety Board to evaluate safety of DOE defense facilities.
- **1989 -** SNL issues RADTRAN IV, which uses route-specific information.


- **1990 -** NRC completes new reactor risk study
  - adds detail event tree for containment
  - improves consequence analysis
  - improves analysis of uncertainties

  NRC funds SNL for LaSalle reactor PRA to get more detailed logic models and consistent treatment of uncertainties.
- **1994 -** NRC funds SNL for detailed study of risks from low power/shutdown for Grand Gulf Reactor.


- **1995 - Aug:** NRC adopts use of PRA for setting policies.

of these activities, along with economic costs and benefits.

### 4.3. Application of Risk Assessment to Nuclear Power Plants

*Reactor Safety Study*

The new atmosphere created by NEPA encouraged AEC Chairman Schlesinger, a former economist at the Rand Corporation, to request, in 1972, a detailed analysis to evaluate risks from severe accidents at commercial nuclear reactors. By August 1974, a 60-member team led by N. Rasmussen, an MIT professor, drafted a report that defined hazards, estimated associated probabilities, and evaluated consequences[7] on the Surrey and Peach Bottom plants for the Nuclear Regulatory Commission[8] (NRC).[14] The *Reactor Safety Study* (or "WASH-1400" report) was significant because it was the first detailed, comprehensive, quantitative, probabilistic look at the health risks from a large, complex facility (Fig. 1). An early review of the draft in April 1975, however, did suggest that besides uncertainty in behavior of the system (i.e., uncertainty associated with event and feature conditions), which had been evaluated through event and fault trees, uncertainty associated with estimates for parameter values should be included.[54] A second review of the *Reactor Safety Study* by the American Physical Society[55] called for more study of uncertainties to correct potential errors in consequences and their probabilities and also requested that the NRC promulgate safety goals for reactors based on risk.

The final version of the *Reactor Safety Study,* released in October 1975, revealed that although the probability of accidents was higher than initially believed, the consequences of accidents were actually lower than first believed. The PRA used scenario classes rather than attempting to itemize every possible future and discovered an important scenario class for nuclear power plant operation—the potential for human error to transform a critical but controllable situation into a severe accident.[56] The *Reactor Safety Study* set a standard for risk assessments of nuclear reactors for the next 20 years. Two aspects of risk assessment for nuclear facilities were evident: (1) large multidisciplinary teams were needed to adequately explore all facets of the system and to present sufficient diversity of opinion to adequately capture uncertainty, and (2) the size of the resulting study required a dedicated multidisciplinary team of reviewers.

Because users of the PRA methodology were immediately compelled to consider uncertainties in parameters, efforts were begun to incorporate parameter uncertainty into the analysis. The Monte Carlo method was adopted for propagating uncertainty of parameters in a detailed code, and the LHS (Latin Hypercube Sampling) scheme was developed in 1975 to increase efficiency of samples.[57]

Although the move to assess probability and consequences of nuclear power plant accidents was a natural progression from the earlier analysis of system components, it also generated, and is still generating, considerable controversy, which is beyond the scope of this article. Opponents of the PRA questioned the ability of the analysis to meaningfully assess risk, much as opponents of cost–benefit analysis have challenged its capability to provide a worthwhile assessment of benefits and costs.[18]

*Influence of Reactor Accident at Three Mile Island*

On March 28, 1979, at 4 A.M., a clogged pipe in the second unit of the Three Mile Island Reactor initiated events that opened a pressure relief valve and inserted control rods that shut down the reactor to relieve pressure. Human errors and organizational failures compounded the problems caused by the clogged pipe, causing an accident severe enough to melt the fuel. Cleanup costs exceeded $1 billion.[5,58]

Although the exact sequence of events that caused the accident at the Three Mile Island Reactor was not in the *Reactor Safety Study,*[9] proponents of PRA emphasized that human error in combination with a loss-of-cooling event was indeed represented

[7] The 1975 *Reactor Safety Study* quantitatively defined risk as risk {consequence/time} = frequency {events/time} × magnitude {consequence/event}, from which evolved the notion within the risk profession (but not necessarily outside the profession) of risk as "probability times consequence" (i.e., expected adverse health effects per year).

[8] In 1974, the *Energy Reorganization Act* (Public Law 93-438) split the Atomic Energy Commission (AEC) into the Energy Research and Development Agency (ERDA) and the Nuclear Regulatory Commission (NRC).

[9] Those dealing with risk perceptions also like to use the various interpretations of the severe accident at the Three Mile Island Reactor as an example of how little individual perceptions change once formed and how new data are interpreted through these formed perceptions.[59,60]

in the scenario classes. Initially, the NRC had been concerned about using a PRA to support passage of regulations, but the incident at Three Mile Island eventually prompted the NRC to endorse the PRA method.[61] Specifically, in 1986, the NRC promulgated three safety goals for a nuclear reactor: (1) the probability of nuclear accidents must be less than 0.1% of all other types of accidents, (2) the annual expected value of cancer death within a 10-mile radius must be less than 0.1% of other types of cancer deaths (or $\sim 3 \times 10^{-6}$ yr$^{-1}$ assuming normal cancer mortality of $\sim 3 \times 10^{-3}$ yr$^{-1}$), (3) the frequency of large release of radionuclides must be less than $10^{-6}$/yr. Also, uncertainty was to be included in the estimates (51 FR 28044). Thus, 11 years after the American Physical Society had made the suggestion in its review of the *Reactor Safety Study,*[55] general safety goals based on risk were adopted. In 1990, the NRC concluded its update of the PRA for nuclear reactors[62,63] and, 4 years later, proposed extensive use of PRAs for setting policies within the NRC on all types of nuclear facilities (59 FR 63389; i.e., PRA was endorsed for policy analysis); the proposal was accepted in 1995 (60 FR 42622) and explicitly equated PRA with PA in the United States.

### 4.4. Other Assessments of Engineered Systems

The first applications of PRA and PA in other fields and industries were usually initiated as the result of accidents (see Fig. 5).

*Assessments in Response to Accidents at Chemical Plants*

In 1974, a make-shift bypass pipe ruptured in a chemical plant, killing 28 workers and releasing cyclohexane vapor into the town of Flixborough, England. The incident prompted the British to require risk analysis for chemical plants.[64] By 1980, an extensive risk analysis on the further expansion of the Canvey Island petrochemical complex near London had occurred. Eight years later, in 1988, an explosion on the Piper Acpua, an offshore oil well platform in the North Sea, prompted the British to require risk assessments in the oil exploration industry as well. Although assessments of risk at chemical plants had occurred within the United States, more extensive risk assessments within the chemical industry were encouraged as the result of a disaster in 1984 that killed 3,000 and disabled 10,000 near a Union Carbide chemical plant in Bhopal, India.[5,65]

*Reevaluation of Risk Assessment After Challenger Accident*

The explosion of the Challenger space shuttle in 1986 caused a reevaluation of risk assessment at the National Aeronautical and Space Administration (NASA). Similar to the missile program, NASA had adopted hazard identification through qualitative Failure Mode/Effects Analysis for the human space program in the 1960s. However, in 1966, the Apollo Program at NASA abandoned fault-tree techniques because estimates of failure were both too high and too low.[66] Thus, NASA abandoned risk analysis because of its imprecision, rather than continuing to refine estimates, but continued rigorous testing of components. As seen later with the Challenger explosion in 1986, the decision to abandon risk assessment allowed an unwarranted belief in the high reliability and safety of rockets for human space flight to evolve.[67] Consequently, when engineers intuitively sensed a dangerous situation for the Challenger during the launch at cold temperatures, their inability to quickly quantify and substantiate their intuition proved disastrous.[26] The subsequent review of the Challenger space shuttle accident suggested adopting risk assessment.[5,67,68]

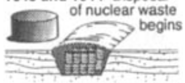
### 4.5. Application of Probabilistic Risk Assessment to Nuclear Waste Repositories

*Early History of Radioactive Waste Disposal*

Initial disposal of radioactive waste by the Manhattan Engineering District in 1945 included burying solid nuclear waste in shallow trenches and augured holes at Los Alamos National Laboratory, New Mexico, and Hanford Reservation, Washington.[69,70] Although the newly formed AEC continued these practices, it tentatively explored more permanent solutions, beginning in 1955, when the AEC asked the NAS to examine the disposal issue. The 1957 NAS report[71] indicated that disposal in salt beds was the most promising method to explore, which it reaffirmed in 1961, 1966, and 1970.[70,72]

After tentatively selecting an abandoned salt mine near Lyons, Kansas, as a repository in 1970 (Fig. 7),[73] the AEC discovered the presence of drill

1943 and 1944 Disposal of nuclear waste begins

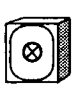


- **1943** - Plutonium separation operations and disposal of nuclear waste in trenches begins at Oak Ridge National Laboratory (ORNL).
- **1944** - Disposal of nuclear waste begins at Los Alamos National Laboratory (LANL) (using trenches, ponds, augered holes), and Hanford Reservation (using railroad cars, trenches, ponds, underground caissons).
- **1946** - Atomic Energy Commission (AEC) continues practice (started by Manhattan Project) of burying solidified nuclear waste in trenches. Started storing liquid wastes in tanks.
- **1952** - Radioactive Waste Management Complex (RWMC) for storing and burying waste is completed at Idaho National Engineering and Environmental Laboratory (INEEL).
- **1953** - Savannah River Plant begins waste storage and disposal on site at "Old Burial Ground".
- **1954** - **Aug:** Rocky Flats, Colorado, begins shipping transuranic (TRU) waste to INEEL for disposal at RWMC.
- **1955** - AEC asks National Academy of Sciences (NAS) to examine issue of permanent disposal of radioactive waste. First Atoms for Peace Conference to evaluate peaceful uses of nuclear explosives.

1957 NAS recommends exploring waste disposal in salt beds

- **1957** - NAS suggests radioactive waste disposal in salt as most promising method.
- **1959** - NAS commission on oceanography reports on coastal disposal of low-level radioactive waste.

1963 ORNL Project Salt Vault



- **1963** - ORNL begins Project Salt Vault, a large-scale field test in which electric heaters are placed in existing salt mine at Lyons, Kansas, to study near-field effects.
- **1966** - NAS reaffirms use of saltbeds for nuclear waste disposal and severely criticizes current practices of AEC.
- **1968** - AEC again asks NAS to examine issue of radioactive waste disposal. NAS creates committee on radioactive waste management; later permanent "Board".

1970 NAS concludes bedded salt disposal safest choice now available

- **1970** - Disposition study for Gnome site is conducted for Atomic Energy Commission. **Jun:** AEC tentatively selects mine in Lyons, KS, as repository. AEC states commercial high-level waste (HLW) must be solidified within 5 yr and sent to federal repository within 10 yr; retrievable concept applied to defense TRU waste. Board of Radioactive Waste Management of National Academy of Sciences issues report concluding bedded salt satisfactory and best choice now available for nuclear waste disposal.
- **1971** - After AEC discovers many drill holes and solution mining near Lyons, KS, Congress directs AEC to stop Lyons project.

1972 Lyons site judged unacceptable

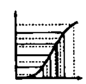

- **1972** - **May:** AEC abandons Lyons project. AEC announces plans for retrievable surface storage facility.
- **1973** - EPA prohibits disposal of HLW, SNF, TRU in oceans and sets criteria for disposal of other radioactive waste (40 CFR 220).

1976 Bishop Lodge Conference to explore PRA for geologic disposal

1976 Ford orders demonstration of nuclear waste disposal

- **1976** - ERDA funds conference on modeling of geologic disposal systems to bring engineers and earth scientists together to explore predicting geological features, events, and processes. President Ford orders EPA to develop standards for permanent disposal of nuclear waste. **Oct:** Ford orders major expansion of ERDA program to demonstrate permanent disposal for nuclear waste by 1985 and orders EPA to develop standards, based on recommendations of interagency task force. **Dec:** NRC funds conference to develop generic list of potential hazards for repositories.
- **1977** - Geohydrology is important aspect of geologic isolation; hence, mathematical modeling of groundwater flow is required. **Feb:** In response to Ford's directive, EPA conducts 1st workshop to understand public concerns and technical issues of waste disposal.
- **1978** - NRC funds SNL to work on probabilistic PA and apply to hypothetical bedded salt repository (resulting method abandons fault trees and uses simple event trees). DOE funds SNL to work with Canadians, British, and other Nuclear Energy Agency (NEA) countries to analyze deep, subseabed disposal option. **Nov:** EPA publishes "Criteria for Radioactive Wastes" as guidance and seeks comments. U.S. Congress passes Uranium Mill Tailings Radiation Control Act to clean up mill tailings (90% federal funding) and control future use and disposal.

1980 LHS applied to PA Sensitivity Analysis



- **1980** - LHS is applied to sensitivity analysis for an assessment of the performance of a hypothetical geologic repository in bedded salt. Congress passes Low-Level Radioactive Waste Policy Act (LLRWPA) to allow states to form compacts to build several Low Level Waste (LLW) disposal sites.

1981 SNL proposes PA methodology

- **1981** - Draft of final report to NRC on performance assessment (PA) is applied to hypothetical bedded salt repository readily available – uses a set of loosely connected codes, precursors to SWIFT_II (fluid flow code), and NEFTRAN (network transport code). **Mar:** Developing generic disposal criteria for radioactive wastes difficult, thus EPA starts developing standards for each waste type.
- **1982** - EPA drafts 40 CFR 191, defines PA, suggests use of complementary cumulative distribution function (CCDF) to show results.
- **1984** - **Feb:** EPA's Science Advisory Board endorses probabilistic approach in 40 CFR 191 but states criteria too restrictive.

1985 EPA promulgates probabilistic criteria in 40 CFR 191

- **1985** - EPA promulgates 40 CFR 191 for disposal of SNF, HLW, and TRU waste:
  - probabilistic criteria indirectly based on population health risk
  - desires inclusion of all uncertainty in CCDF

  U.S. Congress amends LLRWPA to allow more time for states to form compacts and build LLW disposal sites.
- **1988** - SNL extends probabilistic PA method to hypothetical basalt repository for NRC. Subseabed team reports on use of local and regional embedded detailed models for simulating ocean currents for subseabed disposal (concept used for WIPP PA).

**Fig. 7.** Early risk studies for nuclear waste repositories to develop an assessment methodology.

holes and solution mining. The project was officially abandoned in 1972, and the AEC then announced plans for a Retrievable Surface Storage Facility. The EPA, formed in 1970, and antinuclear groups claimed in comments on the EIS that the retrievable storage facility was *de facto* permanent disposal, which prompted the AEC to continue to search for a suitable disposal site. Soon after, the AEC, ORNL, and U.S. Geological Survey (USGS) recommended the large salt beds of southeastern New Mexico,[70] which would eventually host the Waste Isolation Pilot Plant (WIPP) discussed in Section 6.

*Development of Risk Assessment Methods for Nuclear Waste Repositories*

As discussed here, the method that was conceived and accepted by the engineering community in the United States, and by the EPA and NRC as regulators for evaluating the acceptability of a disposal system, was a probabilistic PA. In this respect, PAs in the United States remained similar to "Level 3" PRAs for nuclear reactors in which offsite health risks are evaluated.[61–63,74] The PA method was first described in a 1981 draft report submitted to the NRC (final report, 1987)[75,76] for a hypothetical bedded salt repository. The method was somewhat similar to an all-encompassing total system approach that had been proposed earlier by geoscientists at PNL.[77] What follows in this section are concepts specifically developed by the NRC at that time. Applications are discussed in Section 6 and in Helton *et al.* (this issue).

*System Definition/Characterization.* In 1976, the ERDA (Energy, Research, and Development Administration, a precursor to the DOE) sponsored two conferences to bring together two groups of professionals: nuclear engineers familiar with the recently developed PRA methodology for reactors and earth scientists familiar with the uncertainties of geologic investigations[78] (Fig. 1). At the time, other countries were also addressing the need for nuclear waste disposal and, in 1977, the International Atomic Energy Agency (IAEA) recommended site selection criteria.[79] The ERDA conferences provided an opportunity to exchange viewpoints among representatives from various disciplines and produced ideas about how to perform an assessment for a geologic disposal system, which were examined in the following years by the NRC.[77] In general, the proposed method sought answers in the form of system engineering analysis, rather than a conceptual analog model, by developing a mathematical model, $C(\cdot)$, and an appropriate parameter space, $\mathbf{x} = \{x_1, x_2, \ldots x_{nP}\}$, where $nP$ is total number of parameters. Because of the inclusion of natural components (components that do not "fail" but rather evolve) and the need to evaluate the interaction of the natural component with engineered components, earth scientists pointed out that the mathematical model had to analyze basic natural phenomena over long periods.[78] The blending of the disciplines to produce a performance assessment has not been without tension. Ewing *et al.*[80] continue the dialog among various disciplines in this special issue.

*Hazard Identification and Scenario Development.* For hazard identification (or risk identification as it was called by Rowe[81]), an initial, generic list of features, events, and processes (FEPs) (i.e., "universe") is defined for consideration in the assessment. Although hazard identification is a part of all risk assessments, the formality with which FEPs are selected for inclusion in modeling is distinctive of PAs and PRAs.

In a companion draft report to the NRC also available in 1981 (final report published in 1990), Cranwell *et al.*[82] proposed a method to screen out unreasonable FEPs, and form a limited number of scenarios based on only discrete events and features, not processes. Other early efforts included the generation of a starting list of FEPs that was developed by a panel of scientists and engineers supporting the NRC in 1976–1977[76,82]; an international effort on hazards by the IAEA in 1981[83]; and development of scenarios for a hypothetical repository in basalt in 1983.[84] In developing scenarios, the parameter space was conceptually divided into two subsets, $\mathbf{x} = [\mathbf{x}^s, \mathbf{x}^p]$, although not described in those terms at the time. One subset included the parameters that defined certain conditions for a scenario, $S_j \subset \mathbf{x}^s$, that an analyst may want to highlight in the analysis (or because the Monte Carlo integration to evaluate the uncertainty was easy to perform separately for this subset). For example, for the WIPP, discussed in Section 6 and Helton *et al.* (this issue), $S_j$ defined conditions for human intrusion and location of a brine reservoir, respectively.[9,85] The second subset contained the remaining parameters.

*Probability Evaluation.* For parameter uncertainty, ideally, a joint probability density function is defined, $D(\mathbf{x}^p)$, but $D(\mathbf{x}^p)$ is usually represented by $D_1(x_1^p) \cdot D_2(x_2^p) \ldots \cdot D_{nU}(x_{nU}^p)$, where the individual parameter density functions are assumed independent and $nU$ is the number of uncertain parameters. To propagate parameter uncertainty through the analysis, the LHS technique was proposed in 1978.[75,76,86,87]

At first, the NRC insisted that Sandia, as contractor to the NRC, directly apply the techniques of the *Reactor Safety Study*[14] with only minor modification to calculate the probability of the scenarios, $P_r\{S_j\}$, mentioned here. However, discretization of a geologic disposal system by means of event and fault trees was not a simple task for the highly coupled system, as experienced by the WIPP Project[88] (see also Section 6). Eventually, it became clear that calculating probabilities of scenarios of a geologic system from fault trees was not practical.[89] In the late 1970s and early 1980s, an ad hoc assignment of probabilities of parameters and scenarios was used because initially only hypothetical sites were studied.

*Consequence Evaluation.* The consequence modeling for the hypothetical salt repository proposed in 1981[75] consisted of an exposure pathway assessment using a model comprised of loosely connected series of codes (precursors to the finite-difference flow code, SWIFT II, and the network transport code, NEFTRAN[75]) specifically designed for the task. The study simulated a steady-state groundwater flow field, evaluated a particle pathway, and then calculated radioisotope transport along this pathway from a simple source. Because the implementation of a numerical solution for the partial differential equations describing radioisotope transport was difficult in practice, a single pathway or network transport code was used. A similar consequence evaluation was also completed in 1988 for a hypothetical disposal site in basalt.[90]

*Sensitivity/Uncertainty Analysis.* A feature that was adopted early in PAs of hypothetical repositories[75,76] was the inclusion of a sensitivity analysis. This type of analysis explored the individual parameters, $x_n$, and model forms (e.g., $f_\alpha(\cdot)$) that most influence the regulatory criteria discussed as follows.

