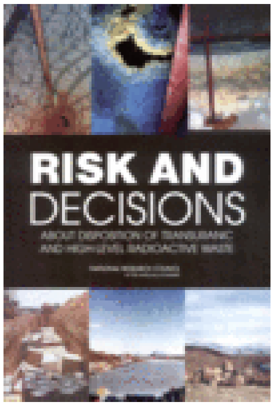

Risk and Decisions About Disposition of Transuranic and High-Level Radioactive Waste

National Research Council

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RISK AND DECISIONS

ABOUT DISPOSITION OF TRANSURANIC AND HIGH-LEVEL RADIOACTIVE WASTE

Committee on Risk-Based Approaches for Disposition of Transuranic and High-Level Radioactive Waste

Board on Radioactive Waste Management

Division on Earth and Life Studies

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making the published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The content of the review comments and draft manuscript remains confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their participation in the review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by Louis Lanzerotti, Bell Laboratories, Lucent Technologies, and New Jersey Institute of Technology, Murray Hill and George Hornberger, University of Virginia, Charlottesville. Appointed by the National Research Council, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the National Research Council.

Preface

Risk has become a pervasive concept in modern society. The public confronts it in almost every aspect of life, from recreational sports to investments to surgical procedures, and people are urged to consider risks described in qualitative or quantitative terms. In our society we are not satisfied to wait in ignorance to see how a future event comes out. In financial decisions, potential shareholders must be fully informed of the risks before investing; in medicine, patients must be informed of the health risks of a drug or medical procedure; and in protecting the environment and human health, regulators do not wait for actual harm to occur before taking protective action. In some places, owners of buildings that may be vulnerable to earthquakes must post notices of that risk at their entrances. And for thirty years, the federal government has had a requirement that the risks associated with major federal actions be assessed as part of the decision-making process. This committee's study is about the role of risk and risk assessment in decisions about federal actions that will cost tens of billions of dollars, require decades of work by possibly thousands of workers, and affect the environment for millennia.

Much work precedes this committee's efforts on the role of risk in decision making and on the disposition of long-lived radioactive waste. The committee has not, therefore, tried to reinvent what has been done so ably by its predecessors. Instead, the committee has endeavored to apply insights from prior studies to the specific situation of disposition of relatively low hazard high-level radioactive waste and transuranic waste. Readers should note that the study does not cover spent nuclear fuel, commercial high-level radioactive waste, or DOE wastes with undetermined waste classification or disposition path ("orphaned wastes").

Experts appointed by the National Research Council to review this report asked several interesting questions that were beyond what the committee could examine in the current report. We share these here in hopes that the ideas will not be lost. Questions were asked about the nature, time requirements and expenses associated with the RCRA delisting process. Questions were also raised about adhering to the exemption process schedule. It may be useful to explore the effects of protracted scheduling delays on cost and human health risk as a potential drawback to seeking exemptions.

The statement of task states that the study "will examine the application of risk-based approaches to selected DOE waste streams to assess their practical usefulness." In the report, the committee examines three waste types and endorses a risk-informed approach for addressing their disposition. The committee, however, specifically declines to make a recommendation concerning the disposition of these wastes. The risk-informed approach requires a formal, well-defined, participatory process for evaluating risks and other impacts; it would be inconsistent to recommend such a process and in the same report purport to conduct a useful risk analysis for disposition of the waste streams without following the approach. For the same reasons, the committee does not dictate how different factors should be balanced or valued.

An important component of the study was a survey of prior studies. The literature on environmental health risks and decisions is vast and summarizing all of the previous reports would have been too large a task resulting in a too-large report. The summaries in Appendix A therefore cover only the points directly relevant to disposition of transuranic and high-level radioactive waste and the summaries in Appendix B address only studies directed at helping DOE incorporate risk into its environmental management program.

There have been several political and legal developments during the course of this study. The states of Washington and Oregon and the Confederated Tribes of the Umatilla Indian Reservation and the Confederated Tribes and Bands of the Yakama Nation all filed notices of intent to sue DOE over natural resource damages at the Hanford Site. The State of Washington overwhelmingly passed a ballot initiative requiring that no additional wastes could be added to the Hanford site until waste that is already on-site has been cleaned up and stored, treated, or disposed of in compliance with all state and federal environmental laws. The committee did not examine natural resource trusteeships or natural resource damage assessments, and the report does not address the Washington ballot initiative. As the committee's report was about to enter peer review, the U.S. House of Representatives and the U.S. Senate agreed on legislation that could change the legal context for high-level waste significantly, at least in South Carolina and Idaho. President Bush signed the act into law on October 28, 2004. In a further twist, the U.S. Court of Appeals for the Ninth Circuit reversed a lower court decision on provisions of DOE's Order 435.1 that allow for DOE to manage some waste in its HLW tanks as transuranic or low-level waste. The report now presents a few of the details of these developments, but does not explore all of the issues that led to differing opinions on the issues by the different states and courts because they are not essential to the committee's message. It is not yet clear how either of these actions will affect plans and waste disposition, but they do not change the approach recommended by the committee. Indeed, if anything, they lay the stage for DOE to use the approach recommended here to develop its plans for disposition of TRU and HLW. If DOE is able to implement this approach in a collaborative manner with the stakeholders, American Indian nations, states, and federal regulators then the nation may avoid further litigation and legislation on these issues.

The committee held public meetings in Washington, D.C., Idaho Falls, Idaho, Augusta, Georgia, and Richland, Washington. We recognize that a great deal of effort went into making these meetings possible and supporting the committee's requests for information. The committee thanks the many people at DOE headquarters and the field offices, site specialists (lab scientists and contractors), U.S. EPA headquarters and regional representatives, U.S. NRC personnel, state regulators, representatives of American Indian tribal nations, local governments, public-interest groups, and interested citizens for the time and effort they put into our study. Many of these people are listed in Appendix C as presenters at the committee's meetings. We specifically note support provided by Keith Lockie, Bill Pearson, and Mary Goldie, who served as the points of contact at INEEL, SRS, and Hanford, respectively, and coordinated excellent tours and meetings. Finally, the committee thanks the staff of the Board on Radioactive Waste Management, Micah Lowenthal, Darla Thompson, Angela Taylor, Toni Greenleaf, Marili Ulloa, and Kevin Crowley, for their assistance to the committee in completing the study.

David Daniel, *Chair*
John Applegate, *Vice Chair*
Committee on Risk-Based
Approaches for Disposition
of Transuranic and High-
Level Radioactive Waste

Contents

Executive Summary

The U.S. Department of Energy's (DOE's) Office of Environmental Management asked the National Academies to recommend how DOE might implement risk-based approaches for disposition of transuranic (TRU) and high-level radioactive waste (HLW). This entails recommending technically sound approaches for using risk assessment in selecting disposition paths, including alternatives to deep geologic disposal, for TRU and HLW. DOE asked that the study explicitly address the following:

- key elements of a risk-based approach;
- criteria for risk assessment;
- potential alternatives to geologic disposal for disposition of low-hazard waste;
- compatibility with current regulatory regimes;
- knowledge and technology gaps for implementation; and
- broader implications, if any, for disposition of other DOE wastes.

Finally, the committee was asked to examine the application of recommended approaches to some DOE waste streams to assess the practical usefulness of these approaches.

In fulfilling its charge, the committee had to consider first whether a risk-based approach is appropriate and desirable in disposing of TRU and HLW. The nation has a system for classification of radioactive waste and existing or proposed disposition options for each waste class, although there are unique wastes within some waste classes that do not yet have a disposition option. Cleanup and waste disposal programs across the country remain controversial and involve substantial uncertainty, and the DOE program is no exception—with additional complications related to the unique HLW and TRU wastes for which the path forward is unclear. The critical questions for these wastes are the following:

1. Should the nation consider pursuing alternatives to deep geologic disposal for some waste currently classified as TRU or HLW? If the answer is yes, then other questions must follow:

2. What are legitimate and appropriate bases and processes for determining that alternative disposition should be used for a specific waste stream?

3. How should such processes be implemented?

The committee has framed the report around these questions and addressed the elements of the statement of task throughout the report. Chapter 1 discusses the statement of task and how the committee fulfilled that task. It also provides an overview of the current situation, including general descriptions of the wastes, definitions of the waste classes, and the history of the planned disposition for each class of waste. Chapter 2 discusses the need for flexibility in disposal options under the current regulatory regime and describes the candidate waste streams suggested by the committee. Chapter 3 argues that the nation should continue to treat deep geologic disposal as the presumptive disposition method but should adopt a formal, well-structured process for deciding on disposal paths for special cases of HLW and TRU waste streams. Chapter 4 describes key elements and attributes of a risk-informed approach to decision making, including procedures and criteria for risk assessment. Chapter 5 identifies and examines technical and institutional impediments to implementation of a risk-informed approach. Chapter 6 summarizes the findings and recommendations from the study. Appendix A gives a historical account of prior studies on risk and risk assessment. Appendix B summarizes previous risk studies carried out for or by DOE for its environmental management program.

MAJOR FINDINGS AND RECOMMENDATIONS

Finding 1: Deep geologic disposal is the default disposition option for HLW and TRU waste.

There is a long history of studies supporting deep geologic disposal of long-lived radioactive wastes. Deep geologic disposal remains the nation's approach for disposal of TRU and HLW.

Finding 2: Some waste currently classified as TRU or HLW may not warrant disposal in a deep geologic repository, either because (1) it is infeasible to recover and dispose of every last bit of waste that might conceivably be classified as TRU or HLW, or (2) the effort, exposures, and expense associated with retrieval, immobilization, and disposition in a repository may be out of proportion with the risk reduction achieved, if any.

Recovery of every last gram of TRU and HLW will be technically impractical and unnecessary. Recovery of some of the waste that is hardest to retrieve may result in little reduction in risk compared to disposing of it in situ while substantially increasing other risks, impacts, and costs. Further, processing and treatment methods can separate highly radioactive material from some wastes, which greatly reduces their hazards. But because of the definition of HLW found in the law, this latter waste, even if it contains very low concentrations of hazardous radionuclides, could also be classified as HLW and, therefore, require deep geologic disposal. Some of these wastes, then, may not warrant deep geologic disposal.

Finding 3: The committee makes no recommendation whether specific wastes should be approved for alternative disposal, but it has identified three waste types that contain waste streams that merit consideration: (1) HLW remaining in tanks (heels); (2) low-activity products from treatment of HLW; and (3) buried TRU waste (not buried in a manner that facilitates retrieval).[1]

[1] This term refers to TRU wastes generated prior to 1970 that were buried by shallow land burial before a directive was issued to segregate and retrievably store TRU wastes. DOE does not currently have plans to retrieve waste buried prior to 1970.

The nation must confront disposition decisions for each of the waste types listed. Each of these waste types spans a range of characteristics, from relatively low radioactivity and hazard to relatively high and volumes ranging from a few thousand liters to possibly billions of liters. The costs and risks of packaging and disposing of these wastes are very large. There is, then, the potential for a disproportion between the risk-reduction achieved and the costs and risks incurred for some wastes.

Finding 4: The nation needs a way to determine which of the wastes mentioned in Finding 3, if any, will be disposed in some manner other than deep geologic disposal.

Litigation over authority and agreements about waste disposition has left DOE's waste disposition program with substantial uncertainty concerning the path forward. Given the various disputes and the reality that not all of the waste will or can be recovered and disposed of in a deep geologic repository, an acceptable exemption process is needed.

Finding 5: Without a formal, well-structured, decision-making process, less desirable, ad hoc approaches will emerge.

Given the costs and difficulties of sending all waste that could be classified as HLW or TRU waste to a deep geologic repository, some approach will arise for deciding what waste gets geologic disposal and what does not. A formal, well-structured exemption process is needed regardless of the outcome of the various lawsuits and appeals concerning these wastes. The alternative to a reasoned, planned process is an ad hoc one, which could lead to inconsistent or poorly thought-out decisions that are not in the public interest.

Finding 6: Human health risk is a good basis or starting point for considering whether a waste stream should be granted an exemption, but it is not a sufficient basis for deciding these questions. At a minimum, costs, work-related risks, risks to ecosystems, technical feasibility, cultural and societal impacts, land use implications, pre-existing agreements, and other, site-specific factors are also relevant in what is called a risk-informed approach.

Risk-informed approaches are necessary to include all valuable information in an exemption process. Human health risk is an essential consideration for exemptions because (1) risk reflects one of the basic values being protected—human health—and therefore is a sensible starting point; and (2) risk analysis is a powerful, structured, well-developed way of considering human health effects, and its strengths and weaknesses are well established. This report focuses on human health risk because it is of concern for all of the waste streams and because it has traditionally been studied in risk analysis. However, the committee does not mean to imply that other risks such as ecological or cultural are unimportant. A proper risk analysis should identify and consider all of the relevant risks at a given site. The process of performing a risk assessment is useful, too, because it draws attention to the critical assumptions and focuses thought on the most significant contributors to risks. The question of how such decisions should be reached, including the roles of these factors and ethical considerations, is critically important, but is entirely a policy question that is beyond the task statement of this technical committee.

Finding 7: The credibility of DOE's planning and decision making is reduced by the apparent conflict of interest created by DOE's authority both to propose and to approve disposition plans for radioactive waste.

The burden of proof for departing from the default disposition option must be on the petitioner seeking alternative disposition. Allocating the burden of proof to DOE is meaningful only if DOE is not also the decision maker. That is, the burden of proof would be weak indeed if it was simply a matter of DOE convincing itself that it is right. DOE's status as a self-regulating agency is problematic because of the perceived and real conflict of interest: DOE is both petitioner and decision maker. Outsiders might reasonably question whether DOE is able to separate these functions so that the agency is neutral in the latter role. Having DOE's application for exemption subject to the judgment of an independent arbiter would make the process more credible to skeptics, of which, in this area, there are many.

Therefore, the burden of proof implies, and the committee here makes it explicit, that a separate federal entity is needed as the regulatory decision maker for exemption purposes. DOE is, of course, regulated by a number of different federal and state entities. Persuasive arguments could be made for either the U.S. Environmental Protection Agency (U.S. EPA) or the U.S. Nuclear Regulatory Commission (U.S. NRC) as regulator, because both have significant expertise in the regulation of radioactive materials. The committee does not have a basis for making a recommendation for either agency but offers some observations on the merits of each for this role.

The U.S. EPA would appear to be the most obvious regulator for TRU waste, because it is already the decision maker identified by law and has worked extensively with such waste at the WIPP facility. U.S. EPA also has been the principal regulator for cleanup at the sites at which HLW and TRU waste is found and U.S. EPA has extensive experience with stakeholder interaction under several statutes; probably more experience than U.S. NRC has. The U.S. NRC, on the other hand, is the agency mentioned in the current definition of HLW. U.S. NRC will rule on DOE's license application for a HLW repository and is the regulator for the cleanup of waste, including HLW, at DOE's West Valley site, which is perhaps the experience that is technically most similar to the management and cleanup of HLW at Hanford, Savannah River, and INEEL. Also, U.S. NRC is legally an independent agency and has some distance from the administration in power. At the same time, however, U.S. NRC is perceived by some to be a captured regulator, serving the interests of the nuclear industry. Further, coming as it does from the same parent agency (the Atomic Energy Commission), U.S. NRC is perceived by some as being too close to DOE and therefore having an institutional bias for DOE.

Finally, the committee notes that it is desirable, but not essential, for the sake of efficiency and consistent application, that the same agency be the exemption decision maker for both HLW and TRU waste.

Recommendation 1: The nation should pursue a formal, well-structured, risk-informed approach to decide which specific waste streams within the waste types enumerated in Finding 3, if any, should be disposed in some manner other than deep geologic disposal.

The adoption of a formal, well-structured, risk-based approach cannot be the work of one institution alone. DOE must take the initiative, but it is constrained by legislation, the regulation of multiple federal agencies, state regulation, and formal and informal agreements with states, American Indian nations, and other stakeholders. Each of these has a role in the adoption and implementation of such an approach. The committee has recommended that DOE's exemption applications be reviewed and approved or rejected by an independent regulator (or decision maker). Where it is possible and appropriate to identify a particular actor who should be responsible for a particular part of the process described herein, the committee has done so. However, in several settings, the choice of a regulator and their authority is essentially a political one, and beyond the committee's mandate.

Recommendation 2: DOE should *not* attempt to adopt these changes unilaterally. Likewise, the exemption process that the committee recommends must be implemented in the context of DOE's existing or renegotiated compliance agreements.

Put another way, if DOE wants to renegotiate its compliance agreements, it must make a case for renegotiation that is informed by risk, sets out clear criteria for an exemption, comprehensively addresses health risks (including worker, transportation, and long-term risk), and follows a transparent process that allows and enables meaningful public input.

Recommendation 3: DOE and its regulators for HLW and TRU waste should adopt a six-step process for risk-informed decision making: (1) initiate the process, laying out viable options and potential decisions; (2) scope the information and analysis; (3) collect data and refine models; (4) prepare refined risk assessment; (5) develop additional analyses and data collection, as needed, to support decisions; and (6) finalize the decision.

Finding 8: An effective and credible risk-informed-decision-making process has several characteristics. It is (1) participatory; (2) logical; (3) consistent with current scientific knowledge and practice; (4) transparent and traceable; (5) structured with reasonable independence of the decision authority from the petitioner; (6) subjected to thorough, independent peer review; (7) technically credible, with believable results; and (8) framed to address the needs of the decision process.

A risk-informed process that fails to meet any of these eight essential characteristics would likely be ineffective. In order to be effective, a risk-informed approach must be trusted. The eight characteristics listed above are intended not only to ensure a *result* that can be trusted, but *equally importantly* to create a process that can be trusted. For example, a technically credible risk-based approach that lacks participation or transparency would likely not be trusted and, therefore, would likely be ineffective in supporting a waste exemption process.

In summary, Findings 7 and 8 describe the key elements of a risk-informed approach as being a well-structured, participatory, and transparent process with an independent decision maker that uses current scientific knowledge and practice to address human health risk but also takes into account other impacts to reach a decision.

Finding 9: The biggest challenges to developing a meaningful risk-informed decision process, such as recommended herein, are minimizing disruption to existing laws, regulations, and agreements; creating buy-in to the approach; and enabling meaningful participation by participants who have few resources.

Disrupting existing laws, regulations, and agreements (e.g., changing the rules to allow potentially unsafe practices to proceed without due process) will tend to cause resistance and unintended consequences of an exemption process. Any meaningful decision process that involves stakeholders such as the risk-informed process recommended here will require finding ways to implement an exemption process in the least disruptive manner possible with regard to existing laws, regulations, and agreements. This process is difficult but important to maintain predictability, to create fewer unintended consequences, and to avoid destabilizing the policy equilibrium that has been reached as people have acted in reliance on the existing framework. The committee does not know how many exemptions DOE might seek or a regulator might approve. Assuming that the number will be relatively few, the committee has recommended exemptions because they can minimize disruption while preserving the desirable features of a risk-informed approach (see Section 3.2).

Recommendation 4: Congress, DOE, U.S. EPA, and U.S. NRC should take actions as necessary to enable DOE to implement effectively the risk-informed approach recommended here. Specifically, they should provide for a formal, well-structured exemption process, institute technical review of the risk analysis independent of the agency producing the analysis, give decision-making authority to an agency outside DOE, and ensure that sufficient resources are relia-

bly available for regulators, American Indian nations, and stakeholders to participate meaningfully in the process from the outset.

The committee did not develop detailed actions for each entity/agency for the steps necessary to implement this recommendation. There are many possible distributions of responsibilities; what one agency might contribute toward implementation of the recommendations depends heavily on what others would contribute. The implementation of the recommendation should be achieved jointly by the entities involved, without attempting to define in advance of inter-agency discussions what each should contribute.

Finding 10: The DOE risk assessments and decision processes examined by the committee do not exhibit all of the characteristics of an effective and credible risk-informed decision-making process, listed in Finding 8. Other bodies have made similar recommendations on how DOE should incorporate risk into environmental decision making, and DOE has made progress, but institutional factors appear to have interfered and perhaps undermined attempts to implement these approaches. This implies that changes are needed at DOE to address internal and external impediments to the risk-informed approach.

In its site visits the committee requested that DOE present its best examples of risk assessment informing waste disposition or cleanup decisions. Through DOE's presentations to the committee and the committee's review of documents, the committee examined many risk assessments and decision processes. DOE and its contractors have performed technically complex risk assessments, and in many cases have performed risk assessments as part of regulatory processes that lead to cleanup decisions with stakeholder input. Yet the cases examined by the committee do not meet the needs identified and described in this report for the following reasons. The complex analyses were not decision oriented and were not carried out in a transparent manner needed for meaningful participation by those outside DOE. The actions supporting regulatory decisions in many cases also were lacking—the steps in the processes appeared to have been performed simply to meet procedural requirements and most did not appear to have taken the kind of cooperative approach that the committee sees as essential to reach credible decisions and to foster buy-in by other relevant parties.

That the risk assessments examined by the committee do not exhibit all of the characteristics of an effective and credible risk-informed decision-making process does not imply that DOE has been derelict. These are technically difficult cleanup problems being addressed in a complex political and social environment. DOE has stabilized into safe, although temporary, conditions dangerous wastes and facilities across the complex, and in most cases has an enviable safety record in its cleanup program. Working toward effective and credible risk-informed decisions on these issues is very difficult. Further, many of the risk assessments examined by the committee were addressing smaller although significant problems, and so may not have warranted the effort recommended in this report. Also, the risk assessments were not necessarily aimed to fill the role described in this report. But on the latter point, the committee notes that numerous studies summarized in Appendixes A and B make recommendations consistent with those made in this report on how to incorporate risk into environmental decision making. DOE has made progress, but these approaches still have not permeated DOE's decision-making apparatus. It appears that institutional factors both inside and outside DOE have impeded attempts to implement risk-informed approaches. These factors include a tradition of internal rather than open decision making, incentive structures that favor distorting or ignoring risk, and a public wariness or mistrust of DOE's use of risk assessment to justify proposed actions.

The committee's role is to help DOE to bring the best practices to bear on the challenges DOE is addressing on the nation's behalf. DOE's difficulty in adopting risk-based or risk-informed approaches recommended previously by other committees and observers implies that DOE needs to make changes and perhaps changes are needed more broadly in the nation's approach toward managing risks at DOE sites.

Recommendation 5: To address the challenges of implementation and acceptance, DOE should form an authoritative, credible, and reasonably independent group to revamp the way DOE goes about implementing risk-informed approaches applied to waste disposition decisions.

These are enormously complex problems with numerous parties involved and a great deal of institutional inertia (as evidenced by unsuccessful previous attempts to change). The committee sees a need to break out of old approaches, so DOE needs an action-oriented group that provides advice and identifies alternatives, but also assists with implementation and draws in major stakeholders to get buy-in. The group must be credible, and to be credible the group must be authoritative on the issues it addresses and independent so as to be unbiased and free of conflicts of interest. Before implementing this recommendation, it would be useful to consider the extensive experience of a variety of federal agencies with outside advisory committees, including the committees' roles and effectiveness.

1

Introduction and Background

1.1 INTRODUCTION

The U.S. Department of Energy (DOE) manages dozens of sites primarily devoted to research, design, and production of nuclear weapons and nuclear reactors for defense applications. These sites are legacies of the Manhattan Project and the Cold War, and some continue to support defense activities. Wastes and contamination at these sites pose a national challenge: DOE's Office of Environmental Management plans to spend several decades and well over $100 billion to clean them up, and even then waste and contamination will remain. Some of the greatest projected risks, cleanup costs, and technical challenges come from processing and disposition of transuranic (TRU) and high-level radioactive waste (HLW). DOE estimates that it has approximately 340,000 cubic meters (m^3) of HLW containing about 835 million curies of radioactivity, and at least 287,000 m^3 of TRU waste containing a few million curies of radioactivity at its sites. A multitude of waste streams make up these totals. Deep geologic disposal is the only disposition path contemplated for some of them,[1] but DOE has sought alternative disposition paths for others.

[1] The committee uses the term "disposal" to mean the emplacement of waste in a facility without the intention of retrieval. "Disposition" is a broader term referring to

DOE's Office of Environmental Management asked the National Research Council of the National Academies to provide advice on technically sound approaches for using risk assessment in selecting disposition paths, including alternatives to deep geologic disposal, for its TRU and HLW. To fulfill this request, the National Research Council appointed an eleven-member committee under the auspices of the Board on Radioactive Waste Management. The committee's statement of task appears in Sidebar 1.1, and biographical sketches of the committee members can be found in Appendix E.

Sidebar 1.1: Statement of Task

This study will examine risk-based approaches for transuranic and high-level radioactive waste disposition and provide recommendations, as appropriate, on implementation by the Department of Energy in its cleanup program. To this end, the study will explicitly address the following issues:

- key elements of a risk-based approach;
- criteria for risk assessment;
- potential alternatives to geologic disposal for disposition of low-hazard waste;
- compatibility with current regulatory regimes;
- knowledge and technology gaps for implementation; and
- broader implications, if any, for disposition of other DOE wastes.

The study also will examine the application of risk-based approaches to selected DOE waste streams to assess their practical usefulness. The waste streams to be examined will be selected in consultation with DOE and regulators to illustrate a range of real-world applications.

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positioning of waste, whether in interim storage or permanent isolation (disposal) in a repository.

Statement of Task

The committee's charge is to recommend how DOE might implement risk-based approaches for disposition of high-level and transuranic radioactive waste. When discussing a risk-based approach for waste disposition, the committee views human health risk as the primary analysis outcome, and human health risk is what the committee means when it uses the term risk (unless otherwise qualified). For the sake of clarity, societal or cultural risks (e.g., impacts on community well-being and social cohesion), environmental or ecological risks (e.g., impacts on the environment, ecosystems, and endangered species), and technological or programmatic risks (e.g., the risk that a cleanup technology or a program will not perform as effectively as expected) are considered separately, except to the extent that they affect estimated human health risk. This report focuses on human health risk because it is of concern for all of the waste streams and because it has traditionally been studied in risk analysis. However, the committee does not mean to imply that other risks such as ecological or cultural risk are unimportant. A proper risk analysis should identify and consider all of the relevant risks at a given site. When assessing costs one must consider indirect costs such as those incurred by degrading ecosystem services (NRC, 2004). As will become apparent to the reader, the committee believes that it is important to consider all of these factors.

In fulfilling its charge, the committee had to consider first whether a risk-based approach is appropriate and desirable in disposing of TRU and HLW. The nation has a system for classification of radioactive waste and disposition options for each waste class. DOE's cleanup and waste disposition programs, however, are now the center of great controversy and uncertainty. DOE's proposals, plans, and declared authority for deciding on on-site, near-surface disposal of waste streams that are (or are made from processing) TRU and HLW have strained its relationships with many of the regulators, nearby American Indian[2] nations, and local communities at the DOE sites. This has left the path forward unclear.

[2] The committee uses the term American Indian throughout the report. In the context of this report, in which several different federally recognized American Indian tribal nations are active stakeholders and have special rights or claims, the committee decided it is more appropriate to use a general term, rather than list each nation. Also, the committee chose the term American Indian because while there appears to be no consistent preferences among Indigenous American groups for that term or for the term Native American, some term had to be chosen.

Thus, the critical questions for these wastes are the following:

1. Should the nation consider pursuing alternatives to deep geologic disposal for some waste currently classified as TRU or HLW? If the answer is "yes," then other questions must follow.
2. What are legitimate and appropriate bases and processes for determining that alternative disposition should be used for a specific waste stream?
3. How should such processes be implemented?

The committee has framed its report around these questions and addressed the elements of the statement of task throughout the report. This chapter describes how the committee carried out the study and provides background on TRU and HLW and the requirement for deep-geologic disposal. In Chapter 2, the committee argues that the cost of permanent geologic disposal may be disproportionate to the risks actually posed by some HLW and TRU waste. Chapter 2 also describes the types of wastes that are candidates for seeking alternative disposition paths, potential alternatives to deep geologic disposal for disposition of low-hazard waste,[3] and compatibility with current regulatory regimes. In Chapter 3, the committee argues that our nation should have an explicit mechanism to allow alternative disposition of some fraction of these wastes, rather than taking an ad hoc approach. The committee finds that risk is a good basis or starting point for a process to decide on disposition paths, and describes a system that could allow alternative disposition for a small set of TRU and HLW, using risk as the basis or starting point. The committee describes this approach as risk-informed rather than risk-based to emphasize that risk is one of several factors on which decisions must be based. As described in Chapter 3, the committee focuses on an exemption process for making disposition determinations for problematic wastes because such a process has emerged as the least disruptive way to seek reasonable, appropriate, and acceptable resolution of the disposition questions. Exemptions, as outlined in the report, do not offer direct relief from legal agreements concerning cleanup, but the process recommended in the report provides a persuasive way for DOE to approach renegotiation of the agreements. The committee recognizes that there are potential

[3] "Low-hazard waste" has no consistent or agreed-on definition. In general terms, the committee considers waste that has low concentrations of harmful radionuclides and is in a physical and chemical form that does not facilitate exposure over the duration of the hazard to be low-hazard waste.

pitfalls to this approach, nonetheless the committee judged that this was the approach to recommend. Chapter 4 describes the key elements of a risk-informed approach and criteria for risk assessment. Chapter 5 discusses technical and institutional impediments to such an approach, including knowledge and technology gaps for implementation. Chapter 6 summarizes the committee's findings and recommendations.