*Regulatory Criteria*

Society's definition of acceptable risk from geologic disposal (i.e., society's "utility") was evaluated over the same period as various analysis tools for the PA process were being developed. In 1977, the EPA conducted several public meetings to develop societal consensus on regulatory criteria (41 FR 53363; 43 FR 2223). Initially, the EPA proposed generic criteria on all radioactive waste in 1978 (43 FR 53262), but after receiving generally unfavorable responses, they withdrew the proposed regulations in March 1981, and began developing standards for individual categories of radioactive waste.

In 1982, in response to a requirement in the Nuclear Waste Policy Act of 1982 (Public Law 97-425), the EPA published a draft of the nuclear waste disposal regulation in Title 40 of the Code of Federal Regulations Part 191 (40 CFR 191; 47 FR 58196), which had already undergone more than 20 revisions. The EPA did not promulgate the final version of 40 CFR 191 until 1985 (50 FR 38066), 3 years after submitting the proposed regulation, and then only after drawing a lawsuit to hasten its promulgation.[10] The 40 CFR 191 Standard established criteria for the disposal system as a whole and specified PA as the type of calculations to be used to show compliance with this regulation.[11]

The analysis conducted in support of regulatory standards for deep geologic disposal[30] convinced the EPA that the risks to society from such a disposal method were low. Furthermore, the EPA argued that very stringent requirements could be placed on the disposal system without adding substantially to the initial cost (50 FR 38066; i.e., the EPA indirectly adopted an ALARA policy). Thus, the EPA considered maintaining equity of risks and benefits between generations over a very long regulatory period (10,000 years) with regard to radioactive waste disposal, even though other potentially hazardous activities, such as disposal of hazardous chemicals or coal fly ash from utilities, could not sustain such an expensive program. Even considering the proposition of intergenerational equity, however, the EPA's Science Advisory Board (SAB) claimed in their review of the analysis that the release limits were an order of magnitude too stringent.[91] Furthermore, the regulations assumed a static society (i.e., using current technology during the 10,000-year period), which added another level of conservatism. (This is a conservative assumption provided one accepts the proposition that the waste is most hazardous to a society living under current conditions rather than one with a lesser or greater degree of technological prowess.) A compilation (Okrent, this issue) of the reviews and philosophical discussions held during the development of 40 CFR 191 gives the reader more background on the regulatory spirit of 40 CFR 191.

The need to model natural components over long time periods encouraged development of probabilistic performance criteria in 40 CFR 191 to account for uncertainty in characterization knowledge. For a mixture of radioisotopes, the EPA required the sum of all releases $C(\mathbf{x}^P)$, where each radioisotope ($i$) is normalized with respect to its radioisotope limit ($L_i$), should have less than 1 chance in 10 of exceeding 1 and less than 1 chance in 1,000 of exceeding 10 (50

[10] Changes in the 1985 final version of 40 CFR 191, primarily the Individual and Groundwater Protection Requirements, led to a lawsuit by the same group, the Natural Resources Defense Council, that had sued earlier to accelerate promulgation. The courts remanded the regulation shortly thereafter (as reported in Vol. 824 of Federal Reporter, second series [824 F.2d. 1258]), but the EPA repromulgated the standard in 1993 for the WIPP without changes to the most influential section, the Containment Requirements (58 FR 66398).

[11] Specifically, PA was defined as an "analysis that (1) identifies the processes and events that might affect the disposal system; (2) examines the effects of these processes and events on the performance of the disposal system; and (3) estimates the cumulative release of radioisotopes, considering the associated uncertainties caused by all the significant processes and events. These estimates shall be incorporated into an overall probability distribution of cumulative release to the extent practicable" (50 FR 38066).

FR 38067; 58 FR 66398; Fig. 8). The EPA specified radioisotope limits ($L_i$) so that only an exposure pathway assessment was needed for the consequence analysis. Adhering to tradition, the dose-response assessment performed by the EPA to determine $L_i$ depended on bounding-type dose evaluations[30]; thus, a PA in the United States is not entirely probabilistic. Moreover, they specified an evaluation of cumulative releases of radioisotopes ($Q_i$), which required the EPA regulator to convert through crude calculations from dose, which depends on rate of release, to obtain the allowable $L_i$.[30] The EPA rejected dose as the primary requirement because its use might encourage disposal near large bodies of water to allow for dilution (47 FR 58196) or disposal in numerous small repositories. A dose criterion was also believed to encourage expensive engineered containers, a situation that has indeed occurred at the potential Yucca Mountain repository, as discussed in Section 6.2.[30,92] For comparison to limits in 40 CFR 191, uncertainty in the cumulative normalized release was displayed as a complementary cumulative distribution function (CCDF) (Fig. 8). Thus, the risk measure was not the first moment of the distribution (the expected value of the results) or the second moment of the distribution (the variance of the results, as in risk analysis of stock portfolios).[2] Instead, the entire distribution of the results was used.[12]

## 5. RISK ASSESSMENT FOR HAZARDOUS CHEMICAL EXPOSURE AND DISPOSAL

Assessments of health and environmental issues show great variability in their comprehensiveness and use of the general steps of a risk assessment. The desires of Congress, and its responses to several important environmental issues, have influenced the comprehensiveness of such assessments. Furthermore, the focus of many assessments is on only one of the general steps (i.e., evaluating the dose response of a receptor to a chemical agent). For example, in 1993, the National Academy of Public Administration (NAPA) reported that 7,579 risk assessments had been conducted by the EPA. Most (6,166 assessments) were small 2-day assessments to screen potential chemical carcinogens; only a few of the assessments were extensive, requiring 1 or 2 years to complete and costing more than 1 million each.[93]

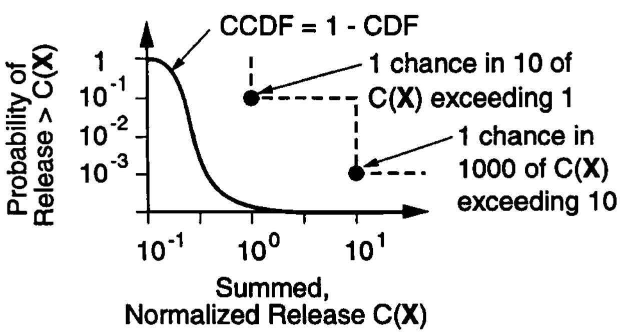



**Fig. 8.** In the United States, the uncertainty in a PA is expressed as a CCDF and compared with the limits in 40 CFR 191.

With such a large and diverse population of risk assessments for health and environmental issues, this article does not attempt a direct comparison between assessment techniques, but rather, juxtaposed health and environmental issues, including chemical carcinogens in foods, air pollution, hazardous waste disposal, and pesticides, and of the varying legislative and regulatory responses with issues of nuclear facilities. In contrast to nuclear facilities, risk assessment has not been consistently accepted as valuable input to policy decisions or regulatory control for other types of hazards. Furthermore, there has been no mandate to include uncertainty in the analysis, and thus these risk assessments have evolved outside the traditions of reliability analysis (Fig. 1). Instead, these assessments have generally used plausible upper bounds for parameter values.[74]

### 5.1. Dose-Response Assessments by the FDA

At about the same time as evidence accumulated about X-ray and radium exposure, some scientists hypothesized that no threshold might also apply to chemical carcinogens.[17] The FDA initially adopted safety factors of 2,000 and then 5,000, but in 1950 it banned two artificial sweeteners when animal tests demonstrated carcinogenicity.[27] Then, the FDA proposed to allow use of a carcinogenic pesticide "Aramite" (see 968 F. 2d 985). Congressional response to this chemical carcinogen hazard was the passage of the Food Additive Amendment in 1958, which contained a "Delaney Clause" that prohibited the intentional addition of additives to processed foods that induced cancer in animals or humans[3] (Public Law 85-929). A similar provision was added concerning food coloring in 1960 (Public Law 86-618; Fig. 9). In essence, Congress stated that no exposure to a carcinogen through processed food was safe, and thus only hazard identification was required. However,

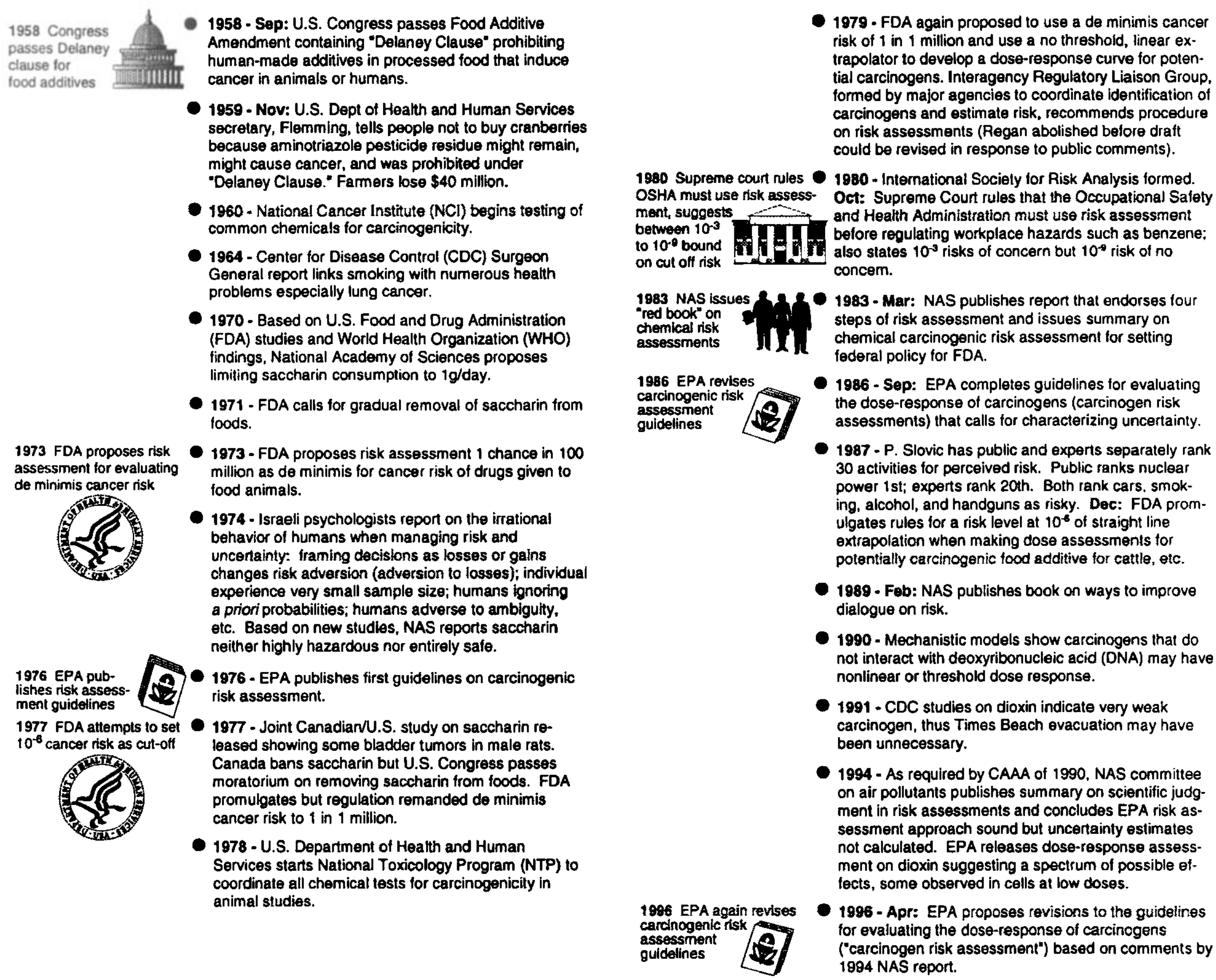



**Fig. 9.** Events influencing evaluation of chemical carcinogens at FDA and risk communication.

the requirement specification that no potentially carcinogenic, human-produced chemical could be intentionally added to *processed* food created gross inconsistencies in policy because different legal treatment of carcinogenic and noncarcinogenic chemicals was mandated.[17]

By the 1970s, an evaluation of consequences from chemical carcinogens, in addition to identifying the potential hazard, was considered necessary in some cases, although a risk assessment could still only highlight—not correct—the discrepancy in policy. In 1976, Lowrance described four steps of risk assessment that emphasized the dose–response aspect of chemical hazards (1) define the conditions of exposure, (2) identify the adverse effects, (3) relate exposure to effect, and (4) estimate overall risk.[4][12]

In the 1980s, the use of risk assessment as a decision-making tool received Congressional support. In 1981, Congress directed the FDA to contract

[12] Lowrance also defined the concept of "safe" as used herein, "a thing is safe if its risks are judged to be acceptable." This was somewhat similar to the relationship of safety and risk introduced in the 1925 *Standard Methods for the Examination of Water and Sewage,* 7th ed., by the American Water Works Association,[25] which commented that "to state that a water supply is 'safe' does not necessarily signify that absolutely no risk is ever incurred in drinking it . . . but the total incidence of diseases has been so low that . . . the risk of infection through them is still very small compared to the ordinary hazards of everyday life."

with the NAS to study risk assessment in the federal government. The purpose of the study was to assess the merits of separating the analytical functions of risk assessment from the regulatory functions, consider the feasibility of a single agency performing all federal risk assessments, and consider the feasibility of developing uniform guidelines for all federal risk assessments. In March 1983, the NAS committee reported on its findings concerning risk assessment for cancer from toxic substances; the committee only indirectly considered risk assessment for other types of hazards. The report defined the risk assessment process using the four basic steps that the FDA (and the EPA) still use for their carcinogenic assessments[3]: (1) hazard identification, (2) dose–response assessment, (3) exposure assessment, and (4) risk characterization. Sensitivity analysis was not discussed. Interestingly, the assessment of probabilities (either of various events or parameters) was also omitted, although probability was indirectly referenced with regard to dose response for carcinogens. The NAS recommended developing uniform guidelines for risk assessments and risk management functions, making a clear distinction between the two functions. By this time, a shift in terminology had occurred. Ten years earlier, Otway (1973)[94] defined risk assessment in a manner similar to the current definition of risk analysis. In Otway's definition, a risk assessment consisted of both risk estimation (the NAS definition of risk assessment) and risk evaluation (the NAS definition of risk management).

The FDA had been struggling to define guidelines for assumptions for dose–response assessment and the meaning of significant risk in one particular area for more than a decade. In 1962, Congress amended the Food, Drug, and Cosmetic Act to allow use of potentially carcinogenic drugs in feed or injections for food animals provided no residue could be detected in the edible tissue, "the diethylstilbestrol (DES) proviso" (Public Law 87-781). Between 1962 and 1973, the FDA tested for potentially carcinogenic chemicals using a variety of analytical techniques on a case-by-case basis. However, during the 1960s, the analytical detection methods dramatically improved such that, by 1972, evidence of most drugs administered to animals could be found in edible tissue through radioactive tracer studies[27] (44 FR 17070). Hence, in July 1973, the FDA proposed using risk as a guideline rather than specifying a particular analytical technique to detect residues. The first proposed regulation used a probit-log transformation to establish a dose–response curve as a default inference that may or may not have had a threshold and defined significant risk as a chance of cancer greater than $10^{-8}$ over a lifetime using this curve[95] (38 FR 19226). This was the first proposed regulatory use of low-dose extrapolation, even though it had been in academic use since 1960.[27] In February 1977, the FDA promulgated this guidance but changed the risk limit to $10^{-6}$ over a lifetime (42 FR 10412). Because the cost of testing was a contentious point,[3] the FDA was sued by the Animal Health Institute. The regulations were remanded by the U.S. District Court in the District of Columbia in February 1978, and revoked by the FDA in May (43 FR 22675). In March 1979, the FDA proposed similar regulations; however, the FDA changed to straight-line extrapolation as the default method for developing the dose–response curve (44 FR 17070). A risk limit of $10^{-6}$ and straight-line extrapolation were finally adopted in December 1987 (52 FR 49586; 21 CFR 500, Subpart E).

Also during the 1970s, the FDA was confronted with two other notable carcinogens: the artificial sweetener, saccharin, and aflatoxin, found in peanut butter. In both instances, the FDA evaluated a dose–response curve and compared it with its $10^{-6}$ risk limit to help explain the decisions to ban saccharin in 1977 (42 FR 19996), while continuing to permit contamination of peanut products with aflatoxin in 1974 and 1978 (39 FR 42748).

### 5.2. Risk Assessment for Health Issues at EPA

*Formation of the EPA*

Congress formed the EPA in 1970, transferring to it responsibilities of research, monitoring, standard setting, permitting, and enforcement activities related to the environment (40 CFR 1). The role of standard setting somewhat differentiated the EPA from other "permitting" agencies, such as the NRC. Also, Congress greatly expanded the public's ability (later enlarged by the courts) to influence the process of setting standards. Lawsuits about EPA standards were permitted by citizens or special interest groups, with legal expenses paid by the federal government if the suit was successful, and EPA regulations were made purposely accessible to the public through numerous avenues such as comment periods. As pointed out by political scientists,[96] the increase in public participation broadened the arguments, but also accentuated the difficulty of making decisions. Hence, procedures for setting standards became important and risk assessment, with its well-defined process, was gradually adopted for determining risks when setting standards and policy and as input for decisions.

Yet, even with these general motivating factors, the movement to use risk assessments as input to decisions was not uniform or consistent within the EPA (or across other government agencies). Although the administration of environmental law rested with one agency after 1970, Congress continued the practice of creating legislation that dealt with only one medium at a time (e.g., air, water, or soil). Hence, the EPA's management structure and programs remained fragmented, and risk assessments would often be narrowly focused without considering overall risk.[93] Furthermore, environmental laws were prescriptive, requiring a command-and-control approach,[43] so that the EPA had little flexibility in what could or could not be considered when setting environmental goals.

### *Controlling Pesticide Use*

Congress had exercised some control of pesticide use since the 1900s (e.g., Insecticide Act of 1910; Publication 48 in U.S. Statutes, Public Law 6-152 [36 Stat. 331]), but pesticides were not used extensively in the early 1900s and so the enforcement of the law was lax.[53] The development and use of manufactured chemicals during World War II jump-started their proliferation in the late 1940s. The widespread use encouraged Congress to pass the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in 1947 (Public Law 104 [62 Stat. 163]) for registration and management of the chemicals, but the new law was still largely ineffective.[53]

Significant public concern for the effects of long-term chemical use occurred after the 1962 publication of *Silent Spring* by Rachel Carson,[97] which condemned pesticides such as DDT and argued for strong government control. This desire for regulation of pesticides was a major impetus in the formation of the EPA.[53,98] DDT, a pesticide with low toxicity to most mammals, had a remarkable ability (because it was both effective and inexpensive) to control mosquitoes and thereby malaria, and its synthesis in 1939 had earned its creator, Müller, a Nobel Prize in medicine. However, the discovery of biomagnification in 1960 for persistent chemicals such as DDT,[4,99] the discovery of eggshell thinning in raptors in England in 1967 from DDT, and the synthesis of other more expensive but less persistent pesticides, led EPA's first administrator, W. D. Ruckelshaus, to overturn an administration hearing's conclusion and ban DDT in the United States in 1972 (37 FR 13369). Also, in 1972, Congress rewrote FIFRA, which strengthened the EPA's control of pesticides. However, FIFRA required economic and social benefits to be considered as well as environmental and health risks. By 1975, the use of two other major pesticides, aldrin/dieldrin and chlordane/heptachlor, was suspended, based primarily on qualitative arguments of health versus social benefits. Scientific information was gathered only during adversarial hearings.[98]

### *Dose–Response Assessment Guidance for Carcinogens by EPA*

In the summary of the administrative hearings on suspended pesticides (e.g., DDT), the attorneys for the EPA implied that only a total ban of useful but potentially carcinogenic pesticides was permissible. These "cancer principles," as they were called, were widely criticized.[3,27,98] Partly in response to the broad criticism of the cancer principles,[100] the EPA produced its first guidelines on assessments in May 1976 for evaluating the carcinogenic potential of a chemical; the EPA termed the evaluation a carcinogenic risk assessment (41 FR 21402). These guidelines were used to evaluate toxic air pollutants, toxic water pollutants, hazardous waste chemicals, and pesticides under the following acts: Clean Air Act (CAA); Federal Water Pollution Control Act (FWPCA); the FIFRA; the Resource Conservation and Recovery Act (RCRA); and the Comprehensive Environmental Response Compensation and Liability Act (CERCLA), discussed later in this article.

The 1976 guidelines proposed a two-step process: hazard identification, followed by risk management to decide whether and how to mitigate hazards. The two steps mirror the concept contained in the "Delaney Clause" that any exposure to carcinogens is unsafe. However, the guidelines stated that risk assessment was part of the second step. Hence, an important transition occurred with regard to recognizing the impracticality of enforcing zero risk from useful chemicals. Yet, by 1983, the transition was not complete nor was tension dispelled over the concept of an "ample margin of safety" (as specified in the Clean Air Act Amendments of 1970 [Public Law 91-

604], discussed in the next section) and risk assessment.[98] Furthermore, the EPA was embroiled in concerns about asbestos in schools[101] and the high rate of potential cancer deaths that had been purported in a draft epidemiology study in 1978, which indicated that 17% of all future cancer deaths would be caused by asbestos.[99] Hence, in June 1983, just 1 month after taking over as EPA administrator for a second time, W. D. Ruckelshaus strongly encouraged the EPA to increase its use of risk assessment in its policy decisions, as endorsed by the March NAS report,[3] and to include a discussion of uncertainty[7] (Fig. 1).

In 1986, the EPA extensively revised the carcinogenic risk assessment guidelines (51 FR 33992), providing guidance on default inferences to use when bridging gaps in knowledge and data for evaluating the carcinogenic potential of a chemical or estimating the dose response, as recommended by the NAS in 1983.[3] In contrast to the FDA's method, the EPA suggested a slightly more complex, linear, multistep model for extrapolating responses to low doses that had been used by the EPA since 1980.[98,102] Similar to straight-line extrapolation, the model was believed to provide a plausible upper bound to dose response in humans. In 1996, the EPA again revised the carcinogenic risk assessment procedures in response to suggestions by the NAS[103] and as mandated by the Clean Air Act Amendments of 1990. The scheme for weighting evidence indicating whether a chemical was a carcinogen was modified, descriptors for categories of potential carcinogens were changed, and the method of developing the dose–response curve was altered so that it included a simple linear extrapolation as a default option, similar to the FDA's method. Despite the EPA Administrator having encouraged an increased use of uncertainty on risk assessments in 1983,[7] the NAS committee on Hazardous Air Pollutants concluded more than 10 years later that uncertainty estimates were still not calculated routinely in EPA risk assessments.[93,103] Hence, the 1996 guidance attempted to explicitly require at least a qualitative description of uncertainty in the assessment. However, in May 1997 the EPA explicitly requires bounding estimates when evaluating human dose response.[103a] Although the report is still in draft, also in 1997, the EPA explored evaluating the uncertainty in the human dose response for radiation and radioisotopes, for which much data have been collected (see Section 2.4; 62 FR 55249; 63 FR 36677). This effort was similar to the uncertainty evaluation also done by the NCRP in 1997.

*Factors of Protection for Noncarcinogens*

In 1977, in a study mandated by the Safe Drinking Water Act of 1974, NAS recommended an approach for noncarcinogens similar to that adopted by the FDA in 1954, by suggesting a factor of protection of 100 when estimating ADIs for contaminants in drinking water. Furthermore, they added another factor of 10 when the contaminant threshold was estimated from short-term nonchronic animal studies. In 1980, the EPA adopted this NAS recommendation and added an additional factor between 1 and 10 when only a LOAEL (lowest observed adverse effects level) was known for setting an ADI (45 FR 79347).

In 1984, Rodericks (1984)[104] proposed a sensible but controversial approach for relating ADIs for noncarcinogens to a unit cancer risk (UCR) for carcinogens[13]; in this approach, the ADI for a noncarcinogen was assumed to represent between $10^{-5}$ and $10^{-6}$ chance of adverse effects. The approach was extended to radioisotopes and applied in an exploratory study using risk to rank chemical and radioisotope hazards at mixed waste sites at U.S. Department of Energy (DOE) facilities.[105] In general, however, studies of noncancerous chemicals are still only hazard assessments combined with a calculation of an allowable threshold dose, which is considered safe by means of standardized factors of protection, without any explicit mention of risk.

*Air Pollution Laws*

The earliest laws related to the environment concerned air pollution. For example, about 1300, Edward I forbade the use of "sea coal" in London. Only when wood was depleted by 1500 did coal become tolerated[106]; by 1661, ill health from smoke around London was observed (Fig. 3). In the United States, Ohio attempted to regulate air emissions from coal-fired industrial boilers as early as 1890. Much later, in 1947, California passed the first comprehensive air pollution statute.[93] Shortly thereafter, Congress encouraged more state control: the Air Pollution Control Act in 1955 (Public Law 84-150, July 14, 1955, ch. 360 [69 Stat. 322]) to fund research by the states; the Clean Air Act in 1963 (Public Law 88-

[13] In the 1980s, the EPA began using the term "reference dose" (RfD) for ADI and "carcinogenic potency factors" (CPF) for UCR.

206) to help states establish their own air pollution control agencies; and an Air Quality Act in 1967 (Public Law 90-148 [81 Stat. 485]) to set air pollution standards to be enforced by the states. Also, in 1965, Congress passed the Motor Vehicle Air Pollution Control Act (amendments to National Emissions Standards Act; Public Law 89-272), which required the federal government to set emission standards.[14] Many consumers were reluctant to support such standards when fuel efficiency dropped precipitously after the standards were first applied in 1968.(43)

In December 1970, Congress passed the Clean Air Act Amendments (Public Law 91-604), which authorized the recently formed EPA to set and enforce federal (rather than state) air quality standards, specifically, the National Ambient Air Quality Standards (NAAQS) for pollutants. Section 112 of the act also required standards be promulgated within the short time of 90 days for toxic pollutants to provide "an ample margin of safety to protect the public health." That is, human health was the sole basis of regulation and "risk" was not mentioned.(101) In response, the EPA listed arsenic, asbestos, mercury, beryllium, radioisotopes, benzene, and vinyl chloride. The EPA circumvented the impossible dictum of "ample margin of safety" for carcinogens by adopting a regulatory requirement for industry to use the "best available technology,"(101) which was more stringent than the 1972 amendments to the Federal Water Pollution Control Act that specified use of the "best practicable technology" (Public Law 89-234). In the Clean Air Act Amendments in August 1977 (Public Law 95-95), Congress mentioned risk for the first time when requiring risk assessments for setting the NAAQS for common air pollutants. The amended act also included a technology standard that required scrubbers on new coal-fired power plants, regardless of sulfur output,(93) to protect coal mining jobs in the East. This technology standard limited the risk management techniques that EPA could allow an industry to use for solving air pollution.(43)

In 1990, Congress passed the Clean Air Act Amendments (Public Law 101-549) that, besides phasing out the use of pollutants affecting stratospheric ozone, expanded the hazardous pollutants for which the EPA was required to set technological standards from 8 to 189, rather than use risk assessment (Fig. 10). However, in a limited endorsement of risk assessments, the Clean Air Act Amendments of 1990 required the NAS to evaluate the use of risk assessments (as noted previously) and the EPA to evaluate residual risks from hazardous pollutants 6 years after enactment.

*Stratospheric Ozone Assessment by NAS*

In 1975, the NAS studied the impact of the Supersonic Transport on stratospheric ozone. The NAS repeated the analysis of ozone depletion in 1976, this time including other sources of chemicals, such as chlorofluorocarbons (CFCs), which catalyzed the conversion of the protective layer of ozone to oxygen. The 1976 study also roughly approximated the influence of uncertainty in seven reaction rates believed to control ozone concentrations. In another iteration of the stratospheric ozone depletion analysis in 1979, under the chairmanship of statistician, John Tukey, uncertainties in parameters were formally described with probability distributions and then propagated through the models using the Monte Carlo technique to arrive at a distribution of the results. This 1979 analysis represented an early application, outside studies for nuclear facilities, of the Monte Carlo technique for evaluating the uncertainty of consequence predictions. The ozone depletion program also chose to periodically conduct the analysis as more information became available.(13)

*Control of Hazardous Chemicals*

In developing ways to manage chemical waste at active disposal sites, Congress has been slow to accept risk assessment. In 1976, Congress substantially amended the Solid Waste Disposal Act of 1965 (Public Law 89-272) in its passage of the Resource Conservation and Recovery Act (RCRA; Public Law 94-580), which sought to reduce or eliminate hazardous waste

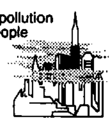
[14] In the United States, similar types of laws on a similar timeline were passed to control water pollution. For example, New Mexico territory passed water pollution laws between 1860 and 1900, and Congress passed a law in 1899 requiring permits from the Army Corps of Engineers to discharge refuse in navigable rivers (March 3, 1899, ch. 425 [30 Stat. 1152]). The Federal Water Pollution Control Act (FWPCA) in 1948 (June 30, 1948, ch. 758 [62 Stat. 1155]) and 1956 (July 9, 1956, ch. 518 [70 Stat. 498]) helped states to build wastewater treatment plants; the Water Quality Act in 1965 (Public Law 89-234) required states to set their own water quality standards. In 1972, Congress completely revamped the FWPCA; in the 1977 amendment (Public Law 95-217), Congress renamed the act "the Clean Water Act" and specified 65 priority toxic pollutants that required standards to be set and were to be monitored.

- **1939 - Müller synthesizes dichlorodiphenyltrichloroethane (DDT) and discovers its value as insecticide with low toxicity to mammals.**
- **1942 - Hooker Chemical Company obtains permission from the State of New York to dispose of waste in clay-lined abandoned Love Canal.**
- **1947 - U.S. Congress passes the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) because WWII had stimulated use of pesticides, but statute largely ineffective. State of California passes air pollution statute.**
- **1948 - Müller awarded Nobel Prize in medicine for contribution of DDT to controlling disease. DDT prices drop and DDT becomes widely used throughout world; use roughly correlates with population declines of some raptors due to eggshell thinning.**
- **1952 - Dec:** Temperature inversion traps pollution in London fog for 5 days; death rate increases 5 fold.
- **1953 - Niagara Falls Board of Education demands Love Canal land and builds school, thus disrupting clay covering disposal site; city develops neighborhood around canal.**
- **1955 - Jul:** U.S. Congress passes Air Pollution Control Act to fund research by states.
- **1960 - Discovery of biomagnification of DDD (chlorinated hydrocarbon similar to DDT) pesticide used to kill gnats occurs at Clear Lake, California, where fish concentrate pesticide and the Western Grebes birds die when consuming fish.**

1962 Carson publishes *Silent Spring*


- **1962 - R. Carson publishes book Silent Spring** that condemns use of pesticides, especially DDT and Dieldrin.
- **1963 - Dec:** Congress passes Clean Air Act to set up state air pollution control agencies for stationary sources and allow Department of Health, Education & Welfare (HEW) to set nonmandatory federal air quality standards.
- **1965 - Oct:** U.S. Congress passes Motor Vehicle Air Pollution Control Act to set emission standards for mobile sources.

1966 Air pollution kills 80 people in New York City



- **1966 - Air pollution trapped in temperature inversion in New York City kills 80.**
- **1967 - Ratcliff discovers eggshell thinning in raptors throughout Britain and hypothesizes DDT is to blame. Congress passes Air Quality Act to set criteria to regulate air pollution by states.**
- **1969 - Sweden bans DDT, but lifts in special case, when alternate pesticide is not effective against pine weevil and spruce budworm.**

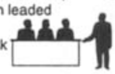
1970 Congress forms EPA

- **1970 - U.S. Congress forms the U.S. Environmental Protection Agency (EPA) and transfers to it responsibilities of research (conducted at 56 laboratories), monitoring, standard setting, and from 6 agencies enforcement activities related to environment; eventually becomes the agency producing or requiring the most risk assessments. U.S. Congress forms Occupational Safety and Health Administration (OSHA) to regulate work place hazards. Also, becomes agency to use risk assessments. Dec:** Because of dissatisfaction with results from Air Quality Act, U.S. Congress passes Clean Air Amendments of 1970 authorizing EPA role in setting and enforcing air quality standards; to provide "ample margin of safety for public health" sets timetable for reducing auto emissions; makes human health sole basis of regulations does not mention "risk". Act also requires the EPA to set National Ambient Air Quality Standards (NAAQS) for pollutants within 90 days; EPA lists $SO_2$, CO, $O_3$, NOx, particulates. Act also requires standards for toxic pollutants; EPA lists As, asbestos, Hg, B, radioisotopes, benzene, and vinyl chloride. In implementing the act, EPA requires use of "best available technology". Canada restricts use of DDT.

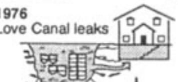
1971 Bliss spreads PCBs and oil over Times Beach roads

- **1971 - Northeastern Pharmaceutical and Chemical Company (NEPACO) asks Bliss, a waste-oil hauler, to remove waste in tanks contaminated with dioxin from production of Agent Orange when plant owned by Hoffman Taft.**
- **1971 - (con't)** Bliss mixes waste with used oil, and sells as heating oil and dust suppressant on dirt roads and horse arenas. Horses die and 4 children severely injured when playing in stable dirt. Bliss continues to spread waste over dirt roads in Times Beach, Missouri, through 1976 and throughout Missouri until 1980.
- **1972 - Jun:** U.S. Congress rewrites FIFRA to strengthen EPA control of pesticides, but requires EPA factor in economic and social benefits, in addition to environmental hazards. Ruckelshaus of EPA overturns administrative hearing findings and totally bans DDT in the United States.
- **1974 - CDC discovers 31,000 ppb dioxin in soil as cause of animal deaths and children's injuries in horse stables in Missouri. Jun & Sep:** Scientists report that chlorofluorocarbons (CFCs) put chlorine into stratosphere and that catalyze conversion of ozone to oxygen.
- **1975 - National Academy of Sciences (NAS) studies impact of Super Sonic Transport (SST) on stratospheric ozone.**

1976 Appeals court upholds ban on leaded gasoline based on risk assessment



1976 Love Canal leaks



1976 Congress passes RCRA

- **1976 - U.S. Congress passes Resource Conservation and Recovery Act (RCRA), which seeks to reduce hazardous waste generation; prescriptive approach to hazards without any risk assessment beyond hazard identification, troubles with dioxin at Times Beach, Missouri, provides impetus.** After 6-yr high rainfall, Love Canal overflows banks. In response to citizen complaints, New York Environmental Department investigates and finds low levels of 82 chemicals in storm sewers. U.S. Court of Appeals upholds EPA decision to reduce lead in gasoline using risk assessment based on "speculative scientific estimates." NAS continues study of thinning stratospheric ozone; reported predictions ranged between 2% (tolerable) to 20% (intolerable).
- **1977 - Aug:** Congress amends Clean Air Act; requires risk assessment for setting NAAQS for common air pollutants, but still prohibits consideration of costs; does include technology standard requiring scrubbers regardless of sulfur output on new coal fired plants (to protect coal miner jobs in east).
- **1978 - Alar tests on rats and mice show signs of causing cancer. EPA bans CFCs as propellants in aerosol cans based on predictions of ozone destruction from models. Health Education and Welfare secretary warns of asbestos hazard in schools and cites risk that 17% of future cancer deaths would be from asbestos. Although study questioned, extreme risk management option to remove all asbestos in schools, was eventually adopted.**
- **1979 - NAS continues to iterate analysis of ozone depletion more carefully, including uncertainty on the results through Monte Carlo Analysis.**

1980 Congress passes Superfund



- **1980 - Congress passed Acid Precipitation Act of 1980 to create National Acid Precipitation Assessment program (NAPAP) inventory problem catalog mitigation strategies. Dec:** U.S. Congress passes Superfund Act for emergency response to spills and remediation of inactive chemical waste sites (paid through tax on chemicals) not covered by other environmental laws. Impetus for passage provided by fires at waste sites at Chester, Pennsylvania, and Elizabeth, New York; groundwater contamination at Rocky Mt. arsenal near Denver, Colorado; EPA survey of Love Canal and thousands of abandoned waste sites.
- **1982 - NAS continues to iterate ozone depletion analysis. EPA presents use of Hazard Ranking Scheme (HRS) for listing sites on National Priorities List (NPL) under Superfund. Dec:** Missouri Department of Health discourages Times Beach residents from returning after flooding because of 100 ppb dioxin along roads as measured by Center for Disease Control (CDC) of public health service and EPA.

**Fig. 10.** Events influencing environmental laws and indirectly risk assessment.

1983 Ruckelshaus encourages inclusion of uncertainty for EPA risk assessment

- **1983** - Reagan creates task force on Times Beach that recommends buying affected homes. **Jun:** Admin. Ruckelshaus announces EPA intent to use risk assessment more and include uncertainties rather than report single value. Congress passes Hazardous and Solid Waste Amendments (HSWA) (amends RCRA):
  - bans hazardous waste disposal in land fills without accepted pretreatment, unless disposal site has petitioned successfully for a "no-migration" variance.
  - prescriptive approach to hazards regardless of health risk
- **1985** - EPA promulgates 40 CFR 300 listing procedures for site cleanup under Superfund Act that includes detailed risk evaluation phase and consideration of cleanup costs. EPA decides to accelerate phasing out leaded gasoline based on assessment of lead's non-ca ncerous health effects. **Sep:** After reviewing EPA data and arguments of Uniroyal, EPA Scientific Advisory Board (SAB) concludes proposed ban on Alar not justified by current tests.
- **1986** - **Jan:** EPA announces it will not ban Alar, based on SAB conclusion; however, apple processors refuse to buy Alar treated apples. Prompted by Ruckelshaus initiative in 1984, EPA publishes Superfund public health evaluation manual giving carcinogenic potency factors for many chemicals. U.S. Congress reauthorizes Superfund Act (SARA); permits citizens to petition EPA for risk assessments of any site, requires revision of HRS, requires public comment period on proposed remedial plans, and starts research on radon gas.

1987 EPA ranks environmental problem based on risk

- **1987** - NAS recommends that EPA *not* apply "Delaney Clause" to carcinogenic pesticide residues in food and use risk assessment instead. EPA senior managers rank and compare environmental problems in four categories in ***Unfinished Business***. **Sep:** Based on atmospheric models, Montreal Protocol signed by 60 United Nations (UN) members to reduce use of CFCs; agreement calls for periodic review.
- **1988** - EPA adopts NAS recommendation of using risk assessment for determining allowable amounts of carcinogenic pesticide residues in or on food, limit set of $10^{-6}$ cancer risk. EPA publishes guidance on risk assessments for Superfund sites. **Oct:** NRDC hires Fenton Communications to publicize soon-to-be released risk assessment on Alar through television, popular magazines, etc.
- **1989** - **Feb 1:** Based on preliminary toxicity studies EPA required Uniroyal to conduct in 1986 - 1987, EPA publishes decision to stop all use of Alar on food, but allows use for 18 months because added risk from extension felt insignificant. **Feb 26:** CBS "60 Minutes" uses NRDC information and causes panic about Alar in apple juice while alleging EPA's dereliction. **Feb 27:** NRDC releases risk assessment deploring Alar residues in children's food. **Jun:** Uniroyal stops selling Alar in the United States. EPA publishes guideline on safety factors to apply in dose response assessment.
- **1990** - **Jan:** Scientists questioned need for the drastic asbestos abatement programs for schools. EPA Science Advisory Board (SAB) reviews ***Unfinished Business*** and produces own ranking of environmental ***Problems In Reducing Risk***. SAB also recommends ecological risks be assessed (a topic EPA had been exploring in various regions since 1986). **Dec:** Congress passes Clean Air Act Amendments (CAAA) of 1990 that includes phasing out use of pollutants affecting stratospheric ozone and requires EPA to set technology standards (versus risk standards) for 189 hazardous pollutants to speed up process and requires EPA to conduct risk assessments 6 yrs after enactment for "residual risks" and ambient air risks (risks must be reduced to below $10^{-6}$). Act also allows utilities to buy and sell pollution credits for $SO_2$ pollutants. Act also requires cost benefit analysis of reducing acid rain, and sets goal of reducing $SO_2$ emissions by $10^7$ ton from 1980 levels. "London Revision" to Montreal Protocol calls for total ban on CFCs by 2000 in developed countries and 2010 in other countries based on great concern raised by revised atmospheric models.
- **1991** - UN panel of experts concludes Alar safe for use on apples throughout world.
- **1992** - Office of Management and Budget (OMB) finds EPA spending vast sums on low risks at toxic waste sites while relatively little on high risks such as lead poisoning. After suit filed by NRDC, U.S. Court of Appeals rules that EPA must strictly apply "Delaney Clause" for carcinogenic pesticide residues and cannot use risk assessment and a *de minimis* risk policy. EPA issues Exposure Assessments Guidelines stating importance of adequately characterizing uncertainty. Montreal Protocol again amended to ban CFCs by 1996 in developed countries and 2006 in other countries.
- **1993** - Study finds that cost effectiveness of federal regulations for averting premature death varies from \$1 x $10^5$ to \$5.7 x $10^{12}$.
- **1996** - Based on exploratory studies since 1986, EPA publishes proposed guidelines for assessing risks to entire ecosystem.
- **1998** - **Apr:** EPA finalizes guidelines for ecological risk assessment stating "risk assessment explicitly evaluate uncertainty".