Data Gathering

The committee held five information-gathering meetings, including visits to the Idaho National Engineering and Environmental Laboratory (INEEL) in December 2003, the Savannah River Site (SRS) in January 2004, and the Hanford Site in March 2004. Through these meetings and its review of documents, the committee gathered information on DOE's waste streams and disposition options; how risk assessment is done at the different sites (by DOE and others); and how DOE, regulators, affected American Indian nations, and the public think risk should be used in decision making.

The committee has endeavored to hear from interested parties at each site by inviting participation by representatives of DOE, its contractors, tribal governments, national laboratory scientists, the U.S. Environmental Protection Agency (U.S. EPA), the U.S. Nuclear Regulatory Commission (U.S. NRC), the states, local governments, and public interest groups. The committee has also invited the general public to participate in open evening sessions at each field location. DOE and participants from each of the other groups and entities, as well as interested individual citizens, have been generous with their time and have shared their knowledge, views, and judgment in the course of the meetings and through written input. DOE, regulators, and members of the public suggested numerous HLW and TRU waste streams that might serve as case studies for this report. DOE has also accommodated the preferences and procedural needs of the committee by opening each site tour to members of the public who requested to participate. A list of speakers at each of the committee's information-gathering meetings and a list of facilities visited during the tours can be found in Appendix C. All of these interactions have enhanced the committee's understanding of the topic.

Prior to each site visit, the committee sent the site's DOE field office and other participants lists of questions and requests that presenters were asked to address and that the committee would be probing (see Sidebar 1.2). To evaluate the approach to decision making and how risk figures into the waste disposition process, the committee requested presentations from individuals at DOE who are in charge of specific waste management and cleanup projects at the sites.

As a side note, DOE's risk-based end states (RBES) corporate project[4] started to become publicly known just as this study began. The coincident timing of the RBES project with the committee's study and the similarity in their titles has caused a certain amount of confusion at DOE sites and among the public about the relationship between the two. The RBES project was not the focus of the committee's activities; the committee was not charged with, nor did it undertake, a peer review or other assessment of RBES, per se. However, to the extent that the RBES project represents a use of risk assessment in DOE's decision making, it was relevant to the committee's charge. Consequently, the committee requested presentations and discussions on the RBES project at each of the visited sites. Section 5.4 and Appendix B discuss the RBES project further.

Sidebar 1.2: Questions for Information Gathering

Questions posed and requests made to DOE:

- *Wastes.* The committee requested from each site a simple table describing the types of waste, their locations, physical and chemical forms, and disposition plans and options.
- *Disposition alternatives.* What alternatives for management, treatment, and disposal of radioactive waste have been examined? What are the health risks, costs, and time lines for each alternative?
- *Risks.* What kinds of risks are considered (worker, public, exposure pathways and scenarios, etc.)? How are the risks calculated? Under what assumptions and over what time frame? What factors drive the risks for different disposal alternatives? Are those factors and the underlying mechanisms well understood (with reliable models)? What parts of the calculations introduce

[4] In 2003, DOE issued a policy stating that every site should formulate cleanup plans by (1) developing an end state vision for the site based on an integrated site-wide plan for future land use, (2) developing exposure scenarios based on the end state, and (3) developing remediation alternatives based on the risks associated with the exposure scenarios (DOE, 2003a);. The deadlines that sites were given to draft the first vision documents coincided with the startup of the committee's study.

the greatest uncertainties? Do any distinct groups bear greater risk burdens than others? How is the local public involved in the risk assessments? How will risk decisions be implemented?

- *Regulations.* Are there any cases in which the current regulatory structure is thwarting risk-based decisions?
- *Documents.* The committee requested that DOE provide the following types of documents for HLW tanks and their residual contents and for buried TRU: (1) Detailed risk analyses in support of the current planned cleanup option, (2) detailed risk analyses of any alternative cleanup options that may have been considered, and (3) decision documents that describe weighting of risk and other criteria for decision making (e.g., evidence of incorporation of non-risk considerations). Also, any documents that detail any peer reviews or supporting documentation that explains why the committee, and especially those that are at the receiving end of the particular risks being examined, should believe the results of these analyses to the degree necessary for their use in making decisions.

Questions posed to regulators:

- *Roles and authorities*. What is the regulator's role in decision making and disposal of the site's high-level, transuranic, and low-level waste, including waste in storage and waste from cleanup? Under what authority does the regulator operate for the different wastes? How do the different regulators' authorities fit together?
- *Risk in decisions*. What kinds and levels of risk are considered acceptable? How does risk factor into decisions in these different cases? What other factors are important? Are there pitfalls associated with taking a so-called "risk-based" approach to selecting disposal options? Are there specific examples in which regulations are incompatible with or prevent DOE from pursuing an option that appears preferable from a risk perspective? Are there any broader implications for disposition of other DOE wastes if a "risk-based" approach is taken for HLW and TRU waste?

General questions posed to all parties:

- The committee has to select a few waste streams within the DOE complex to examine as case studies. Which waste streams would you suggest?
- What information and questions has the committee missed?

1.2 BACKGROUND

To understand the committee's data gathering, reasoning, findings, and recommendations, readers need to know some background, including the kinds of wastes that are in question, the reasoning behind the requirement for deep geologic disposal of these wastes, and the physical and institutional situation of the wastes.

Overview of HLW and TRU Waste and the Requirement for Deep Geologic Disposal

In 1944, the T-Plant at the Hanford Site (at that time referred to as Site W) began dissolving irradiated uranium fuel from Hanford's B-reactor to recover traces of plutonium for the Manhattan Project to use in the first nuclear weapons. The liquid waste from the first stages of this and later, more efficient chemical separation processes consisted of an acidic solution containing radioactive fission products and most of the actinides produced in the reactor fuel.[5] The waste was, in most cases, chemically neutralized with sodium hydroxide and stored in large, underground tanks made of carbon steel.[6] Decay of the radioactive constituents generated large amounts of heat and radiation, which required that the storage tanks contain structures to enable active cooling of the waste to prevent self-boiling and made handling this material extremely hazardous (Gephart, 2003). In the 1950s, the Atomic Energy Commission (a predecessor of DOE) referred to this waste as "high-level radioactive waste" and lumped all other radioactive wastes into two other categories: medium- or intermediate-level waste and low-level waste. These latter two categories were both disposed at or near the surface (NCRP, 2002). Thus, HLW was originally defined primarily by its source and that approach has not changed (U.S. Code, Title 42, Section 10101):

> **High-Level Waste** is (A) the highly radioactive waste material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such liquid waste that contains fission products in sufficient concentrations; and (B) other highly radioac-

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[5] For a solvent extraction separation process, this liquid remainder is called the raffinate; thus, the term "first-cycle raffinate" appears in some documents.

[6] Tanks at INEEL and a tank at the West Valley Demonstration Project were made of stainless steel, and the wastes in these tanks were not neutralized for storage.

> tive material that the Commission, consistent with existing law, determines by rule to require permanent isolation.[7]

Until the middle 1970s, it was planned that spent fuel from power reactors would be reprocessed in relatively modern facilities to yield HLW which, like the waste from the nuclear weapons program, would pose major challenges in waste management and disposal. For several reasons, most notably economic and political, reprocessing of civilian spent nuclear fuel was realized on only a small scale, halted in the 1970s, and has not been pursued in the United States since then.[8]

The Atomic Energy Commission considered several possible ways of disposing of highly radioactive liquid waste. In 1957, the National Research Council's (NRC's) Committee on Waste Disposal (a predecessor of the current Board on Radioactive Waste Management) issued a report requested by the Atomic Energy Commission recommending that high-level radioactive waste be disposed of in a deep geologic formations (NRC, 1957). The report highlighted salt formations as looking particularly promising.

Deep geologic disposal has the advantage of isolating radioactive waste in an environment that is designed to require little ongoing active maintenance. Because some radioactive waste will remain hazardous for millennia, it is important to dispose of it in a way that protects future generations from harm in the event that institutional knowledge of its whereabouts and hazards is lost. During the first 300-500 years after HLW is generated, the radioactivity, the heat generation, and radiation emitted by the waste are dominated by relatively short-lived isotopes, such as strontium-90 and cesium-137. Thereafter, as these shorter-lived radioisotopes decay, the actinides (uranium, neptunium, plutonium, and americium)[9] and long-lived fission products (technetium-99 and iodine-129) remain and dominate the hazard.

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[7] A provision added in the FY 2005 Defense Authorization Bill modifies this definition to some extent. See discussion of recent legal and regulatory developments that affect TRU and HLW disposal later in Section 1.2 of this report.

[8] For descriptions of the history of the DOE sites and activities, see DOE (1995, 1997). Waste from reprocessing of civilian nuclear reactor fuel is not addressed in this report, but for two perspectives on the decision not to continue commercial reprocessing in the United States see http://www.pbs.org/wgbh/pages/frontline/shows/reaction/readings/us.html.

[9] All TRU isotopes (isotopes with atomic number greater than 92) are radioactive and many are alpha emitters, which are particularly hazardous when inhaled or ingested. Every TRU isotope is long-lived or has a long-lived decay product. This means that after

In the 1960s, the Atomic Energy Commission tried to develop a disposal site in salt formations near Lyons, Kansas. The effort fell apart when technical and political difficulties with the site became evident. Attention then shifted toward sites in the Delaware Basin, a large geologic formation covering much of the Southwestern United States. In particular, a site near Carlsbad, New Mexico, was selected for extensive study. This site was a candidate to host a HLW repository, but later was selected to dispose of TRU waste.

By 1980, the nation still had no formal strategy for developing disposal capacity for spent nuclear fuel and HLW. In 1982, however, Congress enacted the Nuclear Waste Policy Act (NWPA). The NWPA codified the source-based definition of HLW and officially adopted the deep geologic repository concept as the nation's long-term strategy for HLW disposal.[10] Yucca Mountain in Nevada was designated by the Nuclear Waste Policy Amendments Act of 1987 as the only site to undergo characterization to determine its suitability to host a repository for commercial spent nuclear fuel and defense high-level waste. Congress also allocated the space available at this repository between the spent nuclear fuel coming from U.S. nuclear power plants and defense HLW (i.e., spent nuclear fuel and HLW produced by DOE facilities). In 2002, the secretary of energy recommended that the President find that the Yucca Mountain site is suitable for development of a deep geologic repository. The President did so and Congress overrode the veto exercised by the State of Nevada, as authorized in NWPA. DOE has said it plans to submit a license application to the Nuclear Regulatory Commission for construction of a repository at Yucca Mountain. The U.S. Court of Appeals for the D.C. Circuit invalidated the radiation standards that govern licensing of a HLW repository at Yucca Mountain.

At the time of the 1957 NRC report, management of radioactive waste from weapons production was undergoing some changes. The bismuth phosphate process used by the first chemical separation plants was inefficient and generated large volumes of waste. Because tank space was in short supply, from the late 1940s the operators at Hanford pumped liquid waste through a cascade of tanks, allowing settling and precipitation to remove insoluble components of the waste. These solids, which remained in the bottoms of the tanks, contained most of the acti-

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a relatively brief period during which the initial shorter-lived isotopes decay, the hazard posed by TRU waste does not diminish substantially for millennia.

[10] Nuclear Waste Policy Act of 1982, Public Law No. 97-425, 96 Stat. 2201, January 7, 1983.

nides and strontium from the waste, like the sludge found in the tanks today. The liquid supernate, which contained the soluble constituents (notably tritium, technetium, iodine, and cesium) was discharged to the soil. The practice of cascading the wastes was discontinued in the 1950s, but the supernate was still discharged to the soil after most of the cesium had been removed by precipitation by adding potassium ferrocyanide (Gephart, 2003; NRC, 2001a). Like these liquid wastes, until 1970 those solid wastes deemed *other than* high-level waste (i.e., not the solids in the HLW tanks, but all other solid radioactive wastes) were disposed of by dumping them in near-surface pits and trenches.

In 1969, the Atomic Energy Commission General Manager's Task Force on Operation Waste issued an immediate action directive calling for segregation and retrievable storage of plutonium and solid waste contaminated with transuranic material above 10 nanocuries per gram (nCi/g) from waste destined for shallow land burial because it concluded that the practice of shallow land burial was unsuitable for TRU waste (DOE, 1988).[11] In 1973, the commission issued Chapter 0511 of the Atomic Energy Commission Manual, which defined TRU waste as waste that is "contaminated with certain alpha-emitting radionuclides of long half-life and high specific radiotoxicity to greater than 10 nanocuries per gram" (Smith, 1982). That definition was revised when DOE issued Order 5820.1, Management of Transuranic Contaminated Material, in 1982: "TRU-contaminated material includes alpha-emitting radionuclides of atomic number greater than 92 and half-life greater than 20 years in a concentration greater than 100 nCi/g (DOE, 2001; WIPPLWA, 1992). The boundary of TRU was raised from 10 to 100 nanocuries per gram (nCi/g) based on the recommendations of the *Proceedings of Alpha Contaminated Waste Management Workshop* (ORNL, 1982). The recommendations were based on considerations of risk and practicality presented in numerous technical papers. The Waste Isolation Pilot Plant Land Withdrawal Act (Public Law 102-579) provides the current definition:

> **Transuranic Waste** is waste containing more than 100 nanocuries of alpha-emitting transuranic isotopes [atomic number greater than 92] per gram of waste, with half-lives greater than 20 years, except for:
>
> - High-level radioactive waste;

[11] The implementation period for this notice extended into 1970, so the "effective date" of the directive is often cited as 1970 (Perge, 1982).

- Waste that the Secretary [of Energy] has determined, with the concurrence of the Administrator [of the Environmental Protection Agency], does not need the degree of isolation required by the disposal regulations; or
- Waste that the Nuclear Regulatory Commission has approved for disposal on a case-by-case basis in accordance with part 61 of title 10, Code of Federal Regulations.

Most of the volume of transuranic waste is equipment and clothing contaminated with transuranic elements (such as plutonium) during the design and production of nuclear weapons. However, some of the wastes (e.g., sludge from cleanup) have much higher concentrations of plutonium. TRU waste is subclassified as "contact handled" or "remote handled" based on the penetrating radiation it emits: these designations are most often used as a basis for defining operational requirements in the facility generating the waste, transportation, or disposal operations, although both contact-handled TRU and remote-handled TRU require disposition in a deep geologic repository, by law. Distinctions are also made between TRU waste that is of civilian origin and TRU waste that is of defense origin based on the purpose of the program that generated the waste. This is a political distinction made important because Congress decided to develop a repository for the disposal of TRU waste that is of defense origin.

As noted above, a site near Carlsbad, New Mexico, was under investigation as a potential deep geologic repository. The Waste Isolation Pilot Plant (WIPP) began as a tunnel in bedded salt nearly 700 meters below the earth's surface. Investigations continued for more than 20 years and Congress passed the Waste Isolation Pilot Plant Land Withdrawal Act in 1992 to create a formal mechanism for DOE to seek permission to operate a repository there for disposal of defense-origin TRU waste. DOE constructed a mined repository and applied to U.S. EPA for certification of the application.[12] U.S. EPA certified WIPP, and the facility began accepting TRU waste for geologic disposal in 1999.

Following the 1969 directive, most DOE sites began storing TRU waste by stacking the waste containers (mostly barrels and boxes) on the ground and covering them with soil. Many of these "retrievably buried" packages are in poor condition now, but DOE is committed to retrieving them for disposal in a deep geologic repository and storage practices im-

[12] Certification is the term used for the approval process created in the WIPP Land Withdrawal Act. It is analogous to a license-application approval used in other regulatory processes.

proved so the challenge of working with corroded or disintegrating packages does not extend to all TRU.

In addition to retrievable TRU waste, large volumes of waste that meet the concentration specifications in the TRU definition were disposed of in trenches and pits prior to the 1969 directive. This "buried TRU" waste is regulated under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, see 40 CFR Parts 300-374 for the regulations), the Resource Conservation and Recovery Act (RCRA), or applicable state statutes because it is an uncontrolled release of hazardous substances into the environment. DOE currently manages buried TRU on a site-by-site basis with local regulatory authority, like it does environmental restoration issues at the sites. The CERCLA process illustrates how some decisions about buried TRU are made.

Within the context of the CERCLA process, a remedial solution to remove, reduce, and/or manage the contamination can be judged as a potentially "acceptable solution" through the application of nine evaluation criteria, as follows:

1. overall protection of human health and the environment;
2. compliance with applicable or relevant and appropriate requirements (ARARs) unless a waiver is granted;
3. long term effectiveness and permanence;
4. reduction of toxicity, mobility, or volume through the use of treatment;
5. short term effectiveness;
6. implementability;
7. cost;
8. state acceptance; and
9. community acceptance.

CERCLA calls for remedial actions at hazardous waste sites that (1) satisfy standards from other federal and state environmental programs that are "applicable or relevant and appropriate under the circumstances (ARARs)" and (2) are protective of human health and the environment (U.S. EPA, 1989). Qualitative preferences for remedies that provide reliable and long term protection are stated, but numerical standards (allowable content of contaminant in a specific volume of environmental media) and acceptable or allowable risk limits are not listed. In addition, CERCLA provides no paradigm to consider its nine balancing criteria in an explicit and consistent manner. See Section 5.4 for more discussion of DOE risk assessment processes, such as CERCLA.

The geologic-disposal requirement for TRU waste is an ARAR under CERCLA. CERCLA §121(d) and its implementing regulations (the National Contingency Plan) provide exceptions for meeting ARARs, including a process for seeking ARARs exemptions (see Sidebar 3.3). Depending on what action is selected in the record of decision at each of these disposal sites, buried TRU waste may be exhumed, characterized, treated, and shipped for disposal at WIPP, or other remedial actions may be taken. In selecting a remedy under CERCLA, the long-term effectiveness of the remedy must be considered and there is a preference for permanent solutions. Some see these provisions as indicating a default preference for retrieval and deep geologic disposal of buried TRU waste.

Thus, the disposition path for nearly all HLW and TRU waste is presumed to be deep geologic disposal, where disposal refers to emplacement with no intent to retrieve. Since the publication of the 1957 National Research Council report, other options for dealing with TRU and HLW have been considered, including (1) extraterrestrial disposal, (2) subseabed and deep borehole disposal, and (3) partitioning and transmutation, which is now being explored by several nations.[13] Although these alternative methods could hold promise for future generations, emplacement in a deep geologic repository now remains the best prospect for permanent isolation. Another NRC committee recently reaffirmed this recommendation (NRC, 2001b), and disposition in a deep geologic repository remains the preferred option for disposing of long-lived radioactive waste[14] produced by defense facilities, nuclear power plants and other sources (NRC, 1990, 2001b).

[13] Schemes for partitioning and transmutation involve chemical separation of long-lived constituents of spent nuclear fuel or HLW and irradiation of these constituents in a critical or subcritical nuclear reactor. Such schemes can reduce the quantity of long-lived radioactivity in the waste, although some remains and long-lived isolation is still required (see, e.g., NRC, 1995a, and NRC, 2001b pp. 119–124).

[14] Long-lived radioactive waste is radioactive waste that requires isolation from the biosphere for thousands of years or more.

Summary of Waste Inventories and Current Expected Disposition Paths

DOE estimates that it has approximately 340,000 m^3 of HLW,[15] which consists mostly of mixed fission products containing approximately 835 million curies (MCi) of radioactivity.[16] DOE also estimates that it has at least 287,000 m^3 of retrievably stored and buried TRU waste containing more than 3.1 MCi of TRU radioactivity, including some fission and activation products (DOE, 2001) at its sites. High-level waste includes small volumes of intensely radioactive material and large quantities of nonradioactive chemicals mixed with various radionuclides (e.g., saltcake containing sodium nitrate and cesium-137). The TRU waste includes some waste that requires remote handling to protect workers and also includes much less radioactive equipment, rags, and protective clothing near the 100 nCi/g contamination limit that defines TRU waste.

The buried TRU waste is highly heterogeneous and was generally dumped into pits and trenches, with no effort made to keep waste packages intact and little effort expended on record keeping. For these reasons and because of the hazards that could be incurred by digging into it, characterization of these wastes has been difficult. DOE estimates that the total volume of buried TRU waste in near-surface pits and trenches is approximately 126,000 m^3 containing about 397,000 curies (Ci) of TRU radioactivity.[17] Another 11,000 m^3 containing 10,000 Ci is disposed of at greater depths.[18] Soils contaminated such that they are considered TRU waste (found mostly at Hanford) comprise an additional 32,000 m^3 containing about 33,000 Ci (DOE, 2000). The volumes of buried TRU are not included in the wastes planned for disposal at WIPP.

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[15] This volume of HLW would occupy nearly 9400 standard tanker trucks, or about one and one-half large oil tanker ships.

[16] These numbers do not include spent nuclear fuel, which is outside the scope of this study. The total radioactivity, obtained from site personnel during this study, is inconsistent with that found in DOE (2001), which reports larger total radioactivity in HLW at SRS and INEEL than any other DOE source the committee found.

[17] This is the projected value correcting for decay through 2006 (DOE, 2000).

[18] These wastes were disposed of by injecting waste grout into cracks in shale formations 250-360 meters below the surface (a method called hydrofracture) at the Oak Ridge Reservation from 1963 to 1984, by placement in roughly 20-meter-deep shafts (for post-1971 remote-handled TRU) at the Los Alamos National Laboratory; and by placement in thirteen 40-meter-deep boreholes at the Nevada Test Site (for classified TRU waste) (DOE, 1998a, 2001; SNL, 2004). "Greater depths" is intermediate depth.

Deep geologic disposal is the only contemplated ultimate disposition path for several waste streams. These include:

- HLW already immobilized in approximately 1750 canisters of HLW glass stored at SRS and the 275 canisters stored at the West Valley site,
- the high-actinide-content waste streams from processing the remaining 330,000 m^3 (about 91 million gallons) of HLW at Hanford and SRS (Hintze, 2004; Wiegman, 2004), and,
- nearly all of the approximately 115,000 m^3 of retrievably stored TRU waste across the DOE complex.

DOE has been evaluating alternative disposition approaches for a diverse set of waste streams including lower-activity waste streams from processing HLW (e.g., sodium-bearing waste at INEEL, lower-activity saltcake at SRS, and low-activity waste and supplemental treatment waste at Hanford), "heels" (liquids from tank washing and some original waste solids remaining in tanks after substantial retrieval) in more than 200 HLW tanks; 131 MCi of encapsulated cesium and strontium sources separated from Hanford's HLW (DOE, 2002a); tens of curies of corrosion products from spent fuel stored in the K Basins at Hanford; buried TRU waste (potentially more than tens of thousands of cubic meters) about which DOE and states disagree on ultimate disposition; and TRU waste on which DOE says the WIPP waste acceptance criteria impose major burdens. Some of these are described in greater detail in Chapter 2.

The foregoing discussion has focused on the waste and how it will be managed, but the wastes are part of the DOE cleanup program and so are handled in the context of the overall cleanup at the sites. Each of the three sites visited by the committee has a federal facility agreement (FFA) that defines what DOE's cleanup efforts must accomplish, when it must accomplish each step, and in many cases, the means by which the accomplishments are to be achieved (Hanford FFA, 2003; INEEL FFA, 1991; SRS FFA, 1993). These compliance agreements are legally enforceable. Violations of these agreements have occurred and led to fines being imposed on DOE by the state.

The compliance agreements involve at least three parties: DOE, the site's regional EPA office, and the host state, which is usually represented by its department of environmental compliance or equivalent. Because DOE is self-regulating concerning the radionuclide content of the

TRU and HLW waste streams, these agreements focus on laws—CERCLA, the RCRA, the Safe Drinking Water Act—that apply to certain radioactive wastes but were designed for other environmental hazards.[19]

In most cases the agreements do not cover all details of long-term efforts, such as cleanup of HLW tanks and buried TRU waste. Instead, the agreements are fairly prescriptive for the next few or several years and then identify only general directions or simply the need to make a decision at some point in the future. An example of this is the Hanford agreement, which has milestones and other details including minimum removal requirements for tank wastes, but does not yet specify how or when tanks will be closed once retrieval is completed. To allow for such evolution, the agreements are "living documents" that can be modified to accommodate progress and changing circumstances. The evolving nature of these agreements is a practical necessity given that it would be impossible to know everything in sufficient detail at the outset to prescribe actions over the life of a multiple-decade project. The committee was told that the Hanford agreement had been modified hundreds of times.[20] Significantly, all three parties must agree to make any change in the agreement or even to enter discussion of making changes in the agreement before these events can occur.

Recent Legal and Regulatory Developments That Affect TRU and HLW Disposal

In the 1980s, DOE determined that immobilizing all of the HLW in the complex without some kind of separations would send enormous numbers of canisters of HLW to the HLW repository. To reduce the number of canisters destined for a repository (see Chapter 2 for more details), DOE developed plans to chemically process or treat HLW to

[19] SRS operates under a wastewater permit from the South Carolina Department of Health and Environmental Quality.

[20] "Since it was first approved on May 15, 1989 there have been 428 change requests approved to the Hanford Federal Facility Agreement and Consent Order (Tri-Party Agreement). Each of these approved change requests can consist of many different types of changes. For example a change request can consist of a minor modification such as the update of a person's title or it can be a major modification to the milestones controlling a large scope of work. Many of the approved change requests have added milestones (additional work scope) which has increased the number of enforceable milestones from the 161 original milestones to 1,188 today" (Morrison, 2004).

separate most of the long-lived and highly radioactive constituents into a high-activity waste stream leaving only low concentrations of radioactivity in a large volume of low-activity waste. The high-activity waste stream would still be considered HLW and would require disposal in a deep geologic repository. The remaining low-activity waste stream would be much less hazardous and DOE reasoned that it would not require the isolation required for HLW.

To address the various waste streams that emerged from this treatment of HLW, in 1999 DOE issued Order 435.1 which set out a procedure for determining some waste to be "incidental to reprocessing" and therefore classified and managed either as low-level waste or transuranic waste (see Sidebar 1.3).[21] As low-level waste, the material could be disposed of in a near-surface facility onsite at the DOE facilities where the wastes were generated.

The first official document referring to waste incidental to reprocessing appears to be a 1969 Atomic Energy Commission Notice of Proposed Rulemaking on regulations for nuclear fuel reprocessing plants. The Final Rule in 1970, Appendix F to 10 CFR Part 50, dropped the incidental waste description, and was the first regulation to define liquid HLW as "those aqueous wastes resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles…." In the late 1980s and early 1990s, DOE sought U.S. NRC concurrence on how DOE proposed to determine when HLW has been retrieved to a point sufficient that residues in tanks, pipes, and equipment, and the waste in the separated low-activity streams could be classified as something other than HLW (Rizzo, 1989; Bernero, 1989). U.S. NRC denied a petition by the states of Oregon and Washington which requested that U.S. NRC assert authority over HLW classification determinations and "establish a procedural framework and substantive standards by which the Commission would determine whether reprocessing waste...is HLW" (Bernero, 1993). U.S. NRC instead found that the principles for waste classification are well established," endorsing the criteria DOE later used in Order 435.1.

[21] DOE regulates itself on matters covered by the Atomic Energy Act (most relevant here are nuclear materials and radioactive waste). Similar to regulations at U.S. NRC and U.S. EPA, DOE orders are the rules that govern DOE facilities on these matters. DOE Order 435.1 is titled "Radioactive Waste Management" (see www.directives.doe.gov). A prior DOE order with the same title, DOE Order 5820.2A, did not contain the provisions for determining waste to be incidental to reprocessing.

Sidebar 1.3: Waste Incidental to Reprocessing

DOE Order 435.1 states:

> [wastes incidental to reprocessing] may include, but are not limited to, spent nuclear fuel reprocessing plant wastes that:

(a) Will be managed as low-level waste and meet the following criteria:

1. Have been processed, or will be processed, to remove key radionuclides to the maximum extent that is technically and economically practical; and
2. Will be managed to meet safety requirements comparable to the performance objectives set out in 10 CFR Part 61, Subpart C, Performance Objectives; and
3. Are to be managed, pursuant to DOE's authority under the Atomic Energy Act of 1954, as amended, and in accordance with the provisions of Chapter IV of this Manual, provided the waste will be incorporated in a solid physical form at a concentration that does not exceed the applicable concentration limits for Class C low-level waste as set out in 10 CFR 61.55, Waste Classification; or will meet alternative II-14 DOE G 435.1-1 7-09-99 Chapter II High-Level Waste Requirements for waste classification and characterization as DOE may authorize.

(b) Will be managed as transuranic waste and meet the following criteria:

1. Have been processed, or will be processed, to remove key radionuclides to the maximum extent that is technically and economically practical; and
2. Will be incorporated in a solid physical form and meet alternative requirements for waste classification and characteristics, as DOE may authorize; and
3. Are managed pursuant to DOE's authority under the Atomic Energy Act of 1954, as amended, in accordance with the provisions of Chapter III of this Manual, as appropriate.

The implementation of DOE Order 435.1 was challenged in federal district court in 2001 on the grounds that, contrary to law, the order grants DOE the authority to reclassify waste arbitrarily and unilaterally (*NRDC v. Abraham*, 2002, Case 01-413). The court reviewed the definition of HLW in the NWPA and DOE's interpretation of the definition. In its ruling, the court stated that "DOE's Order 435.1 directly conflicts with NWPA's definition of HLW. NWPA's definition pays no heed to technical or economic constraints in waste treatment. Moreover, NWPA does not delegate to DOE the authority to establish alternative requirements for solid waste."[22] Following the Idaho court decision that rejected DOE's Order 435.1 process for exempting wastes, there were no regulatory exceptions to the characterization of tank wastes as HLW.