**Fig. 10.** (Continued.)

generation and control hazardous waste disposal at active sites. Its overall purpose was to minimize present and future threats to human health and the environment through control of hazardous chemicals from "cradle to grave." An important impetus for RCRA was the environmental problem that was caused by the actions of a used oil hauler, Bliss, which had been asked to remove and dispose of hazardous wastes in 1974. The wastes were from a former manufacturing plant for the herbicide, Agent Orange, often contaminated with dioxins. Bliss inappropriately mixed the waste with used oil and sold it as a heating oil and dust suppressant on dirt roads and horse arenas in Missouri through 1980, thus creating the problem at Times Beach (Fig. 10).[99]

RCRA is fairly prescriptive in its manner of controlling chemical hazards. Hazard identification is the only risk assessment component specified, and risk management practices are strictly defined. This prescriptive approach was even more pronounced in the 1984 Hazardous and Solid Waste Amendments (HWSA; Public Law 98-616) to RCRA, which banned nearly all hazardous waste disposal in landfills without pretreatment. In EPA's implementing regulations 40

CFR Parts 260 through 281, a specific technology was prescribed to treat waste before disposal, regardless of any risk assessment.

*Remediation of Abandoned Chemical Disposal Sites*

In December 1980, Congress passed the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) or "Superfund" (Public Law 96-510) for emergency response to spills and remediation of inactive chemical waste sites not covered by other environmental laws (e.g., RCRA). The impetus for passage was provided by fires at waste sites in Pennsylvania and New York; groundwater contamination at the Rocky Mountain Arsenal near Denver, Colorado; an EPA survey of thousands of abandoned waste sites; and the well-publicized problems at Love Canal in New York.

CERCLA did not completely embrace the notion of risk assessment, but in contrast to RCRA's prescriptive approach, CERCLA did allow the EPA more latitude in determining the emergency response for an inactive chemical waste site. The EPA's 1982 Hazard Ranking Scheme (HRS) for listing sites on the National Priorities List under CERCLA lacked a sound relation either to risk assessment or the use of underlying consequence models.[105] However, the EPA chose to conduct a detailed site characterization and a feasibility study of various remediation options for those same sites in 1985, accompanied by an assessment of associated risks and cleanup costs (Fig. 10). Because the mining and smelting industry expressed concern that HRS was the real assessment and that the purpose of any risk assessment during the feasibility study would be only to justify the results of HRS (or other decisions already made), Congress asked for a reevaluation of HRS in the 1986 Superfund Amendment and Reauthorization Act (SARA; Public Law 99-499 [100 Stat. 1613]) to eliminate the potential for disparate results from HRS and later risk assessments for the feasibility study. (SARA allowed any citizen to petition for a risk assessment of a disposal site.) Unfortunately, a substantial change in HRS might have required a reevaluation of past work or already settled lawsuits under CERCLA, and thus the opportunity for change was minimal. SARA also required research on the risks of radon gas in homes, a rediscovered hazard prevalent in many areas because of better sealed and insulated homes. The impetus was the publicized problem of using uranium tailings in Grand Junction, Colorado.

### 5.3. Court Rulings on Use of Risk Assessment

In 1976, the U.S. Court of Appeals upheld a decision by the EPA to reduce lead in gasoline using risk assessment based on "speculative scientific estimates."[17] In 1980, the U.S. Supreme Court ruled in favor of the American Petroleum Institute and the American Industrial Health Council, and against the AFL-CIO labor union and environmental groups, when it stated that the Occupational Safety and Health Association (OSHA) must use risk assessment before regulating workplace hazards (as reported in vol. 100 of the *Supreme Court Reporter,* page 2844 [100 S. Ct. 2844]). The court also suggested that an individual's chance of hazard of $10^{-3}$ per year was of concern but that a chance of $10^{-9}$ per year was not, thus bracketing the $10^{-6}$ health risk cutoff that had first been proposed by the FDA in 1977[3] (42 FR 10412), as mentioned earlier. An advantage of risk assessment was its ability to provide a meaningful method to organize scientific information and document administrative decisions and thus facilitate judicial review.

Even with this important Supreme Court ruling, in 1985, Professor of Law R. Merrill noted that the "courts are schizophrenic" concerning the use of risk assessment.[107] Although the situation is somewhat different in the 1990s, in that the courts expect to see arguments posed in terms of risk, they do not always agree that risk is germane to the case. For example, this support for risk assessments did not translate into moderation with regard to the "Delaney Clause." In 1987, the NAS recommended that the EPA *not* apply the "Delaney Clause" to carcinogenic pesticide residues in food; instead, the EPA should use risk assessment.[108] One year later, the EPA adopted the NAS recommendation and set residue limits on food for four pesticides at a chance of $10^{-6}$of inducing cancer per year.[93] However, in a 1992 suit filed by several petitioners that included the National Resources Defense Council, the U.S. Court of Appeals, Ninth Circuit, ruled that the EPA must strictly apply the "Delaney Clause" and could not use risk assessment and a *de minimis* risk policy until Congress enacted such a change (968 F. 2d 985).

## 6. PERFORMANCE ASSESSMENT APPLICATIONS

The EPA 40 CFR 191 Standard (50 FR 38066) established criteria for radioactive waste disposal but acknowledged that "the procedures for determining compliance with subpart B have not been formulated and tested yet." These procedures were not completely formulated until they were applied to actual sites. Two applications are presented here as background for specific topics discussed in this special issue. The first application is the PA conducted for the WIPP in the late 1980s and early 1990s.[109-114] The second application conducted by the YMP has somewhat different practical details.

### 6.1. Application of Performance Assessment to Waste Isolation Pilot Plant

*Legal Setting and Compliance Assessment*

In 1979, Congress established the purpose of the WIPP as a research and development facility for storage and disposal of only transuranic waste generated by defense programs (Public Law 96-164). Yet, the actual compliance process was not defined until 1992, when Congress transferred ownership of the WIPP site to the DOE and designated the EPA as the regulator of the WIPP (Public Law 102-579). In 1996, the EPA promulgated 40 CFR 194 (61 FR 5224), a regulation to implement its 40 CFR 191 standard, which imposed several new requirements and interpretations on the modeling style for the WIPP PA. Basically, however, 40 CFR 194 adopted the risk process, as outlined here, that Sandia had implemented (Fig. 11).[11,12,109,115,116]

*Site Selection and Characterization*

With the tacit approval of New Mexico's governor, the AEC, the USGS, and ORNL examined and identified a potential site in the Delaware Basin in southeastern New Mexico in 1973, based on physical geologic criteria such as thick salt beds of high purity, little evidence of dissolution, tectonic stability, public support, low population density, and absence of land use conflicts. The first large-scale field test was the drilling of two wells in March 1974.[69,70] In January 1975, Sandia became the lead laboratory to draft an EIS,[117] initiate scientific studies on nuclear waste disposal in bedded salt, develop the conceptual design,[118] and select and characterize a site. The preliminary design for the repository was developed in 1977[118] and included two levels: one for TRU waste and one for other radioactive waste. The basic concept remained largely unchanged in the final design, as reported in 1986, with the exception of the removal of the level for other radioactive waste in the 1980 Final EIS[117] and some modifications to drift dimensions and storage volumes. Site characterization activities before 1989 were undertaken primarily (1) to satisfy needs for EISs in 1978 and 1989, (2) to satisfy negotiated agreements with the state of New Mexico in 1981, and (3) to develop a general understanding of selected natural phenomena associated with nuclear waste disposal. Thereafter, site characterization studies were gradually directed toward data needs for the four preliminary PAs, conducted between 1989 and 1992, and the PA for certification in 1996.

*Hazard Identification and Scenario Development*

In 1974, ORNL conducted the first scenario development and deterministic scoping analysis for the possible repository location.[72] For the Draft EIS in 1979, Sandia developed three scenario categories (diffusive migration of radioisotopes through salt, transport of radioisotopes to an overlying aquifer through a borehole, and direct exposure during drilling).[88] This initial work became the foundation for scenarios later used for the PAs. For preliminary PA calculations in 1989,[110, 119] features such as the presence of a brine reservoir under the repository, events such as exploratory drilling into the repository and potash mining above the repository, and processes such as climate change influencing flow in the brine aquifer overlying the repository, were included as features and events. These basic scenarios were studied in the 1990, 1991, and 1992 PAs.[69,70,111-114,120] For the final Compliance Certification Application (CCA) on the WIPP,[121] submitted to the EPA in October 1996, a formal screening process was conducted that fully documented the reasons for omitting or retaining specific features, events, and processes.[122] Although the hazard identification relied heavily on the 1980 EIS,[88,117,119,125] the screening process was similar to that initially proposed by Cranwell *et al.* (1990)[82] in the 1980s based on scenario probability, consequence, or regulatory criteria.

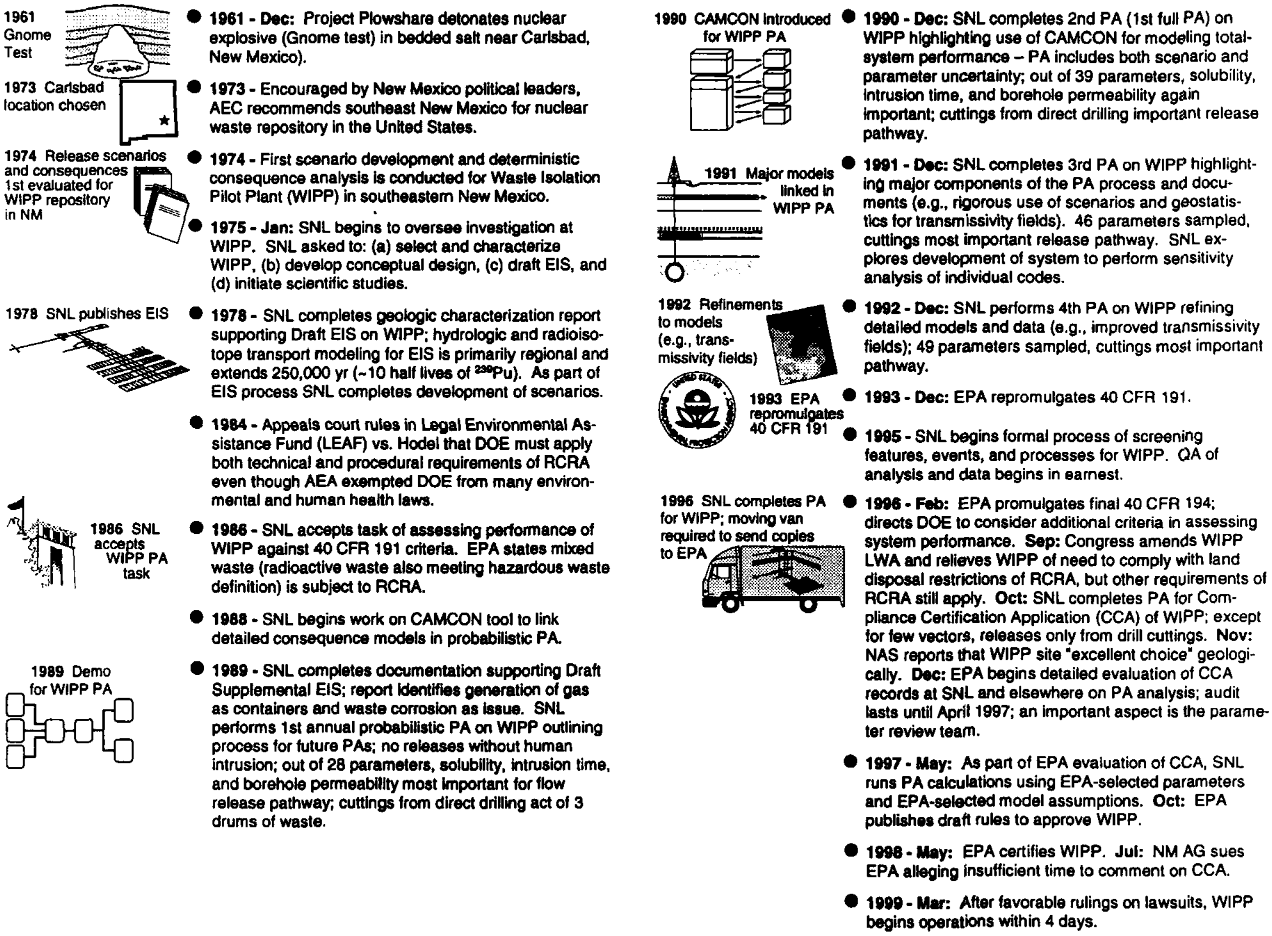



**Fig. 11.** Application of performance assessment at the WIPP.

*Probability Evaluation*

For the WIPP, as in the method proposed for the NRC in 1981,[75,76] the distribution of the results was estimated using Monte Carlo techniques. Furthermore, the Monte Carlo integration was eventually performed in two stages to facilitate flexibility. The first stage was concerned with parameter uncertainty, $\mathbf{x}^p$, and the second stage, with scenario uncertainty, $\mathbf{x}^s$. That is, the deterministic model, $C(\cdot)$, was run using $nK$ realizations of the parameter vector, $\mathbf{x}^P$, which yielded a sequence of $nK$ results of the form $C(\mathbf{x}_1^p)(\mathbf{x}_2^p)\ldots,(\mathbf{x}_{nK}^p)$ for each scenario, $S_j$, which were used to approximate the CCDF (Fig. 8).

Although the theory for probabilistic model simulation is not difficult, the practical aspects of performing the calculations are daunting for a complex system such as geologic disposal. Developing distributions for the uncertain parameters, $D_n(\mathbf{x}_n^p)$, and appropriate values for the fixed parameters in a manner sufficiently traceable for regulatory review is particularly challenging. Hence, traceable procedures for the WIPP were developed in the early 1990s,[123] which matured into an extensive quality assurance program by 1996. In addition, an important practical problem for parameter uncertainty was determining the appropriate number of uncertain parameters to propagate. Out of ~1,560 parameters, the number of uncertain parameters studied for the WIPP grew from 28 in 1989[110,111] to 57 in 1996.[69]

*Consequence Evaluation*

The major role of modeling in a PA made computer software fundamental to the process.[124]

*Development of Computational Tools.* A practical problem for a geologic disposal system is the need to model several scales (e.g., the source term, repository, local transport, and regional fluid flow). Hence, for the WIPP PA, the exposure pathway model was a concatenation of many submodels[70] (designated by $\alpha, \beta, \gamma$), $C(\cdot) = f_\alpha\{f_\beta[f_\gamma(\cdot)]\}$. Additional practical problems for analyzing a disposal system are determining the appropriate level of detail for the individual submodels so that the calculation is tractable and linking the models together, so that they are sufficiently traceable and repeatable for regulatory review.

Between 1988 and 1990, Sandia devised a scheme to link together through a controller, CAMCON, any number of complicated numerical or simple analytical codes for the WIPP.[109,120] As built, CAMCON allowed the analyst the flexibility to choose several variations of one model type (designated by $\alpha$); i.e., $f_\alpha^1, f_\alpha^2, \ldots f_\alpha^{nM}$, where $nM$ is the number of models that perform a similar function) to directly make use of the existing submodel codes and select the code with the appropriate level of detail. The latter option allowed the analysts to use CAMCON for both detailed examination of system components as well as overall disposal system performance.

*Detailed Modeling Style.* Sandia's contribution to the Draft EIS, issued in 1978, relied heavily on mathematical modeling using the SWIFT code to examine the potential for movement of radioisotopes by groundwater.[125] By the second iteration of the WIPP PA in 1990,[111,112,120] analysts had again chosen a modeling approach that included phenomenological detail, offered multiple dimensions in the model, and avoided conservative models and parameter values wherever possible.[123] Encouraging comments regarding detailed modeling were received from the EPA[112] on the first iteration of the WIPP PA. In addition, a detailed modeling style was generally accepted in the United States because of its earlier use in the 1975 *Reactor Safety Study*[14] and its 1990 update,[62,63] and the proposal for extensive use of PRAs in the 1995 PRA Policy Statement (60 FR 42622).

The principal advantage of a detailed modeling approach was that it incorporated a sufficient level of realism to (1) provide or demonstrate general scientific understanding, (2) explore potential sources of uncertainty, and (3) tie any lack of understanding or sources of uncertainty directly to measurable data. Note, however, that the WIPP PA continued to contain some conservative assumptions and bounding models. For example, a few conservative assumptions were built into the analysis (e.g., a stationary future and a conservative dose–response model) and others were adopted during the analysis (e.g., insufficient information was available on shear strength of corroded waste during human intrusion). Hence, the probabilistic analysis was conditional on these conservative assumptions.

*Iteration of Calculations.* In 1989, the WIPP PA analysts adopted the idea of conducting sequential PAs (i.e., conducting an initial PA with simple or incomplete complicated models and preliminary data), followed by other PAs with better data and more detailed computational models.[109] Sandia conducted four preliminary PAs from 1989 through 1992, with each building on the preceding PAs.[15] In October 1996, the certification PA for the CCA was completed. In May 1998, after receiving accepting comments on the proposed rule published in October 1997 (62 FR 58792), the EPA approved operation of the WIPP (63 FR 27354). Operations began in March 1999, after favorable rulings on lawsuits. Although the results are voluminous, the application of past PAs for the WIPP has been presented by Helton *et al.*, in several journal articles.[126–128] In addition, Helton *et al.* present a summary of the certification PA in this issue.[121]

### *Sensitivity Analysis*

Sensitivity analysis was an important feature in early PAs of hypothetical repositories[75,86,87] and was quickly adopted for the WIPP evaluation. Because Monte Carlo techniques had been used to propagate uncertainty in the WIPP analysis, sensitivity of the results to changes in parameter values could be easily estimated by scatterplots, or developing a statistical regression model and comparing the size of the standardized regression coefficients.[110,112,113,126] Sensitivity analysis of alternative conceptual models was also conducted in 1989 and 1991.[111,127] Other techniques for sensitivity analysis, such as developing surrogate analytical expressions for the results ("response surface development") or differential analysis of normalized partial derivative of parameters ("adjoint procedure"), were also proposed in the 1980s.[129] However, these were never used routinely for a large-scale sensitivity analysis such as the WIPP disposal

[15] Using the terminology of the 1996 EPA ecological risk guidelines (61 FR 47552; 63 FR 26846), these repetitions were a "tiered assessment" because they were planned repetitions rather than "iterations," which EPA describes as unplanned repetitions.

system that included linked several complicated models.

Sensitivity analysis, in combination with multiple PA iterations, provided guidance to managers on how to direct experimental resources, especially after the 1992 PA. Other purposes of the sensitivity analysis[123] were to gain understanding and insight about the system, verify the correctness of the calculations, and evaluate the influence of various engineering design options. Garrick and Kaplan describe the impact that a PA can have on waste disposal decisions in this special issue.[130]

In the 1989 and 1990 WIPP PAs, the most important parameters were those associated with the scenarios for inadvertent human intrusion from exploratory drilling for oil and gas: solubility of radioisotopes, the time of intrusion into the repository, and the assumed permeability of the resulting but abandoned borehole. In the 1991 and 1992 WIPP PAs, direct release of cuttings to the surface from inadvertent human intrusion again dominated total radioisotope release. The three most important parameters were the rate constant in the Poisson model for time and number of intrusions, borehole permeability, and solubility of radioisotopes.[114] Thus, by 1992, it was evident that regulatory mandated assumptions with regard to human intrusion were dominating the results. Continued evaluation of the characteristics of the disposal system was not considered to be warranted, except for specific areas such as an evaluation of radioisotope solubilities in the repository, retardation distribution coefficients, and alternative conceptual models for transport in an overlying brine aquifer in the Culebra Dolomite.