In *United States of America v. Dirk Kempthorne,* Governor of Idaho (*USA v. Kempthorne*, Case No. 91-054-S-FJL, March 31, 2003), a different judge in the U.S. district court in Idaho ruled that a 1995 settlement agreement between the State of Idaho and DOE requires that DOE remove *all* TRU waste, including buried TRU waste, from the INEEL by the end of the year 2018. DOE is also seeking to reverse this ruling.

DOE appealed both of these rulings to the U.S. Court of Appeals for the Ninth Circuit. In the first case, DOE also asked Congress to restate the definition of HLW consistent with DOE's interpretation in Order 435.1 by amending the NWPA (Abraham, 2003). DOE is also negotiating with the States of Idaho, Washington, South Carolina, and New Mexico on HLW issues, seeking to ease requirements under the federal facility agreements that DOE has signed with U.S. EPA and the states.

On October 8, 2004, the U.S. House and Senate Armed Services Committees conferees agreed on the contents of the National Defense Authorization Act of 2005, Section 3116, which concerns waste incidental to reprocessing. President Bush signed the act into law on October 28, 2004. Sidebar 1.4 contains the text of that section. In summary, the legislation qualifies the definition of HLW by stating that reprocessing waste that meets certain criteria (i.e., has had highly radioactive radionuclides removed to the maximum extent practical; does not require permanent isolation in a deep geologic repository; and performance objectives for low-level waste) is not HLW. DOE is to make such determinations in consultation with the U.S. NRC, and disposal must be in accord with a

[22] The U.S. district court in Idaho ruled that the NWPA grants DOE no discretion in the question of disposal method. It further held that the statutory definition admits of no exemptions from HLW for liquid reprocessing waste. Solid waste derived from such liquid waste, on the other hand, need not be classified as HLW if it is does not contain "sufficient concentrations" of radionuclides. However, the court invalidated DOE's method for reclassification of wastes for three reasons. First, it applied to both liquids and derived solids, and liquids do not have exemptions. Second, the statutory language refers only to concentrations of radionuclides as the proper criterion for reclassification, and DOE's internal regulations included cost and technical feasibility as criteria. Third, the DOE regulations did not meaningfully limit its discretion to reclassify such wastes. The court was neither presented with, nor did it address the possibility of a general de minimis exemption for disposal of minute amounts of liquid or solid HLW (*NRDC v. Abraham.* 2003. Memorandum Decision. Civ. No. 01-0413-S-BLW. U.S. District Court for the District of Idaho. 271 F. Supp. 2d 1260. July 2, 2003).

closure plan approved by the host state. Section 3116 of the act applies to the States of South Carolina and Idaho only. Washington, Oregon, and other states aside from Idaho and South Carolina explicitly are not subject to this provision of the law.

Finally, the Court of Appeals for the Ninth Circuit ruled on both of DOE's appeals. On November 5, 2004, a three-judge panel overturned the District court's summary judgment in the HLW case because the case was not ripe, i.e., DOE had not yet applied Order 435.1 to a particular situation (Case No. 03-35711, D.C. Number CV-01-00413-BLW). The court therefore could not address the merits of the case. On December 3, 2004, the same panel of judges remanded the decision on INEEL's buried TRU waste back to the District court, as DOE requested, to consider extrinsic evidence central to DOE's argument (Case No. 03-35470, D.C. Nos. CV-91-00054-HLR/EJL and CV-91-00035-HLR/EJL).

This committee has no authority to determine matters of law and offers no opinion on the merits of the litigation or other actions taken to change or preserve the current legal interpretation of HLW or to determine final disposition of the buried TRU waste at INEEL. The foregoing information is provided to illustrate the events surrounding DOE's request for review of the risk-based disposition of HLW and TRU waste and the committee's deliberations. As described in Chapter 3, the committee contends that the approach advocated in this report should be pursued under the new law, regardless of the outcome of the litigation. Even if DOE's existing exemption process is found legally valid, its substance and procedure would be improved by the process set out herein.

Sidebar 1.4: The Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005

Section 3116. Defense Site Acceleration Completion.

(a) IN GENERAL.—Notwithstanding the provisions of the Nuclear Waste Policy Act of 1982, the requirements of section 202 of the Energy Reorganization Act of 1974, and other laws that define classes of radioactive waste, with respect to material stored at a Department of Energy site at which activities are regulated by a covered State pursuant to approved closure plans or permits issued by the State, the term "high-level radioactive waste" does not include radioactive waste resulting from the reprocessing of spent nuclear fuel that the Secretary of Energy (in this section referred to as the "Secretary"), in consultation with the Nuclear Regulatory Commission (in this section referred to as the "Commission"), determines—

(1) does not require permanent isolation in a deep geologic repository for spent fuel or high-level radioactive waste;

(2) has had highly radioactive radionuclides removed to the maximum extent practical; and

(3) (A) does not exceed concentration limits for Class C low-level waste as set out in section 61.55 of title 10, Code of Federal Regulations, and will be disposed of—

(i) in compliance with the performance objectives set out in subpart of part 61 of title 10, Code of Federal Regulations; and

(ii) pursuant to a State-approved closure plan or State-issued permit, authority for the approval or issuance of which is conferred on the State outside of this section; or

(B) exceeds concentration limits for Class C low-level waste as set out in section 61.55 of title 10, Code of Federal Regulations, but will be disposed of—

(i) in compliance with the performance objectives set out in subpart C of part 61 of title 10, Code of Federal Regulations;

(ii) pursuant to a State-approved closure plan or State-issued permit, authority for the approval or issuance of which is conferred on the State outside of this section; and

(iii) pursuant to plans developed by the Secretary in consultation with the Commission.

(b) MONITORING BY NUCLEAR REGULATORY COMMISSION.—

(1) The Commission shall, in coordination with the covered State, monitor disposal actions taken by the Department of Energy pursuant to subparagraphs (A) and (B) of subsection (a)(3) for the purpose of assessing compliance with the performance objectives set out in subpart C of part 61 of title 10, Code of Federal Regulations.

(2) If the Commission considers any disposal actions taken by the Department of Energy pursuant to those subparagraphs to be not in compliance with those performance objectives, the Commission shall, as soon as practicable after discovery of the noncompliant conditions, inform the Department of Energy, the covered State, and the following congressional committees:

(A) The Committee on Armed Services, the Committee on Energy and Commerce, and the Committee on Appropriations of the House of Representatives.

(B) The Committee on Armed Services, the Committee on Energy and Natural Resources, the Committee on Environment and Public Works, and the Committee on Appropriations of the Senate.

(3) For fiscal year 2005, the Secretary shall, from amounts available for defense site acceleration completion, reimburse the Commission for all expenses, in-

cluding salaries, that the Commission incurs as a result of performance under subsection (a) and this subsection for fiscal year 2005. The Department of Energy and the Commission may enter into an interagency agreement that specifies the method of reimbursement. Amounts received by the Commission for performance under subsection (a) and this subsection may be retained and used for salaries and expenses associated with those activities, notwithstanding section 3302 of title 31, United States Code, and shall remain available until expended.

(4) For fiscal years after 2005, the Commission shall include in the budget justification materials submitted to Congress in support of the Commission budget for that fiscal year (as submitted with the budget of the President under section 1105(a) of title 31, United States Code) the amounts required, not offset by revenues, for performance under subsection (a) and this subsection.

(c) INAPPLICABILITY TO CERTAIN MATERIALS.—Subsection (a) shall not apply to any material otherwise covered by that subsection that is transported from the covered State.

(d) COVERED STATES.—For purposes of this section, the following States are covered States:

(1) The State of South Carolina.

(2) The State of Idaho.

(e) CONSTRUCTION.—

(1) Nothing in this section shall impair, alter, or modify the full implementation of any Federal Facility Agreement and Consent Order or other applicable consent decree for a Department of Energy site.

(2) Nothing in this section establishes any precedent or is binding on the State of Washington, the State of Oregon, or any other State not covered by subsection (d) for the management, storage, treatment, and disposition of radioactive and hazardous materials.

(3) Nothing in this section amends the definition of “transuranic waste” or regulations for repository disposal of transuranic waste pursuant to the Waste Isolation Pilot Plant Land Withdrawal Act or part 191 of title 40, Code of Federal Regulations.

(4) Nothing in this section shall be construed to affect in any way the obligations of the Department of Energy to comply with section 4306A of the Atomic Energy Defense Act (50 U.S.C. 2567).

(5) Nothing in this section amends the West Valley Demonstration Act (42 U.S.C. 2121a note).

(f) JUDICIAL REVIEW.—Judicial review shall be available in accordance with Chapter 7 of title 5, United States Code, for the following:

(1) Any determination made by the Secretary or any other agency action taken by the Secretary pursuant to this section.

(2) Any failure of the Commission to carry out its responsibilities under subsection (b).

2

Why Consider Flexibility in Disposal Options?

Why should the nation consider flexibility in disposal options for some waste currently classified as transuranic (TRU) or high-level waste (HLW)? In this chapter, the committee explains that some waste currently classified as TRU or HLW may not warrant disposal in a deep geologic repository because the effort, exposures, and expense associated with retrieval, immobilization, and shipment to a repository may be out of proportion with the reduction in human health risk achieved, if any. The committee identifies three waste types, each of which contains some wastes that merit consideration by the Department of Energy (DOE) and others for alternative disposal. These waste types are described in detail as case studies.

This chapter establishes the basis for the committee's consideration of a process that could be applied to DOE's request for alternative disposition of some HLW and TRU waste by discussing the difficulties caused by the current definitions of HLW and TRU, and by describing three waste types containing waste streams that could be candidates for alternative disposal. The committee's approach toward greater flexibility was the result of many factors, including gaps and uncertainties in the definitions in Chapter 1, recent litigation, congressional action targeting HLW disposal, along with the testimony from DOE, its contractors, stakeholders, and citizen groups on management strategies for HLW and TRU waste.

Finding 1: Deep geologic disposal is the default disposition option for HLW and TRU waste.

There is a long history of studies supporting deep geologic disposal of long-lived radioactive wastes. Deep geologic disposal remains the nation's approach for disposal of TRU and HLW.

2.1 SOURCE-BASED DEFINITIONS—WIDELY VARIED WASTE

Until the October 2004 legislation, all reprocessing waste that met the old statutory definition of HLW was required to be disposed of in a permanent geologic repository. If the waste were exempted from the definition or reclassified, then it could be disposed of elsewhere. However, the general thrust of this definition is inclusion, not exclusion; that is, it offers opportunities in the second clause of paragraph (A) and in paragraph (B) for an agency (the U.S. Nuclear Regulatory Commission [U.S. NRC]) to add to what is considered HLW, not to create exemptions (see the definition repeated below). The inability to create exemptions may help to limit potential abuses by preventing loopholes, but it also prevents the consideration of reasonable alternatives when they make sense.

> **High-Level Waste** is (A) the highly radioactive waste material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such liquid waste that contains fission products in sufficient concentrations; and (B) other highly radioactive material that the Commission, consistent with existing law, determines by rule to require permanent isolation. (U.S. Code, Title 42, Section 10101)

The definition states that any solid material derived from liquid HLW containing fission products in sufficient concentrations is HLW. This implies a concentration-based standard, but it is indeterminate: the definition seems to establish that certain solid wastes derived from high-level liquid waste could contain fission products below some undefined "sufficient concentration" that would fall outside the HLW definition

(Burket, 2004; Mears and Ruple, 2004).[1] However, liquid reprocessing wastes have no statutory exemptions. While there may also be an implicit de minimis exception to the definition for both liquid and solid reprocessing wastes (the last few grams in a tank or a kilogram or two of contaminated soil?) this has not been claimed by the relevant agencies or tested in the courts.[2] It would also be possible to elaborate on the meaning of "highly radioactive" to exclude certain fractions (however derived) of the initial reprocessing waste stream. This is a logical possibility, but it too is undefined. Following the Idaho court decision that rejected DOE's process for exempting wastes (see Sidebar 1.3), there were no exceptions to the characterization of wastes from reprocessing as HLW that are agreed upon as valid. The recent legislation created exemption criteria for waste in South Carolina and Idaho based on the U.S. NRC's concentration limits and performance objectives for near-surface disposal of low-level radioactive waste and requirements that the waste be treated to remove highly radioactive radionuclides "to the maximum extent practical" (see Sidebar 1.4).

The definition of TRU waste is, by exclusion of HLW, also a source-based definition. Most TRU waste is indeed quite different from HLW, but some is substantially similar. In contrast to HLW, 98 percent of TRU waste is contact handled: it has relatively low concentrations of the shorter-lived fission products and, thus, emits less radiation and generates less heat, but the long half-lives of the transuranic isotopes and their decay products mean that the hazard they pose does not diminish sub-

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[1] Technically, this is not an exemption in the sense of shifting the burden to the regulated entity to obtain a deviation from the general rule. Read literally, the definition suggests that derived solids are HLW *only if* they contain sufficient concentrations of radionuclides; otherwise, apparently, derived solids generally are *not* HLW. As a practical matter, however, both the solid and the liquid fractions of the tank waste begin their existence as a single, highly radioactive primarily liquid waste; therefore, it is usually a matter of treating the solid derived wastes to reduce radioactivity, rather than deciding whether they contain *enough* radioactivity.

[2] Such an interpretation would not be unprecedented. Courts have interpreted certain parts of the Clean Air Act to include a de minimis exception, *Alabama Power Co. v. Costle*, 636 F.2d 323, 360 (D.C. Cir. 1979) ("Categorical exemptions may also be permissible as an exercise of agency power, inherent in most statutory schemes, to overlook circumstances that in context may fairly be considered de minimis"), but in other cases have declined to do so because the statute clearly precluded it; (see, e.g., *Public Citizen v. Young*, 831 F.2d 1108 D.C. Cir. 1987; Delaney Clause of the Federal Food, Drug, and Cosmetic Act).

stantially for millennia.[3] Like HLW, remote-handled TRU waste can contain high concentrations of radionuclides that emit penetrating radiation,[4] and thus are similar to HLW in terms of its requirements during waste management and disposal. Remote-handled TRU waste constitutes only about 2 percent by volume and 3-4 percent of the radioactivity of the total inventory of TRU waste.

The definition of TRU waste provides administrative mechanisms for removing waste from the TRU waste classification. In this way it contrasts sharply with the definition of HLW, which does not contain parallel language. However, which TRU waste should be managed by means other than permanent geologic disposal is ill-defined, and DOE and its regulators have not made much use of alternative disposal provisions for TRU waste. As far as the committee is aware, only one exception has been granted for TRU waste. In this exception, DOE disposed of some TRU waste near the surface and some at intermediate depth. Specifically, DOE disposed of about 60 metric tons of classified TRU waste containing around 330 curies (Ci) of plutonium-239 in four boreholes approximately 35 meters deep at the Nevada Test Site between 1984 and 1989 (SNL, 2004). Sandia National Laboratories carried out a performance assessment to demonstrate that this disposal meets the Environmental Protection Agency's (U.S. EPA's) requirements for disposal of TRU waste (40, CFR 191). DOE and U.S. EPA agreed that disposal of this waste in this manner was satisfactory.

As noted in Finding 1, the committee recognizes the necessity and appropriateness of deep geologic disposal for HLW and TRU waste. However, as explained more fully below, the evolution of HLW management and treatment (among other things) has led to the creation of a series of different waste streams. Changes in treatment technology and other factors suggest to the committee that in certain limited cases a process could be considered for reclassification and disposal of HLW and TRU waste.

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[3] Transuranic isotopes have very long half-lives (i.e., plutonium-239 has a half-life of 24,400 years; neptunium-237 has a half-life of 2 million years) or decay into isotopes that have long half-lives, which can potentially give rise to long-term management problems and uncertainty in exposure scenarios.

[4] Penetrating radiation can come from fission products or transuranic isotopes. Some transuranic isotopes, like americium-241 (a decay product of the relatively short-lived plutonium-241) emit gamma rays and others, like plutonium-238 and -240, cause neutron emissions through (alpha,n) reactions in lighter nuclei or through spontaneous fission.

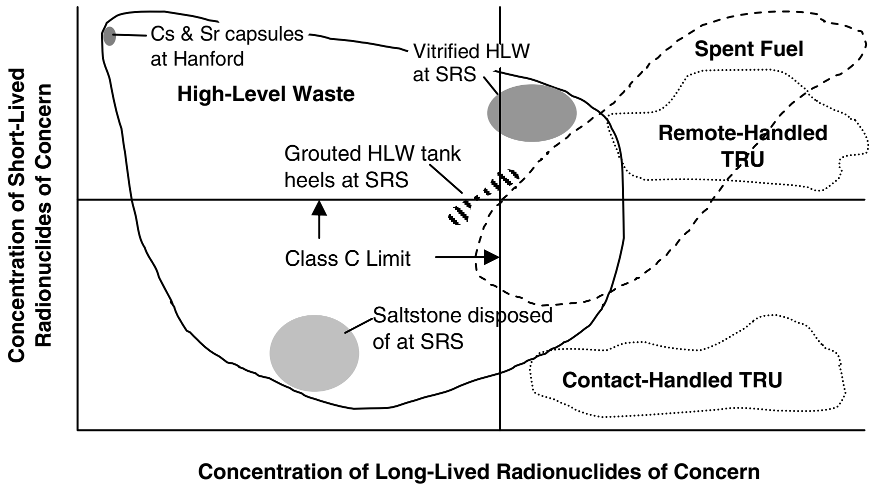

FIGURE 2.1 Chart of the concentrations of short-lived and long-lived radionuclides for waste that might be considered HLW along with TRU waste and spent nuclear fuel. The boundary of each waste class is meant to surround the various waste streams and does not represent quantities. Class C limit demarcations represent radionuclide concentrations in low-level waste below which near-surface disposal is permitted. Note that Saltstone[5] would not now be considered HLW. See extensive discussion of this diagram in the main text.

The range of variation within the different types of waste is represented qualitatively in Figure 2.1, which illustrates the long-lived and short-lived radionuclide composition of HLW, TRU waste, and spent nuclear fuel. In this figure, adapted from one by Fehringer and Boyle (1987), moving to the right reflects an increase in the concentration of long-lived radionuclides of concern (e.g., americium-243) and moving

[5] Saltstone is DOE's name for the cementitious waste form used at the Savannah River Site to immobilize liquid waste from processing HLW that is being sent to the vitrification plant (see discussion on Waste in HLW Tanks at the Savannah River Site below).

up reflects an increase in the concentration of shorter-lived radionuclides of concern (e.g., cesium-137). Radionuclide concentration limits that are generally acceptable for near-surface burial of low-level wastes (Class C limits contained in 10 CFR 61) are represented by a vertical line and a horizontal line within the chart. The regulation contains a table of concentration limits for short-lived radionuclides and a table of concentration limits for long-lived radionuclides, so these boundaries are simply notional demarcations indicating that low-level waste in the lower, left quadrant is generally acceptable for near-surface disposal under the regulations.[6] Congress used the Class C limits and the performance objectives from 10 CFR 61 as part of the new law's criteria for determining what reprocessing waste is not HLW. The inclusion of Class C limits should not be construed to imply that the committee has determined that waste that sits below those limits is suitable for near-surface disposal. The limits are included as reference levels only.

The figure illustrates the varied nature of waste and material that might be considered HLW. In the upper left corner is the most concentrated radioactive material in the DOE complex: the cesium and strontium capsules at Hanford. Low-activity waste from the treatment of HLW at the Savannah River Site already disposed of on-site—the Saltstone—is at the lower left portion of the HLW boundary.[7] Vitrified HLW and calcined HLW are near the upper right. The waste grouted in two tanks that were declared closed at the Savannah River Site (tanks 17 and 20) is displayed straddling the Class C limit because the waste is below the Class C limit if one averages the concentration over the grout in the tank, but the Natural Resources Defense Council (NRDC; Cochran, 2003) has argued that there is not substantial mixing, and the concentration of the waste itself remains above the Class C limit. It is possible that the quantities and concentrations of the heels in tanks 17 and 20 may be lower than those of other tanks (d'Entremont and Thomas, 2002), so the waste depicted on the figure might not be representative of future grouted tanks. By definition, TRU waste has relatively high concentra-

[6] Greater-Than-Class-C low-level waste is not deemed generally acceptable for near-surface disposal, currently is stored, and has no ultimate disposition path under development. In its FY2005 budget request, DOE sought to create a program within a new Office of Future Liabilities to take responsibility for disposal of Greater-Than-Class-C waste (DOE, 2004).

[7] This waste was not considered HLW when it was disposed of and may not be considered HLW under Section 3116 of the Defense Authorization Act of 2005.

tions of long-lived radionuclides or of radionuclides that will decay into long-lived radionuclides.[8] Remote-handled TRU waste has higher concentrations of short-lived fission products and so appears higher in the figure. The concentration of radionuclides in spent nuclear fuel depends on the burnup of the fuel (i.e., how many fissions have occurred per unit fuel). Lightly irradiated fuel has relatively low concentrations of radioactivity.

2.2 WASTE STREAMS THAT MAY NOT WARRANT DEEP GEOLOGIC DISPOSAL

Finding 2: Some waste currently classified as TRU or HLW may not warrant disposal in a deep geologic repository, either because (1) it is infeasible to recover and dispose of every last bit of waste that might conceivably be classified as TRU or HLW or (2) because the effort, exposures, and expense associated with retrieval, immobilization, and disposition in a repository may be out of proportion with the risk reduction achieved, if any.

As Chapter 1 and the discussion above show, HLW and TRU waste classification schemes define waste based primarily on their source. Source-based schemes are often the best way to manage classification for a number of reasons. They tend to be simple and easy to apply. Waste classification systems are normally established without knowing the specific characteristics of all of the waste streams that will be produced. A source-based classification system is thus useful because it avoids problems with some other systems that require revision of the waste classification system for each new waste stream or advance in treatment technology. In addition, it can provide direction to the implementing agency or agencies so that plans for treatment and disposal, and allocation of costs and responsibilities, can be made at the waste's source.

Source-based classification systems have certain disadvantages, too. One potential drawback is that such systems lack flexibility to reclassify waste or to treat waste in such a way that it minimizes impacts to human

[8] The New Mexico Environment Department fined DOE for shipping TRU waste that had failed to meet waste acceptance criteria due to low radionuclide concentrations from the Idaho National Engineering and Environmental Laboratory to the Waste Isolation Pilot Plant.

health and the environment. In the United States disposal options are dictated by the waste class (i.e., waste of a given class may be disposed of only in the manner designated for that class), and when the class is based on the source rather than on the measurable characteristics of the waste, the disposition options may not match the risks posed by the waste. Some source-based definitions accommodate flexibility by providing for exceptions or exemptions of waste, based on meeting a very stringent set of health or risk-based criteria. Chapter 3 contains a more detailed discussion of these classification schemes and an analysis of the "over- and underinclusive" problem of defining waste. Chapter 3 also sets out the basis for the committee's transparent and constrained risk-informed process for considering alternative disposal.

As case studies, the committee selected three waste types that are illustrative of the reasons for considering alternatives to disposition in a deep geologic repository for some HLW and TRU:

1. They appear to include wastes that are relatively low in radioactivity and/or hazard compared to other HLW and TRU waste that DOE manages, and perhaps could be managed in some manner other than disposition in a deep geologic repository.

2. For some of these wastes it is infeasible to recover and dispose of every last bit of waste that might conceivably be classified as TRU or HLW.

3. The effort, exposures, and expense associated with retrieval, immobilization, and disposition in a repository may be out of proportion to the risk reduction achieved (if any).

For the same reasons, these waste types also contain specific waste streams that DOE could consider as candidates seeking approval for alternative disposal if a process for considering such matters were to be put in place. The waste types are

1. HLW remaining in tanks ("heels"),

2. low-activity products from treatment of HLW, and,

3. buried TRU waste (not buried in a manner that facilitates retrieval).

Finding 3: The committee makes no recommendation whether specific wastes should be approved for alternative disposal, but it has identified three waste types that contain waste streams that merit consideration: (1) HLW remaining in tanks (heels); (2) low-activity products from treatment of HLW; and (3) buried TRU waste (not buried in a manner that facilitates retrieval).

The remainder of this chapter provides a discussion of the three waste types. The first two of these are discussed together in the next section to avoid redundant descriptions of the tank wastes. Note that whether or not the waste streams are indeed of relatively low radioactivity and low risk, and whether the cost of cleanup is indeed disproportionate to benefits, have to be evaluated independently as part of any potential exemption process.

HLW Remaining in Tanks (Heels) and Low-Activity By-Products from Treatment of HLW

DOE is responsible for managing and disposing of wastes from nearly 250 tanks containing HLW at the Idaho National Engineering and Environmental Laboratory, the Savannah River Site, and the Hanford Site. The wastes are diverse, comprising a highly heterogeneous mix of chemicals with the radioactive and non-radioactive constituents in a variety of physical and chemical forms. The plans for these wastes established in existing compliance agreements at various levels of detail are conceptually similar.

Waste in HLW Tanks at Hanford

Chemical separation plants at Hanford dissolved the irradiated fuel from on-site plutonium production reactors. The HLW generated from these operations was pumped to underground tanks that were grouped in sets called tank farms. Several different chemical separation processes were used at Hanford at different times, and some waste streams were subjected to further separations to recover residual uranium and to separate cesium and strontium. As generated, the wastes were acidic, but sodium hydroxide was added to reduce the corrosive effects of the waste on the carbon steel used to line the concrete tank structures. This neutralization step increased the waste volume dramatically and resulted in the precipitation of many constituents out of the liquid waste and settling of these constituents to the bottom of the tanks as sludge. Waste varies from tank to tank, but in many tanks the waste can be understood as existing in three roughly defined phases: the sludge, which contains most of the actinides and strontium; a soluble crystalline solid called saltcake; and a liquid supernate. The latter two phases contain some strontium and most of the cesium, iodine, and technetium. Complicating these waste streams are other materials that were added to the tanks, such as debris, cement, diatomaceous earth, and broken or obsolete contaminated equipment.

Until 1964, all of the tanks at Hanford were constructed with no second liner to contain waste in case of a failure of the primary tank liner. There are four different designs of these 149 single-shell tanks.[9] At least 67 of the tanks have leaked between 2700 and 5400 m^3 (750,000 and 1.5 million gallons) of HLW into the ground (Gephart, 2003). Another 28 tanks were constructed after 1964, all with a secondary liner, so they are called double-shell tanks. Because of leaks in some of the single-shell tanks, the pumpable liquids from those tanks have been pumped into the double-shell tanks.

Hanford now has approximately 196,000 m^3 (54 million gallons) of HLW, about 60 percent in single-shell tanks and about 40 percent in double-shell tanks (Wiegman, 2004). The saltcake and sludge (which each constitute about one third of the waste each) in the single shell tanks contain a little over 100 million curies (MCi) of radioactivity. The double-shell tanks have a little over 90 MCi contained in waste consisting mostly of liquids, but also sludges and salts (Wiegman, 2004).

HLW must be retrieved from the tanks and immobilized for eventual disposal in a deep geologic repository. For most tanks, DOE currently plans to use techniques such as dissolution and sluicing followed by pumping of the resulting solutions and slurries from the tank, ultimately using steam jets and vacuum heads to get at the last portions, although some amount of waste (the heel) is expected to be irretrievable using these techniques. DOE estimates that if it immobilized all of the retrieved waste for disposal in a geologic repository without putting the HLW through a separations process, Hanford would generate more than 100,000 canisters of HLW (GAO, 2004). This is lower than a 1993 estimate reported in a 1995 report (NRC, 1995a) which put the figure at

[9] For a description of the tanks and the wastes, see Gephart (2003).

220,000 canisters. In either case, the disposal cost of such an approach (estimated at more than $65 billion now, up from $15 billion in 1993; GAO, 2004) was deemed by DOE to be too high compared to the risk reduction achieved relative to alternative approaches.[10]

An alternative approach (one referred to as the "baseline" approach, which was agreed to by the parties to the existing compliance agreements) is to chemically process the retrieved waste to concentrate most of the radioactivity in a high-activity waste stream and concentrate most of the nonradioactive chemicals and relatively small amounts of radionuclides in a relatively low-activity waste (see Sidebar 2.1). This reduces the volume of high-activity waste and creates a larger waste stream of lower-activity waste,[11] but the latter waste stream is planned for immobilization and near-surface on-site disposal.

The amounts in each category depend on the details of the approach, but the current plan at Hanford would produce up to 14,500 canisters (15,700 cubic meters [m^3]) of vitrified high-activity HLW (DOE, 2002b) and around 270,000 m^3 of low-activity waste for disposal on-site. The overall cost of this approach, which sends all of the waste through the Hanford Waste Treatment Plant, is estimated by the U.S. Government Accountability Office (GAO) to be $26 billion (net present value; GAO, 2004).[12] However, because of the large amount of vitrified low-activity waste compared to the glass production rate of the planned low-activity vitrification facility, the baseline plan does not meet the 2028 completion date agreed to in the federal facility agreement for Hanford (Hanford FFA, 2003). The DOE accelerated cleanup effort has proposed cost and schedule savings by sending more than half of the low-activity waste to "supplemental treatment," instead of through the Waste Treatment Plant. Supplemental treatment options include bulk vitrification, steam reforming,

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[10] This view was not shared by some people who spoke before the committee, most notably some of the representatives from American Indian nations.