### 6.2. Application of Performance Assessment for Yucca Mountain Project

Most of the issues associated with disposal of defense and commercial wastes are the same, but the congressional policy and administrative histories are different in the United States. Consequently, the approach between projects has varied for each of the risk assessment steps, as discussed here.

#### *Legal Setting and Compliance Assessment*

Three laws are significant to setting national policy on radioactive waste disposal from commercial nuclear power reactors: the Nuclear Waste Policy Act of 1982, the 1987 amendment to this act, and the Energy Policy Act of 1992 (Public Law 102-486 [106 Stat. 2776]). These laws not only establish the policy that the current generation must bear the costs of developing a permanent disposal option, but they also define steps to achieve this goal. However, each act changes the emphasis of the various steps.

The Nuclear Waste Policy Act of 1982 (Public Law 97-425) set up a mechanism to select a site and fund its selection and operation, and assigned responsibility for the construction and operation of the potential repository to a new office within the DOE, the Office of Civilian Radioactive Waste Management (OCRWM), which absorbed many of the functions for commercial waste disposal performed by the National Waste Terminal Storage Program established in 1976. The act formed a large trust, funded by utilities owning nuclear reactors, to pay for the repository; required the DOE to identify two repositories for commercial spent fuel; assigned responsibility to the DOE to select, build, and operate one repository; established a strict timetable for operating the first repository; suggested placing defense high-level waste in the commercial repository; and suggested building a monitored retrievable storage facility. The amendment of 1987 (Public Law 100-203) selected Yucca Mountain in Nevada as the first site to characterize, extended the opening date to 2010, and delayed consideration of a monitored retrievable storage facility and a second repository.

The Energy Policy Act of 1992 (Public Law 102-486) set new policy that generated substantial changes in the regulatory setting. The act required the EPA to seek advice from the NAS and to promulgate a site-specific standard for the potential nuclear waste repository at Yucca Mountain and the revision of the NRC implementing regulation, 10 CFR 60, to agree with the new EPA standard. The act strongly suggested prescribing the maximum allowable annual effective dose equivalent to individuals near the repository (possibly because of Congressional criticism of the derived limits in 40 CFR 191 when applied to gaseous release of $^{14}C$ along an air pathway). In 1995, NAS recommended[131] three changes from previous regulatory practice: (1) use a maximum individual risk evaluated from an annual effective dose equivalent as the criterion for protecting public health, (2) evaluate the maximum annual effective dose equivalent during a 1 million-year period, and (3) eliminate evaluating the probability of inadvertent human intrusion and instead evaluate only potential consequences of a few selected situations.

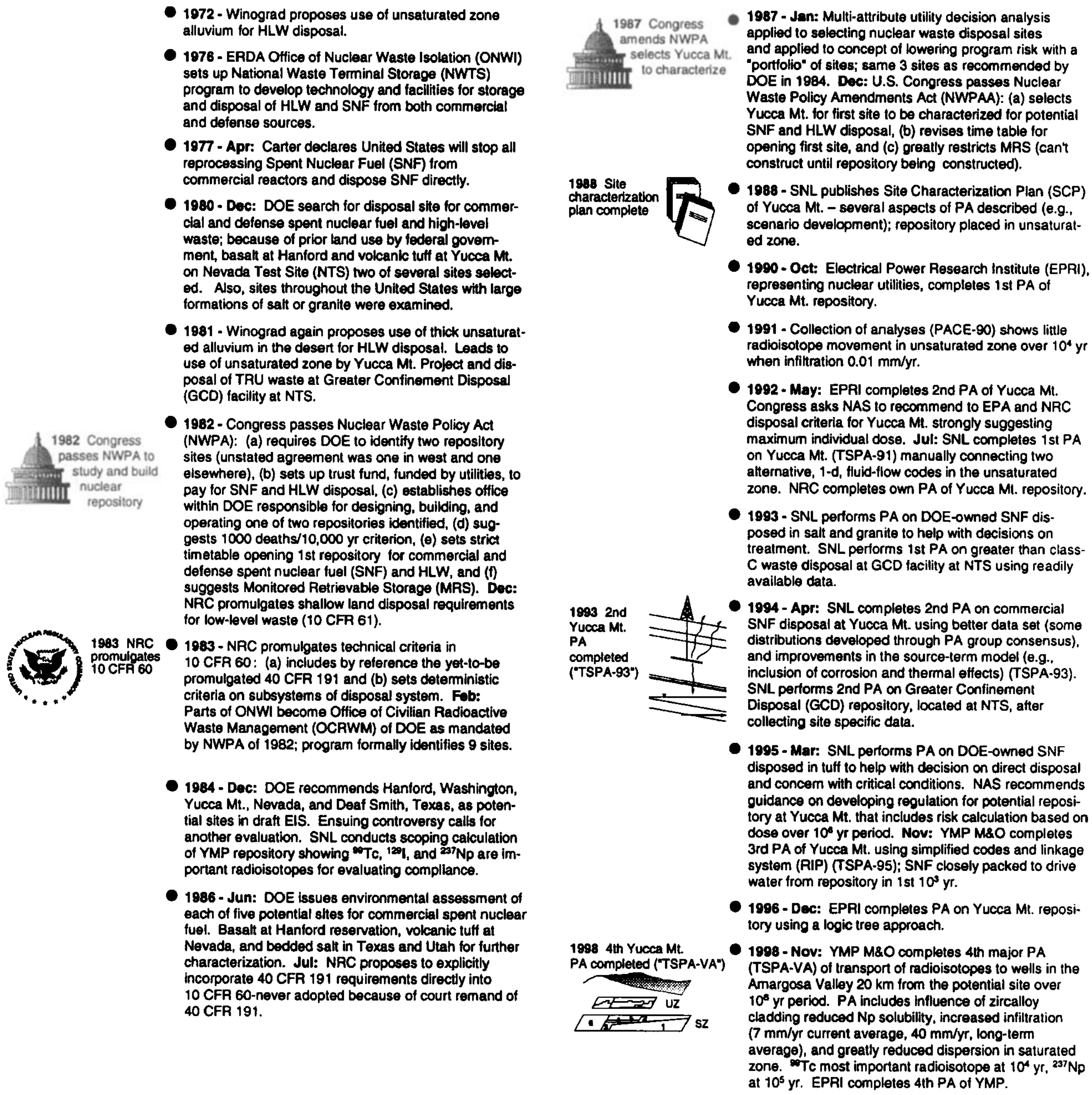



**Fig. 12.** Application of performance assessment at the YMP.

In the United States, the NRC is responsible for ensuring that a disposal system for commercial-generated spent nuclear fuel meets the requirements of EPA's standards for commercial nuclear waste, such as 40 CFR 191. In 1983, prior to final promulgation of 40 CFR 191, but cognizant of its likely contents, the NRC promulgated 10 CFR 60 (46 FR 13971; 48 FR 28194; 10 CFR 60) that incorporated the EPA standard by reference but also set deterministic technical criteria on subsystems of the waste disposal system (Fig. 12). In 10 CFR 60, the technical criteria established stringent minimum requirements for disposal subsystems: 1,000-year groundwater travel requirement on the geologic barrier 300-year container life without substantial failure, and a maximum release rate from the container after initial failure. These criteria were not probabilistic, despite the NRC's support of PRAs in the late 1970s (see Section

4.2). In 1986, the NRC proposed to explicitly incorporate the requirements of the EPA standard, 40 CFR 191, into 10 CFR 60 but the changes were never adopted (51 FR 22288) because 40 CFR 191 was remanded by the courts (824 F. 2d. 1258). The NRC proposed 10 CFR 63 in February 1999 (64 FR 8640) for the repository at Yucca Mountain, again cognizant of the likely contents of the EPA Standard, 40 CFR 197 recently proposed in August 1999 (64 FR 46977). The NRC regulation proposes a dose limit of 25 mrem/yr during a 10,000-year period from drinking water and consumption of vegetables, given a small community well about 20-kilometer downgradient from the site. The NRC eliminated all subsystem requirements since they could cause expensive suboptimal designs (64 FR 8640).

*System Characterization*

Although salt was an appealing disposal medium for commercially generated nuclear waste, the DOE began an intensive search in 1976 for repositories in several types of rock in 36 states. By 1980, the DOE's Nuclear Waste Terminal Storage Program had settled on nine sites, including volcanic tuff at Yucca Mountain near the Nevada Test Site.(36) DOE ownership of the land, the adsorptive capability of the tuff (especially the zeolitized portions), the belief at that time that spent nuclear fuel could be easily retrieved from tunnels for reuse or disposal elsewhere, and the extremely dry climate were important reasons for consideration of this site.(36,132) As with the WIPP, a PA was not used directly in site selection. Rather, a comprehensive study was published in 1986. (Although it caused confusion, the study was called an Environmental Assessment [EA] but was not related to the EA defined in 40 CFR 1501 regulations promulgated in 1979 to implement NEPA.) Under 10 CFR 60, the NRC required the DOE to prepare a site characterization plan (SCP) (46 FR 13971; 48 FR 28194; 10 CFR 60), which was completed in 1988.(133) The massive SCP described almost every experiment or study that might be required to characterize the highly fractured tuff and generate mathematical models of waste dissolution and movement of radioisotopes in groundwater. As with most aspects of the YMP, the characterization studies were conducted by several research organizations in addition to Sandia, including the USGS, Los Alamos National Laboratory, Lawrence Livermore National Laboratory, Lawrence Berkeley National Laboratory, Argonne National Laboratory, PNL, and contracting organizations such as SAIC, Inc.; Raytheon, Inc.; Reynolds, Inc.; and later TRW, Inc.

The design of the repository at Yucca Mountain has varied considerably over the life of the project. Initially, the repository was placed in the saturated zone, but arguments in 1981 for disposal of high-level waste in unsaturated alluvium derived from tuff deposits(134) prompted consideration of the unsaturated zone at Yucca Mountain. By 1988, the SCP envisioned a repository in the unsaturated zone. Even though construction of the repository was far off, DOE awarded a management and operations (M&O) contract in 1993. Shortly afterwards, the design was modified to include large disposal containers emplaced directly in the drifts to reduce mining and operating costs. Also, by 1995, the project seriously considered closely packing the wastes such that the heat would dry out the unsaturated zone for ~1,000 years,(135) instead of keeping temperatures low such that perturbations to the geologic environment would be small, as envisioned by the NAS in 1957.(71) Although tunneling costs were reduced, acquiring sufficient understanding of the geologic environment to confidently predict the benefits of drying out the host tuff effects in turn necessitated gathering more characterization data, an expensive undertaking. The most recent design envisions closely spaced containers to dry out the tunnel, but widely spaced tunnels to keep the area between tunnels cool, and thereby allowing water drainage.

*Hazard Identification and Scenario Development*

As with the WIPP, hazard identification for YMP examined what features, events, or processes could negate the initially perceived advantages of the site. The hazard identification and scenario development process for this and later PAs generally recognized volcanism, seismicity, and human intrusion as important events and climate change as an important process to consider. Elaborate event trees with many changes in physical processes in addition to basic events(136) were developed in 1995 to promote a qualitative understanding of the issues and were similar to the event trees developed for the 1979 Draft EIS on the WIPP. However, the event trees were not used directly in simulations. Rather, only small portions of the trees were considered. Kessler and McGuire report on more extensive use of logic trees for a PA of the Yucca Mountain repository in this special issue.[137] Currently, the YMP has adopted a hazard identification and scenario development procedure identical to that used by the WIPP Project in the 1990s, which in turn had been proposed to the NRC in 1981.[82,122,138]

*Consequence Analysis*

Simple analytical calculations to determine the relative importance of various phenomena present at Yucca Mountain were conducted in 1984 (which identified $^{99}$Tc, $^{129}$I, and $^{237}$Np as important radioisotopes for evaluating compliance)[139] and 1988 (performed in conjunction with the SCP).[133] The first large-scale analysis of fluid movement through the unsaturated zone occurred in 1990.[140] Shortly thereafter, a series of deterministic calculations using best estimates for model parameters were run by several organizations—Sandia, PNL, and Los Alamos National Laboratory—to simulate the expected performance of the disposal system in the unsaturated zone. Percolation was set at 0.01 mm/yr and four radioisotopes were transported through a 19-layer one-dimensional model of the mountain. No radioisotopes reached the underlying aquifer ~300 meters below the repository.[141]

*Initial Performance Assessments.* In 1992 (16 years after a search was begun and 11 years after site selection), the YMP completed the first probabilistic PA[16] of the Yucca Mountain disposal system that evaluated releases to a 5-kilometer boundary (TSPA-91),[142] generally following the process outlined in the 1988 SCP.[133] For fluid flow in TSPA-91, Sandia used a one-dimensional model and PNL a two-dimensional model. For the first time, gaseous flow of $^{14}$C and a probability distribution (exponential distribution with mean of 1 mm/yr) for percolation that was believed to incorporate future climatic changes were included.

The second PA (TSPA-93)[143] included an improved source-term model and a saturated zone model. The analysis also greatly expanded the data used for defining distributions for hydrologic and geochemical parameters. Percolation was divided into two distributions: one for the current dry climate (exponential distribution with mean of 0.5 mm/yr) and one for a hypothetical wet climate (exponential distribution with mean of 10 mm/yr).

Also, the Electric Power Research Institute (EPRI) conducted two early PAs in 1990[144] and 1992,[145] and PNL conducted a PA that used detailed multidimensional models of flow and transport, but evaluated consequences for only a limited number of different model parameters. In 1996, EPRI completed a third iteration of their PA,[146] described further in this special issue.[137] Similar to some international regulatory agencies,[147] the NRC has developed an independent capability to perform a PA.[148] The NRC completed their initial PA in 1992[149] and a second in 1995.[150]

*Studies for Design Options.* Between 1992 and 1995, the YMP reported each year on a fairly simple modeling system (Repository Integration Program [RIP][151]) originally intended to rapidly simulate the behavior of the disposal system to evaluate design systems. The system used a variety of techniques such as curve fits to previous results and selection of distributions for particular data (e.g., percolation fluxes) to incorporate previous results.[152] That is, RIP used simplified model types, $f_\alpha(\cdot)$, for most of the necessary components (designated by $\alpha$) of the exposure pathway model, $C(\cdot)$. For instance, in the unsaturated zone in 1992 and 1994, a one-dimensional phenomenological model was used and, in 1995, analysts developed steady-state velocity fields and percolation flux distributions, from a few simulations using phenomenological models. This simplified modeling style, called "abstraction," had been originally proposed in the 1988 SCP[133] as the culmination of sensitivity analysis on process models. A purported advantage of this approach is that it allows for rapid calculations and thus potentially helped managers allocate resources for further characterization studies. The analyses using RIP were the only PAs performed by the YMP from 1995 to 1997.[135,153,154] During this time, the choice of corrosion-resistant material for the disposal container shifted from Inconel 625 to Incoloy 825 to Hastelloy C-22. Furthermore, the 100-mm layer of carbon steel, which was to serve as corrosion-allowance, has been replaced with 50-mm layer of stainless steel, which is to serve primarily for structural strength.

*Licensing Studies.* In 1997, Congress mandated in its energy appropriation bill that the YMP evaluate

[16] The YMP calls its PAs "total system PAs (TSPA)" to emphasize that the assessment includes all the major subsystems and components of the disposal system. Because of the definition of PA used within this report, the term is unnecessary here. However, the term "total system" does serve to explicitly connect performance assessment to systems engineering, a connection that was recognized in the 1970s (e.g., Rowe's book, *Anatomy of Risk*,[81] was part of the engineering systems analysis series of Wiley-Interscience).

the likelihood that the potential Yucca Mountain disposal system would meet EPA and NRC requirements (Public Law 104-206). A viability PA (TSPA-VA) was thus initiated using anticipated new NRC regulatory criteria (10 CFR 63); TSPA-VA was completed in November 1998.[155] Although TSPA-VA used RIP, numerous changes and additions were made to the TSPA-95 models, including the addition of more phenomenological models. Some of these changes included the influence of the zircaloy cladding on commercial spent nuclear fuel, evaluation and inclusion of geochemistry changes near the waste package, colloid formation and transport, and a factor of 100 reduction in solubility of Np. Numerical dispersion in codes modeling the saturated zone was avoided by using six stream tubes; the infiltration of moisture was increased a factor of 10 to a current mean of 7 mm/yr and a long-term average of ~40 mm/yr; and a new risk measure, dose to a 100-member farming community 20 kilometers from the site, was calculated. Similar to past analyses, the TSPA-VA found that the amount of seepage and the distribution of this seepage were the most important aspects determining failure of waste packages and releases of radioisotopes. EPRI also produced a fourth iteration of their PA.[156] Future licensing analyses currently planned include (1) a Draft EIS to be completed by the end of July 1999, (2) a site recommendation PA (TSPA-SR) to be submitted to the president by July 2001, and (3) the license application to be submitted to the NRC by March 2002.

*Probability Evaluation*

In its first probabilistic assessment of the potential Yucca Mountain disposal system as reported in 1992 (TSPA-91),[142] the YMP was at a relatively early stage in conceptual model development. Thus, TSPA-91 was similar in formality to the 1989 WIPP PA with regard to assigning probability distributions to the uncertain parameters or probabilities for specific scenarios. The probability of human intrusion was evaluated with the Poisson distribution, and the probability of volcanism was based on consensus of analysts within the YMP PA group. Parameter values and distributions were determined primarily by individual PA analysts. The formality increased when uncertain parameters were evaluated in YMP's second PA (TSPA-93), reported on in 1994,[143] in that distributions for many more parameters were developed and were more often based on the consensus of several PA analysts, accompanied by input from site characterization scientists. The basic information on parameter distributions reported in TSPA-93 was then used for subsequent simplified PAs in 1995, 1996, and 1997,[135,153–154] although values were sometimes changed for parametric sensitivity analysis. Improved data for a few parameters (e.g., solubility of neptunium) were incorporated into the TSPA-VA. However, many parameter values that were estimated in the early 1990s have not yet been confirmed. However, the requirement to conduct the TSPA-VA spurred the process of developing an analysis that could withstand regulatory scrutiny, and have generated numerous quality assurance (QA) procedures were applied.

### 6.3. Other Assessments for Repositories

*Other Performance Assessments in the United States*

Besides PAs conducted specifically for the WIPP and the YMP, other PAs were conducted by the United States. Three projects in the United States that benefited from PA were (1) a reexamination of deep seabed disposal of nuclear waste in 1977 that concluded in 1988 and that applied some techniques, such as embedded models, that were later adopted for the WIPP Project[157]; (2) an exploration of the feasibility of demonstrating compliance for greater-than-class C low-level waste (e.g., tritium) and other transuranic waste, which was disposed of at the Nevada Test Site in 1981[158,159]; and (3) analyses in 1993 and 1995 of the behavior of DOE-owned spent nuclear fuel to test the viability of direct disposal of the waste in salt, granite, and tuff that used tools developed for the WIPP[9,160] (Fig. 11).

*International Assessments*

In contrast to the United States, most countries have anticipated relatively long-term surface storage of spent nuclear fuel and high-level waste, so there has been less motivation to follow a strict timetable for permanent disposal.[161] The Canadians and British support probabilistic assessments, but most other international PAs tend to be deterministic. Other differences include the omission or inclusion of future human intrusion and the length of the regulatory period. For example, Germany does not consider human intrusion in its assessments nor specify a regulatory time period. Also, countries other than the United States sometimes place greater emphasis on analog models in addition to mathematical models for predictions of future behavior[15,16] and use a dose (or individual risk) rather than a cumulative release limit. Figure 13 is a summary depiction of analysis and disposal criteria in several international assessments of nuclear waste disposal. B.G.J. Thompson reports on various regulatory issues addressed in the international community in this special issue.[147]

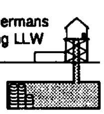
## 7. SUMMARY

### 7.1. Common Foundations and Comparisons Between Risk Assessments

Risk assessment has evolved from hazard identification for relatively straightforward problems to methods that incorporate probability and uncertainty of knowledge for more complex situations, when society is unsure about how to either interpret or respond

- **1967** - West Germany begin experiments for radioactive waste disposal in abandoned Asse salt/potash mine.
- **1975 - Oct:** International Nuclear Energy Agency (NEA) forms Radioactive Waste Management Committee to foster exchange of information on nuclear waste disposal.
- **1977** - Sweden begins underground research at Stripa mine. IAEA recommends site selection criteria for geologic disposal sites.
- **1978** - Canada announces Atomic Energy of Canada, Ltd. (AECL), given task of developing nuclear waste disposal concept. West Germany starts suitability study of abandoned Konrad iron ore mine for disposing of radioactive waste with no heat (primarily low and intermediate level waste [LLW & ILW]). Sandia WIPP project begins technical exchange with German salt disposal project at Asse salt mine.
- **1979** - West Germans start investigating high-level waste disposal in salt dome at Gorleben, near East-W est boarder.
- **1980** - Swedes reject nuclear power in national referendum, must find source for 50% of electric power needs by 2010. Switzerland regulator (HSK) sets max individual dose at 0.1 mSv/yr for HLW without time limit.

1981 Canadians publish SYVAC-1



1981 East Germans start disposing LLW & ILW at Morsleben

- **1981 - Apr:** East Germans start disposing low and intermediate alpha-emitting radioactive waste in Morsleben, abandoned mine in domal salt, near Gorleben under 5 yr license. Canada announces no site selection until after EIS on disposal concept. Canadians proponents (AECL) develop SYVAC-1, single set of primarily analytic models for total-system geologic and subseabed disposal (concept expanded on by CAMCON). IAEA recommends procedure for PA and potential list for scenarios.
- **1982** - U.K.'s regulator (HMIP) adapts SYVAC-1 for use in low-, inter- mediate-, and high-level waste disposal. Germans complete suitability study of Konrad and start developing license application.
- **1983** - Commission of European Communities (CEC) develops LISA PA code. To continue developing nuclear power, Swedes publish PA of disposal of HLW in fractured granite using copper canister and bentonite backfill. German regulator (BMU) promulgate radioactive standards, mostly qualitative except for maximum dose limit of 0.3 mSv/yr without time limit.
- **1984** - NEA sets up group from various countries to exchange ideas on PA. NEA suggests maximum individual human health risk of $10^{-5}$ cancers per year from HLW. Swiss begin field tests in fractured granite in Swiss Alps at Grimsel.
- **1985** - Canadians complete second interim assessment on conceptual design using SYVAC-2 and begin underground research at Lac du Bonnet, Winnipeg. Swiss proponents (NAGRA) publish Project Gewahr PA of vitrified HLW in a 1200-m deep repository in granite. Spain's nuclear safety council publishes safety criteria.. Sweden nuclear waste studies at Äspö Laboratory.
- **1986** - East Germans grant Morsleben permanent disposal license. West Germany begins construction of 2 shafts in Gorleban salt dome. Swedish Nuclear Power Inspectorate (SKI) starts "Project-90" to examine hypothetical granite repository with 100-mm thick copper canister. U.K. simulates glacial climate changes in PA.
- **1987** - Canada sets maximum individual risk at $10^{-6}$/yr for $10^4$ yr for HLW disposal.
- **1988** - Canada's proponent AECL announces disposal concept ready for EIS review.
- **1989** - U. K. develop VANDAL, combination of SYVAC and precursor of NEFTRAN, as PA tool. NEA holds major symposium on state-of-the-art nuclear waste disposal.
- **1990** - Sweden's regulator complete Project 90 (deterministic PA on "what if" conditions).

1991 Sweden complete major PA

- **1991** - Swedish proponents publish assessment focusing on role of geosphere ("SKB-91"). Finland sets maximum individual dose at 0.1 mSv/yr for normal and 5 mSv/yr for accident conditions without time limit. Administrative count issues preliminary injunction to stop waste emplacement at Morsleben.

1992 U.K. complete "Dry Run 3" PA

- **1992** - Canada's Minister of Natural Resources issues guidelines for EIS on disposal concept to AECL. Finland publishes deterministic PA of disposal concept ("TVO-92"). U.K.'s regulator (HMIP) completes "Dry Run 3" – full probabilistic PA including long-term glaciation of site using VANDAL, a network simulation code. First integrated PA of HLW disposal is performed in Japan.
- **1993** - U.K.'s regulator (HMIP) sets $10^{-6}$/yr for individual risk or 0.1 mSv/yr dose without time limit.

1994 Canadians publish EIS on HLW repository concept

- **1994** - Canada's proponent AECL publishes EIS for disposal concept recommending siting phase. Netherlands publishes probabilistic PA of disposal of vitrified HLW in salt domes. Swiss proponents (NAGRA) update their 1985 PA in Kristallin I. German court lifts injunction and waste emplacement begins again at Morsleben.
- **1996** - Sweden's regulator completes SITE 94 (large study of features, events, and processes) for a hypothetical repository with geologic characteristics derived from the Äspö laboratory.
- **1998 - Jun:** Final signatory of Konrad license application refuses to sign license until after German elections. **Sep:** Superior Administrative Court orders emplacement of waste to stop at Morsleben's "eastern field" however, all emplacement stopped voluntarily. **Dec:** Germans elect socialist Green coalition to power that vows to stop reliance on all nuclear power over next 4 yr (33% of energy use, plants represent 61 billion in assets); want all waste disposal to stop until reevaluation of sites and one site selected.

**Fig. 13.** Standards and assessments in the international community for nuclear waste disposal.

to an identified hazard for which there is only limited experience. Furthermore, risk management decisions often are constrained to use (through regulations) different kinds of risk information and, thereby, encompass varying degrees of detail.

*Definition of Risk Criteria*

Until a regulatory environment has been established, any risk assessment must deal with defining risk criteria and goals. Initially, Congress decreed zero probability of cancer from food additives in the "Delaney clause" in 1958 (Figs. 1 and 9). However, in the 1970s and 1980s, several technological and environmental risk goals were defined. In 1973, the FDA proposed evaluating cancer risks (Figs. 1 and 9), and in 1977, the FDA proposed a probability of less than $10^{-6}$ cancers per year as a risk goal (42 FR 10412; 52 FR 49572), assuming dose–response models with plausible upper bounds. (That is, the risk criteria are dependent on the methods used to assess the risk.) The Supreme Court endorsed a similar risk goal for OSHA in 1980 (100 S. Ct. 2844). From 1977 to 1985, the radiation program within the EPA set about establishing risk limits for radioactive waste repositories to promulgate 40 CFR 191 (50 FR 38066). The EPA is currently establishing site-specific risk limits for a potential site at Yucca Mountain in 40 CFR 197 (64 FR 46976).

*Characterization of System*

In antiquity through the 1930s, system definition and characterization was relatively informal and primarily based on experience with an activity or technology. System characterization is necessary for any scientific modeling of a natural system, whether its purpose is to gain insight or illustrate possible future behavior. Hence, even before safety goals and a compliance process were established for radioactive waste disposal, characterization of the WIPP near Carlsbad, New Mexico, was undertaken for the EIS in the late 1970s (Figs. 1 and 11).

*Identification of Hazards and Development of Scenarios*

Many practical risk management techniques have been rapidly and inexpensively deployed to reduce risks by means of a hazard assessment. Simple hazard identification and appropriate risk management, such as linking cholera to contaminated well water (Figs. 1 and 3) and later purified water supplies,[25] improved sanitation, and medical services, were responsible for the dramatic rise in human longevity from about 25 years at the time of the Roman Empire to about 63 years in 1940. Applied risk management, such as improved medical services, in turn lead to identifying new hazards (e.g., radium paint; Figs. 1 and 4).[19] Although, NASA abandoned tools of probability and consequence assessments for the Apollo Program in the 1970s, it retained hazard assessment through Failure Mode/Effects Analysis.[66] The initial assessment of an abandoned chemical waste site for emergency response under CERCLA is a hazard assessment.

*Evaluation of Probability*

From its inception around 1660, probability theory has been intimately involved with individual and societal decisions about actions that can be taken today, such as insuring life or property (e.g., the Dutch), to mitigate possible unwanted future outcomes (Figs. 1 and 2).[1] Reliability/system analysis became important during development of aircraft technology in the 1930s and missile technology in the 1940s and 1950s (Figs. 1 and 5).[40] For these technologies, a trial-and-error, design-and-construction approach was insufficient.

A major difference among types of risk assessments is whether uncertainties in knowledge of parameters and model forms are included. For a deterministic evaluation, the risk assessment displays only a conditional result $C(\mathbf{x})$, where $\mathbf{x}$ are expected or best estimate values of parameters or, more often, plausible upper bounds. Unless the system under study is linear, the use of expected parameter values in models will not necessarily result in expected values of the consequence—a measure of risk promoted in the early 1980s (e.g., Ref. 162). The use of plausible upper-bound parameter values can present additional problems because the location of the conservative result with regard to distribution is not known and the degree of conservatism in risk from different hazards can differ greatly, as pointed out as early as 1985.[74] Furthermore, comparison of *mean* benefits to *conservative* risks for various options is problematic when making decisions.[17,74] Even though encouraged in the early 1980s (Figs. 1 and 10), the absence of a mandate to include uncertainty in risk assessments for hazardous waste disposal contributed to the inconsistent use of uncertainty analysis into the mid-1990s.[93]

A PRA displays the entire distribution function and avoids the dilemma in which events of low probability and high consequence are equated to events of high probability and low consequence, although conservative models and parameters are still incorporated, as in the dose–response assessment and conditions of future society. Until uncertainty is included in the risk assessment, the risk measure will likely diverge from a common historical meaning of the word risk, associated with variance, and thus contribute to misunderstanding. Requiring explicit, quantitative inclusion of uncertainty by the EPA in 40 CFR 191 was a natural progression from the 1975 *Reactor Safety Study* (which, in turn, had progressed from smaller studies in the late 1960s; Fig. 1). The stochastic analyses for nuclear facilities have yielded (and continue to yield) by far the largest analysis of uncertainty in mathematical modeling.

### *Evaluation of Consequence*

A consequence evaluation determines the effects of realizing a hazard through a dose–response assessment and an exposure pathway assessment. Initially, in the early 1900s, scientists assumed a model of human dose response with a threshold below which there was zero risk of toxicity. By the 1940s, however, observed effects of radiation and radioisotope toxicity studies (Figs. 1 and 4) brought into question whether a practical threshold existed for radiation[17,35] and, in 1948, the NCRP recommended an ALARA policy for radiation. By the mid-1970s, the FDA and EPA were adopting non-threshold guidelines for developing bounding dose—response curves as risk analysis was introduced for carcinogenic chemicals (Figs. 1 and 10). According to current EPA guidelines, PA and PRA included, the dose–response assessment (i.e., modeling internal to the human body) uses plausible upper bounds for parameter values, but uncertainty in radiogenic dose–response has been explored (62 FR 55249; 63 FR 36677).

The prediction of consequences along exposure pathways external to humans became important as society grew concerned about the consequences of technologies or activities of which little was known. Soon after passage of the Atomic Energy Act of 1954 (Public Law 83-703 [68 Stat. 919]), the financial risk to the federal government from a calamity at a nuclear power plant motivated an examination of consequences in the late 1950s.[20,50] The *Reactor Safety Study* in 1975 investigated risks from the nuclear power plant by combining concepts of reliability analysis, exposure pathway analysis, and radiation pharmacology, thus inaugurating the concept of a PRA on a grand scale. This study was later updated in 1990 (Figs. 1 and 6).

In assessing the safety of a geologic disposal system for the first time in the mid 1970s (Figs. 1 and 7), a new challenge was understanding long-term behavior of system components (e.g., waste containers and their interaction with the host rock environment). Especially in the United States, a PA became intimately tied to the process of building a mathematical model of the system. The passage of stringent risk criteria required a more realistic, rather than a highly conservative but simple, analysis. In turn, the realistic analysis required evaluating the uncertainty associated with stylized situations for regulatory analysis. Monte Carlo analysis, originally developed and applied in 1947 for nuclear weapon design on the first computers (Figs. 1 and 5). LHS has been frequently used for sensitivity and uncertainty analysis of several linked models in the United States.[11,115] The LHS technique, a simple scheme developed in 1975[57] to judiciously sample the parameter domain in Monte Carlo Analysis, was used to gain insight about the pipe ruptures in nuclear power plants in 1975[57] and important parameters of a geologic disposal system in 1978 in PAs and PRAs.[86,87]

### *Evaluation of Risk Measure and Comparison with Risk Goals*

A significant difference between a PA for radioactive disposal and other policy analyses is that the PA (by definition), is designed to test *compliance* to a set of standards rather than just elucidate understanding. Certainly, PA can be used to enhance understanding through sensitivity analysis; however, the assessment for radioactive waste disposal is essential to determine whether the selected risk management technique, deep geologic disposal of nuclear waste, is likely to meet the selected risk limits using stylized circumstances selected by the regulator. Although the disposal assessment does not represent a complete examination of intergenerational equity, it is unique among regulations in the United States in at least indirectly acknowledging the issue (40 CFR 191;

50 FR 58196).[92] Building on the work conducted at Sandia in the late 1970s and 1980s,[62,63,75–77,157] the assessment for the WIPP in 1996 consisted of a PA that included many quantifiable uncertainties (Figs. 1 and 11). The distribution of cumulative radioisotope release results, expressed as a CCDF, was compared with probabilistic regulatory criteria.[109–114]

In contrast, for an active hazardous waste disposal site, specified methods for treatment and disposal of the waste at a site with specific engineered features, such as plastic liners as required by regulations implementing RCRA (40 CFR Parts 260–281), are used to determine compliance. Furthermore, because a ready funding source is available from the DOE or users of electrical power generated by reactors, the resources that are marshaled and the costs incurred for evaluating consequences, incorporating uncertainty into the analysis, and demonstrating compliance with nuclear waste disposal regulations are one or two orders of magnitude greater than might be expected for clean up of an abandoned Superfund site (using the WIPP Project as an example).[70] Hence, several other aspects also differentiate chemical and nuclear waste risk assessments. More extensive site-specific information is produced for a nuclear waste site than for a chemical site[70]; the inventory of radionuclides is fairly well determined[111]; the feature, event, and process screening and scenario development are more detailed[72,88,119,122]; the exposure pathway assessment uses more detailed phenomenological models[113,114,127]; modeling assumptions are more consistent because of the use of database and computer control of the analysis[109,120]; several iterations of the analysis are performed and sensitivity analysis is extensive.[126,128] When evaluating mixed waste problems and disposal sites, analysts have had to resolve some of the differences in assessment assumptions,[105] but much more could be done.

### 7.2. Influence of Risk Assessments

The first two steps of a risk assessment, basically hazard assessment have clearly led to improvements in general human welfare since ancient times. Yet, the addition of consequence and probabilistic evaluation steps have also produced some valuable input for documenting administrative decisions for controversial projects likely to be reviewed by a court.[17] Basic risk evaluations have been used at OSHA since the U.S. Supreme Court ruled that a risk assessment was required before OSHA could promulgate an occupational exposure regulation (100 S. Ct. 2844). The FDA has used risk assessment to reach more reasoned decisions such as in 1980, when the FDA successfully argued that the risks from lead acetate, a possible carcinogen, were reasonable when used in hair coloring (45 FR 72112).

Sophisticated risk assessments, such as the PAs for the WIPP, blend information from multiple disciplines and thus multiple viewpoints, which can be a strength when dealing with large uncertainties, rather than relying on only one discipline, such as geology.[17] The NRC eventually became a staunch supporter of PRAs in managing risks at nuclear reactors and adopted them as the main tool for setting policies in 1995. Similarly, the EPA became convinced of the benefits of a PA for radioactive waste disposal. Nevertheless, except for PA and PRA for nuclear facilities and policy setting at OSHA and FDA, risk assessment has not been uniformly recognized as a valuable input to policy decisions, regulatory control of other environmental concerns within the EPA, possibly because of the inconsistent mandate provided by Congress and the courts.

Risk assessment has also been used to influence other types of policy decisions. For example, the federal government has used risk assessment results to examine dollars spent on risk management in proportion to potential lives saved.[17,93] Yet, just as conclusions of cost–benefit analysis are dependent on the assumed future interest rate or the value of a human life, the results from risk assessments can become dependent on basic assumptions about the conditions under investigation (e.g., assumptions concerning future human activities; such as exploratory drilling) and land use (such as a housing development). At the WIPP, this dependency was acknowledged when information about the geologic disposal site was deemed sufficient because assumptions on inadvertent human intrusion continued to dominate the risk results at the later stages of disposal characterization. Not acknowledging such a dependency can be detrimental if the decision makers assume that the assessment calculates an absolute risk such that comparisons of risks from different hazards and activities are valid. The latter situation could occur when comparing calculated risk from radioactive hazardous and waste disposal, even though the time frames of the analyses are very different and the assessment as-

[17] However, adequate documentation and competent peer review are required lest the risk assessment become less than the sum of the disciplines ("parts").

sumptions include the potential for human intrusion in one case but not in the other.

Although many have urged inclusion of uncertainty when quantifying risks, not all elements of uncertainty can properly or easily enter the assessment, and thus other factors must enter into a risk management decision. For example, the PA for disposal of radioactive waste at the WIPP, which included more than 80,000 pages of documentation, has not by itself produced a change in the public's basic beliefs about radioactive waste disposal in New Mexico that is politically significant.[60,163,164] That is, the assessment has not been considered by the public as a complete measure of the uncertainty of the repository. Rather, the public has used factors such as knowledge of the type of waste to be stored at the WIPP, its perception of risk associated with transporting the waste, and, as part of the overall uncertainty, its trust of public officials' personal acceptance or resistance to the WIPP repository. (The concept is similar to a banker's "risk premium" on interest rates.)

Furthermore, risk assessment cannot always lead to the desired understanding of the issues or to more reasoned decisions.[93] In some cases, risk assessments have inadvertently increased the public's concern over safety. For example, the initial assessment of risks at Times Beach, Missouri, overestimated risks, confirmed public fears, and contributed to the decision to evacuate residents. Subsequent studies by the Centers for Disease Control and Prevention, including a revised risk assessment in 1991, suggested that the first assessment exaggerated the risks and that a less drastic risk management choice such as paving dirt roads may have made the evacuation unnecessary.[99] Similarly, a questionable study of the cancer risk from asbestos in 1978[99] eventually led to the extreme risk management decision to remove all asbestos insulation in schools. A more moderate risk management approach, which left undisturbed asbestos insulation in good condition, was not instituted until the 1990s, and then only after prodding by scientists[165] and after billions had been spent. Finally, in 1989, the Natural Resources Defense Council (NRDC) used a risk assessment to challenge EPA's decision to phase out during an 18-month period the use of Alar (a growth stimulant regulated as a pesticide). The news story, which had started with results from the NRDC assessment, caused unnecessary public avoidance of apples and contributed to economic ruin of several small apple farmers.[166] Therefore, we should not as a profession expect too much of a "simple paper study" in its ability to further acceptance of a particular activity nor hastily conclude that a "simple paper study" cannot contribute to unintended harm.

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## REFERENCES

*Note:* See Ref. 8 for a more complete listing of primary references.

1. I. Hacking, *The Emergence of Probability: A Philosophical Study of Early Ideas About Probability, Induction and Statistical Inference* (Cambridge University Press, New York, 1975).
2. P. L. Bernstein, *Against the Gods: The Remarkable Story of Risk* (John Wiley & Sons, New York, 1996).
3. National Academy of Sciences/National Research Council (NAS/NRC), *Risk Assessment in the Federal Government: Managing the Process,* Committee on the Institutional Means for Assessment of Risks to Public Health, Commission on Life Sciences, National Research Council (National Academy Press, Washington, D.C., 1983).
4. W. W. Lowrance, *Of Acceptable Risk: Science and the Determination of Safety* (W. Kaufmann, Los Altos, CA, 1976).
5. M. W. Martin and R. Schinzinger, *Ethics in Engineering,* 2nd Ed. (McGraw-Hill, New York, 1989).
6. R. B. Cumming, "Editorial: Is Risk Assessment a Science?" *Risk Anal.* **1**(1), 1–3 (1981).
7. W. D. Ruckelshaus, "Science, Risk, and Public Policy," *Science* **221**(4615), 1026–1028 (1983).
8. R. P. Rechard, *Historical Relationship Between Performance Assessment and Other Types of Risk Assessment in the United States* (Sandia National Laboratories, Albuquerque, NM, in preparation).
9. R. P. Rechard (ed.), *Performance Assessment of the Direct Disposal in Unsaturated Tuff of Spent Nuclear Fuel and High-Level Waste Owned by U.S. Department of Energy,* SAND94-2563/1/2/3 (Sandia National Laboratories, Albuquerque, NM, 1995), pp. 1–3.
10. S. Kaplan and B. J. Garrick, "On the Quantitative Definition of Risk," *Risk Anal.* **1**(1), 11–27 (1981).
11. J. C. Helton, D. R. Anderson, M. G. Marietta, and R. P. Rechard, "Performance Assessment for the Waste Isolation Pilot Plant: From Regulation to Calculation for 40 CFR 191.13," *Oper. Res.* **45**(2), 157–177 (1997).