[11] Because of the difficulty of removing them, current treatment plans leave the fission products technetium-99 and iodine-129 in the low-activity waste stream. These radioisotopes are long-lived and mobile in the environment.

[12] The values reported here for GAO's estimates are the mean values. The range on these values is as small as about ± 7 percent for some estimates and as large as ± 12 percent for others. These ranges do not affect the general conclusions that can be drawn from looking at the mean value. The committee has not examined these cost estimates in detail but observes that past project costs often have differed from estimates by far more than 12 percent, most commonly exceeding estimates.

containerized grout ("caststone"), and sulfate removal (to enable more effective processing in the Waste Treatment Plant). GAO estimates that DOE's accelerated cleanup plans could save $12 billion.

Sidebar 2.1: Plans for Tank Wastes

The generic description of DOE's plans for processing and immobilizing leads to three wastes requiring disposal:

1. HLW glass logs produced by adding glass-making materials to the high-activity waste, melting this mixture to drive off water and some volatile anions such as nitrates, and pouring the molten glass-waste mixture into stainless steel cylinders where it solidifies, these glass logs are to be stored on-site until they can be transported to and emplaced in a geologic repository presumed to be the proposed site at Yucca Mountain, Nevada;
2. an immobilized, solid, low-activity waste that is to be buried in near-surface disposal facilities established at the site; and
3. tanks containing residual waste that are to be filled with grout or other stabilizing and immobilizing materials.

It is not technologically possible to remove every gram of HLW from the tanks without removing the tanks themselves. Few are suggesting that the tanks be exhumed, decontaminated, and reburied because the costs (estimated by DOE at $6 billion and by GAO at over $67 billion for all of the single shell tanks; GAO, 2004) are likely to be far out of proportion to any human health risk reduction. It stands to reason that the risk to workers involved in this effort would be considerable. Yet some HLW residuals will remain in the tanks. The amount, concentration, and form of that tank heel, along with the barriers that should be emplaced to isolate the residual waste, are central issues in the disposition debate. Present plans based on compliance agreements call for DOE to remove either 99 percent of the volume of HLW (the allowable remainder volume weighted according to the capacity of each single-shell tank) or the limit of waste retrieval technology capability, whichever leaves less in the tank. At its site visits, the committee received comments that this standard is, variously, reasonable, unrealistic, arbitrary, not connected to risk, and leaving a lot in the ground.

The extent of retrieval depends on the physical and chemical form of the waste in the tank, the physical structures within the tank, physical access to the tank, and the technology used to retrieve the waste. In the single-shell tanks at Hanford, the wastes are highly heterogeneous, and the tank heels will range from hard, insoluble crusts to thick, claylike layers and patches to viscous sludge. It is possible that sluicing, dissolution, and more aggressive methods for recovering the wastes from single-shell tanks could lead to further leaks, although this has not been demonstrated to be the case.[13] The physical design of the older tanks makes waste retrieval quite challenging. Tank access ports are limited in number and size, which will impede access to the tank contents, and many of the tank bottoms are uneven and contain internal structures that further complicate waste retrieval.

DOE's current plan, once a regulatory decision has been made determining a tank waste-retrieval operation is complete, is to fill the tank with materials to aid in immobilizing the residual tank contents[14] and to provide structural support to avoid future tank collapse that could lead to water ingress (DOE, 1997b). Other engineered barriers would then be placed over and perhaps around the tanks. DOE has not selected the material that would be used to fill the Hanford tanks.

Waste in HLW Tanks at the Savannah River Site

The Savannah River Site (SRS) has approximately 135,000 m^3 (37 million gallons) of HLW: 123,000 m^3 (34 million gallons) of saltcake and supernate containing 204 million curies (MCi), and 11,000 m^3 (3 million gallons) of sludge containing 215 MCi of radioactivity. All of the 51 HLW tanks at the SRS have a secondary layer of containment,

[13] One can reason that mobilizing encrusted radionuclides and spraying high-pressure jets into a tank that has leaked would probably result in further leakage through the same perforations and that leakage might further mobilize wastes that have already leaked into the soil immediately around the tanks. Alternatively, one could hypothesize that the perforations only leak when there is a substantial weight load in the million-gallon tank, and that the half-inch thick steel can withstand water jets, even if the steel is somewhat corroded. The behavior has not been tested, but the risk of further leakage might not be worth taking.

[14] The NRDC has questioned the effectiveness of DOE's approach with respect to immobilizing the residual waste, arguing that DOE has not properly accounted for the radioactive constituents of the waste (Cochran, 2003).

although 24 of the oldest ones have only a secondary pan (sometimes described as a "saucer" to the tank "teacup"). Most of these "noncompliant" tanks have a history of cracks or leakage (WSRC, 2004),[15] but only one is believed to have leaked a small quantity of waste to the environment (Davis et al., 1977). Compared to the Hanford single-shell tanks, the Savannah River tanks are in relatively good condition. Two of the tanks have been closed and filled with grout, and three more are empty, to the extent DOE has deemed technologically and economically practical. The other 46 tanks contain wastes that are less chemically varied (produced by and subjected to fewer chemical processes and containing less troublesome additives) than those at Hanford and are generally more amenable to retrieval than the Hanford wastes because they are more soluble and access within the tanks is easier.

DOE has been retrieving waste at the SRS and piping the sludge in the form of slurry to the Extended Sludge Processing Facility for sludge washing (removing the soluble nonradioactive chemical components) and then to a vitrification facility, called the Defense Waste Processing Facility, which began operations in 1996. So far, SRS has produced more than 1750 canisters of HLW, vitrifying about 2.9 m^3 (800 gallons) of sludge to produce about 2000 kilograms (4400 pounds) of waste glass for each waste canister. The plan, under which DOE has processed its HLW, as approved by the State of South Carolina, would send all of the retrievable sludge to the Defense Waste Processing Facility. Some 300,000 m^3 of salt waste, made up of the supernate and saltcake dissolved in water added to the waste, containing 207 MCi of radioactivity (including 201 MCi of cesium-137, or nearly 95 percent of the site's cesium-137) is to be pumped to a Salt Waste Processing Facility, which is to extract over 99.9 percent of the radioactivity, concentrate it in 11,000 m^3 of waste, and send that to the vitrification plant. The remaining radioactivity (75 kCi, including 10 kCi of cesium-137, 20 kCi of technetium-99, 200 Ci of strontium-90, and 500 Ci of actinides) residing in a dilute solution in 315,000 m^3 of liquid would go into a low-activity waste form, called Saltstone, for disposal in near-surface vaults on-site.

Despite the fact that the Savannah River Site's wastes are easier to retrieve than those at Hanford, DOE still has difficulty recovering the last

[15] Thirteen tanks are known to have leaked waste out of the primary containment. Most of these leaks were small and some dried before the waste reached the secondary containment pan (WSRC, 2004).

fraction of the waste from the tanks. The two tanks that are grouted had on the order of a thousand gallons of residual waste (approximately equivalent to one inch in the bottom of the larger tanks) in each tank bottom. The approach used to isolate the heels in these tanks is to fill the tanks with successive layers of various types of cementitious grout to inhibit water access to the heel and collapse of the tank due to deterioration. Initial layers of grout are designed to establish reducing conditions in the tank that serve to minimize the solubility and mobility of most radionuclides. Other layers are designed to provide structural support. The nature of the engineered barriers if any, to be considered outside of the tanks has not yet been decided.

The Savannah River Site also has had difficulty developing the chemical processes to be used in the future Salt Waste Processing Facility. After it was found that the preferred approach, an in-tank precipitation process to remove cesium, unexpectedly generated large amounts of benzene, DOE asked the National Research Council (NRC, 2000a) to make recommendations on how DOE should develop the needed technology and bring the facility on-line. The NRC committee appointed for that study recommended that DOE pursue several technology options until a preferred technology option is proven to work. The committee also noted that the wastes vary dramatically in chemical composition, so DOE may want to use different technologies for different wastes—a tailored approach. DOE is still working to develop the technologies and the facility for this processing.

Saltstone is DOE's name for the cementitious waste form used at Savannah River to immobilize liquid waste from processing HLW that is being sent to the vitrification plant. The reference composition of Saltstone is given in Table 2.1. It is made up of Portland cement, blast-furnace slag, and fly ash mixed almost one-to-one with the waste salt solution.

TABLE 2.1 Saltstone Reference Formulation

Ingredient	**Reference Saltstone Dry Solids Premix (wt. %)**	**Reference Saltstone (wt. %)**
Portland cement, Type I	8	54
Slag, grade 100	46	
Fly ash, class F	46	
Reference salt solution, 29 wt. % salt	NA	46
Water: cementitious solids ratio	NA	0.605

Source: WSRC, 2001.

The Saltstone Facility is a fairly simple operation that mixes the waste flow with the cement ingredients and pumps the mixture out to disposal vaults. Concentrations of radioactivity in the waste handled to date have been low enough to allow unshielded operation. DOE has already filled one six-cell concrete vault with Saltstone and has begun filling a 12-cell vault. Each cell holds approximately 6600 m^3 of the waste form. Once a vault is filled, the monolith is mounded over to direct water away from the waste and to provide earthen shielding of radiation from the waste. The majority of Saltstone production has not begun because the Savannah River Site so far is processing and immobilizing only the sludge from its HLW tanks, and the vast majority of the salt waste will come from processing the saltcake and supernate from the tanks.

DOE has shut down all work at the Saltstone facility pending resolution of the *NRDC v. Abraham* (2003) decision. The NRDC and the states of Washington, Idaho, and South Carolina have contended that DOE need not have ceased this operation under the terms of the Idaho District court decision in *NRDC v. Abraham*.

DOE has proposed to accelerate processing of HLW by sending less waste through the Salt Waste Processing Facility. The proposed plan, called "tailored salt processing," would separate the salt waste into three streams by draining the liquid (which will carry most of the cesium), and then sending the high-curie, high-actinide salt (including the liquid with the cesium) to the Salt Waste Processing Facility, which would operate as before, with cesium and actinides going to the Defense Waste Processing Facility and decontaminated salt solution going to Saltstone. The remaining salt, from which liquid was drained, is called "low-curie salt" and "low-curie, high-actinide salt." The former would go directly to Saltstone. The latter would go through an actinide removal facility, sending the actinides to the Defense Waste Processing Facility and the rest to Saltstone. This would leave 17.6 MCi of cesium-137, 1.7 MCi of strontium-90, 100 kilocuries (kCi) of actinides, and 20 kCi of technetium-99 in the Saltstone.[16] Another way of looking at this is that the cesium in Saltstone would increase by a factor of 1750, the strontium by a factor of 8400, and the actinides by a factor of 200, while the technetium content would stay the same. The concentrations would not rise by similar factors because the overall quantity of Saltstone would increase significantly, but a new Saltstone Facility would be required to allow shielded operation.

DOE says this would save $7 billion and enable it to finish shipping canisters to a HLW repository up to 20 years sooner. One of the advantages, from DOE's perspective, is that waste would be removed from the tanks and solidified earlier. Another is that DOE can start processing some wastes now and bring the Salt Waste Processing Facility on-line later when DOE has fully developed the technology to make the facility accomplish its design goals.

Waste in HLW tanks at INEEL

DOE has 11 underground tanks used for storage of liquid radioactive waste in the Idaho Nuclear Technology and Engineering Center Tank Farm at the Idaho National Engineering and Environmental Laboratory (INEEL). These tanks are among the newest in the DOE system and are much smaller than those at either the Savannah River Site or Hanford. This allows good access to most parts of the tank. In addition, most of the waste is from chemical processing of spent nuclear fuel from the Naval Reactors Program, which uses highly enriched uranium fuel. The purpose of this processing was not to recover plutonium for the weapons

[16] This could bring the waste concentrations close to the class C limits found in 10 CFR 61.55.

program, but to recover the residual highly enriched uranium. However, some of this highly enriched uranium remained in the waste after separation, and to avoid criticality accidents that could occur if too much uranium precipitated in the tanks, the waste was not neutralized. The tanks had to be constructed of stainless steel to contain the acidic waste.

Most of the HLW generated at INEEL was sent to a facility that calcined the waste, that is, rapidly oxidized the waste into a granular solid, likened to laundry soap, which was stored in large, stainless steel bins. This waste which currently contains about 44 MCi of radioactivity, is to be immobilized in a form suitable for disposal in a HLW repository and then shipped out of the state for disposal. For the roughly 500 kCi of radioactivity in 3600 m^3 of liquid radioactive waste remaining at the Idaho Nuclear Technology and Engineering Center tank farm (INEEL, 2004), DOE estimates that 1-3 percent by volume is liquid waste from the first cycle of reprocessing (what DOE considers HLW) and 20-30 percent is from second and third cycle liquids. The remainder consists of decontamination washing solutions from the calcine facility, evaporator bottoms, and other process wastes.

"Sodium bearing waste" is the term used to describe the mixture of liquid wastes from all of these sources except the first cycle of reprocessing (DOE, 2002c). This liquid waste stream has substantial quantities (more than 2 moles per liter) of sodium nitrate salts, resulting from the addition of sodium hydroxide to the washing solution to enhance its effectiveness in removing some residues. The mixture was concentrated through evaporation, and some was sent through the calciner to produce calcine waste, although the high sodium content makes the direct calcination process perform poorly, so treatment prior to calcination is needed. DOE is now consolidating all of its wastes from the tanks into three of the roughly 1100 m^3 (300,000 gallon) tanks while it cleans seven other tanks. An eleventh tank is a clean spare. The consolidation operation will further commingle the waste.

The vast majority of the waste is in a liquid form, but a small amount of insoluble solids can be found at the bottoms of the tanks. Samples from several tanks were analyzed extensively. In a typical tank, the liquid contains a higher concentration of strontium than do the solids, and the solids have a higher concentration of cesium than the liquid. In tank WM-187, for example, strontium and cesium together contribute 97 percent of the total radioactivity of 0.22 Ci per liter. Isotopes of plutonium (mostly plutonium-241 and plutonium-238) constitute 1.9 percent (Barnes et al., 2004). The classification of this waste has been in dispute and is the subject of litigation. The State of Idaho considers this waste to be HLW; DOE considers the waste to be mixed transuranic waste.

Waste processing at INEEL has an important difference from that at the other two sites: there are no plans to perform chemical separations on the liquid waste to generate a high-activity fraction and a low-activity fraction. All of the waste is to be converted to a solid waste form, although the technology to be used and the waste form have not been finalized.

Buried TRU

As noted in Section 1.2, "buried TRU" is waste that meets the definition of TRU waste, but was disposed of in near-surface pits and trenches prior to the practice of retrievable storage for disposal at the Waste Isolation Pilot Plant (WIPP).

Buried TRU at INEEL

The Idaho National Engineering and Environmental Laboratory contains the Radioactive Waste Management Complex (RWMC) in the southwest portion of the site. The RWMC consists of about 177 acres contained within natural and constructed earthen dikes and was established in 1952 to handle the testing station's waste. It was also the disposal location, starting in 1954, for virtually all of the radioactive waste generated by the Rocky Flats Plant in Colorado and shipped off-site.[17] Indeed, practically all (on the order of 95-98 percent) of the waste in the RWMC is from Rocky Flats.

The Subsurface Disposal Area, a 97-acre portion of the RWMC, has been used to dispose of 56,920 m^3 of radioactive waste from Rocky Flats, INEEL, and a few other sites. This waste includes buried TRU (ordinary TRU and mixed TRU waste "irretrievably" disposed prior to 1970), alpha-LLW (ordinary and mixed low-level waste [LLW] that contains TRU isotopes with alpha activity between 10 and 100 nCi/g), and LLW (mixed LLW until 1984 and ordinary LLW to the present). For regulatory purposes, both buried TRU and alpha-LLW, an estimated total

[17] Large amounts of waste remained onsite at Rock Flats, mostly in the form of contamination in buildings, in pipes and equipment, and in the soil.

36,800 m^3 containing 297,000 Ci of TRU radioactivity (DOE, 2000),[18] are being managed by INEEL as TRU waste. Much of the site is slated for cleanup under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and the preliminary plan was to exhume most of the buried TRU waste from the RWMC (about 90 percent by volume and about 70 percent of the TRU radioactivity). The retrieved waste would be treated and shipped for disposal at WIPP.

The waste was disposed of in several units:

- 20 pits containing contact-handled TRU waste (pits 1-6, 8-12), LLW, and volatile organic compounds;
- 58 trenches containing remote-handled TRU waste (trenches 1-10, 19, 32) and LLW;
- 21 soil vault rows (narrow trenches with concrete lining) containing remote-handled TRU and LLW;
- Pad A containing LLW and waste contaminated with nitrate salts and uranium; and,
- one acid pit containing partially grouted, contaminated soil.

The management of TRU waste is difficult in a number of ways: it poses serious radiological hazards (to varying degrees); some (so-called mixed waste) also poses toxicological hazards; a small portion is fissile material, which raises criticality concerns; and it is also possible that classified waste was mistakenly disposed of, which raises security concerns, although the Rocky Flats Plant assured INEEL that this is not the case. Waste from the post-1970 period appears to have been well documented when placed in storage, and its present configuration was designed to facilitate retrieval. (The process of characterizing it and preparing it for shipment off-site is nevertheless extraordinarily elaborate and expensive.) However, the pre-1970 material in the Subsurface Disposal Area is highly miscellaneous—photographs of the disposal process show barrels, boxes, trucks, industrial equipment, and debris simply dumped into the disposal units—and was not meant to be retrieved. Through an

[18] This represents only the radioactivity from isotopes meeting the definition of TRU, decay corrected to 2006.

effort termed *Ancillary Basis for Risk Analysis* (Holdren et al., 2002; Zitnik et al., 2002), INEEL has identified several contaminants of concern for each pathway from the Subsurface Disposal Area.

Pit 9 was chosen as a demonstration case for remediation of the operable unit that covers the Subsurface Disposal Area under CERCLA. Pit 9 was selected because it is at the western edge of the Subsurface Disposal Area, near the road access, so operations there are unlikely to disturb other pits and trenches, and because waste in the pit was disposed of more recently, so records were expected to be more useful for characterization. Efforts at carrying out the selected remedy (physical separation, treatment, and stabilization) proved much more difficult than expected, mostly because of contamination of the soil in the pit, which poses inhalation hazards. After spending tens of millions of dollars on subsurface characterization and after a $200-million failed start with the first attempt at limited retrieval, DOE successfully completed a demonstration project (the glovebox excavator method, or GEM, pilot project) that recovered about 454 barrels (about 77 cubic meters) of waste from Pit 9 at a cost of $79 million (including the cost to build the facility).

Buried TRU at Hanford

By volume, the Hanford Site has more buried TRU waste than any other site, with a total of 75,800 m^3. But this waste contains a little over 60,000 curies of TRU activity, or about one fifth as much as INEEL's buried TRU waste (DOE, 2000). In addition, Hanford has over 31,000 m^3 of TRU-contaminated soils containing 32,400 curies of TRU activity as a result of liquid waste discharges in cribs, ditches, and trenches. DOE plans to manage most of these wastes by containing them in place.

Two companion burial grounds that DOE plans to exhume (DOE, 2000) likely constitute some of the most difficult technical challenges faced by DOE with respect to TRU waste at Hanford: The 618-10 and 618-11 Burial Grounds. This summary is based on information provided to a workshop of technical experts sharing experience in dealing with buried TRU waste (Hulstrom, 2003) and on information provided during the committee's visit to the Hanford Site.

The 618 Burial Grounds received waste from the Hanford 300 Area. The 300 Area was used for fuel fabrication, research and development activities (pilot-scale tests) supporting the development of processes used in the 200 Area (e.g., PUREX), and other activities such as those developed in the Plutonium Recycle Test Reactor (PRTR) facility. Exact inventory records are limited and often contradictory and, in some cases, based only on interviews with people who operated the facilities.

The 618-10 Burial Ground, which operated from 1954 to 1963, occupies approximately 2.3 hectares (5.7 acres) about 3.8 kilometers west of the Columbia River. It contains an estimated 98,000 m^3 of waste, including 8.4 m^3 of remote-handled transuranic waste (RH–TRU). These 8.4 m^3 are the only TRU wastes in the burial ground. Wastes were disposed of in 12 trenches and 94 "vertical pipe units." Most trenches are presumed to contain low-level waste and low-level mixed waste. The vertical pipe units are estimated to contain a mixture of low-level mixed waste and RH–TRU. In 1961, a fire occurred in one trench. During stabilization operations in 1983, oil puddled to the surface indicating the breach of a container and the presence of liquids.

The 618-11 Burial Ground operated from 1962 to 1967. It spans 8.6 acres and is located 3.6 miles west of the Columbia River. The 618-11 Burial Ground contains an estimated 78,000 m^3 of waste, with 94 m^3 of RH–TRU and 10,200 m^3 of contact-handled transuranic waste (CH–TRU). Wastes were disposed of in three trenches, 50 vertical pipe units, and three to five caissons. Similar to the 618-10 Burial Ground, the trenches predominantly contain low-level waste and low-level mixed waste. The vertical pipe units and caissons are estimated to contain mostly RH–TRU.

The radiological hazards presented by these burial grounds include cesium, strontium, thorium, uranium, plutonium, americium, curium, and neptunium. Other hazards include beryllium, uranium, and zirconium metals, and sodium-potassium metals (some of which are pyrophoric), petroleum products, and organic chemicals. The wastes believed to be in the burial grounds include spent nuclear fuel, HLW, CH– and RH–TRU waste (some mixed), and LLW (some mixed). Hanford officials informed the committee that radiation levels at the edge of the burial grounds have been measured to be as high as 5 rem per hour and contact doses as high as 500 rem per hour. Although the general practice was to place the higher-activity waste in the vertical pipe units or caissons, some such waste likely exists within the trenches.

The waste is both a source of environmental contamination and a hazard to remediation workers and inadvertent intruders. A tritium plume in the vicinity of the 618-11 Burial Ground has concentrations of 8.1 million pCi/L (400 times the drinking water standard). The estimated time for a contaminant to travel from the burial grounds to the Columbia River is between 3 to 30 years. As noted above, the RH–TRU waste may have contact doses of up to 2500 times the contact-handled limit. Further, some pyrophoric waste (easily ignited materials) may be present in the burial grounds (Hulstrom, 2003).

Cleanup of these burial grounds is difficult because the contents are poorly characterized, diverse, reactive, and intensely radioactive. DOE is currently exploring technologies that might be used for cleanup. However, there is no clear plan or schedule for such cleanup, and DOE representatives expressed the hope that these burial grounds could be closed without retrieval because of the high cost and occupational risk anticipated in any attempt to retrieve and treat the wastes.

2.3 THE NEED FOR FLEXIBILITY IN DISPOSAL OPTIONS IDENTIFIED

The foregoing descriptions of three waste types and plans for managing them illustrate the variability in the composition and condition of each waste type and the costs of retrieval or waste-form production. This discussion does not provide a complete picture: The descriptions of the wastes could be translated into an understanding of the hazards of the wastes, but a description of exposure pathways and scenarios is needed to understand the risks they pose. The analysis of costs is incomplete, with little treatment of uncertainty and no sensitivity analysis. And other impacts, such as those on ecosystems, are not addressed. But while there is not yet sufficient analysis to support a decision on how to manage each waste stream, the information presented indicates a need.

Finding 4: The nation needs a way to decide which of the wastes mentioned in Finding 3 should be disposed of in a deep geologic repository and which, if any, should be allowed alternative disposal.

Litigation over authority and agreements about waste disposition left DOE's waste disposition program with substantial uncertainty concerning the path forward. Provisions in the Defense Authorization Act of 2005 create a process for addressing HLW at the Savannah River Site and at the Idaho National Engineering and Environmental Laboratory, although many details remain to be resolved and Hanford is not affected directly by the legislation. TRU waste already had an exemption provision, but disputes remain. Given the various disputes and the reality that not all of the waste will or can be recovered and disposed of in a deep geologic repository, an acceptable process for deciding what wastes require repository disposal is still needed. The recent legislation should remove some of the obstacles to DOE's working with others in South Carolina and Idaho to implement the approach recommended in this report.

3

Exemption Process

The description of the high-level waste (HLW) and transuranic (TRU) waste streams in Chapter 2 and the legal standards applicable to them demonstrate that the Department of Energy's (DOE's) existing HLW and TRU waste include a wide spectrum of types and amounts of radioactivity, in many physical and chemical configurations. Consequently, while the waste streams that the committee examined pose human health hazards that require active management now and into the future, they pose a *range* of hazards in the short and long terms. Thus, one might expect that a variety of disposal or disposition options would be appropriate. Current definitions and regulatory standards, however, are inflexible because they treat almost all HLW and TRU waste identically in terms of disposal options; for example, all wastes defined as HLW must be disposed of in a geologic repository designed for permanent isolation of the waste. Therefore, in this chapter the committee recommends the creation of a formal, risk-informed[1] exemption process to provide flexibility in disposal options.

[1] "QRA [quantitative risk assessment] results are never the sole basis for decision making by responsible groups. In other words, safety-related decision making is risk-informed, not risk-based" (Apostolakis, 2004).

In this chapter, the committee first provides a summary of the potential adverse impacts of not being able to consider HLW and TRU waste management strategies that are directly informed by risk, based on the more detailed discussion in Chapter 2. The committee then describes and evaluates alternative approaches to ameliorate the adverse impacts while not sacrificing the core values[2] underlying present approaches to managing HLW and TRU waste. This leads to a recommended approach. Finally, the committee provides an outline of the overall process for implementing the recommended approach.

As discussed in Chapter 1, the committee does not express an opinion on the issues currently being litigated concerning the validity of exemptions from the HLW definition. The committee assumes, however, that for both HLW and TRU waste a formal exemption process of the kind recommended here will require some kind of formal authorization by the appropriate authority—legislative, regulatory, or judicial. For these purposes, it does not matter whether the legal location for the exemption is new language in the definitions, reinterpretation of existing terms such as "highly radioactive" or "sufficient concentrations," or implementation of existing but infrequently used exemption authorities—the exemption process and its characteristics described below could apply to each of these methods.

The committee does *not* recommend that DOE attempt to adopt these changes unilaterally, either through the classification system or by other means. Unilateral action seems likely to exacerbate the sense of mistrust that has developed between DOE and at least some of the parties that are its partners in seeking site cleanup. The exemption process that the committee recommends must also be implemented in the context of DOE's existing or renegotiated compliance agreements. While the committee is aware that there is a widely held view that these agreements contain economically or technically infeasible requirements, the committee strongly cautions against any unilateral abrogation by DOE of any existing agreements. The present classification system is the basis for several such agreements; thus, making the case for an exemption is the necessary prerequisite to any changes—including disposal options—in those agreements. Rather, to the extent that DOE can obtain the consent

[2] These include, most importantly, adequate protection of human health from radiation hazards, protection over the long term (approaching the period during which most radioactive materials remain hazardous), and accounting for the uncertainties in long-term waste management.

of its compliance agreement partners to deviate from its current obligations, a risk-informed exemption process, as described below, is the committee's recommended approach. Put another way, if DOE wants to renegotiate its compliance agreements, it must make a case for renegotiation that is informed by risk, sets out clear criteria for an exemption, comprehensively addresses health risks (including worker, transportation, and long-term risk), and follows a transparent process that allows meaningful public input. Finally, the committee's recommendation of a process for exemptions or exceptions should not be taken to mean that any particular waste stream is suitable for exemption; rather, exemptions must be decided on a case-by-case basis, through the process described herein.

3.1 THE PROBLEM: INFLEXIBILITY IN PURSUING APPROPRIATE MANAGEMENT STRATEGIES

The existence of inflexibility concerning disposal strategies for HLW is based on the committee's understanding of the wastes that were examined, the capabilities of current technologies, and the present regulatory system as interpreted by the courts.

The Problem of Inflexibility

The need to manage all HLW by disposal in a permanent geologic repository and the strong preference for disposing of TRU waste in the same manner represent extremely expensive options, and, indeed, push or exceed the limits of technical feasibility in some cases. Requiring retrieval and permanent geologic disposal also entails additional risks from the retrieval work and transportation, for example, that might be quite high. For these reasons, as described in Chapter 2 and above, DOE has in the past sought and obtained from the U.S. Nuclear Regulatory Commission (U.S. NRC) informal or ad hoc exemptions from the definition of HLW to allow for near-surface disposal of HLW and from the U.S. Environmental Protection Agency (U.S. EPA) to allow near-surface disposal of TRU waste. DOE now seeks the advice of the National Research Council on a risk-informed approach to management of these wastes.

All rules generalize, which means that all rules create problems of over- and underinclusiveness. That is, they include some regulated items that probably should not be in a category and omit or exclude others that should be included. In fashioning a rule, therefore, the question is not whether to generalize, but how much over- and underinclusiveness to tolerate as the cost of simplicity. Like all rules, an inherent part of the definitions of HLW and TRU waste is that they are under- and overinclusive with respect to particular waste streams.

For example, the definition of TRU and the consequent requirement of permanent geological disposal may be overinclusive with respect to some buried TRU waste in very arid and controlled environments where radionuclide migration is expected to be small as a result of the absence of water and intrusion not being expected because of institutional controls and minimal pressures from human activities. Conversely, it may be underinclusive, at least with respect to human health risk, as compared to high-activity, long-lived low-level wastes. An example might be the waste storage silos at Fernald, in which radon-226 levels exceed 100 nanocuries per gram (nCi/g). The so-called K-65 waste resulted from processing of exceptionally rich uranium ore that was obtained during and very shortly after the Second World War. Although radium is not transuranic, the K-65 wastes produce a substantial external dose due to gamma-ray emission and the risks they pose may even exceed those posed by some transuranic wastes and are at least similar based on the intrinsic toxicity of the isotopes involved.