12. J. C. Helton, "Risk, Uncertainty in Risk, and the EPA Release Limits for Radioactive Waste Disposal," *Nucl. Technol.* **101**(1), 18–39 (1993).
13. M. G. Morgan, M. Henrion, and M. Small, *Uncertainty, A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis* (Cambridge University Press, New York, 1990), p. 292.
14. N. C. Rasmussen, *Reactor Safety Study: An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants,* NUREG-75/014, WASH-1400 (U.S. Nuclear Regulatory Commission, Washington, D.C., 1975), pp. 1–8.
15. Nuclear Energy Agency (NEA), *Disposal of High-Level Radioactive Wastes: Radiation Protection and Safety Criteria, Proceedings of an NEA Workshop, Paris, 5–7 November 1990* (NEA, Organisation for Economic Co-Operation and Development, Paris, 1991).
16. Nuclear Energy Agency (NEA), *Disposal of Radioactive Waste: Review of Safety Assessment Methods,* A Report of the Performance Assessment Advisory Group of the Radioactive Waste Management Committee, OECD Nuclear Energy Agency (NEA, Organisation for Economic Co-Operation and Development, Paris, 1991).
17. J. D. Graham, "Historical Perspective on Risk Assessment in the Federal Government," *Toxicology* **102**(1/2), 29–52 (1995).
18. K. Shrader-Frechette, *Science Policy, Ethics, and Economic Methodology: Some Problems of Technology Assessment and Environmental-Impact Analysis* (D. Reidel, Boston, 1985).
19. V. T. Covello and J. Mumpower, "Risk Analysis and Risk Management: An Historical Perspective," *Risk Anal.* **5**(2), 103–120 (1985).
20. J. N. Stannard, *Radioactivity and Health: A History,* DOE/RL/01830-T59 (Pacific Northwest Laboratory, Richland, WA, 1988).
21. N. Smith, *A History of Dams* (The Citadel Press, Secaucus, England, 1971), pp. 9, 230–234.
22. J. R. Newman, (ed.), *The World of Mathematics, A Small Library of the Literature of Mathematics from Ah mosé the Scribe to Albert Einstein* (Simon & Schuster, New York, 1956), pp. 1–3.
23. Random House, *Webster's College Dictionary,* Rev. Ed. (Random House, New York, pp. 1998).
24. R. W. Burchfield (ed.), *The Oxford English Dictionary* (Clarendon Press, Oxford, 1982), Vol. VIII, p. 714.
25. National Academy of Sciences/National Research Council (NAS/NRC), *Drinking Water and Health,* Safe Drinking Water Committee, Board on Toxicology and Environmental Health Hazards, Assembly of Life Science, National Research Council (National Academy Press, Washington, D.C., 1977).
26. E. R. Tufte, *Visual Explanations: Images and Quantities, Evidence and Narrative* (Graphics Press, Cheshire, CT, 1997).
27. P. B. Hutt, "Use of Quantitative Risk Assessment in Regulatory Decisionmaking Under Federal Health and Safety Statutes," in D. G. Hoel, R. A. Merrill, and F. P. Perera (eds.), *Risk Quantitation and Regulatory Policy, Proceedings of the Banbury Center Conference, Lloyd Harbor, May 13, 1994,* CONF-8405356, Banbury Report 19 (Cold Spring Harbor Laboratory, Cold Spring Harbor, 1985), pp. 15–29.
28. M. L. Dourson and J. F. Stara, "Regulatory History and Experimental Support of Uncertainty (Safety) Factors," *Regul. Toxicol. Pharmacol.* **3**, 224–238 (1983).
29. B. D. Goldstein, "The Problem with the Margin of Safety: Toward the Concept of Protection," *Risk Anal.* **10**(1), 7–10 (1990).
30. U.S. Environmental Protection Agency (EPA), *Background Information Document Final Rule for High-Level and Transuranic Radioactive Wastes,* EPA 520/1-85-023 (EPA, Office of Radiation Programs, Washington, D.C., 1985).
31. International Commission on Radiological Protection (ICRP), *Report of Committee II on Permissible Dose for Internal Radiation (1959): Recommendations of the International Commission on Radiological Protection,* ICRP Publication 2 (Pergamon Press, New York, 1959).
32. International Commission on Radiological Protection (ICRP), *Limits for Intakes of Radionuclides by Workers: A Report of Committee 2 of the International Commission on Radiological Protection,* ICRP Publication 30, Part 1, Annals of the ICRP, Vol. 2, No. 3/4 (Pergamon Press, New York, 1979).
33. R. D. Evans, "Inception of Standards for Internal Emitters, Radon and Radium," *Health Phys.* **41**(3), 437–448 (1981).
34. R. D. Evans, R. S. Harris, and J. W. M. Bunker, "Radium Metabolism in Rats and the Production of Osteogenic Sarcoma by Experimental Radium Poisoning," *Am. J. Roentgenol.* **52**, 353–373 (1944).
35. E. B. Lewis, "Leukemia and Ionizing Radiation," *Science* **125**(3255), 965–972 (1957).
36. L. J. Carter, *Nuclear Imperatives and Public Trust: Dealing with Radioactive Waste* (Resources for the Future, Washington, D.C., 1987).
37. E. Teller, "The Plowshare Program," *Proceedings of the Second Plowshare Symposium, San Francisco, CA, May 13–15, 1959, Part I, Phenomenology of Underground Nuclear Explosions,* Plowshare Series Report No. 2, UCRL-5675 (Lawrence Radiation Laboratory, Livermore, CA, 1959), pp. 8–13.
38. H. Kumamoto and E. J. Henley, *Probabilistic Risk Assessment and Management for Engineers and Scientists,* 2nd ed. (IEEE Press, New York, 1996), pp. 1–54.
39. N. Metropolis and S. M. Ulam, "The Monte Carlo Method," *J. Am. Statist. Assoc.* **44**(247), 335–341 (1949).
40. J. Neufeld, *The Development of Ballistic Missiles in the United States Air Force 1945–1960* (Office of Air Force History, U.S. Air Force, Washington, D.C., 1990), pp. 169, 215.
41. N. Wiener, *Cybernetics or Control and Communication in the Animal and the Machine,* 2nd Ed. (MIT Press, New York, 1961).
42. A. F. Hixenbaugh, *Fault Tree for Safety,* D6-53604 (Boeing Military Aircraft Product Development, Seattle, 1968).
43. J. R. Kahn, *The Economic Approach to Environmental and Natural Resources,* 2nd Ed. (The Dryden Press, Fort Worth, TX, 1998), pp. 110–113.
44. J. M. Hammersley and D. C. Handscomb, *Monte Carlo Methods* (John Wiley & Sons, New York, 1964).
45. D. B. Hertz, "Risk Analysis in Capital Investment," *Harvard Bus. Rev.* **42**(1), 95–106 (1964).
46. H. Raiffa, *Decision Analysis: Introductory Lectures on Choices Under Uncertainty* (Addison-Wesley, Reading, MA, 1968).
47. R. L. Keeney and H. Raiffa, *Decisions with Multiple Objectives: Preferences and Value Tradeoffs* (John Wiley & Sons, New York, 1976).
48. R. L. Keeney and K. Nair, "Selecting Nuclear Power Plant Sites in the Pacific Northwest Using Decision Analysis," in D. E. Bell, R. L. Keeney, and H. Raiffa (eds.), *Conflicting Objectives in Decisions* (John Wiley & Sons, New York, 1977), pp. 298–332.
49. M. W. Merkhofer and R. L. Keeney, "A Multiattribute Utility Analysis of Alternative Sites for the Disposal of Nuclear Waste," *Risk Anal.* **7**(2), 173–194 (1997).
50. Atomic Energy Commission (AEC), *Theoretical Possibilities and Consequences of Major Accidents in Large Nuclear Power Plants: A Study of Possible Consequences if Certain Assumed Accidents, Theoretically Possible But Highly Improbable, Were to Occur in Large Nuclear Power Plants,* WASH-740 (AEC, Washington, D.C., 1957).
51. G. E. Apostolakis, *Mathematical Methods of Probabilistic Safety Analysis,* UCLA-ENG-7464 (University of California

at Los Angeles, School of Engineering and Applied Science, Los Angeles, 1974).

52. C. Starr, "Social Benefit Versus Technological Risk: What Is Our Society Willing to Pay for Safety?" *Science* **165,** 1232–1238 (1969).
53. J. G. Arbuckle, M. E. Bosco, D. R. Case, E. P. Laws, J. C. Martin, M. L. Miller, R. D. Moran, R. V. Randle, D. M. Steinway, R. G. Stoll, T. F. P. Sullivan, T. A. Vanderver, Jr., and P. A. J. Wilson, *Environmental Law Handbook,* 11th Ed. (Government Institutes, Rockville, MD, 1991), pp. 328–369, 406–442, 471–628.
54. H. W. Lewis, R. J. Budnitz, H. J. C. Kouts, W. B. Lowenstein, W. D. Rowe, F. von Hippel, and F. Zachariasen, *Risk Assessment Review Group Report to the U.S. Nuclear Regulatory Commission,* NUREG/CR-0400 (U.S. Nuclear Regulatory Commission, Washington, D.C., 1978).
55. American Physical Society(APS), "Report to the American Physical Society by the Study Group on Light-Water Reactor Safety," *Rev. Mod. Phys.* **47,** Suppl. 1, S1–S124 (1975).
56. H. W. Lewis, "The Safety of Fission Reactors," *Sci. Am.* **242**(3), 53–65 (1980).
57. M. D. McKay, R. J. Beckman, and W. J. Conover, "A Comparison of Three Methods for Selecting Values of Input Variables in the Analysis of Output from a Computer Code," *Technometrics* **21**(2), 239–245 (1979).
58. J. F. Mason, "The Technical Blow-by-Blow. Details of the Three Mile Island Accident as Excerpted and Edited from Interviews with Nuclear Regulatory Commission Investigators," *IEEE Spectrum* **16**(11), 33–42 (1979).
59. B. Fischhoff, P. Slovic, and S. Lichtenstein, "Weighing the Risks: Which Risks Are Acceptable?" *Environment* **21**(4), 17–20, 32–38 (1979).
60. H. C. Jenkins-Smith and G. W. Bassett, Jr., "Perceived Risk and Uncertainty of Nuclear Waste: Differences Among Science, Business, and Environmental Group Members," *Risk Anal.* **14**(5), 851–856 (1994).
61. B. J. Garrick, "Lessons Learned from 21 Nuclear Plant PRAs," *International Topical Conference on Probabilistic Safety Assessment and Risk Management, Zurich, Switzerland, August 30–-September 4, 1987,* CONF-870820 (Pickard, Lowe and Garrick, Newport Beach, CA, 1987.
62. R. J. Breeding, J. C. Helton, E. D. Gorham, and F. T. Harper, "Summary Description of the Methods Used in the Probabilistic Risk Assessments for NUREG-1150," *Nucl. Eng. Des.* **135**(1), 1–27 (1992).
63. U.S. Nuclear Regulatory Commission (NRC), *Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants. Final Summary Report,* NUREG-1150 (NRC, Washington, D.C., 1990–1991), pp 1–3.
64. C. Perrow, *Normal Accidents: Living with High-Risk Technologies* (Basic Books, New York, 1984), pp. 108–112.
65. F. M. Bordewich, "The Lessons of Bhopal," *The Atlantic* **259**(3), 30–33 (1987).
66. B. J. Garrick, "The Approach to Risk Analysis in Three Industries: Nuclear Power, Space Systems and Chemical Process," in R. A. Knief (ed.), *Risk Management: Expanding Horizons in Nuclear Power and Other Industries* (Hemisphere, New York, 1991), pp. 173–181.
67. E. Marshall, "Feynman Issues His Own Shuttle Report, Attacking NASA Risk Estimates," *Science* **232**(4758), 1596 (1986).
68. U.S. Congress, *Investigation of the Challenger Accident,* Report of the Committee on Science and Technology, House of Representatives, Ninety-Ninth Congress, Second Session, House Report 99-1016 (U.S. Government Printing Office, Washington, D.C.,1986).
69. R. P. Rechard, *Milestones for Disposal of Radioactive Waste at the Waste Isolation Pilot Plant (WIPP) in the United States,* SAND98-0072 (Sandia National Laboratories, Albuquerque, NM, 1998).
70. R. P. Rechard, *Historical Background on Assessing the Performance of the Waste Isolation Pilot Plant,* SAND98-2708 (Sandia National Laboratories, Albuquerque, NM, 1999).
71. National Academy of Sciences/National Research Council (NAS/NRC), *The Disposal of Radioactive Waste on Land: Report of the Committee on Waste Disposal of the Division of Earth Sciences,* Publication 519 (NAS/NRC, Washington, D.C., 1957).
72. H. C. Claiborne and F. Gera, *Potential Containment Failure Mechanisms and Their Consequences at a Radioactive Waste Repository in Bedded Salt in New Mexico,* ORNL-TM-4639 (Oak Ridge National Laboratory, Oak Ridge, TN, 1974).
73. W. C. McClain and R. L. Bradshaw, "Status of Investigations of Salt Formations for Disposal of Highly Radioactive Power-Reactor Wastes," *Nucl. Saf.* **11**(2), 130–141 (1970).
74. M. E. Paté-Cornell, "Uncertainties in Risk Analysis: Six Levels of Treatment," *Reliab. Eng. Syst. Saf.* **54**(2/3), 95–111 (1996).
75. R. M. Cranwell, J. E. Campbell, J. C. Helton, R. L. Iman, D. E. Longsine, N. R. Ortiz, G. E. Runkle, and M. J. Shortencarier, *Risk Methodology for Geological Disposal of Radioactive Waste: Final Report,* SAND81-2573, NUREG/CR-2452 (Sandia National Laboratories, Albuquerque, NM, 1987).
76. J. E. Campbell and R. M. Cranwell, "Performance Assessment of Radioactive Waste Repositories," Science 239(4846), 1389–1392 (1988).
77. J. W. Bartlett, H. C. Burkholder, and W. K. Winegardner, "Safety Assessment of Geologic Repositories for Nuclear Waste," in J. B. Fussell and G. R. Burdick (eds.), *Nuclear Systems Reliability Engineering and Risk Assessment* (Society for Industrial and Applied Mathematics, Philadelphia, 1977), pp. 636–660.
78. S. E. Logan, *Workshop on Geologic Data Requirements for Radioactive Waste Management Assessment Models,* Santa Fe, NM, June 28–July 1, 1976, Y/OW1/SUB-76/81726 (University of New Mexico, College of Engineering, Albuquerque, 1976).
79. International Atomic Energy Agency (IAEA), *Site Selection Factors for Repositories of Solid High-Level and Alpha-Bearing Wastes in Geological Formations,* Technical Report Series No. 177 (International Atomic Energy Agency, Vienna, 1977).
80. R. C. Ewing, M. S. Tierney, L. F. Konikow, and R. P. Rechard, "Performance Assessments of Nuclear Waste Repositories: A Dialogue on Their Value and Limitations," *Risk Anal.* **19**(5), 933–958 (1999).
81. W. D. Rowe, *An Anatomy of Risk* (John Wiley & Sons, New York, 1977), pp. 11–27.
82. R. M. Cranwell, R. V. Guzowski, J. E. Campbell, and N. R. Ortiz, *Risk Methodology for Geologic Disposal of Radioactive Waste: Scenario Selection Procedure,* SAND80-1429, NUREG/CR-1667 (Sandia National Laboratories, Albuquerque, NM, 1990).
83. International Atomic Energy Agency (IAEA), *Safety Assessment for the Underground Disposal of Radioactive Wastes,* Safety Series No. 56 (International Atomic Energy Agency, Vienna, 1981).
84. R. L. Hunter, *Preliminary Scenarios for the Release of Radioactive Waste from a Hypothetical Repository in Basalt of the Columbia Plateau,* SAND83-1342, NUREG/CR-3353 (Sandia National Laboratories, Albuquerque, NM, 1983).
85. J. C. Helton, "Uncertainty and Sensitivity Analysis in the Presence of Stochastic and Subjective Uncertainty," *J. Stat. Comput. Simul.* **57**(1/4), 3–76 (1997).
86. R. L. Iman, J. C. Helton, and J. E. Campbell, *Risk Methodology for Geologic Disposal of Radioactive Waste: Sensitivity*