Under- and overinclusiveness are in the nature of all rules of general applicability. The drafters of general rules are rarely able to anticipate all of the circumstances to which they will apply, and new circumstances often appear that make previous assumptions obsolete. Moreover, general rules often build in under- or overinclusiveness as a way of making a point of principle or as a means of simplifying administration of and compliance with the rule. The question, therefore, when over- or underinclusiveness is found is not how to eliminate it, but how to manage it.

Managing Over- and Underinclusiveness in Regulation

There are two decision points that create the inflexibility in management of HLW and TRU waste. The first is the classification decision, in which the waste products of certain processes and materials with certain atomic composition are automatically designated HLW and TRU waste, respectively, with little or no real opportunity for adjustment based on other factors, such as risk or hazard. The second is the disposal decision, about which the legal structure is extremely prescriptive: if the waste is classified as HLW or TRU waste, it must be disposed in a geologic repository unless, in the case of TRU waste, an exemption is applied for and approved by the U.S. EPA. The result is a highly inflexible system, as described in Chapter 2. Logically, one could create flexibility in one or both of two places: the classification decision or the disposal decision. The committee has chosen to consider flexibility in the classification decision only, for four reasons:

1. It more readily accommodates the kind of exemption that the committee recommends.

2. Classification has been for some time the focus of concern with the disposal provisions for HLW and TRU waste.

3. Such an approach requires the least change in the fundamental structure of the existing HLW and TRU waste disposal requirements.

4. Most importantly, it poses a familiar regulatory problem of overinclusive categories, which has familiar solutions.

Additionally, if the focus is the disposal decision, the inevitable result of an approved exemption would be the existence of at least two types of HLW—for example, "near-surface" HLW and "deep-geologic" HLW—which is sure to result in confusion. It would be a mistake, however, to see the two areas of flexibility as entirely separate. As is plain in the discussions of the exemption process in Section 3.2 of this chapter and of a risk-informed process in Chapter 4, flexibility in classification will require careful consideration of the characteristics, especially as they relate to risk, of alternative disposal options.

The existing system for managing HLW and TRU waste is inflexible because it is based on a system of categories with predetermined consequences. It is a common, if not universal, characteristic of regulatory systems that they establish certain categories at the outset and then specify the different consequences that flow from being placed in one category or another. This is a conceptually simple and administratively manageable way to apply general rules to variegated reality. Moreover, since regulators are not omniscient, it is a way to limit the universe of considerations to those for which the information is obtainable at a reasonable cost (Karkkainen, 2001). It is also common, if not universal, that categories are over- and underinclusive in the sense that they cover either more or fewer—or, often, both—instances than their rationale would indicate should be covered.

There are a few generic ways to handle the problem of over- and underinclusiveness. First, one can choose a classification system that is more precisely tuned to the rationale for the differential treatment that flows from the classification. The more fine tuned a classification system is, however, the more information it requires to make classification decisions and hence the more expensive and time-consuming it is to operate. Second, one can accept overgeneralizations as the cost of an easily understandable and predictable regulatory system. Third, one could retain the general classification, because of its predictability and ease of administration, but permit exemptions where the classification demonstrably fails to fit the situation. This option can be subdivided into two cases: (1) exemptions can be granted on an ad hoc, highly discretionary basis, or (2) exemptions can be granted according to well-defined, preexisting standards.

3.2 OPTIONS FOR ALLOWING NON-GEOLOGIC DISPOSAL OF HLW AND TRU

As stated above, the adverse impacts of over- and underinclusiveness can be handled or at least moderated in four ways:

1. create new categories,
2. accept existing categories,
3. permit ad hoc exemptions, and,
4. establish formal standards for exemptions.

In this section, these options are discussed mainly as they apply to HLW, because no valid exemption currently exists for some HLW (a valid exemption does exist for TRU waste, as discussed above). The conclusions, however, are fully generalizable to TRU waste, as described below.

Option 1; Create New Categories: Establish a Generally Applicable Risk-Based Definition of HLW

One obvious solution to some of the shortcomings of the existing waste classification system is that the current definition of HLW could be replaced with a basic provision related to the factor of greatest concern—human health risk—plus a provision for case-by-case exceptions. Structuring the definition in this manner would make it similar to that of TRU waste. Such an approach would be the logical outgrowth of a general regulatory system that emphasizes human health risk as a measure across numerous areas of environmental, safety, and health regulation.

Systems based solely on risk per se—that is, systems that are finely tuned to the fundamental reason for the rules—are inherently costly to implement because they require that each instance be analyzed in detail to determine precisely how to apply the rule to it. Moreover, such screening requires more detailed information; so the data demands of a fine-tuned system are high, often challenging and sometimes exceeding the available information. A system based on risk per se would likely exhibit this drawback, not so much because of the toxicity component of the risk equation (which for radionuclides is relatively well known), but because of the exposure component, especially for long-term exposure scenarios. In addition, with a wider range of possible classifications (no longer in-out or yes-no), the outcome is far more difficult for either regulators or regulated entities to predict.

Therefore, the committee does not recommend the implementation of a purely risk-based definition of HLW as an alternative approach for management and disposition of TRU and HLW at this time for the following reasons:

1. A high degree of reliance has built up with the existing system—disposition decisions, treatment methods, investment in infrastructure (in the billions of dollars), compliance agreements, and so on. Many of these agreements have been the subject of litigation and judicial interpretation. An entirely new system would place all of these agreements and decisions—many or even most of which have not been completely fulfilled—in question, resulting in chaos in DOE's cleanup program. Whatever efficiencies would be gained by changing the management of a few, special wastes could be outweighed by the loss in efficiency of reopening dozens of completed decisions, many of which required years of data collection, analysis, negotiation, and public involvement.

2. As has been amply demonstrated with the existing definition, changing the definition of HLW could have other unanticipated consequences. Thus, such revision is not advisable without

detailed and comprehensive study to develop a reliable and defensible definition and a large amount of political will to put it in place.

3. It has not been demonstrated that revising the definition of HLW is worth the effort. Such an endeavor is worth pursuing only if a study to identify waste streams that might benefit from a thoroughly revised definition of HLW shows that the adverse impacts of the existing HLW definition are sufficiently pervasive so that the effort is warranted.

4. To a significant extent, the issue that has to be addressed is making a site cleanup decision (e.g., what amount of "heel" can be left in a tank) not a waste classification decision. While waste classification and site cleanup decisions are tightly coupled, the classification of waste as such is not directly relevant to potential risks from various cleanup alternatives.

Alternatively, one could adopt a system that, even though it was not based on risk per se, was based on a closer surrogate of risk. However, even a HLW definition more closely based on risk—for example, one based on the level of radioactivity—would be imperfect. It would replace one generalization—method of production—with a better but still imprecise surrogate of risk. It is a surrogate, because risk depends on the details of the radioisotope (its half-life and the type and energy of radioactive decay), the physical and chemical form of the specific waste stream, and disposal path. Consideration of risk itself requires consideration of exposure, which requires consideration of the actual disposal environment, which includes a consideration of the hydrology, geochemistry, population distribution, and so forth. Whereas, all in all, such a surrogate may now be considered a better proxy for what people most care about, it is still incomplete and susceptible to over- and underinclusion. Such situations could presumably be handled by adding exemption provisions similar to those in the definition of TRU waste.

Wholesale reclassification, however, would pose several dangers of its own. It could create its own set of unintended and irrational results due to unforeseen circumstances. No choice of words perfectly matches the external world they describe. So it is likely that new loopholes and ambiguities would creep into a wholly new system. Moreover, as noted above, substantial parts of DOE's environmental management program depend on agreements and decisions based on existing categories. As a result, it is clearly appropriate to consider the second option, that is, to accept an imprecise system built on generalities as the price of predictable (if inefficient) outcomes and an administratively manageable system.

Option 2; Accept Existing Categories and Retain the Current Process-Based System

Theoretically, it might on the whole be easier to work with the current process-based definition of HLW. Although risk may be the ultimate benchmark, the generating process may be sufficiently closely linked to risk that the additional effort and unpredictability may not justify the change. It is easy to dismiss the administrative costs of a classification system, but a project of the magnitude of DOE's cleanup consumes hundreds of millions of dollars each year in administrative costs. In addition, predictability is not simply a question of the ability of regulators and regulated entities to plan; it is also some assurance of fairness and even-handed treatment of the regulated entities by the regulators—a clear definition treats everyone equally in a formal sense.[3] Moreover, overinclusiveness can be a hedge against the uncertainties inherent in the general definition; that is, can err on the side of protection.

The committee declines to follow this route, however. For reasons stated in Chapter 2, the general definitions of HLW and TRU waste may well be too rigid, at least for some waste streams, so some effort to be more precise is probably "worth it" in terms of administrative complexity. Indeed, arguments for administrative efficiency and equity lose some of their force in the particular DOE context. The sheer vastness of the project and the nature of the wastes make it one of a kind. DOE is the only party responsible for this work, from generation to management and disposal—this is not an industry of thousands of licensees. Also, HLW and TRU waste constitute a relatively limited universe of wastes, and DOE already spends substantial resources in administering them, so the ability to make generic decisions may be less important here than in an ordinary regulatory system.

[3] Certainly, formal equality does not mean equal impact. Formally equal treatment can have intentionally or unintentionally disparate impacts.

Sidebar 3.1: Unintended Consequences of Environmental Policy: The Case of Brownfields

A good example of unintended consequences can be found in the Superfund program under CERCLA as it applies to the environmental cleanup of former industrial property in urban areas—"brownfields." The broad liability provisions were intended to speed cleanup efforts, to assign cleanup costs to industries that are generally responsible for the environmental harm, and to provide a deterrent to future environmental sloppiness. One consequence of the liability scheme, however, was that industrial and commercial developers avoided the reuse of existing industrial areas, even though such areas had preexisting infrastructure and other advantages, because they feared Superfund liability. As a result, urban industrial areas decayed as the industrial base changed, and new industries were built in suburban and rural "greenfields," destroying prime agricultural land, requiring new roads and highways, and contributing to the general blight of urban centers. Recent legislation has attempted to reduce the brownfields effect to remedy the unintended consequence, by providing exemptions from or limitations on liability for specific, defined formal industrial (brownfields) sites (BRERA, 2002).

Back-End Adjustments: Ad Hoc Exemptions or a Formal Exemption Process

The third and fourth options involve an exemption or "back-end adjustment" process for obtaining relief from the disposal requirements of the HLW definition (Shapiro and Glicksman, 2003).[4] Exemptions—which come in many forms—are a means of making case-by-case adjustment to general policies, because there was limited understanding of the full implications at the time a general rule was adopted, new information became available, or circumstances have otherwise changed. It is the nature of "bounded rationality" that human beings cannot know the full implications of regulatory actions they take at the time they take them. They recognize "that formal rules are unlikely to capture the infinite varieties of empirical reality and that increased flexibility in the rulemaking

[4] The discussion of exemption processes generally draws heavily on Shapiro and Glicksman (2003, pp. 158-77).

process is necessary."[5] Without such flexibility, the regulatory action is often undesirable or even unacceptable because it is unnecessarily inefficient, unfair in application, or even inconsistent with the basic purpose of the rule. Additionally, sometimes following one goal too far can conflict (in unexpected ways) with other goals (see Sidebar 3.1).

A familiar example of an exemption process is "delisting" of materials classified as hazardous wastes under the Resource Conservation and Recovery Act (RCRA). U.S. EPA maintains a broad classification to sweep a broad range of materials into the hazardous waste management system because, following the clear directive of Congress to be protective, it wants to err on the side of overinclusion (regulating wastes that are not very hazardous) instead of underinclusion (missing truly hazardous materials). A broadly inclusive classification system also permits U.S. EPA to obtain a

Sidebar 3.2: Variances: An Example From the Clean Water Act

A good model for exceptions is Congress' response to a decision of the Supreme Court that ratified a measure of discretion that the U.S. EPA claimed for granting exemptions for toxic water pollutants (*CMA v. NRDC,* 1985, 470 U.S. 116). Under the Clean Water Act, the general standards for most pollutants can be varied on a number of grounds. For toxic water pollutants, however, Congress rejected such variances. The U.S. EPA nevertheless permitted a certain type of variance—for "fundamentally different factors" (FDFs) of production method. The idea is that variances for cost, for example, should not be allowed to undermine the protections against toxic water pollutants, but that the variance based on the technology used by the polluter was appropriate for technology-based standards. The U.S. EPA had created these variances on its own, without congressional guidance, and environmental groups and Congress worried that it was unconstrained. So Congress amended the Clean Water Act to recognize the need for FDF variances, but it laid out a process and the precise conditions for obtaining them: Any variance must be (1) technically rigorous, (2) democratically responsible, and (3) considerate of the long term (Clean Water Act § 304(n)).

[5] Breger, quoted in Shapiro and Glicksman (2003).

better understanding of the overall hazardous waste problem. However, some wastes just are not as dangerous as initially thought or changes have been made in the process generating the waste. Adjustments can be made in two ways: as ad hoc exceptions to the general rules (the third group), or as a structured process (the fourth) (see Sidebar 3.2).

Option 3; Permit Ad Hoc Exemptions: Allow Informal Exemptions

Ad hoc exceptions constituting the third option are very common in regulatory systems. Exercising enforcement discretion, delay in enforcement, deadline extensions, informally agreed upon changes, or simply ignoring legal requirements are ways to avoid the application of general rules to unanticipated or ill-fitting circumstances. Some of these exceptions are unofficial, back-room deals, not designed to see the light of day. Others are unavoidable—for example, the kind of discretion that police officers and prosecutors exercise on a daily basis—but are extremely situation-sensitive and not susceptible to generalization. Congress has occasionally resorted to this technique with appropriations riders—sometimes inserted into complex or essential legislation—designed to excuse a particular project, for example, from the strictures of general rules.

Whatever their status, however, ad hoc exemptions all suffer from certain drawbacks. They can be lawless, even if legal, in the sense of subverting the general intention of the existing rules. At the extreme, too many exemptions can swallow the rule. If the exemptions are handled in a carefully documented, public process, the need for a multitude of exemptions can be a warning sign that the general rule is dysfunctional. A secretive or uncontrolled system simply undermines the general rule and is subject to abuse. Similarly, ad hoc exemptions do not express a coherent policy, even a policy for exemptions. They can be random, lack a firm factual basis, be inconsistent or perverse, or even reflect favoritism and agency capture. Exemptions can create their own uncertainty. Finally, they can "fly under the radar screen," avoiding public participation in important and difficult public policy choices.

DOE and the U.S. NRC have sought to use what are, arguably, ad hoc variance procedures to deal with some of the waste streams that the committee is considering. Under its self-regulation powers, DOE sought to create a process whereby it could declare some waste from HLW tanks to be "waste incidental to reprocessing" (DOE Order 435.1) that would not require permanent geologic disposal. This was overturned by a federal court in Idaho as lacking legal authority and meaningful standards, although the ruling itself was overturned because the court of appeals deemed that the issue was not yet ripe (see Section 1.2). Even without the Idaho ruling, actions under the DOE order would have suffered from the lack of credibility that often attends self-regulation: lack of a public process, lack of clear standards, and lack of public confidence in the decision maker. This variance does not have the kind of sustained technical basis that would be expected in a regulatory initiative with a complete administrative record. The effect is that the existing system is both technically and democratically indefensible.

Option 4; Establish Standards for Exemptions: A Formal Exemption Process

The fourth option, and the one the committee endorses, is a formal, defined, and transparent exemption system that uses risk to human health as a basis or starting point. A clearly defined exemption process with clearly defined standards can help avoid irrational or counterproductive results, while at the same time retaining the basic efficiency of general rules. It can "accommodate unique or anomalous situations without sacrificing regulatory objectives" (Shapiro and Glicksman, 2003). Having exemptions is consistent with protective regulation, as long as the exemptions are limited to situations that have previously been defined as exceptional, are different from the general rule (i.e., truly exceptional), and are consistent with the level of protection that Congress and DOE have properly and previously selected. A well-defined exemption process has two other benefits. It provides an incentive for the regulated entity to generate reliable information to justify deviation from the strict baseline rule. Also, if there turn out to be too many meritorious applications for adjustments, this provides a useful warning that the baseline rule itself must be fixed. None of these benefits, however, are provided by ad hoc exemptions, because they do not entail limitations or require analysis.

As noted above, delisting provisions for RCRA provide one model for an exemption process. Under the statute, a *solid* waste is subject to the strict management provisions applicable to a *hazardous* waste if the solid waste either (1) exhibits particular hazardous *characteristics,* or (2) is *listed* as a hazardous waste. The technique of listing is itself an example of the advantages and disadvantages of general rules that have already been discussed. It proved to be extremely burdensome for regulated entities and the regulator to test each of the thousands upon thousands of industrial sources of solid wastes for hazardous characteristics;

therefore, U.S. EPA was authorized to list certain waste streams based on certain constituents or certain processes to simplify administration and predictability. It was always clear that such listings would be overinclusive in the sense that they would cover waste streams at particular sites that were not as hazardous as the generality of such wastes. Therefore, Congress provided an exemption process, known as *delisting,* to remedy the inherent imprecision of the listed waste categories. The delisting process is set out generally in the statute, 42 U.S.C. § 6921(f) and described as follows in U.S. EPA's RCRA Orientation Manual (U.S. EPA, 2003):

> The RCRA regulations provide a form of relief for listed wastes with low concentrations of hazardous constituents. Through a site-specific process known as delisting, a waste handler can submit to an EPA Region or state a petition demonstrating that even though a particular waste stream generated at its facility is a listed hazardous waste, it does not pose sufficient hazard to merit RCRA regulation. For example, a waste generated at a specific facility may meet a listing description even though the process uses different raw materials than EPA assumed were used when listing the waste, thus the waste may not contain the contaminants for which it was listed. Similarly, after treatment of a listed waste, the residue may no longer pose a threat to human health and the environment. Specifically, the petition must demonstrate that the waste does not:
>
> - Meet the criteria for which it was listed
> - Exhibit any hazardous waste characteristics
> - Pose a threat to human health and the environment by being hazardous for any other reason (e.g., does not contain additional constituents that could pose a threat).
>
> If the EPA Region or state grants a delisting petition, the particular waste stream at that facility will not be regulated as a listed hazardous waste.

This process contains the key features, also discussed in the text, of criteria for application and constraints (single facility, factors for listing), burden on applicant, relative difficulty of obtaining approval (factors in addition to listing), and a designated decision maker. In this report, the committee uses the term decision maker to refer to the entity with final approval authority, i.e., the regulator.

Reasons to Establish Exemption Standards for HLW

Finding 5: Without a formal, well-structured, decision-making process, less desirable, ad hoc approaches will emerge.

Given the costs and difficulties of sending all waste that could be classified as HLW or TRU waste to a deep geologic repository, some approach will arise for deciding what waste requires geologic disposal and what does not. A formal and well-defined exemption system offers several specific benefits for the management of HLW. First, it is what might be called a minimalist approach; that is, it avoids root-and-branch change in the basic system for regulating HLW. DOE does not challenge, to the committee's knowledge, the general policy of permanent geologic disposal for HLW (and TRU waste), and it has not yet been shown that the adverse impacts of the current definition are sufficiently pervasive to justify a recommendation to modify the basic definition of HLW. Importantly, Congress has a long-standing commitment to permanent geologic disposal as the method of choice for HLW and TRU. At a minimum, therefore, established public policy is that permanent geologic disposal is the starting point for disposal decisions. An exemption system respects this established public policy: it accepts the starting point and then deviates from this only where it can be justified. A baseline rule of geologic disposal with defined exemptions would therefore continue to signal Congress' firm commitment to, in this case, strong protection against radiation hazards.

Considering the characteristics of the waste itself, the three wastes identified by the committee suggest, on the basis of a relatively cursory examination, the utility of alternatives to permanent geologic disposal for some waste forms, because they exhibit the following characteristics:

- They appear to be relatively low in radioactivity, and/or hazard compared to other HLW and TRU waste that DOE manages, and perhaps could be managed in some manner other than disposition in a deep geologic repository.

- For some of these wastes it is infeasible to recover and dispose of every last bit of waste that might conceivably be classified as TRU or HLW.

- The effort, exposures, and expense associated with retrieval, immobilization, and disposition in a repository may be out of proportion with the risk reduction achieved (if any).

An alternative to permanent geologic disposal, therefore, might be preferable for these waste types. The bases listed above provide criteria for considering an exemption. The criteria for granting an exemption must be developed through the exemption process.

Procedurally, a formal exemption system provides transparency and discipline to exceptions. There is some history of ad hoc exemptions, and the committee heard concerns from stakeholders that this undermined their confidence in the safe management of these wastes. Moreover, without a default or presumptive disposal method, regulators and the regulated cannot know or predict how to manage these wastes. What is the tipping point between permanent geological disposal and near-surface (or other) disposal methods—a certain half-life, a certain level of activity, a certain level of risk? If so, who will set that bright line? These are rhetorical questions, of course. Either Congress or an agency must do this in some very generic way, or the system would be totally flexible and give no guidance. Finally, one of the strengths of an exemption system is that it does not require detailed review of every tank or fraction of waste stream, but only those that initially appear to be exceptional (in the sense of inappropriate to the general rule).

As described above, establishing criteria for exempting some HLW from the requirement of geologic disposal could proceed from either of two starting points: (1) reinterpreting key phrases in clause (A) of the current definition of HLW (e.g., "highly radioactive" or "sufficient concentrations," see Section 2.1), or (2) from a "blank slate" in the form of an integrated and consistent set of technically defensible conditions that must be met for a particular waste to be exempted. The committee favors the second approach for two reasons. First, recent litigation made it clear that the definition of HLW is, if not ambiguous, at least capable of different interpretations by different parties. It seems unlikely, therefore, that unambiguous agreement could be reached on inherently vague terms such as "highly" or "sufficient." Second, it is clear that the key phrases in clause (A) of the current definition (see Section 3.1) do not provide an adequate technical basis for defining exemption criteria without a substantial amount of administrative elaboration, for which the statute gives little guidance. In sum, the committee judges that a clear set of technically defensible, formalized standards and well-defined procedures for implementing them would be the best way to avoid future legal disputes of the kind that resulted in the recent Idaho litigation.

Facilitating TRU Waste Disposal Exemptions

As discussed previously, the current definition of TRU waste includes a provision for exempting wastes from the requirement for deep geologic disposal on a case-by-case basis. However, this provision does not appear to have been used almost at all, although there are instances in which DOE clearly must seek exemptions to follow through on its plans. The committee believes that DOE would benefit from using the criteria and process described in the remainder of this report if it applies for such exemptions in the future. In other words, an exemption system is already provided for in the case of TRU waste, so the need is not to create an exemption, but to provide a transparent process and clear, risk-informed criteria.

3.3 AN EXEMPTION SYSTEM

The committee offers the following structured exemption system as one that accommodates the considerations discussed above. The system has four parts: the bases of permissible exemptions, the criteria for granting exemptions, the burden of proof, and the process for obtaining exemptions.

Bases for Exemptions

To begin with what an exemption system should not be, exemptions should *not* be available simply for DOE's convenience, or simply to save time or money. Nor should they undermine either the classification system or the preference for permanent geologic disposal embodied in present laws and regulations. The first step, therefore, is to identify the reasons for which an exemption may be sought (see Sidebar 3.3). Based on

Sidebar 3.3: ARARs

CERCLA provides an example of a detailed exemption process. As discussed in Section 1.2, cleanup remedies selected under CERCLA must meet, among other things, any "applicable or relevant and appropriate requirements" (ARARs) of federal or state law (42 U.S.C. § 9621(d)(2)). In some cases, however, compliance with ARARs is impractical or counterproductive, so the National Contingency Plan (U.S. EPA's regulatory blueprint for remedy selection) permits ARAR waivers in carefully specified circumstances (40 CFR § 300.430(f)(1)(ii)(C)) and by following specified procedures (40 CFR § 300.515(d),(f)). Of the permitted reasons for an ARAR waiver, three are of direct relevance to the difficulties of managing the HLW and TRU waste streams discussed in Chapter 2:

- Compliance with the requirement will result in greater risk to human health and the environment than other alternatives,
- Compliance with the requirement is technically impracticable from an engineering perspective,
- The alternative will attain a standard of performance that is equivalent to that required under the otherwise applicable standard, requirement, or limitation through use of another method or approach (40 CFR § 430(f)(1)(ii)(C)(2)-(4)).

There may be other relevant reasons for DOE to seek a waiver, but they are beyond the scope of this report. The ARAR waiver standards and process could serve as a model for the exemption process that the committee proposes, to encourage a consistent and transparent approach to departures from general rules when there are special circumstances for particular waste streams at specific locations.

the committee's review of the waste streams identified in Chapter 2, four grounds for seeking an exemption from the general rule of permanent geologic disposal appear[6] to merit consideration:

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[6] At this, the gatekeeping stage of the exemption process, it is not necessary for DOE to prove this or any other of these criteria. Instead, DOE simply has to have a sufficient basis for believing that this might be the case to justify the time and expense of seeking an exemption. A final determination of risks and other

1. It is impractical, and in some cases may be technically impossible, to comply with the requirements at an acceptable level of worker safety, ecological impact, and cost, balancing all of these factors.

2. An alternative disposal method would provide long-term protection of human health and the environment, and would not pose unacceptable risks (for example, by meeting existing environmental standards for near-surface disposal).

3. The cost of permanent geologic disposal is extremely disproportionate to the risks actually posed by the waste.

4. The waste stream is a promising candidate for delaying permanent geologic disposal because it can be managed confidently in situ in the near-term future with no or negligible increase in risk, *and* either new, safer management technologies are a reasonable prospect or the waste will experience a substantial decay of dangerous radionuclides in the short term in a safe and stable configuration.

The committee recognizes, of course, that all of these descriptions involve judgments upon which reasonable persons could differ. It will perhaps be helpful to keep in mind two guiding principles in evaluating all requests for exemptions. First, the regulatory system as a whole starts from a preventive, protective baseline that prefers permanent geologic disposal as the technique for reducing present and (especially) future risks of highly hazardous wastes. Second, the exemptions should be special, unusual circumstances. If most or even a major portion of the HLW or TRU waste streams were legitimately granted exemptions, it would call into question the validity of the general rule, as discussed below. To speak colloquially, the exemptions are intended to apply only to situations in which permanent geologic disposal *simply makes no sense*. Finally, the strong technical basis and the open process, both discussed below, provide a further bulwark against these exemptions' being misused.

Mindful of the concern that the exemptions could swallow the general rule, the committee seriously considered whether to recommend limiting the number of exemptions available under this process to ensure

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criteria would be part of another entity's evaluation of DOE's application for an exemption.

that the exemptions are truly exceptions. The committee decided against this course of action, however, because any upper limit would necessarily be arbitrary. It also seems unnecessary, given the strict and limited grounds and criteria for granting exemptions. RCRA, for example, does not limit the number of permitted delistings of hazardous waste, but the standard and procedures for delisting are such that it is a rarity—not because Congress wanted delisting to be a rarity as such, but rather because Congress protectively wanted the definition of hazardous waste to sweep a broad range of wastes into the RCRA management system. Finally, if it turns out that most of the waste streams in fact meet the exemption criteria, then this should be a signal that the baseline rule is fundamentally flawed, and a responsive regulatory system will take that as a signal that a more thorough review of the classification system is required. DOE can assess the anticipated number of HLW and TRU waste exemptions and, if it appears exemptions are not few in number, indicate that a more general fix may be warranted. The committee suggests that DOE begin with the three waste types identified herein, because they are illustrative of the reasons for considering alternatives to deep geologic disposition.

3.4 CRITERIA FOR EXEMPTIONS

Finding 6: Human health risk is a good basis or starting point for considering whether a waste stream should be granted an exemption, but it is not a sufficient basis for deciding these questions. At a minimum, costs, work-related risks, risks to ecosystems, technical feasibility, cultural and societal impacts, land use implications, preexisting agreements, and other, site-specific factors are also relevant in what is called a risk-informed approach.

Risk-informed approaches can provide valuable information for use in an exemption process. Risk analysis provides a fundamental basis for exemptions because risk reflects one of the basic values being protected—human health—and therefore is a sensible starting point. Human health, however, is not the only value at issue, so the approach must be risk informed and not exclusively risk based. Risk *assessment* is the analytical basis of the risk aspect of a risk-informed approach, because it is a powerful, structured, and highly developed analytical tool for organizing (and revealing the absence of) relevant information. Moreover, its theoretical and practical strengths and limitations are—or should be[7]—well known, permitting a clearer understanding of what risk analysis does and does not tell us. The process for using risk analysis is described in Chapter 4.

Consideration of risk must be applied to alternatives: both the risks of the waste materials themselves in their present configurations and the risks of managing them in a different way. Perhaps even more important, given the nature of the wastes at issue, it is essential that the long-term risks of the materials in their current and alternative configurations be thoroughly explored. For example, the National Research Council (NRC, 2000b) and others (e.g., Applegate and Dycus, 1998) have previously warned that reliance on institutional controls to reduce long-term risks is highly problematic. As discussed in Chapter 5, the assessment of long-term risk can be particularly difficult because of the challenges of modeling long-term geochemical and hydrologic processes and because of uncertainties in future land use and other human behaviors.

Even with these guidelines, a risk-informed approach poses major challenges for DOE. One lesson to be drawn from DOE's many attempts to employ risk as a central planning and decision-making tool—described in Appendix B—is that their results in fact gave little useful guidance to the program. Risk alone offered no firm standards for action, embodied no agreed-upon methodology, and had no basis in existing agreements or legal requirements. Risk, in other words, must be considered along with other relevant considerations such as cost and ecological impacts in the context of a focused decision-making process.

In addition, risk analysis is subject to both theoretical and practical limitations in its ability to measure precisely what should be done with these wastes (see Chapter 5). These limitations are also evident in many of DOE's previous efforts to use risk. The results were in no case definitive and, in any event, suffered from data limitations, inconsistency and incommensurability, incomplete factors or considerations, and failures to consider intergenerational and long-term risks. Also, even if one could measure perfectly with risk analysis, it is very clear that there is no societal consensus on the appropriate level of residual or acceptable risk (Babich, 2003). However, risk analysis can identify the exceptional cases (outliers, in other words) in which permanent geological disposal either does not decrease or even increases risk.

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[7] The National Research Council has explored these issues in detail in numerous reports (see Appendix A).

3.5 BURDEN OF PROOF AND INDEPENDENT DECISION MAKER

The basic concept of an exemption process is that exemptions are deviations from the normal rule and that they are exceptional. It follows that the party seeking an exemption must justify the departure from the general rule. The foregoing give the committee's judgments of permissible grounds for seeking a departure and the criteria by which such a departure must be supported. Placing the burden of proof on the party seeking an exemption puts that applicant in the position of having to (1) come forward with sufficient credible data to support its claims *and* (2) persuade a decision maker that the grounds and criteria for an exemption have been met and that an exceptional situation has been demonstrated.

Finding 7: The credibility of DOE's planning and decision making is reduced by the apparent conflict of interest created by DOE's authority both to propose and to approve disposition plans for radioactive waste.

Allocating the burden of proof to DOE is meaningful only if DOE is not also the decision maker. That is, the burden of proof would be weak indeed if it was simply a matter of DOE convincing itself that it is right. DOE's status as a self-regulating agency is problematic because of the perceived and real conflict of interest: DOE is both petitioner and decision maker. Outsiders might reasonably question whether DOE is able to separate these functions so that the agency is neutral in the latter role. Having DOE's application for exemption subject to the judgment of an independent arbiter would make the process more credible to skeptics, of which, in this area, there are many.

Therefore, the burden of proof implies, and the committee here makes it explicit, that a separate federal entity is needed as the regulatory decision maker for exemption purposes. DOE is, of course, regulated by a number of different federal and state entities. In the licensing process for Yucca Mountain, Congress developed a three-party arrangement in which DOE is the applicant, U.S. EPA sets the standards, and U.S. NRC issues the actual license. This or some other arrangement could be adopted, in which U.S. EPA or U.S. NRC is the decision maker. Persuasive arguments could be made for each agency as regulator, because both have significant expertise in the regulation of radioactive materials. The committee does not have a basis for making a recommendation for either agency but offers some observations on the merits of each for this role.

The U.S. EPA would appear to be the most obvious regulator for TRU waste, because it is already the decision maker identified by law and has worked extensively with such waste at the Waste Isolation Pilot Plant. U.S. EPA also has been the principal regulator for cleanup at the sites at which HLW and TRU waste is found and U.S. EPA has extensive experience with stakeholder interaction under several statutes; probably more experience than U.S. NRC has. The U.S. NRC, on the other hand, is the agency mentioned in the current definition of HLW. U.S. NRC will rule on DOE's license application for a HLW repository and is the regulator for the cleanup of waste, including HLW, at DOE's West Valley site, which is perhaps the experience that is technically most similar to the management and cleanup of HLW at Hanford, SRS, and INEEL. Also, U.S. NRC is legally an independent agency and has some distance from the administration in power. At the same time, however, U.S. NRC is perceived by some to be a captured regulator, serving the interests of the nuclear industry. Further, coming as it does from the same parent agency (the Atomic Energy Commission), U.S. NRC is perceived by some as being too close to DOE and therefore having an institutional bias for DOE.

Finally, the committee notes that it is desirable, but not essential, for the sake of efficiency and consistent application, that the same agency be the exemption decision maker for both HLW and TRU waste.

3.6 PROCESS

The process for seeking an exemption need not be complex, but it has four requirements. First, the process must be transparent, in the sense that the proceedings are open to the public from the outset and that the application and the data on which it relies are publicly accessible. In addition, the decision to grant or deny the application must be based on identifiable, publicly available data and its reasoning made clear. Second, there must be adequate opportunities for stakeholders and other interested persons to participate in the process from the outset, not only by receiving information (as above), but by submitting information and views, at a time and in a manner that makes it possible to influence the decision. Third, there must be a neutral decision maker, as discussed above. Fourth, approval of an exemption application by cognizant regulatory authorities must be required *before* any action inconsistent with the general rule is taken, in particular irretrievable actions. For example, it would be unacceptable for DOE to take an action that would preclude permanent geologic disposal of a particular waste stream, in advance (or even in anticipation) of receiving an exemption.

A five-step application process would meet these requirements:

1. DOE would publicly announce its intention to apply for an exemption for a specific waste stream. This would give regulators and stakeholders the opportunity to collect relevant information.

2. DOE would then implement the risk-informed process described in Chapter 4 to generate the information to support an application. The end result of the DOE process, would be an application for an exemption.

3. As part of the internal DOE process, the risk analysis would be thoroughly, independently, and externally reviewed before submitted with the application.

4. DOE would submit its application to the relevant decision maker.

5. If approved, DOE would be authorized to approach other regulators, in particular the states, to seek any necessary changes in compliance agreements.

The final step bears emphasis. As stated at the beginning of this chapter, the committee expressly rejects the unilateral abrogation or amendment of existing compliance agreements by DOE (nor does the committee believe that DOE seeks to do so). The exemption process is the *beginning,* not the end, of renegotiation of compliance agreements, although the process the committee envisions would involve the states from the outset, which should make renegotiation simpler if the exemption is granted. Conversely, if DOE is unable to convince the exemption decision maker that an exemption is justified, it has no basis for approaching the states to renegotiate.

Recommendation 1: The nation should pursue a formal, well-structured, risk-informed approach to consider what parts of the waste types enumerated in Finding 3, if any, should be disposed in some manner other than deep geologic disposal.

Recommendation 2: DOE should *not* attempt to adopt these changes unilaterally. Likewise, the exemption process that the committee recommends must be implemented in the context of DOE's existing or renegotiated compliance agreements.

4

A Risk-Informed Approach: Procedures and Criteria for Risk Assessment to Support an Exemption Process

In this chapter, the committee explains the key attributes of the risk assessment process that it recommends and outlines steps by which risk assessment can be performed *and integrated* into a process to inform decisions on the alternative dispositions of certain high-level and transuranic legacy wastes. The intent of this chapter is to describe the characteristics and provide an example of a process for risk-informed decision making in support of exemption determinations, not to prescribe the specific process.

4.1 USING RISK ASSESSMENT

The general methods of risk assessment for environmental concerns are well established in numerous earlier publications. These include a series of reports on risk assessment methods and processes by the National Research Council (NRC, 1983, 1994a, 1996). Other groups and individuals have written similar general texts on principles of risk analysis (e.g., PCCRARM, 1997a, 1997b). Agencies of the U.S. government have codified specific methods for performing risk calculations in particular applications. For example, the U.S. Environmental Protection Agency (U.S. EPA) has specific guidance for performing risk assessments acceptable for identifying clean up plans under CERCLA (U.S. EPA, 1989, 1990a, 1990b, 1991a, 1991b, 1991c, 1991d, 2001a, 2001b). The U.S. Nuclear Regulatory Commission (U.S. NRC) also has recommended methodologies for carrying out performance assessments for low-level radioactive waste disposal sites and for nuclear reactors (see, e.g., U.S. NRC, 2000). Appendix A summarizes this conceptual background on some of the existing literature on risk assessment and risk management procedures. The approach described here conforms to the general principles and methods that have been established for risk analysis, but it has been crafted specifically to support the exemption process for high-level waste (HLW) and transuranic (TRU) waste described in Chapter 3. The risk terminology used in this report, including the distinction between risk assessment and risk analysis, is described in Sidebar 4.1.

Sidebar 4.1: Risk Terminology

Risk analysis is an umbrella term that includes risk assessment, risk communication, and risk management.

Risk assessment is the scientific evaluation of known or potential adverse effects for an individual, group, society, or the environment resulting from exposure to hazards. The risk-assessment process consists of the following steps: (1) hazard identification, (2) hazard characterization, (3) exposure assessment, and (4) risk characterization. The definition includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk, qualitative expressions of risk, and characterization of the attendant uncertainties (see Appendix A for a more detailed definition from the NRC, 1983). It is distinguished, also per NRC (1983), from risk management, although good practice requires iteration between risk assessment and risk management.

Note that in this report the terms analysis and assessment are not used as shorthand for risk analysis and risk assessment.

Risk management is "the process of evaluating alternative regulatory actions and selecting among them. Risk management, which is carried out by regulatory agencies under various legislative mandates, is an agency decision-making process that entails consideration of political, social, economic, and engineering information with risk-related information to develop, analyze, and compare regulatory options and to select the appropriate regulatory response" (NRC, 1983).

Refined risk assessment: An iterative approach to risk involves doing an initial risk assessment with available data and models. Sensitivity analysis is applied to identify aspects of the assessment that require greater complexity or precision before a decision can be made from the assessment results. After further data collection and/or model development indicated by the initial assessment, a refined risk assessment is prepared using the more complete or detailed information and models.

A conceptual model is a description of the specific processes (e.g., chemical, physical, biological) that are believed to govern the behavior of the system to be assessed. In the case of contaminants in the ambient environment, site-specific geological, biological, and climatological conditions may make different processes relevant in different locations. For quantitative assessments, the conceptual model determines the types of equations and parameters that should be used to make estimates of contaminant release, transport, transformation, and human exposure in a particular location, whereas the conceptual model determines how system behavior is described in qualitative assessments. Once these are defined, then it is possible to start to identify appropriate mathematical models to build, adapt, or adopt for use in the risk analysis, and the relevant types of data to start to assemble or collect. If there is uncertainty or disagreement about the conceptual model, then it may be important to employ alternative models in the risk analysis.

When *alternative conceptual models* are considered, data collection and analysis may also be targeted to allow evaluation of which model or models are most supported by the data. If more than one model provides a similar quality of fit to the observations, risk estimates should be made from the multiple models.

A *risk model* is a mathematical representation of the conceptual model. Once formulated mathematically, and estimates of all the necessary parameters and input data are developed, the conceptual understanding can then be used to simulate or predict the behavior of contaminants in the system, to estimate the risks that may result from them. Mathematical models of the same processes and behavior can be developed with many levels of complexity. Since many of the relevant parameters are likely to be highly uncertain, one should begin with a simple model and use it to explore which uncertainties affect the risk estimates most. A *refined risk model* is created by progressively adding mathematical complexity or more precisely estimated parameters and input data to an initial risk model. Such refinements should be guided by sensitivity analysis results using the initial model.

System behavior: When speaking of an environmental issue, the "system" is the set of all environmental components that interact with each other, including the chemical compounds in the soil, the physical features of the land, the organisms that live in the subsurface and at the surface, and the waters and animals (including humans) that move through the area. The system may also include the air and atmospheric interactions. The "behavior" of the system refers to the way that these interactions occur when a change is made, such as the addition of a contaminant to the environment.

Taken on its own, this chapter may appear to oversimplify the true complexity of the analyses that will have to be performed in the course of the process. The committee cautions that merely performing each step identified in this chapter in a "cookbook" fashion is not sufficient for a successful application of the risk-informed approach. In particular, if the analyses associated with each step ignore or attempt to diminish the importance to decision making of the underlying complexities and unknowns of the processes being modeled, the risk assessment supporting the risk-informed approach will likely be rejected (see Sidebar 4.2). Chapter 5 provides more discussion of these complexities, and describes how the committee thinks they should be incorporated into the risk analysis process. Considering carefully the issues that are discussed more fully in Chapter 5 and preparing a plan that consciously addresses them are essential to this process.

4.2 CHARACTERISTICS OF A GOOD RISK-INFORMATION APPROACH

Chapter 3 notes the importance of creating an exemptions process that is transparent, inclusive of stakeholders,[1] and credible. These characteristics must pertain to the exemption-seeking process as a whole, but they are also important attributes of a good risk analysis in its own right. In addition to procedural considerations, achieving each of these characteristics places specific technical demands on the way that a risk analysis is conducted. Specifically, the risk analysis conducted in support of an exemption application must be as follows:

[1] The term "stakeholder" here includes the interested and affected public.

Sidebar 4.2: Challenges and Difficulties in a Risk-Informed Approach

Risk assessment sometimes is prescribed as a universal solution for problems faced by decision makers. Such thinking is counterproductive. Risk assessment is a tool that can help decision makers reach a solution, but it is difficult to use well and does not guarantee a satisfactory outcome. Chapter 5 details some of the technical and institutional limitations of risk assessment, but it is worthwhile to mention two of them here as a cautionary note to give a fuller picture of the risk-informed process.

Some people may question the credibility of risk assessments. This may happen because the analyses in a risk assessment are not credible, because the institution presenting the risk assessment is not credible, or for both these reasons. At its information-gathering meetings, the committee repeatedly questioned the experts presenting results of risk assessments about how they had established the validity of the models they were using. Few presenters were able address the questions, and fewer still gave satisfactory responses. People without the time or resources to critique the analyses may use the credibility of the institution as a proxy for evaluating the credibility of the analyses.

It is rare (and indeed suspicious to some) for an environmental risk assessment to yield results with small uncertainties. Uncertainties often are so large that the results of a risk assessment must be deemed indeterminate.

Even with these problems, however, the committee believes a risk-informed approach using risk assessment as a structured method to develop an understanding of, and to characterize, risks is the most promising approach.

- **Logical.** The sequence of steps of the risk assessment must map out a coherent chain of cause-effect relationships that link assumptions about the handling and final disposition of the waste stream in question to a set of outcomes that are specifically identified as relevant to the exemption decision.

- **Well founded.** The methods used in each step must be consistent with current scientific knowledge and practices. If the state of science has competing theories, the risk analysis must consider appropriate alternative approaches, rather than choosing one, unless it can be demonstrated that such a simplification would not alter the estimates of outcomes sufficiently to affect the decision between alternative waste disposition options.

- **Transparent and traceable.** Risk analyses can become too complex, obscure, or inaccessible for even knowledgeable outside parties to understand, review, or reproduce. It is useful to resist this tendency by giving care from the beginning to make clear the steps, assumptions, and data that are being used. Identifying and making available sources of information, as well as identifying and characterizing uncertainties, enables others to check them. Documentation after the analysis is completed does not meet this requirement.

- **Participatory.** Most of the parties interested in the outcome of the risk analysis will not be engaged in performing the analysis itself, but they will not trust the results if they are not allowed to participate actively in discussions about how to structure and refine the analysis. Transparency also cannot be achieved unless stakeholders participate in the process from the beginning (NRC, 1996).

The key feature of the risk analysis process described in this section is that the data, modeling, and any other calculations in estimating risk must be structured to inform a **specific and well-defined decision.** A coherent and efficient risk assessment requires that the decision criteria be well defined in advance of any computational or modeling steps. It also requires that a sufficient number of options from which to choose be considered in the decision to avoid excluding potentially superior options. Therefore, the first step is that a decision be defined; and second that a list of decision alternatives from which to choose be considered. In this application, the options would be a list of two or more methods for disposing of a particular high-level or transuranic waste form.

For example, if the Department of Energy (DOE) is seeking an exemption related to closure of a set of HLW tanks, the options must include, at a minimum, (1) complete removal of all HLW for disposal in a deep geologic repository, and (2) a specific plan for how much of tank residuals may be left in a tank and any associated form of stabilization (e.g., grouting) suggested as an alternative disposition that might be allowed as an exemption. DOE may wish to consider more than one alternative disposition, but there must be at least the default and one alternative listed.

The critical issue is that all the options be defined specifically before analysis starts. The second step is to identify all of the information needed for making a decision. That is, what are the types of risks, costs, and other criteria must be considered when determining whether one or some subset of the disposition options would be preferable to the others? As stated earlier, human health risks are an important consideration at any site, and other considerations could have equal or greater importance at some sites. Meaningful quantitative analysis cannot be initiated until these two structuring steps have been completed. The risk assessment can then be designed to address the specific set of relevant considerations for the specific disposition options that have been set forth.

This discussion emphasizes good process rather than good decisions. The committee, unfortunately, cannot prescribe good decisions—good decisions are not definable. A good process is necessary but not always sufficient for a good decision, and can still lead to bad decisions and generate a great deal of outrage. An agency may follow a process—posting a preliminary decision for a required amount of time, meeting a required number of times, listing public comments in a revised document, and issuing a final decision—but essentially undermine the value of the process by making it simply procedural, checking the box off and proceeding on its predetermined course. For the risk-informed approach to be successful, the agencies must embrace it as something not only useful and meaningful, but also essential to its planning.

Risk assessments can be extremely complex, yet shed little light on whether one cleanup option is to be preferred over another. At the same time, the complexity can be a barrier to gaining confidence and trust in any recommendations that may purportedly be justified by the risk analysis. The approach described here embraces the principle that analytical detail and complexity should be limited to the minimum necessary to distinguish the best option or options.[2] If the relative risks and trade-offs can be established with a relatively simple analysis that is nonetheless grounded in empirical data, then this simpler analysis will be easier to explain and easier for non-analysts to understand. A simpler analysis is also easier to validate. This will allow the risk analysis process to move more quickly to the point at which there is communication among stakeholders on how to make the relevant trade-offs. By fostering such discus-

[2] More discussion of the philosophy, structuring, and key elements of the approach described here can be found in NRC (1996), Howard (1966), and Chapter 3 of Morgan and Henrion (1990).

sions early in the process, those managing the process can ensure that stakeholder input is considered and incorporated into the final product.

It bears noting that the risk assessment developed in this process will probably have considerable complexity before it is completed. Also, considerable technical sophistication is needed to produce even a "simple" analysis that can effectively guide the addition of detail. The critical point is that the quantitative analysis be *initiated* with minimal complexity and that the complexity be increased gradually, as the need for it is determined and as all participants gain understanding of the key elements of the analysis that are driving its risk estimates.[3]

It is also possible that the forms of complexity resulting from this iterative process will be quite different from the forms of complexity that would have been added if analysts were to strive to incorporate a final degree of complexity from the outset. For example, risk analysts may set out with models that incorporate detailed dynamics, yet it may turn out that only steady-state outcomes are important to the decision. Wasted effort on details that are merely distracting can be avoided in a process that is guided by insights from an initial, relatively simple analysis.

The *process* of analysis may be more important in achieving transparency, trust, and understanding than thorough documentation of an analysis that is offered as a fait accompli, particularly if the final product on which decisions are made is complex. The committee observed in site visits and related presentations that DOE has tended to generate its analyses without such an iterative, staged process. DOE appears usually to present only the final product of its risk analyses to stakeholders, at a point where the analysis is exceedingly complex and difficult to review or gain intuitive understanding.[4] Focusing on the numerical results can

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[3] Sensitivity analysis is the key method advocated here for determining whether additional complexity is desirable. The junctures where sensitivity analysis is best performed are identified in the step-by-step process that is provided in this chapter.

[4] The Risk-Based End States (RBES) process, mentioned in Chapter 1 and described in greater detail in Appendix B, is an example of a process in which stakeholders were not engaged before apparent decision recommendations had been formed. However, there appears to have been little or no risk assessment underlying that process. In other cases, the committee was presented with risk analyses that had much detail, but failed to provide decision-relevant information such as sensitivity to key assumptions. The presentation on risk from residual radioactive waste in groundwater at Hanford was a case in point (Thompson, 2004).

also obscure one of the most important products of the analysis: Beyond risk estimates, risk analysis can produce insights, which may be highly qualitative.

One must also distinguish a "simple" analysis from one that ignores uncertainty. Uncertainty is a major concern in making estimates of risks, particularly when considering long time scales. Key areas of uncertainty must be explored even in the first phase of the analysis. Using alternative ways of representing physical processes or alternative sets of assumptions helps to address model uncertainty and to understand the sources of sensitivity and boundaries of the risk estimates. That is, one can learn how much risk estimates associated with each disposition option are likely to vary as a result of unknown factors or areas of disagreement. This can be accomplished using quite simple analyses; indeed, more complex analyses can present significant barriers to exploration of uncertainties. Identifying the boundaries of uncertainty created by alternative assumptions is more important than adding computational complexity while still relying on a single set of deterministic assumptions. Many of the risk analyses presented to the committee by DOE have indicated that the opposite has been the practice (see, e.g., DOE, 2002c; Thompson, 2004).

Thus, there are several critical elements to the process for implementing a risk-based approach for deciding on the disposition of high-level and transuranic wastes:

- specific set of options to be considered,
- list of information or data needed for a decision,
- set of criteria for determining the best option(s) developed in advance of any analysis,
- risk computations performed at the minimal level of complexity necessary to separate options according to the decision criteria,
- risk computations performed simulating competing views of the physical processes and using ranges of parameter values that reflect the state of science, and
- uncertainties explicitly explored and retained unless they are demonstrated not to affect the relative ranking of the disposition options.

These are the key elements of what one might call a *decision-oriented* risk analysis approach, but it bears repeating that the *process* by which these elements are put together is exceedingly important to achieving acceptance of any decisions that may be informed by such a risk analysis. The process must be iterative and participatory (see Sidebar 4.3).[5] The institutional impediments outlined in Section 5.4 must be considered in determining who specifically performs the risk assessment and how it is managed and evaluated at an individual site and across the DOE complex.

All of the elements of risk management (which have to be reflected in the final exemption application) are analyzed in parallel. The analysis of each element must meet consistently high standards of quality and credibility so that they will withstand the scrutiny of external review.

4.3 A SIX-STEP PROCESS FOR RISK-INFORMED DECISION MAKING

To better elucidate how one can combine process and analysis, the rest of this section provides an outline of the steps that DOE could follow. Readers familiar with the CERCLA process may find that many of

Sidebar 4.3: Decision Support Systems

A "decision support system" is designed to enable greater participation by non-experts and so could support some of the goals articulated in this chapter. A decision support system, in this context, would be a user-friendly computerized version of the risk models and relevant decision criteria that could be run on a microcomputer with only modest resource requirements. Such tools are intended to provide participants in the process, particularly non-modelers, with an ability to alter assumptions and elements of the risk analysis independently, and to quickly observe the impacts of such "what if" questions on the outcomes viewed as relevant to the decision. This capability can enable modelers and non-modelers alike to gain hands-on familiarity with how the risk model responds to

[5] A recent example where a decision support system was integrated into an iterative and participative public decision process like the risk analysis process described in this chapter can be found in Passell et al. (2003).

alternative assumptions, and help in identifying the most important elements of the risk analysis. If developed well, a decision support system can enhance the sense of empowerment and participation of stakeholders, it can enhance dialogue among stakeholders and modelers, and it can enhance the iterative aspects of the process. It is important also to note that decision support systems can be expensive and time-consuming to develop, because each one requires a well-designed graphical user interface with functions tailored specifically to the risk analysis in question. The software design and development challenges can divert attention and resources away from simply performing a good decision-oriented risk analysis process. Also, if the resulting software product does not meet expectations of performance (which can often become unrealistic), it can unnecessarily undermine the goal of engaging stakeholders' trust and understanding of the analysis. A decision support system is not essential for a good iterative and participatory process, but it can be a valuable supplement if it is created with a proper understanding of its role and limitations, and if appropriate software development resources are allocated.

its elements are familiar and that the whole process is compatible with CERCLA.[6] However, the following steps were devised specifically to illustrate a process for the transuranic and high-level waste disposition decisions that DOE may wish to have considered in an exemption application.

Recommendation 3: DOE and its regulators for HLW and TRU waste should adopt a six step process for risk-informed decision making: (1) initiate the process, laying out viable options and potential decisions; (2) scope the information and analysis; (3) collect data and refine models; (4) prepare refined risk assessment; (5) develop additional analyses and data collection, as needed, to support decisions; and (6) finalize the decision.

[6] For more about the CERCLA process see Section 5.4 or the U.S. EPA web site, available at: http://www.epa.gov/superfund/.

Step 1. Initiate the Process, Laying Out Viable Options and Potential Decisions

To keep the risk analysis efficient and useful, the first step is neither data development nor computational. Rather, it lays the stage for clearly defining the decision that the process will be addressing, and of initiating contact and discussion with stakeholders, states, and regulators so that they are involved throughout the entire process. The intent of this step is to develop the structure needed to carry out a useful risk assessment. The risk assessment will not be useful if it has the appearance of justifying a new disposition option that has already been decided on. The most important aspect is that the analysis be set up as a *comparative* exercise, rather than an attempt to merely prove that the alternative does not pose unacceptable risks (see Sidebar 4.4). The real question is whether the alternative presents a *better* outcome with respect to the relevant criteria, which include tradeoffs among risk, cost, and other considerations. The alternative may have "acceptable risks," but it is important to be able to understand how much it changes the relevant risks and costs in comparison to the presumptive disposition. A comparative focus is important for building confidence in the risk-based approach as well. If DOE attempts to suggest that risks are "acceptable" for an alternative, it puts itself in the impossible position of having to prove that its risk calculations are precise and that uncertainties are not large. Under a comparative approach, DOE and stakeholders need only come to a consensus about which alternative, if any, presents a distinct *improvement* over the others in terms of the overall balance among decision criteria.

Sidebar 4.4: Which Is Safer and What Is Safe?

Decision makers and stakeholders planning environmental cleanups and waste management ask, or are asked, Which option is safer (yields a lower risk), and is it safe? The comparative question is helpful in selecting among cleanup options and often has the advantage of believability: analysts and others may believe the relative risk or the risk ranking even if they mistrust that the absolute magnitudes of the risks have been calculated accurately. Relative risk also is adequate to answer the important question, Does the cleanup reduce risk? However, a relative risk calculation generally is not, by itself, sufficient. Stakeholders, regulators, and responsible parties want to know if it is safe for present and future generations.

Indeed, some see the question, Is it safe? as the crucial one. Decision makers need only select among options that result in acceptable risks, and non-risk factors may override relative risk benefits if all of the options are acceptable from a risk perspective. If none of the options meets a threshold level of acceptability, then another option that does must be found. A risk-informed process may, then, incorporate both of these approaches, using a threshold test as a screening criterion and further risk reduction as a benefit to be weighed with other factors.

Yet the question, Is it safe? presumes that common understanding of what safe means can be found. Then, even if a threshold or "bright line" can be found, one must trust not only the accuracy but the precision of the absolute magnitude of the risk assessment results for the threshold to be used as a screening criterion. Still, there is an advantage to using a threshold: decision makers confronting the relative risk question can get stuck in an endless process of adding and assessing options trying to identify which option is safest. The absolute magnitude approach requires only that there be one good option. If that option results in acceptable risks, other features and impacts of the option may be considered and, if they are acceptable, the option may be adopted. For this approach to work, the option must be clearly acceptable from a risk perspective.

The following elements are part of process initiation:

- **Define the problem and issues.** What is the specific waste or waste area for which a decision has to be considered? What is its current presumptive final disposition? Why does DOE feel it makes sense to consider alternative disposition? What are the general types of alternative disposition options? These questions must be considered in advance, and those seeking the exemption must be prepared to discuss them with stakeholders before initiating any analyses or defining a *single* specific alternative that it wishes to have considered as an exemption. DOE will benefit from coordinating and making use of experts across the complex.

- **Engage public and regulators to discuss and refine issues.** The relevant stakeholders must be identified and contacted to explain that DOE wishes to initiate an exemption application process. Stakeholders are not necessarily a well-defined group. While the process must be open to all, DOE and its regulators will have to grapple with the difficult question of which elements of the public should be included in the process. The process must be inclusive, striving for a breadth of perspectives to be represented. A set of stakeholders that consists only of the most vocal advocates (who are the most easily identified stakeholders) is not likely to fill the need. Funding is needed for groups to participate (see Sidebar 4.5).

Sidebar 4.5: Technical Assistance

There is a mismatch between the budgetary, technical, and legal resources available to DOE and to the other process participants. With its annual budget of more than $7 billion (approximately $2 billion of which goes to Hanford alone), DOE's Office of Environmental Management has funding almost equal to that of the entire U.S. Environmental Protection Agency and far more resources than any state regulatory body. Many American Indian nations, local governments, and citizens groups rely on volunteers to keep them involved in decision making processes (such as those under the National Environmental Policy Act and CERCLA) at DOE sites because few resources are available to them.

There are mechanisms that provide funds for communities that seek to participate in these processes. Technical assistance grants of up to $50,000 are available to communities that form nonprofit organizations for the purpose of participation in CERCLA's public processes. Although much of the funding might be expended in meeting the organizational and reporting requirements for such a grant, they could enable some groups to participate in ways that otherwise would be impossible.

DOE has funded site-specific advisory boards or citizens' advisory boards at most of its major cleanup sites, and these boards advise DOE on citizens concerns, values, and priorities in the cleanup program. Historically, DOE has also provided funds for technical support to the states that were under consideration for hosting deep geologic repositories. In New Mexico, DOE funds supported the Environmental Evaluation Group, which provided technical oversight of the Waste Isolation Pilot Plant. To enable states and American Indian tribes that are affected by the federal high-level radioactive waste disposal program to participate in the activities prescribed by the Nuclear Waste Policy Act of 1982, including review and oversight, the act requires that DOE grant funds to the affected governments. These funds are typically appropriated explicitly by Congress and administered by DOE.