*Analysis Techniques,* SAND78-0912, NUREG/CR-0390 (Sandia National Laboratories, Albuquerque, NM, 1978).
87. R. L. Iman and W. J. Conover, "Small Sample Sensitivity Analysis Techniques for Computer Models, with an Application to Risk Assessment," *Commun. Stat.* **A9**(17), 1749–1842 (1980).
88. F. W. Bingham and G. E. Barr, "Development of Scenarios for the Long-Term Release of Radionuclides from the Proposed Waste Isolation Pilot Plant in Southeastern New Mexico," in C. J. M. Northrup, Jr. (ed.), *Scientific Basis for Nuclear Waste Management, Proceedings of the International Symposium, Boston, MA, November 27–30, 1979,* SAND79-0955C (Plenum Press, New York, 1980), Vol. **2**, pp. 771–778.
89. J. E. Campbell, R. T. Dillon, M. S. Tierney, H. T. Davis, P. E. McGrath, F. J. Pearson, Jr., H. R. Shaw, J. C. Helton, and F. A. Donath, *Risk Methodology for Geologic Disposal of Radioactive Waste: Interim Report,* SAND78-0029, NUREG/CR-0458 (Sandia National Laboratories, Albuquerque, NM, 1978).
90. E. J. Bonano, P. A. Davis, L. R. Shipers, K. F. Brinster, W. E. Beyeler, C. D. Updegraff, E. R. Shepherd, L. M. Tilton, and K. K. Wahi, *Demonstration of a Performance Assessment Methodology for High-Level Radioactive Waste Disposal in Basalt Formations,* SAND86-2325, NUREG/CR-4759 (Sandia National Laboratories, Albuquerque, NM, 1989).
91. Science Advisory Board(SAB), *Report on the Review of Proposed Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes (40 CFR 191),* (High-Level Radioactive Waste Disposal Subcommittee, Science Advisory Board, U.S. Environmental Protection Agency, Washington, D.C., 1984).
92. D. Okrent, "On the Intergenerational Equity and Its Clash with Intragenerational Equity and On the Need for Policies to Guide the Regulation of Disposal of Wastes and Other Activities Posing Very Long Term Risks," *Risk Anal.* **19**(5), 877–901 (1999).
93. National Academy of Public Administration NAPA), *Setting Priorities, Getting Results: A New Direction for the Environmental Protection Agency,* Report to Congress, 1st ed. (Washington, D.C., 1995).
94. H. J. Otway, "Risk Estimation and Evaluation," in *Proceedings of IIASA Planning Conference on Energy Systems, IIASA-PC-3, Baden, July 17–20, 1973,* CP-73-03 (International Institute for Applied Systems Analysis, Laxenburg, Austria, 1973), pp. 354–379.
95. N. Mantel and W. R. Bryan, " 'Safety' Testing of Carcinogenic Agents," *J. Nat. Cancer Inst.* **27**(2), 455–470 (1961).
96. J. Q. Wilson, *Bureaucracy: What Government Agencies Do and Why They Do It* (Basic Books, New York, 1989).
97. R. Carson, *Silent Spring,* 25th Anniversary Ed. (Houghton Mifflin; Boston, 1987).
98. E. L. Anderson and the Carcinogen Assessment Group of the U.S. Environmental Protection Agency, "Quantitative Approaches in Use to Assess Cancer Risk," *Risk Anal.* **3**(4), 277–295 (1983).
99. A. Wildavsky, *But Is It True? A Citizen's Guide to Environmental Health and Safety Issues* (Harvard University Press, Cambridge, MA, 1995).
100. U.S. Environmental Protection Agency (EPA), Respondents motion to determine whether or not the registration of mirex should be cancelled or amended, Attachment A (September 9, 1975).
101. W. D. Ruckelshaus, "Risk, Science, and Democracy," *Iss. Sci. Technol.* **1**(3), 19–38 (1985).
102. K. S. Crump, "An Improved Procedure for Low-Dose Carcinogenic Risk Assessment from Animal Data," *J. Environ. Pathol. Toxicol. Oncol.* **5**(4/5), 339–348 (1984).
103. National Academy of Sciences/National Research Council (NAS/NRC), *Science and Judgment in Risk Assessment,* Committee on Risk Assessment of Hazardous Air Pollutants, Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Research Council (National Academy Press, Washington, D.C., 1994).
103a. U.S. Environmental Protection Agency (EPA), *Policy for Use of Probabilistic Analysis in Risk Assessment at the U.S. Environmental Protection Agency,* EPA/630/R-97/001. EPA, Washington, DC, 1997)
104. J. V. Rodricks, "Risk Assessment at Hazardous Waste Disposal Sites," *Hazard. Waste* **1**(3), 333–362 (1984).
105. R. P. Rechard and M. S. Y. Chu, "Use of Risk to Resolve Conflicts in Assessing Hazards at Mixed-Waste Sites," in A. A. Moghissi and G. A. Benda (eds.), *Mixed Waste, Proceedings at the First International Symposium, Baltimore, MD, August 26–29, 1991,* SAND91-0587C (University of Maryland, Baltimore, 1991), pp. 12.4.1–12.4.15.
106. R. Wilson, "Introduction," in R. Wilson and J. D. Spengler (eds.), *Particles in Our Air: Concentrations and Health Effects* (Harvard University Press, Cambridge, MA, 1996), pp. 1–14.
107. R. A. Merrill, "Legal Impediments to the Use of Risk Assessment by Regulatory Agencies," in D. G. Hoel, R. A. Merrill, and F. P. Perera (eds.), *Risk Quantitation and Regulatory Policy, Proceedings of the Banbury Center Conference, Lloyd Harbor, NY, May 13, 1994,* CONF-8405356, Banbury Report 19 (Cold Spring Harbor Laboratory, Cold Spring Harbor, 1985), pp. 41–52.
108. National Academy of Sciences/National Research Council (NAS/NRC), *Regulating Pesticides in Food: The Delaney Paradox,* Committee on Scientific and Regulatory Issues Underlying Pesticide Use Patterns and Agricultural Innovation, Board on Agriculture, National Research Council (National Academy Press, Washington, D.C., 1987).
109. R. P. Rechard, *Review and Discussion of Code Linkage and Data Flow in Nuclear Waste Compliance Assessments,* SAND87-2833 (Sandia National Laboratories, Albuquerque, NM, 1989).
110. M. G. Marietta, S. G. Bertram-Howery, D. R. Anderson, K. F. Brinster, R. V. Guzowski, H. Iuzzolino, and R. P. Rechard, *Performance Assessment Methodology Demonstration: Methodology Development for Evaluating Compliance with EPA 40 CFR 191, Subpart B, for the Waste Isolation Pilot Plant,* SAND89-2027 (Sandia National Laboratories, Albuquerque, NM, 1989).
111. R. P. Rechard, W. Beyeler, R. D. McCurley, D. K. Rudeen, J. E. Bean, and J. D. Schreiber, *Parameter Sensitivity Studies of Selected Components of the Waste Isolation Pilot Plant Repository/Shaft System,* SAND89-2030 (Sandia National Laboratories, Albuquerque, NM, 1990).
112. S. G. Bertram-Howery, M. G. Marietta, R. P. Rechard, P. N. Swift, D. R. Anderson, B. L. Baker, J. E. Bean, Jr., W. Beyeler, K. F. Brinster, R. V. Guzowski, J. C. Helton, R. D. McCurley, D. K. Rudeen, J. D. Schreiber, and P. Vaughn, *Preliminary Comparison with 40 CFR Part 191, Subpart B for the Waste Isolation Pilot Plant, December 1990,* SAND90-2347 (Sandia National Laboratories, Albuquerque, NM, 1990).
113. WIPP PA (Performance Assessment) Division, *Preliminary Comparison with 40 CFR Part 191, Subpart B for the Waste Isolation Pilot Plant, December 1991,* SAND91-0893/1/2/3/4 (Sandia National Laboratories, Albuquerque, NM, 1991/1992), pp. 1–4.
114. WIPP PA (Performance Assessment) Department, *Preliminary Performance Assessment for the Waste Isolation Pilot Plant, December 1992,* SAND92-0700/1/2/3/4/5 (Sandia National Laboratories, Albuquerque, NM, 1992/1993), pp. 1–5.
115. J. C. Helton, "Treatment of Uncertainty in Performance Assessments for Complex Systems," *Risk Anal.* **14**(4), 483–511 (1994).
116. J. C. Helton, M. G. Marietta, and R. P. Rechard, "Conceptual

Structure of Performance Assessments Conducted for the Waste Isolation Pilot Plant," in C. G. Interrante and R. T. Pabalan (eds.), *Scientific Basis for Nuclear Waste Management XVI, Materials Research Society Symposium Proceedings, Boston, MA, November 30–December 4, 1992,* SAND92-2285C (Materials Research Society, Pittsburgh, 1993), Vol. 294, 885–898.
117. U.S. Department of Energy(DOE), *Final Environmental Impact Statement, Waste Isolation Pilot Plant,* DOE/EIS-0026 (DOE, Washington, D.C., 1980), pp. 1–2.
118. Sandia [National] Laboratories, *Waste Isolation Pilot Plant (WIPP) Conceptual Design Report,* SAND77-0274 (Sandia [National] Laboratories, Albuquerque, NM, 1977).
119. R. L. Hunter, *Events and Processes for Constructing Scenarios for the Release of Transuranic Waste from the Waste Isolation Pilot Plant, Southeastern New Mexico,* SAND89-2546 (Sandia National Laboratories, Albuquerque, NM, 1989).
120. R. P. Rechard, "CAMCON: Computer System for Assessing Regulatory Compliance of the Waste Isolation Pilot Plant," in G. Apostolakis (ed.), *Probabilistic Safety Assessment and Management, Proceedings of the International Conference (PSAM), Beverly Hills, CA, February 4–7, 1991,* SAND90-2094C (Elsevier, New York, 1991), Vol. 2, pp. 899–904.
121. J. C. Helton, D. R. Anderson, H.-N. Jow, M. Marietta, and M. G. Basabilvazo, "Performance Assessment in Support of the 1996 Compliance Certification Application for the Waste Isolation Pilot Plant," *Risk Anal.* **19**(5), 959–986 (1999).
122. D. A. Galson and P. N. Swift, "Recent Progress in Scenario Development for the WIPP," *High Level Radioactive Waste Management 1995, Proceedings of the Sixth Annual International Conference, Las Vegas, NV, April 30–May 5, 1995,* SAND95-0117C (American Nuclear Society, La Grange Park, IL, 1995), pp. 391–396.
123. R. P. Rechard, *An Introduction to the Mechanics of Performance Assessment Using Examples of Calculations Done for the Waste Isolation Pilot Plant Between 1990 and 1992,* SAND93-1378 (Sandia National Laboratories, Albuquerque, NM, 1995).
124. B. G. J. Thompson and B. Sagar, "The Development and Application of Integrated Procedures for Post-Closure Assessment, Based Upon Monte Carlo Simulation: The Probabilistic Systems Assessment (PSA) Approach," *Reliab. Eng. Syst. Saf.* **42**(2/3), 125–160 (1993).
125. U.S. Department of Energy (DOE), *Draft Environmental Impact Statement: Waste Isolation Pilot Plant,* DOE/EIS-0026-D (DOE, Washington, D.C., 1979), pp. 1–2.
126. J. C. Helton, J. W. Garner, M. G. Marietta, R. P. Rechard, D. K. Rudeen, and P. N. Swift, "Uncertainty and Sensitivity Analysis Results Obtained in a Preliminary Performance Assessment for the Waste Isolation Pilot Plant," *Nucl. Sci. Eng.* **114**(4), 286–331 (1993).
127. J. C. Helton, D. R. Anderson, B. L. Baker, J. E. Bean, J. W. Berglund, W. Beyeler, J. W. Garner, H. J. Iuzzolino, M. G. Marietta, R. P. Rechard, P. J. Roache, D. K. Rudeen, J. D. Schreiber, P. N. Swift, M. S. Tierney, and P. Vaughn, "Effect of Alternative Conceptual Models in a Preliminary Performance Assessment for the Waste Isolation Pilot Plant," *Nucl. Eng. Des.* **154**(3), 251–344 (1995).
128. J. C. Helton, D. R. Anderson, B. L. Baker, J. E. Bean, J. W. Berglund, W. Beyeler, K. Economy, J. W. Garner, S. C. Hora, H. J. Iuzzolino, P. Knupp, M. G. Marietta, J. Rath, R. P. Rechard, P. J. Roache, D. K. Rudeen, K. Salari, J. D. Schreiber, P. N. Swift, M. S. Tierney, and P. Vaughn, "Uncertainty and Sensitivity Analysis Results Obtained in the 1992 Performance Assessment for the Waste Isolation Pilot Plant," *Reliab. Eng. Syst. Saf.* **51**(1), 53–100 (1996).
129. J. C. Helton, "Uncertainty and Sensitivity Analysis Techniques for Use in Performance Assessment for Radioactive Waste Disposal," *Reliab. Eng. Syst. Saf.* **42**(2/3), 327–367 (1993).
130. B. J. Garrick and S. Kaplan, "A Decision Theory Perspective on the Disposal of High Level Radioactive Waste," *Risk Anal.* **19**(5), 903–913 (1999).
131. National Academy of Sciences/National Research Council (NAS/NRC), *Technical Bases for Yucca Mountain Standards,* Committee on Technical Bases for Yucca Mountain Standards, Board on Radioactive Waste Management, Commission on Geosciences, Environment, and Resources, National Research Council (National Academy Press, Washington, D.C., 1995), p. 2.
132. R. W. Lynch, R. L. Hunter, D. R. Anderson, F. W. Bingham, J. M. Covan, G. F. Hohnstrieter, T. O. Hunter, R. D. Klett, E. E. Ryder, T. L. Sanders, and W. D. Weart, *Deep Geologic Disposal in the United States: The Waste Isolation Pilot Plant and Yucca Mountain Projects,* SAND90-1656 (Sandia National Laboratories, Albuquerque, NM, 1991).
133. U.S. Department of Energy (DOE), "Chapter 8, Section 8.3.5.13, Total System Performance," *Site Characterization Plan, Yucca Mountain Site, Nevada Research and Development Area, Nevada,* DOE/RW-0199 (DOE, Washington, D.C., 1988), pp. 8.3.5.13-1 – 8.3.5.13-148.
134. I. J. Winograd, "Radioactive Waste Disposal in Thick Unsaturated Zones," *Science* **212**(4502), 1457–1464 (1981).
135. Civilian Radioactive Waste Management System, Management and Operating Contractor (M&O), *Total System Performance Assessment—1995: An Evaluation of the Potential Yucca Mountain Repository,* Document No. B00000000-01717-2200-00136, Rev. 01 (M&O, Las Vegas, 1995).
136. G. E. Barr, R. L. Hunter, E. Dunn, and A. Flint, *Scenarios Constructed for Nominal Flow in the Presence of a Repository at Yucca Mountain and Vicinity,* SAND92-2186 (Sandia National Laboratories, Albuquerque, NM, 1995).
137. J. H. Kessler and R. K. McGuire, "Total System Performance Assessment for Waste Disposal Using a Logic Tree Approach," *Risk Anal.* **19**(5), 915–931 (1999).
138. P. Swift, G. Barr, R. Barnard, R. Rechard, A. Schenker, G. Freeze, and P. Burck, "Feature, Event, and Process Screening and Scenario Development for the Yucca Mountain Total System Performance Assessment," in *Proceedings of the NEA Workshop on Scenario Development, Madrid, Spain, May 10–12, 1999,* SAND98-2831C (Nuclear Energy Agency of the Organisation for Economic Co-Operation and Development, Paris, 1999).
139. S. Sinnock, Y. T. Lin, and J. P. Brannen, *Preliminary Bounds on the Expected Postclosure Performance of the Yucca Mountain Repository Site, Southern Nevada,* SAND84-1492 (Sandia National Laboratories, Albuquerque, NM, 1984).
140. R. W. Prindle and P. L. Hopkins, *On Conditions and Parameters Important to Model Sensitivity for Unsaturated Flow Through Layered, Fractured Tuff: Results of Analyses for HYDROCOIN Level 3 Case 2,* SAND89-0652 (Sandia National Laboratories, Albuquerque, NM, 1990).
141. R. W. Barnard and H. A. Dockery (eds.), *Technical Summary of the Performance Assessment Calculational Exercises for 1990 (PACE-90), Volume 1: "Nominal Configuration" Hydrogeologic Parameters and Calculational Results,* SAND90-2726 (Sandia National Laboratories, Albuquerque, NM, 1991).
142. R. W. Barnard, M. L. Wilson, H. A. Dockery, J. H. Gauthier, P. G. Kaplan, R. R. Eaton, F. W. Bingham, and T. H. Robey, *TSPA 1991: An Initial Total-System Performance Assessment for Yucca Mountain,* SAND91-2795 (Sandia National Laboratories, Albuquerque, NM, 1992).
143. M. L. Wilson, J. H. Gauthier, R. W. Barnard, G. E. Barr, H. A. Dockery, E. Dunn, R. R. Eaton, D. C. Guerin, N. Lu, M. J. Martinez, R. Nilson, C. A. Rautman, T. H. Robey, B. Ross, E. E. Ryder, A. R. Schenker, S. A. Shannon, L. H.

Skinner, W. G. Halsey, J. D. Gansemer, L. C. Lewis, A. D. Lamont, I. R. Triay, A. Meijer, and D. E. Morris, *Total-System Performance Assessment for Yucca Mountain—SNL Second Iteration (TSPA-1993),* SAND93-2675 (Sandia National Laboratories, Albuquerque, NM, 1994).
144. Electric Power Research Institute (EPRI), *Demonstration of a Risk-Based Approach to High-Level Waste Repository Evaluation,* EPRI NP-7057 (EPRI, Palo Alto, CA, 1990).
145. Electric Power Research Institute (EPRI), *Demonstration of a Risk-Based Approach to High-Level Waste Repository Evaluation: Phase 2,* EPRI TR-100384 (EPRI, Palo Alto, CA, 1992).
146. Electric Power Research Institute (EPRI), *Yucca Mountain Total System Performance Assessment, Phase 3,* EPRI TR-107191 (EPRI, Palo Alto, CA, 1996).
147. B. G. J. Thompson, "The Role of Performance Assessment in the Regulation of Underground Disposal of Radioactive Wastes: An International Perspective," *Risk Anal.* **19**(5), 809–846 (1999).
148. N. A. Eisenberg, M. P. Lee, T. J. McCartin, K. I. McConnell, M. Thaggard, and A. C. Campbell, "Development of a Performance Assessment Capability in the Waste Management Programs of the U.S. Nuclear Regulatory Commission," *Risk Anal.* **19**(5), 847–876 (1999).
149. R. Codell, N. Eisenberg, D. Fehringer, W. Ford, T. Margulies, T. McCartin, J. Park, and J. Randall, *Initial Demonstration of the NRC's Capability to Conduct a Performance Assessment for a High-Level Waste Repository,* NUREG-1327 (U.S. Nuclear Regulatory Commission, Washington, D.C., 1992).
150. R. G. Wescott, M. P. Lee, N. A. Eisenberg, T. J. McCartin, and R. B. Baca (eds.), *NRC Iterative Performance Assessment Phase 2. Development of Capabilities for Review of a Performance Assessment for a High-Level Waste Repository,* NUREG-1464 (Nuclear Regulatory Commission, Washington, D.C., 1995).
151. Golder Associates, *RIP Integrated Probabilistic Simulator for Environmental Systems: Theory Manual and User's Guide* (Golder Associates, Redmond, WA, November 1998).
152. R. W. Andrews, T. F. Dale, and J.A. McNeish, *Total System Performance Assessment—1993: An Evaluation of the Potential Yucca Mountain Repository,* Document No. B00000000-01717-2200-00099-01 (INTERA, Las Vegas, 1994).
153. Civilian Radioactive Waste Management System, Management and Operating Contractor (M&O), *Description of Performance Allocation Report,* Document No. B00000000-01717-2200-00177-00 (M&O, Las Vegas, 1996).
154. Civilian Radioactive Waste Management System, Management and Operating Contractor (M&O), *Total System Performance Assessment Sensitivity Studies of U.S. Department of Energy Spent Nuclear Fuel,* Document No. A00000000-01717-5705-00017-00 (M&O, Las Vegas, 1997).
155. Civilian Radioactive Waste Management System, Management and Operating Contractor (M&O), *Total System Performance Assessment-Viability Assessment (TSPA-VA) Analyses Technical Basis Document,* Document No. B00000000-01717-4301-00001, Rev. 01 (M&O, Las Vegas, 1998).
156. Electric Power Research Institute (EPRI), *Alternative Approaches to Assessing the Performance and Suitability of Yucca Mountain for Spent Fuel Disposal,* EPRI TR-108732 (EPRI, Palo Alto, CA, 1998).
157. M. G. Marietta and W. F. Simmons, *Feasibility of Disposal of High-Level Radioactive Waste into the Seabed, Volume 5—Dispersal of Radionuclides in the Oceans: Models, Data Sets, and Regional Descriptions,* SAND87-0753, INIS-XN-177 (Sandia National Laboratories, Albuquerque, NM, 1988).
158. L. L. Price, S. H. Conrad, D. A. Zimmerman, N. E. Olague, K. C. Gaither, W. B. Cox, J. T. McCord, and C. P. Harlan, *Preliminary Performance Assessment of the Greater Confinement Disposal Facility at the Nevada Test Site,* SAND91-0047 (Sandia National Laboratories, Albuquerque, NM, 1993), pp. 1–3.
159. T. A. Baer, L. L. Price, J. N. Emery, and N. E. Olague, *Second Performance Assessment Iteration of the Greater Confinement Disposal Facility at the Nevada Test Site,* SAND93-0089 (Sandia National Laboratories, Albuquerque, NM, 1994).
160. R. P. Rechard (ed.), *Initial Performance Assessment of the Disposal of Spent Nuclear Fuel and High-Level Waste Stored at Idaho National Engineering Laboratory,* SAND93-2330/1/2 (Sandia National Laboratories, Albuquerque, NM, 1993), 1–2.
161. General Accounting Office (GAO), *Nuclear Waste, Foreign Countries' Approaches to High-Level Waste Storage and Disposal,* United States General Accounting Office Report to the Honorable Richard H. Bryan, U.S. Senate, GAO-RCED-94-172 (GAO, Resources, Community, and Economic Development Division, Washington, D.C., 1994).
162. P. C. Fishburn, "Foundations of Risk Measurement. I. Risk as Probable Loss," *Manage. Sci.* **30**(4), 396–406 (1984).
163. University of New Mexico (UNM)), "Focus 1: WIPP," *Public Opinion Profile of New Mexico Citizens* (UNM, Institute for Public Policy Survey Research Center, Albuquerque, 1998), **10**(2), 1–6.
164. H. C. Jenkins-Smith and S. Cullipher, *Public Views of the WIPP Policy Debate in Bernalillo and Santa Fe Counties: December 1997–January* 1998 (University of New Mexico, Institute for Public Policy, Albuquerque, NM, 1998).
165. B. T. Mossman, J. Bignon, M. Corn, A. Seaton, and J. B. L. Gee, "Asbestos: Scientific Developments and Implications for Public Policy," *Science* **247**(4940), 294–301 (1990).
166. E. Marshall, "A is for Apple, Alar, and . . . Alarmist?" *Science* **254**(5028), 20–22 (1991).