The committee did not research these mechanisms in depth, but makes two limited observations based on its examination of risk-informed approaches and DOE's waste management and cleanup activities. First, participation requires resources. Having access to experts, designated representatives who can dedicate time to following DOE's environmental management of a site, and even the funds to hold public meetings makes for more meaningful participation by the affected parties. Meaningful participation makes a participatory, risk-informed decision process, such as is recommended here, more effective. Second, in the cases of assistance both to the state of New Mexico and the state of Nevada, funds for oversight activities were reduced or suspended. This has been perceived by some as an attempt to stifle critics (NNMCAB, 2004; Bingaman, 2004). Without arguing the facts or the reasoning for or against this position, the committee notes that it undermines rather than strengthens a participatory, public process if parties perceived as biased can limit the ability of the other parties to access independent technical expertise and engage in the process in a meaningful way.

- **Define potential decisions and land use options.** The list of potential decisions to be evaluated must, *at a minimum,* include the current presumptive disposition and an alternative disposition approach. It is possible that no specific alternative will have been identified, but that DOE feels strongly that the presumptive path needs to be modified. In this case, the initial phase of the process includes brainstorming with technical experts, but also giving stakeholders a chance to comment or to specify an alternative that could be considered. Even if a specific alternative has already been identified, for the process to work an open exploration among experts and stakeholders is needed to see if other alternatives also merit consideration. If another option is identified later in the process, the parties must go through the full process for the new option.

- **Define list of criteria.** DOE will need an initial list of the criteria that are relevant to decision making. As noted by an NRC committee, "A risk characterization must address what the interested and affected parties believe to be at risk in the particular situation, and it must incorporate their perspectives and specialized knowledge. It may need to consider alternative sets of assumptions that may lead to divergent estimates of risk; to address social, economic, ecological, and ethical outcomes as well as consequences for human health and safety…" (NRC, 1996). The decision criteria will obviously include health risk, costs, and regulatory compliance. However, DOE will have to define the metrics of risk that it will allow to have a significant influence on the decision. Metrics of risk that could be used include excess lifetime cancer risk to an individual, population-wide cancer incidence risk, and so forth. It is important that the relevant metrics of risk be identified clearly at this early stage so that DOE can ensure that any analysis it performs will be designed to provide those specific outputs. Distributional outputs, or the question of who bears the burden of risks and costs, are usually relevant in such questions. Those seeking the exemption need also to work with stakeholders at this stage to determine how to define the groups of concern and what measures of distributional impact it will be appropriate to use.

- **Develop process plan.** DOE will need an outline of the process by which analysis and consultation will proceed. Such a plan would contain each of the remaining steps outlined below, but would include timing and parties to be involved. The plan would clearly identify points throughout the process at which new information releases will occur.

- **Review and feedback.** In completing each of the elements above, DOE, of course, has to make initial internal deliberations to prepare for meetings, but all of the elements of the analysis must be discussed and refined in a consultative process with stakeholders. Consultations can be both informal and formal. Before proceeding to the next step, DOE must be able to summarize all of the elements coherently and specifically.

Step 2. Scope Information and Analysis

Once DOE has defined two or more disposition alternatives to be compared, and the key criteria on which they will be compared, it can begin the process of estimating the specific risks that will be part of that comparison. However, the process is a gradual one, and the next step involves only a relatively simple set of risk calculations, which can be characterized as a scoping analysis, before consultation occurs again.

Scoping analysis results may presage the likely direction of the decision, but it is unlikely that any decision can be finalized at this stage. The elements of the scoping step follow:

- **Sketch out the structure of the risk analysis.** At this point DOE will know what measures of risk it needs to calculate and can prepare a blueprint of the types of calculations that are required to make these estimates. This will help identify data and models needed. It may also help identify models that are not relevant. Often a risk assessment proceeds using models that are readily available, and these may not always provide the actual type of information that is needed for the decision at hand. The result is a side-tracking of the analysis effort onto results that are not of much use for guiding the decision at hand. The point of this step is to identify what is needed and to keep all analysis efforts targeted to those needs.

- **Identify parameters, data, and models required.** When the risk analysis blueprint is completed, it will reveal the inputs that are required, and these become the basis of a list of data and models to develop. Judgments must be made for how to model the system(s) with respect to scale, complexity, whether to use deterministic or probabilistic methods, and which conceptual models might apply. At this stage, differences of opinion about appropriate modeling methods may come to light. For example, many models of subsurface contaminant transport are based on the use of partitioning coefficients (K_d) to represent retardation of transport due to sorption of contaminants on solid surfaces. In many subsurface environments, however, small solid particles called colloids move with the groundwater. Sorption on these colloids facilitates transport rather than inhibiting it. Contaminant transport in solution using K_d for retardation and colloidal transport represent competing models of the dominant physical processes that affect risk estimates from groundwater pathways. If competing conceptual models exist, and none can be proven to be the more appropriate for the specific situation being assessed, all must be identified for use in the risk assessment, at least during the scoping step.[7]

- **Collect and review existing needed information.** The goal of this step is to find out how much of the needed information is *already* known. Data probably exist on most problems, but if they are not necessary for the risk calculations that have been identified in the structuring step, no effort need be placed on assembling them, particularly given the cost and difficulty involved in collecting some data. Doing so would waste resources, slow the process, and detract from the goal of helping stakeholders gain insight and trust in the decision. The criterion for collecting more information is whether having the additional information could actually change the ranking of the alternative disposition options under consideration. This can be established with scoping risk calculations.

- **Perform scoping risk assessment and sensitivity studies to identify critical parameters requiring the greatest attention.** The risk calculations at this stage may be simpler, principle-based analyses with less detail than may ultimately be required, and their main purpose is to identify the most important needs for additional data development and additional model complexity. Basic risk calculations will be performed following the risk analysis blueprint. If relevant model packages are readily available, they could be used, but complex model development should not occur yet if the relevant models do not exist. Similarly, data gaps are to be tested for their significance at this stage to determine how much effort is warranted for filling these gaps. For each data gap, educated guesses of their possible values, focusing on identifying a range of such values, are more useful than a "best guess" value.[8] Sensitivity analysis is then applied to these

[7] Risks must be calculated with each potentially viable model. Results of independent and mutually exclusive models must not, however, be treated simply as increasing the variance of a result distribution-characterized median or mean value. Each model generates its own result distribution, and mixing or averaging them corrupts the information they would otherwise yield, producing a meaningless outcome.

[8] A practice in some risk assessments (e.g., under CERCLA) is to fill data gaps with default values. EPA provides lists of such default values. Use of de-

estimated ranges to determine which data gaps are important to the final decision and how much precision is required when collecting the necessary new data.

- **Describe data gaps and data collection plan.** The most important output of the analysis at this stage is identification of information that is critical to making a decision. It should also be possible to determine whether competing model formulations have to be retained as the analysis moves forward. Insights from the sensitivity analysis are the most important determinants of a sound data collection plan. "Value of information" (VOI) is a method sometimes prescribed for determining what additional information to collect (Howard, 1966; Morgan and Henrion, 1990). VOI is useful for determining how much effort should be expended to resolve uncertainty regarding risk calculations or input assumptions that do affect the choice among alternatives. In its formal sense, VOI cannot be calculated unless the risk analysis is prepared to formally weight and combine all the decision-relevant criteria into a single "outcome" that is to be optimized. This is rarely acceptable in a process to inform a complex policy decision that involves many different stakeholder groups. However, there is value in gathering more precise information on any uncertain variable that is "sensitive" (i.e., that could alter the choice of disposition alternatives by taking on different possible values over its range of uncertainty). Thus, simple sensitivity analysis is a sound first step towards a well-targeted data collection plan. How much effort to expend on data collection or model refinement for each sensitive input must be a judgment that balances the degree of its observed sensitivity, the cost of the additional data collection on that variable, and the likelihood that the additional data collection will reduce its range of uncertainty enough to help clarify the choice between the alterative waste disposition paths.

- **Conduct review and feedback of data collection and analysis plans by experts and stakeholders.** Review here need not be in-

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fault values has the drawback of obscuring rather than highlighting the importance of the data gap to obtaining a sound risk estimate. At this scoping stage, the goal is to identify information to collect for the risk assessment, not to produce an actual risk estimate. Use of default values would undermine this goal.

terpreted in the formal sense, but presentation and discussion of results must be conducted despite a likely sense on the part of DOE that it has no "real results" at this stage. The process of consultation is a critical element even at this preliminary stage. If results are not publicly presented and discussed at this stage, opportunities to gain the confidence of stakeholders in the final risk assessment will likely be lost. Because this is a very simple level of analysis, it should be easy to present and explain to stakeholders. It should not be presented as if it is a final analysis, but only as a preliminary analysis intended to define further model and data development needs. The emphasis in communicating findings should be on the sensitivities identified, not on the risk estimates that were generated. When presenting results of this scoping analysis, all of the data gaps must be listed, along with the range of possible values explored and a summary of how much the risk estimates under each disposition alternative were altered as a result of varying the input over that range of values. The impact on results of using competing representation of physical processes must also be presented.

- **Finalize work plan and move forward.** Following discussions with multiple types of parties, DOE will need a clear but brief statement of the next steps of the analysis. Such a statement usefully includes only elements that have been demonstrated in this step to be relevant to improving the choice among disposition alternatives. To instill this, DOE can explain briefly how each modeling or data collection element of the plan would affect the quality of the decision. To be useful, the statement should also indicate the degree of precision required for each type of information to be gathered,[9] and data that might help resolve uncertainties about appropriate conceptual models if the choice of model is itself still in question.

[9] The overall goal and approach of the scoping step is consistent with the concept of data quality objectives that have been promoted by EPA (2000) for data collection efforts under Superfund and other programs. The express purpose of the data quality objectives process is to identify the quantity and degree of precision needed in a effort.

Step 3. Collect Data and Refine Models

This represents a straightforward implementation of the data collection plan developed in Step 2 after review of the scoping analysis results.

- **Collect quality data that describe the waste and the site.** The degree of precision (both sampling density and instrumentation) must meet the standards identified in the data collection plan. The uncertainties in resulting data must be characterized.

- **Describe and collect data regarding engineering remedies under consideration (identified in Step 1).** Often the emphasis in a risk assessment is on site-related data. However, for HLW and TRU waste disposition, there will also be substantial uncertainties regarding the technologies that would be used. During this step, the uncertainties in the performance and costs of the technologies that would be used also have to be described.

- **Refine model logic.** While data collection proceeds, modelers can be engaged in adding the types of refinements to the modeling frameworks that were also identified as important during Step 2. Refinements must be tested carefully. A summary of the impacts of the model changes on estimated results would facilitate review. Validation runs must be conducted and reported as well.

- **Disclose the information.** The new data and information assembled in this step must be clearly documented and made accessible to non-DOE groups. Access to data must be made possible as they become available and in advance of a formal review. Online posting of data files at a dedicated web site might be helpful in this regard.

- **Review by experts and stakeholders.** As with all the steps, an external review of the output of this step would build confidence before moving to the next step, which is to use these new data in revised risk calculations. In such a review, experts would be engaged to comment on the quality of the new data, and whether they sufficiently meet the objectives that were established in the scoping step. Other experts would review the way the revised models function and comment on whether it appears that the models are producing realistic results for specific test cases.

Step 4. Prepare Refined Risk Assessment

In this step, the refined data and models are combined to produce risk estimates that would be used to inform the exemption decision. The elements of this step follow:

- **Define the range of uncertainty in parameters for modeling, making use of collected data.** The raw data will have to be interpreted into the form required for input to the model. Although data will have been refined by this stage, it is still important to define the remaining range of uncertainty and to preserve an understanding of this uncertainty on risk estimates.

- **Conduct analyses, including uncertainty analysis. Risk estimates are now produced.** Uncertainty analysis need not entail probabilistic combinations of alternative assumptions. In fact, it may be most illuminating to continue to produce separate results using alternative conceptual models, if this model uncertainty could not be resolved as a result of the additional data collection. With regard to remaining uncertainties in the parameters, best estimates must now be developed, and sensitivity analysis performed again.

- **Perform a validity check ("laugh test"): Are results reasonable in light of real-world experiences?** DOE would be well served if it were to require a conscious effort at this stage to sit back and ask itself if the risk estimates being produced by the refined model are reasonable. Are there any observable situations against which the model's outputs can be tested? The risk estimates themselves would be difficult to validate, but intermediate outputs of the model, such as contaminant concentrations and rates of transport, should be fundamentally possible to validate. Written summaries of the various ways in which DOE has been able to confirm that the model can reasonably well reproduce observed system behavior would make the models easier to believe and harder to discredit.

- **Perform a thorough quality assurance and quality control of model logic and data inputs.** If the risk model passes the validity checks, it is time to prepare a thorough review of all the code and data inputs that were used to produce the risk estimates. If any problems are detected, the risk estimates must be revised.

- **Summarize the results of risk assessment, with uncertainty.** In preparation for public and peer review, the results must be summarized in writing. As always, the summary should be open and thorough in explaining ranges of uncertainty that remain and critical sources of sensitivity. Often a given uncertain parameter will affect risk estimates for each of the alternatives under consideration in a similar manner. It is important that the summary of uncertainties be done in a comparative manner, indicating how they affect the *differences* in risks estimated for the disposition alternatives. If this is not done, one may get the useless result that all alternatives have large and overlapping ranges of uncertainty. However, the real case may be that one alternative is consistently lower in risk than the other(s) and that the only uncertainty is the absolute amount by which it is lower. Thus, differences in risk among alternatives are more important to report than the absolute risk of each alternative.[10]

- **Peer review of model results.** DOE would build greater credibility if an independent panel of individuals who have expertise in all the relevant aspects of data, modeling methods, and uncertainty analysis reviewed and commented on the findings. Revisions should be made to address any identified problems.

- **Release results to the public per agreed plan.** The results would be released after completion of the peer review. A meeting of stakeholders would be needed to present the results and discuss their implications for decision making. In the course of the meeting, additional areas of desired refinement might be identified.

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[10] Of course, the absolute risks of each alternative must be computed and should be reported as well, but the use of differences becomes an important way to help clarify the significance of the uncertainties.

Step 5. Conduct Additional Analyses and Data Collection as Needed to Support Decisions

If additional analyses or refinements are needed, they would be done following a plan agreed on with stakeholders. It is likely that such planning will result in analyses and data collection being iterative; additional data collection might be necessary as learning progresses and the need for additional analyses is identified.

Step 6. Finalize Decision

Risk estimates will never be completely free of uncertainty or even controversy. However, at some point the "sufficient" information will have been developed, and DOE must decide whether the balance of evidence on risks and other decision criteria appears to support an alternative disposition option. If so, DOE would summarize the findings, the process by which they were obtained, and the issues raised by stakeholders and use this summary to support a formal request for an exemption from the appropriate authorities, as discussed in Chapter 3. In deciding to make such an exemption request, DOE must also be mindful of the need to negotiate changes in existing agreements with the states, U.S. EPA , and U.S. NRC and must consider the prospects for success in such a negotiation. If the prospects for success in negotiation are poor, this should have become apparent in the course of performing the risk assessment, especially if the iterative and participatory process above has been followed.

4.4 PROCESS FINDINGS AND RECOMMENDATIONS

Finding 8: An effective and credible risk-informed decision-making process has several characteristics. It is (1) participatory; (2) logical; (3) consistent with current scientific knowledge and practice; (4) transparent and traceable; (5) reasonably independent of decision makers; (6) subjected to thorough, independent peer review; (7) technically credible, with believable results; and (8) framed to address the needs of the decision process.

Drawing from points throughout this chapter, the committee summarizes the characteristics of an effective and credible risk-informed decision-making process in the list above. A risk-informed process that fails to meet any of these eight essential characteristics would likely be ineffective. In order to be effective, a risk-informed approach must be trusted. The characteristics listed above are intended not only to ensure a result that can be trusted but, equally important, to create a process that can be trusted. For example, a technically credible risk-based approach that lacks participation or transparency would likely not be trusted and, therefore, would likely be ineffective in supporting a waste exemption process.

With the process fully described, the committee reiterates that simply following these steps as a checklist is insufficient for a successful application of the risk-informed approach. These steps are difficult and there are impediments to effective use of a risk-informed approach. These are discussed in more detail in Chapter 5.

Finding 9: The biggest challenges to developing a meaningful risk-informed decision process, such as recommended herein, are: minimizing disruption to existing laws, regulations, and agreements; creating buy-in to the approach; and enabling meaningful participation by participants who have few resources.

Disrupting existing laws, regulations, and agreements (e.g., changing the rules to allow potentially unsafe practices to proceed without due process) will tend to cause resistance and unintended consequences of an exemption process. Any meaningful decision process that involves stakeholders such as the risk-informed process recommended here, will require finding ways to implement an exemption process in the least disruptive manner possible with regard to existing laws, regulations, and agreements. This process can help to maintain predictability, to create fewer unintended consequences, and to avoid destabilizing the policy equilibrium that has been reached as people have acted in reliance on the existing framework. The committee does not know how many exemptions DOE might seek. Assuming that the number will be relatively few, the committee has recommended exemptions because they can minimize disruption while preserving the desirable features of a risk-informed approach.

Recommendation 4: Congress, DOE, U.S. EPA, and U.S. NRC should take actions as necessary to enable DOE to implement effec-

tively the risk-informed approach recommended here. Specifically, they should provide for a formal, well-structured exemption process, institute technical review of the risk analysis independent of the agency producing the analysis, give decision-making authority to an agency outside DOE, and ensure that sufficient resources are reliably available for regulators, tribal nations, and stakeholders to participate meaningfully in the process.

The committee did not develop detailed actions for each entity/agency for the steps necessary to implement this recommendation. There are many possible distributions of responsibilities; what one agency might contribute toward implementation of the recommendations depends heavily on what others would contribute. The implementation of this recommendation should be achieved jointly by the entities involved, without attempting to define in advance of inter-agency discussions what each should contribute.

5

Impediments to a Successful Application of the Risk-Informed Approach

The risk-informed approach outlined in Chapter 4 can be useful in an exemption process, but the committee is concerned that this process not leave the impression that the risk-informed approach will be easy to perform successfully. In fact, the committee wishes to emphasize that risk analysis cannot be performed in "cookbook fashion" if it is to be meaningful and useful in decision making. In this chapter, the committee reviews some of the unavoidable and irreducible complexities in performing risk analysis and other important sources of concern with risk assessments. In order to apply the risk-informed approach successfully, the Department of Energy (DOE) must be fully aware of the complexities that a good risk analysis will encounter and be prepared to address them directly with exceptional intellectual and analytical effort. Additionally, DOE must accept that the results of the risk analysis should be only a part of a decision-making process, not the sole basis for the final decision.

The first section of this chapter discusses the limits and uncertainties of science in modeling long-term environmental processes and future risks. These complexities need not prevent progress toward making sound decisions about the disposition of waste streams, as long as the uncertainties are acknowledged, addressed where possible, and incorporated into decision-making deliberations. However, doing so may require a change in one's perspective about the goals of the risk analysis. The goal of the risk analysis in the risk-informed approach described in this report is to inform DOE, regulators, American Indian nations, local governments, and the public of the full range of outcomes that might occur by accounting as much as possible for the limitations of our knowledge of the systems involved. The analysis should inform the process participants of the ways in which undesirable outcomes may occur and provide insight into how to better engineer for or manage those risks. The committee cautions against using risk analysis to generate a specific quantitative estimate of risk (or risk ranges) that would then be deemed "acceptable" or "unacceptable" for the purpose of arguing for an exemption. Such strictly quantitative interpretations of risk estimates likely will fail in the face of the complexities and unknowns of the science underlying them. The committee describes a structured process, but does not provide decision criteria. The purpose of the risk analysis is not to produce a de facto decision, but rather to inform.

Sections 5.2 to 5.4 highlight a range of other issues that also could be impediments to the successful application of a risk-informed approach. These include stakeholder and decision-maker concerns and impediments in institutional culture. Again, the process recommended in this report and the set of steps outlined in Chapter 4 are designed to address and manage these concerns. Nevertheless, in this chapter each issue is discussed individually to emphasize that DOE must grapple directly with these complexities if the proposed risk-informed approach is to be applied successfully. The National Research Council (NRC, 1996) provides a more in-depth exploration of these and other issues. That reference can serve to supplement the material in this chapter.[1]

[1] The "analytic-deliberative process" described in NRC (1996) is consistent with and, indeed, a foundation for the risk-informed approach recommended here. This report describes an analytic-deliberative process that has been tailored specifically to support decision making on disposition of high-level and transuranic wastes, and it focuses its discussion on those concerns that appear to present the greatest impediments in this particular application.

5.1 RISK MODELING ISSUES

At the core of the risk-informed exemption process recommended in this report is the estimation of the risk that results from different disposition options associated with a given waste type at a specific location. In most cases, this will be an analysis of the risk posed by waste, nominally classified as HLW or TRU waste, that is left at a site rather than being removed and disposed of in a geologic repository, as currently required by law. Once calculated, the risk can be weighed against other relevant factors, such as cost and worker impacts, and this information becomes a part of the risk-informed decision-making process.

Properly done, risk assessment is a powerful tool for systematically organizing the information and understanding the behavior and impacts of radioactive waste at a particular location. Although the "risk" associated with disposition of different types of radioactive waste may be judged initially by the properties of the waste (e.g., amount of radioactivity, chemical form, toxicity, half-life, complexity of composition), the actual risk assessment that is used to evaluate a disposition strategy will involve models of the interaction of the waste components with the near-field and far-field environments, including interactions with engineered barriers or other containment mechanisms and the natural geochemical and hydrological systems. The site analysis provides the basic data used to calculate the risk that results from the many different exposure pathways in the biosphere. Thus, the risk assessment is composed of a series of coupled models used to describe the relevant processes. The quality of the risk analysis that would inform exemption decisions will rest on the quality of the data and on the scientific understanding of the underlying physical, chemical, and behavioral phenomena, and how well that understanding is reflected in the analysis.

Risk-informed approaches have been endorsed by several previous committees (e.g., NRC, 1990, 1996) to support decision making on complex social policy problems. However, actual applications of risk assessment by DOE to its waste management issues have brought out the difficulties of achieving scientific and technical consensus.[2] Further, risk assessment in general is not accepted by everyone (Tal, 1997). The

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[2] An illustration of the challenges involved in such a risk assessment when long time horizons are in question is the experience with the performance assessments of the proposed geologic repository at Yucca Mountain for spent nuclear fuel and high-level waste (e.g., Budnitz et al., 1999; Long and Ewing, 2004).

committee is aware of these difficulties, and its recommendations have been prepared with these concerns in mind. In particular, the committee has recommended a risk analysis process that emphasizes sensitivity analysis to understand how lack of knowledge can affect decisions on waste disposition, rather than blindly adding model complexity without first demonstrating its necessity or value to making a better decision. Additionally, the committee has recommended a risk-informed process rather than decision making based solely on the quantitative output of the risk analysis itself.[3] This being said, it is useful to explore the objections to risk analysis that have been expressed and their historical underpinnings. The following discussion emphasizes risk analysis of geologic systems, but similar concerns relate to other environmental systems and their pathways, such as air and surface contaminant exposures.

Scientists may object to the results of a risk analysis because the models used may not capture the actual system behavior of the radionuclides at a specific site. The calculation of risk over long periods of time or to future generations is especially problematic. The agency or institution responsible for completing the risk assessment may have a real or perceived bias that compromises the credibility of the results. Stakeholders may be excluded from the process and skeptical of results that become the basis for changing previous agreements, particularly when the decision is to leave the waste in place. Decision makers may be baffled by the complexity of the analysis and uncomfortable with equivocal results that, in fact, may have a high uncertainty.

Rechard (1999) reviewed the history of the use of risk analysis and performance assessments of geologic systems. Performance assessments, and their supporting methodologies, were first used to evaluate the reliability of nuclear weapons delivery systems. In the early 1970s, probabilistic risk assessments (PRAs) were used to evaluate the risk and consequences of nuclear power reactor accidents. The WASH-1400 report by Rasmussen and colleagues was the first comprehensive, probabilistic analysis of the health risks from a large and complicated technological system, a nuclear power plant (Rasmussen, 1975). The crossover point for the use of risk assessments for geologic systems came in 1976 when the Energy Research and Development Administration sponsored two

[3] This philosophy is also central to the analytic-deliberative process recommended in the NRC report (1996). The committee believes that some of the difficulties in DOE's risk assessment track record are attributable to a failure to reflect such a philosophy in practice.

workshops that brought together nuclear engineers who were conversant with the recently developed PRA technique and earth scientists involved in modeling geologic systems. Much of the faith in risk assessments of geologic systems is based on a belief that the methods of risk analysis, as developed for analyzing nuclear reactor safety, can be used to analyze geologic systems over long periods (Garrick and Kaplan, 1995). However, as early as 1978, John Bredehoeft and colleagues had clearly outlined the challenges to geosciences in attempting to model the long-term behavior of a geologic system used for the disposal of radioactive waste (Bredehoeft et al., 1978). One of their conclusions is worth quoting:

> In summary, predictive models are an essential step in the selection and implementation of a radioactive-waste repository and a radioactive-waste treatment system. They are invaluable tools for analyzing the problem and for identifying factors that are likely to have the greatest effect on radionuclide migration. However, some components of the models are inherently unpredictable at present and are likely to change at different times. In no sense, therefore, will these models give a single answer to the question of the fate of radioactive waste in geologic repositories….

A quarter of a century later, there is an ongoing debate about the value and limitations of risk assessments (Ewing et al., 1999). At the heart of the discussion are the clear limitations in the predictive capabilities of models in principle (Oreskes et al., 1994) and in practice (Oreskes and Belitz, 2001). Models of radioactive waste in geologic systems are inevitably limited for the following reasons:

1. They are simplified, hence, incomplete descriptions of the system.

2. The governing equations of the models may not provide unique solutions.

3. They cannot be calibrated to data sets that include the relevant spatial and temporal scales to be modeled.

4. Boundary conditions may change over time in ways that are unforeseeable.

5. Relevant, critical processes may have been omitted from the analysis.

Each of these five issues is inherent in any risk assessment and may never be completely eliminated by additional work or research. The fifth issue, conceptual model uncertainty, is probably the greatest source of uncertainty and yet the most difficult to estimate or characterize (NRC, 1995b, 2001b). The committee returns to the issue of conceptual model uncertainty below.

In addition to the fundamental limitations in the use of models for risk assessments, there is ample opportunity for additional, but more manageable, sources of error to enter into the analysis, which add to the uncertainty of conclusions that may be drawn from it:

- Input data may be wrong.
- The governing equations may have been solved incorrectly.
- Parameter distribution functions may be wrong.
- Estimated probabilities of critical events may be wrong.

Analysts must make judgments about how to set parameters and how to characterize their variability or uncertainty. A known difficulty in this step is that such judgments are subject to a number of heuristic biases, the net effect of which is that the true uncertainty is frequently underestimated (Morgan and Henrion, 1990; NRC, 1996). Analysts may sometimes make judgments that are subconsciously (or even consciously) anchored in values that can systematically drive the results towards their personal prior view of the risk endpoint. There are methods to correct for judgmental biases (Morgan and Henrion, 1990), and it is important that they be applied in risk analysis. Other elements of the analysis process in Chapter 4 also can help reduce these errors, such as quality assurance programs, review committees, public input, and having an external authority to judge the merits of the evidence in favor of an exemption.

Even when the above issues are addressed carefully and the input data are as good as the current state of knowledge allows, uncertainty in the analysis will remain. The final risk assessment will still be model dependent, and conceptual model uncertainty will be a concern. This uncertainty will be exacerbated by the fact that the risk assessment will entail a coupling of many models (e.g., waste form degradation, geochemical interactions and speciation, hydrology, biosphere pathways), and the connections between these models may have complicated feedback relations. New emergent behaviors that come about through complex interactions of different components of nonlinear systems may be extremely difficult or nearly impossible to predict. This means that understanding of behavior hinges upon resolving complexity, a feature often found in nonlinear systems, yet there are no general rules for recognizing and resolving such complexities. Thus, despite great advances in science during the past 50 years in describing, modeling, and even predicting the behavior of systems, the types of errors described above remain substantial. Examples of remaining difficulties in modeling hydrological and geochemical systems are provided in Sidebar 5.1; but similar issues are important for all of the physical, chemical, and behavioral systems that must be considered in a complete risk assessment, especially if the analysis will attempt to project outcomes thousands of years in the future.

In sum, uncertainty is an inherent aspect of risk assessment, emanating from several sources (see Sidebar 5.2). The challenge is not to diminish the role of uncertainty, but rather to properly and fully reflect it in information that decision makers will be asked to consider. Often analysts believe that this means that the risk assessment must be performed probabilistically. However, probabilistic analysis can increase the complexity and opacity of the analysis, yet distract from the most important form of uncertainty: conceptual model uncertainty.[4] NRC (1996, pp. 113–114) acknowledged the limitations of probabilistic uncertainty analysis in the face of this general source of uncertainty:

[4] For example, a Monte Carlo analysis may incorporate explicit representation of uncertainty on dozens or hundreds of parameters of a model, yet never address the possibility that the model itself could be inappropriate. A more useful "uncertainty analysis" might be accomplished with a just few model runs from two alternative conceptual models.

Sidebar 5.1: Uncertainties in Hydrologic, Geologic, and Geochemical Components of Modeling

The heterogeneous, near-surface earth environment has been termed the “critical zone,” because it is the region where the hydrosphere, biosphere, geosphere, and atmosphere interact with one another and with the human sphere in a highly complex manner (see, e.g., NRC, 2001c). The complexity of the critical zone presents special challenges to the development of long-term predictive models. During the past 50 years, earth scientists have made substantial strides in describing, modeling, and even predicting the behavior of critical zone systems. Nevertheless, our knowledge, understanding, and ability to model critical zone processes are strained by the demands of risk assessments extending for many thousands of years into the future.

Modelers are trying to predict waste form and contaminant behavior at DOE sites, including some of the most complicated and as yet poorly understood types of critical zone hydrogeologic systems, including vadose zones, regions of groundwater-surface-water interactions (including the poorly understood hyperheic zone, which is the geologic material immediately surrounding and underlying rivers and streams), arid regions, and fractured flow regimes. Konikow and Bredehoeft conducted postaudits of a number of hydrologic systems, comparing predicted behavior to actual behavior over periods of decades (Konikow, 1986, 1992, 1995; de Marsily et al. 1992; Konikow and Bredehoeft, 1992; Bredehoeft and Konikow, 1993). A particularly important conclusion was that for models based on a history match (i.e., a calibration to previous hydrologic data), the predictive capability diminishes rapidly for periods longer than that of the historical data (Bredehoeft, 2003). This limits confidence in the predictive capabilities of hydrologic models to no more than some hundreds of years. One might argue that for some of the most highly complex and poorly understood hydrogeologic settings, the limits of confidence could be considerably shorter.

Geochemical systems are subject to the same types of uncertainty as hydrologic systems, particularly conceptual model uncertainty (Bethke, 1996; Nordstrom, 2004). Areas of ongoing research, such as the role of nanoparticles, bacteria, and organic matter in the fate and transport of radionuclides, highlight some of the current challenges in understanding geochemical interactions. Geochemical models may have non-unique solutions (Bethke, 1992), can be highly sensitive to very small changes in fundamental input parameters (Ewing et al., 1999) and may produce greatly differing results at different spatial scales and for changing boundary conditions (Duro et al., 2000; Madé et al., 2000; Jensen et al., 2002; Wang et al., 2003).

The most widely used types of models are reactive transport codes that are meant to describe coupled thermal-hydrologic-geochemical processes (Lichtner et al., 1996), although such models often do not adequately address biogeochemical or nanoscale processes. Browning et al. (2003) reviewed a reactive transport model for the ambient unsaturated hydrogeochemical system at Yucca Mountain. They found model predictions to be particularly sensitive to assumptions about percolation flux, fracture-matrix interactions, groundwater compositions, and the rate of volcanic glass dissolution; each of these processes is knowable to a greater or lesser degree. However, the coupling of these processes presents challenges to reliable predictions of radionuclide transport. Hughson et al. (2000) tested risk analysis models by using them to describe the migration of trace elements from metallic artifacts preserved in a volcanic tuff some 3600 years ago by a volcanic eruption on Aktori, Greece. They found that different conceptual models, matching the site data, produced different predictions attributed to underdetermined parameters and changing boundary conditions.

These are just a few examples of the challenge presented in modeling hydrogeologic systems, but they are representative of the types of limitations that one should expect of a risk assessment of a hydrogeologic system. The key to success in modeling highly coupled geologic systems is the careful integration of experimental results with field observations (Bethke, 1996; Nordstrom, 2004). The initial risk assessments are likely to reveal the need for additional site characterization, experimental data, and perhaps development of better multiscale modeling approaches.

> Unfortunately, experience shows that it is often these unknown circumstances and surprise events that shake risk analyses and topple expectations, rather than the factors (important though they might be) that have been recognized and incorporated into formal analyses… Also, formal uncertainty analysis may not help if the uncertainty in the fundamental understanding of the basic processes that drive the risk… is so large that a quantitative estimate can only lead to obfuscation… In such cases, identification of important issues and perhaps some selected analysis of scenarios (without assigning probabilities to these scenarios), is the best that can be accomplished.

Consistent with this earlier NRC report, the approach outlined in Chapter 4 emphasizes use of sensitivity analysis (which includes "scenario analysis") to understand the role of uncertainties. Sensitivity analyses are important in testing the potential inaccuracy of a risk model and determining which of the many forms of remaining uncertainty are important enough to affect decision-making deliberations. As noted in Chapter 4, if there are competing conceptual models, sensitivity analyses should start by considering the impacts of the alternative models on risk estimates. This stands in direct contrast to a procedure of first selecting a single conceptual model to simplify the analysis demands and then performing sensitivity analyses on that model's parameters. The latter approach will only exacerbate the potential for controversies among scientists on the merits of the risk analysis results, and this, in turn, can only further deepen the widespread skepticism and distrust that members of the general public express for risk analyses.

Sidebar 5.2: Sources of Uncertainty

Uncertainty of mutual estimate increases as models based on laboratory experiments or limited field data are extrapolated to larger spatial and temporal scales. The uncertainty has three main sources: (1) data uncertainty; (2) scenario uncertainty; and (3) conceptual model uncertainty (Andersson and Grundteknik, 1999). Data uncertainty can enter the analysis at any point. There will be uncertainties about the composition and form of the radioactive waste, the composition of the groundwater, groundwater flow paths, and so forth. Scenario uncertainty will have more to do with the boundary conditions that will affect the site, such as climate change, recharge rates, and seismicity. Boundary conditions also change over time and space, for example, along the groundwater flow path. Conceptual model uncertainty is related to whether the relevant processes have been included in the models. As an example, a number of different conceptual models have been used to describe fluid flow and transport in the unsaturated zone (above the water table). In previous studies, initial estimates of groundwater travel times—that is, the time it takes for a contaminant to travel to some reference point—have decreased by as much as four orders of magnitude as the conceptual models have been changed (see Sidebars 6.1 and 6.2 in NRC, 2001b). Finally, the theoretical and mathematical foundations of multiscale modeling are themselves currently incomplete.

In addition to the shift in emphasis toward exploring conceptual model uncertainty, risk analysis results may be viewed and communicated most effectively as relative indicators of potential impacts under different disposition alternatives. In fact, it would be misleading to consider such a risk assessment as yielding "quantitative" results, in the sense that the absolute results have reliable magnitudes. The uncertainties in the results remain large and increase with time. A risk assessment is quantitative only in the sense that it provides a numerical result, but the meaningfulness of the result is actually more qualitative. By treating the results as if they have quantitative significance, one can mislead decision makers into concentrating on numerical comparisons rather than on evaluation of the adequacy of the strategy for the safe disposal of a particular type of radioactive waste.

Despite these enumerated limitations, risk assessment remains a powerful tool in organizing our understanding of the behavior of a physical and behavioral system. However, a risk assessment is only one element in a properly made risk-informed decision (Apostolakis, 2004) and is not, by itself, a sufficient basis for determining that a site or strategy is "safe."

5.2 PUBLIC PARTICIPATION AND STAKEHOLDER ISSUES

Participation by members of the interested public (commonly referred to as stakeholders) in risk analysis and risk management—especially those who will be directly affected by the decisions made—has changed considerably in the past two decades. At its most unsophisticated level, public participation has been thought to mean "educating" the public about the "truth and wisdom" of expert analysis or informing the public about a final decision. As is discussed in greater detail in Section 5.4, when DOE was actively involved in decision making against the backdrop of the Cold War, it often addressed public participation as an afterthought or item of secondary importance.

Under this management model, deficiencies in public participation were marked by the following common features:

- Stakeholders are presented with the risk assessment at the end of the process.

- The risk assessment is opaque and difficult to understand.

- Those who present the risk assessment may not have been intimately involved with the work and are unable to answer important questions.

- Stakeholder comment periods are too short.

- Stakeholder comments and questions are dismissed or not addressed adequately, particularly in ways that visibly affect the results of the risk assessment.

- New knowledge often does not result in a change in the conclusions.

- There are so many "knobs," that is assumptions and choices made during the analysis, that there is a perception that adjustments are made to arrive at "wanted" results.

It is not surprising, then, that citizen groups have asked the question, What environmental decision-making tools do we have other than risk assessment? (Raffensperger and Tickner, 1999).

As the use of unilateral approaches has receded, and as risk assessment and risk management have evolved to recognize that stakeholder input is necessary early in and throughout the risk analysis process, federal, state, and local agencies have adopted an analytic-deliberative model for risk-informed decision making. The analytic-deliberative model calls for continuous stakeholder input. A more complete description of this model is set out in Appendix A.

Although the important role of stakeholders in risk-informed decision making is now widely acknowledged, past practices have made stakeholders suspicious and skeptical of the results of risk analyses, no matter how well conceived and executed. In a survey of environmental groups in the United States, Tal (1997) found that "[a]lmost unanimously, environmentalists resent the technocratic, exclusionary nature of risk assessments that undermine democratic participation in local environmental decisions." The risk analysis is seen as a political tool that uses science as a rationalization for decisions that have already been made. Agendas that are as much political as scientific, such as deregulation, are closely tied to risk analyses.

Finally, the focus on risk inevitably emphasizes excess cancers as the final criterion or end point of the analysis, but not every stakeholder group shares this perspective or value system. In particular, American Indians are often concerned with the availability of natural resources, which are essential for the maintenance of a tribal life-style and community health (NEJAC, 2004). A group or a culture may legitimately place value on what it perceives as broader environmental and ecological consequences.

As discussed previously in this report, risk-informed decisionmaking is a process for making choices, not merely an exercise for drafting a final stand-alone report on risk. Unless equal or greater attention is paid to the process, the final conclusions of the risk analysis may not be accepted by the affected parties (NRC, 1996).

Studies of stakeholder involvement and effective decision making suggest that there are ways to allay stakeholder concerns:

- Involve stakeholders at the earliest stages of initiating a risk assessment.
- Define the problem that is to be addressed by the risk analysis.
- Define the measures that are used to judge the final outcome of the analysis.
- Develop a process that shows and records the response to the important issues that are raised by stakeholders.

As risk practice has evolved, success in decision making has increasingly come to be characterized by success in meaningfully involving stakeholders in the risk assessment. Many models incorporate early and frequent stakeholder interaction. By using such a model, stakeholders may actually participate in the risk assessment (van den Belt, 2004), or they may be provided resources that allow them to hire their own team of experts who participate in the risk assessment or review it throughout the entire process (see Sidebar 4.5).

Some readers will respond that the DOE process already involves stakeholders, uses risk assessment effectively, and reaches credible decisions through environmental impact statements under the National Environmental Policy Act (NEPA) and through the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) process. As noted in Chapter 4, the committee's recommended approach is compatible with the CERCLA process. Although the committee did not examine the NEPA process in detail, it believes the risk-informed approach probably is compatible with that process too. It is a strength of the recommended approach that it does not require a major overhaul of the regulatory system in order to be implemented. But there is a difference between the recommended approach and that used in the environmental impact statements and the records of decision the committee examined. The difference is in how the parties go about implementing the approach. The risk-informed approach recommended in this report requires a cooperative approach to framing the decisions and carrying out the risk assessment. Even the appearance that DOE decides first and then does a pro forma risk assessment to support its decision—a view the committee heard several times from some participants at its meetings—delegitimizes DOE's actions in the eyes of some regulators and other interested parties. Even more aggravating to these parties, however, was the perception that DOE tries to circumvent CERCLA and the tri-party agreements.

The committee noted in its site visits that there was substantial disaffection among stakeholders with DOE's Risk-Based End States (RBES) project (DOE, 2003), which was initiated about the same time as this committee was formed. The RBES project is an outgrowth of the DOE Office of Environmental Management (EM) Top-to-Bottom Review (DOE, 2002d), which was undertaken when Assistant Secretary Roberson was appointed to run the EM. DOE announced that each site must develop a site-wide vision document describing for each cleanup activity an end state that is consistent with the anticipated future land use at the site. The guidance required sites to identify variances to seek from current plans, regulations, and agreements. Deadlines for the vision documents occurred over the span of the committee's site visits, and the committee heard presentations on the RBES project at each site.

DOE's announcement and initial implementation of the RBES project triggered negative responses from the U.S. Environmental Protection Agency (EPA), host states, local governments, American Indian nations, and environmental groups. DOE did not articulate well the problem it was simply trying to address by instituting the project, which led many outside DOE to suspect that its purpose was simply to enable DOE to do less cleanup. DOE developed the first drafts of the vision documents with virtually no input from outside. Thereafter, very little time was allowed for public input and even when deadlines were extended, people who were not brought on board at the beginning were reluctant to contribute to the project for fear of legitimizing it. The deadlines for the vision documents were extended further and DOE acknowledged some of the mistakes it made in implementing the project. To try to move beyond the hostility DOE's implementation of the project fomented, DOE worked with the National Governors Association to hold a meeting with many of the interested and affected parties. The meeting was held on October 6 and 7, 2004. Many at the meeting said that the RBES project had undermined trust between DOE and the other parties, and DOE representatives acknowledged errors made in implementing the policy. At the same time, DOE still sees the RBES project as valuable and wants to pursue it. At the time of preparation of this report, it was not clear whether DOE had created enough buy-in from other parties to make the project effective.

If DOE is to implement successfully a risk-informed process for requesting exemptions from requirements for deep geologic disposal of HLW and TRU waste, DOE must strive to avoid these pitfalls. Some stakeholders may view the process with suspicion, charging that DOE is changing the rules to make legal an unacceptable outcome. The goal of the risk-informed process is to find mutually acceptable outcomes and, where necessary, change the rules to make an illegal, mutually acceptable outcome into a legal, acceptable outcome. Failure to follow diligently and seriously the stakeholder involvement aspects of the process in DOE's first attempt to implement the recommended risk-informed process not only would engender the same degree of stakeholder concern, but would likely doom the chances of the committee's proposed risk-informed exemptions process to be used at all. The step-by-step process in Chapter 4 was designed with this concern in mind.

5.3 DECISION-MAKER ISSUES

Once a risk analysis is complete it becomes an important part of the final decision. However, even in the best circumstance, some disagreements and uncertainty inevitably will remain. One cannot expect that every scientific uncertainty will have been eliminated or that all stakeholders will accept the results of the analysis. Moreover, science and scientific analysis cannot answer every question necessary to a decision. Policy, political, and value choices remain. These questions—sometimes called "transscientific" (Weinberg, 1971, 1972)—are informed by scientific analysis but are not resolved by such analysis. Perhaps the best example of a transscientific question is the level of acceptable risk. Technical analysis can provide estimates of risk, describe timing and receptors of risk, and point out uncertainties, but it cannot identify the level of risk that society should tolerate.

Transscientific decisions such as the level of acceptable risk are among the most difficult facing public officials in Congress and administrative agencies. They can look for guidance to the risks apparently or explicitly accepted in other activities (assuming they are analogous), and they can look at cost and other factors. Ultimately, however, it is a balancing of many factors—scientific and nonscientific—that results in a decision (Jasanoff, 1990; Wagner, 1995). Sometimes the technical analyses all seem to point in one direction, making the decision easier (or at least easier to justify), but often this is not the case. It is therefore to be expected that public officials will look to science in the hope that it will give a clear direction for hard choices. In addition, science has an allure, as one writer puts it, of precision and objectivity that can provide much needed support for politically unpopular decisions (Applegate, 1995; Hornstein, 1992). (The cynic may find this use to be no more than seeking political cover; but more charitably, it is perfectly reasonable to seek a firm basis for decisions that hurt some people's interests.) In both cases (that is, hoping for clear direction and looking for objective justification), however, the tendency is to expect or claim more than science can legitimately deliver.

The National Research Council has repeatedly warned of the overreliance on science in the context of risk analysis. As early as the Red Book (NRC, 1983), it called for a distinction, as far as possible, between the risk- and impact-assessment aspect of the process and the policy-oriented, risk-management aspect (NRC, 1983, 1994a, 1996). Scientific analyses should take care (1) to disclose fully limitations and uncertainties in their conclusions, and (2) to distinguish carefully between science and nonscientific judgments.[5]

Ultimately, a decision maker cannot avoid making hard decisions in the face of the uncertainty in the analysis or continued disagreements among the stakeholders. The dilemma has been well summarized by Herrick and Sarewitz (2000):

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[5] This is not to say that scientists should shrink from judgments or recommendations that are not purely scientific in character. On the contrary, it is imperative that the scientific community be actively involved in the important issues of the day, especially those with a technical aspect. Rather, scientists should be clear as to the basis for—and, if appropriate, the limitations of—their judgments.

> Unreasonable expectations about the nature and character of scientific knowledge support the widespread political assumption that predictive scientific assessments are a necessary precursor of environmental decision making. All too often, the practical outcome of this assumption is that scientific uncertainty becomes a ready-made dodge for what is in reality just a difficult political decision. Interdisciplinary assessments necessary to address complex environmental policy issues *invariably result in findings that are inherently contestable,* especially when applied in the unrestrained realm of partisan politics.

(Italics are the committee's.)

Although the "inherently contestable" quality of a risk or performance assessment cautions against overreliance on science, it does not justify disregarding the results of such an analysis. A rigorous scientific analysis provides a logically coherent organization to the many factors in a decision, provides essential information for the decision, and clarifies areas of remaining uncertainty and remaining (nonscientific) choices. Scientific analysis, therefore, deserves to be a core part of decision making on questions of public significance, but it will not ultimately relieve the public decision maker of the weighty responsibility of hard choices.

To continue a theme in Chapter 4, the scientific information captured in a risk assessment, or any risk assessment process, is a tool for decision makers that is most useful when taken as an integrated whole. Summarizing an entire risk process in a single point estimate or even risk range is not helpful for decision makers or those who need to understand how a decision was made.

5.4 ISSUES OF INSTITUTIONAL CULTURE

The above discussion of scientific issues has used examples from some of the most difficult problems that DOE faces, such as the proposed Yucca Mountain repository for HLW. Here, the problem is with predicting the behavior of a complex natural and engineered system expected to contain long-lived radionuclides over extremely long time periods. The Yucca Mountain problem is being addressed by use of a complex integrated performance assessment model, but according to a white paper of the Board on Radioactive Waste Management, this complexity is viewed as virtually incomprehensible to nonspecialists (NRC, 1999).[6]

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[6] "There are many indications that publics neither understand nor trust the expert community on radioactive waste issues. For the non-specialists, the array

DOE faces many other technical problems of a simpler nature. These less complex problems would appear to be more amenable to efforts to gain public confidence by virtue of their being addressed by a simpler risk-informed process. To the committee's knowledge, however, even these simple problems are not currently being addressed by anything resembling the risk-informed process recommended here.

It seems that nearly every new assistant secretary for the Office of Environmental Management has come into office with the expressed desire to reform the process in order to make it focus more on risk and achieve cleanup "faster, better, and cheaper." The committee is also impressed by the number of other committees (see Appendix B) that have recommended virtually the same thing: the implementation of a risk-based or risk-oriented process to focus attention and money on the problems that really do require action and not to spend unnecessarily large amounts of money on problems that are not, in fact, a source of significant risk to either humans or the environment. Some of these committees were specifically charged at the time to help DOE determine how to use the risk assessment and management process effectively. DOE has asked other groups to examine the environmental management problem and those groups have come up with similar recommendations.

In spite of these multiple recommendations and the apparent openness of persons high within the DOE management structure, and in spite of this committee's attempts to find examples of a risk-based or risk-informed decision process at work, it appears that, with rare exception, the process of risk assessment is not being utilized effectively by the nation. Virtually all of the so-called risk assessment activities presented to this committee were being performed principally because they were required by the U.S. EPA under the CERCLA or the Resource Conservation and Recovery Act (RCRA). (These requirements typically followed on from the listing of the various sites on the National Priorities List [NPL].) It is the committee's impression that these risk assessment activities were not being regarded within DOE as particularly significant or effective input into the decision-making process. While in public presentations some site personnel stated that risk currently is the driving factor for decisions through the regulatory process, in private some of the same people indicated that factors other than risk fixed many decisions. For example, many decisions were made in the federal facility agreements,

of applicable scientific data and proposed methods is so complex as to be virtually incomprehensible" (NRC, 1999).

which were established before most of the risk assessments were conducted.

Thus, one of the fundamental questions that the committee asks is Why is risk assessment not already one of the foundations of DOE's environmental management program? What are the impediments? Some members of this committee have participated over periods of approximately 15 years on other committees or review groups examining these questions. None of the members of this committee has actually worked for DOE, so committee members can examine these fundamental questions only as outsiders with the information furnished from DOE, regulatory agencies, and members of the public. Some or perhaps many impediments may lie beyond DOE in the larger institutional or societal structure.

Although U.S. EPA's use of risk assessment in some of its programs has been criticized severely, U.S. EPA has, in comparison, used the risk-assessment process relatively effectively at many of the sites it regulates under RCRA and CERCLA, and at WIPP. Risk analyses are accepted as an important part of the process of regulatory decisions and cleanups conducted by the U.S. EPA. Russell (2000) attributes U.S. EPA's use of risk assessment to the efforts of Administrator William Ruckleshaus to change the U.S. EPA's culture from a "…view of its goal of eliminating pollution to one of assessing and then managing risk in order to reduce harm to people and the environment." DOE has never had a similarly influential risk management champion.

Some of the fundamental differences between U.S. EPA and DOE relate to the differences in the history and structure of the two organizations. The U.S. EPA is a relatively new organization with a clear, narrowly defined mission. DOE has its roots in the Manhattan Project, and DOE has a variety of different missions, some of which may inherently conflict with each other. The organization of DOE (actually its predecessor agencies, the Manhattan Engineering District of the Army Corps of Engineers and the Atomic Energy Commission) was unique from its very first days. The first mission of the original predecessor agency was to develop and build a few deliverable nuclear weapons. This was a sophisticated scientific and engineering problem for which the members of the usual government bureaucracies had no experience or expertise. Thus, from the beginning there was an unusual dependence of DOE upon private contractors of one kind or another. Urgency and secrecy were also fundamental to the early days of DOE. The urgency led to unprecedented steps to achieve the fundamental mission with little importance attached to environmental considerations, although considerable attention was always focused on the health and safety of workers. The secrecy led to islands of knowledge that were known in detail only to persons outside of the main bureaucracies.

Over time, the DOE management style also came to depend on field organizations. Some of these organizations, such as the Richland (Hanford), Oak Ridge, and Savannah River Field Offices, became very powerful. Persons at these three field offices oversaw large enterprises, run by management and operations (M&O) contractors, whose financial contributions to the local and regional economies became very substantial, if not dominant. This economic influence did not escape the notice of local and regional politicians, and each major DOE site inevitably built up its own base of political influence based on its economic power.

Enormous changes have occurred within DOE during the last two decades. The major mission, the production of special nuclear materials and the fabrication of nuclear weapons, has virtually been eliminated. Some of the smaller DOE sites have been, or are being, decommissioned and dismantled. At about the same time that this major structural shift within DOE was occurring, the powerful trend of environmental protection and/or remediation was developing. As the production of special nuclear materials was winding down, the concern about (and the legal liabilities from) the residues of contamination from decades of urgent production came to the fore. This concern led to the establishment at DOE of an Office of Environmental Management and, at each DOE site still run by M&O contractors, of a new organization devoted to environmental management or cleanup. At many of the remaining DOE sites, this environmental management organization was about the same size and had about the same budget as the former production organizations.

In spite of this fundamental shift, DOE tried to manage as it had previously by using a decision-making process that was rather closed. One of the sea changes that eventually swamped this previous methodology was the loss of DOE's exclusive self-regulation. One of the early changes was the empowerment of U.S. EPA to regulate airborne emissions from DOE facilities under the Clean Air Act; eventually, it became clear that the U.S. EPA had the power to regulate DOE under the terms of other environmental laws, notably CERCLA and RCRA. The real meaning of these changes was brought home to DOE by the realization that U.S. EPA had the power to levy fines and even enforce personal criminal penalties. This was illustrated dramatically by the raid by Federal Bureau of Investigation and U.S. EPA Enforcement Police on the Rocky Flats Plant; one result of the raid and other investigations was criminal conviction of M&O officials at the Rocky Flats Plant.

During this period of the late 1980s and early 1990s the possibility of DOE sites being listed on the NPL was viewed by personnel at most sites as threatening and negative. After the first DOE site was listed, however, it received a large amount of funding to deal with its environmental problems. This flow of funds was not lost on environmental protection personnel at other sites, and a form of subtle competition soon evolved in which listing on the NPL was accompanied by receiving larger amounts of money. Eventually, most significant DOE sites become listed on the NPL, and while fines have been assessed, no additional high profile criminal convictions have occurred.

An additional activity carried out during this period was the negotiation of triparty compliance agreements among DOE, U.S. EPA, and local (usually state) regulators. These agreements typically contained binding statements on what would be done, along with a time scale over which the specified work would be done. Persons negotiating these agreements on behalf of DOE were concerned mainly with legal, managerial, and political issues. A result was that many of these agreements contained commitments to perform work that was technically or economically infeasible and might pose substantial risk to workers using present technologies. This eventually led to the need to renegotiate many agreements and to some loss of credibility for all participating agencies. Another important aspect in terms of the deliberation of this committee was that these agreements were not based on an analysis of the risks posed by the considered wastes. In some cases, agreements were reached to perform cleanups that not only were expensive, but also would have resulted in little or no reduction in risk (DOE, 2002d). In essence, this process of negotiating compliance agreements without thorough and detailed consideration of risk, cost, or technical feasibility represents an enormous lost opportunity for the nation to insert discipline into the environmental management process.

There have been several attempts by Congress and high-level DOE management personnel over the last several years to insert such discipline at DOE sites; these activities are discussed in Appendix B. Such activities have not been particularly successful and may have been resisted by a variety of ad hoc consortia at the various sites. Members of such consortia might include persons from DOE field offices, management and operations contractors, state and local regulators, environmental groups, state governors, and members of the U.S. Congress. A strong theme binding such diverse groups together has been the thousands of jobs and billions of dollars at stake. The emotions and issues are similar to those that periodically surface when the Department of Defense contemplates closure of military bases.

Another important theme is that local persons feel that top-down imposition of discipline, whether through risk assessment or other means, would be a violation of the content and spirit of the agreements that have been negotiated. In some cases, risk-based approaches are also seen to be in conflict with national or local laws. A persistent problem is that the nation has permitted and perhaps even encouraged a lack of focus on cleanup as a result of viewing some site cleanups as regional economic entitlement programs (see, e.g., Greenberg et al., 2002; Probst and Lowe, 2000; Russell, 1997).

DOE has adapted itself to the environment in which it operates. The complexity, constraints, and politicization make these problems very challenging and bear some responsibility for the situation. Stated bluntly, there is a conflict between the wishes of the nation to limit the costs and time of the DOE cleanup program (and the attempts of the various assistant secretaries of energy for environmental management to implement these wishes) and the incentive to persons at local sites to ensure a large and sustained influx of funds. This is a fundamental institutional barrier to the use of a risk-based approach to environmental management at DOE sites. Local persons have frequently stated that they could be comfortable with the use of risk assessment to allocate priorities among subsites (or "operable units" in the official jargon) at their overall site, but they state a strong resistance to the use of a risk-based approach, or any other approach, to set priorities among sites. Such statements are apparently motivated by fears of the possible loss of funding for their site in favor of another site. These fears may be accompanied by a sense that if funding is lost, cleanup programs could be curtailed or even abandoned, leaving cleanups unresolved and local stakeholders totally marginalized.

The problems of DOE legacy wastes are most severe at Hanford, Idaho, and Savannah River. There are two important reasons for this. The more obvious is that these sites have most of the wastes within the system. The other less obvious factor is that these three sites were purposely located in rural areas to place their hazards farther from large populations. The DOE contribution to the regional economy in these areas has been dominant. Thus, the abrupt withdrawal of DOE's contribution would be catastrophic to these local economies. However, a short-term view is dangerous and only postpones the inevitable. Russell (1997) has argued that these communities are entitled to transitional economic assistance, but that hijacking the DOE environmental management program is not a productive avenue to achieve this reasonable goal. Rather, Russell has argued that the cleanup and transitional assistance programs should be divorced. Probst and Lowe (2000) have made similar arguments.

In summary, the institutional barriers to the implementation of a risk-based approach to cleanup at DOE sites have been demonstrated to be effective and deeply entrenched. Although Congress has repeatedly criticized the DOE process, members of Congress representing the individual sites have sometimes contributed to the problem by the long-established method of introducing special legislation in favor of a particular site. Nearly every new assistant secretary for environmental management has tried to reform the system, but it does not appear that any assistant secretary has sufficient power to impose discipline on the system. Finally, the coalitions of interests at each site are extremely resistant to any priority-setting activity that might remotely result in a loss of funding for that site. These factors, coupled with the legally binding agreements that have been made at each site, present a formidable barrier to the implementation of the risk-based process advocated in this report.

Is there a solution? The answer is not clear, but it does not seem likely that a solution will be forthcoming without strong instructions from the Congress to the highest level of management at DOE.

The DOE's Top-to-Bottom Review Team made the following statement, "The results of the Team's review make clear that there is a systemic problem with the way EM has conducted its activities: the EM program's major emphasis has been on managing risk, rather than actually reducing risk to workers, the public, and the environment" (DOE, 2002d, pp. ES-1-ES-2). As a consequence of this conclusion, DOE redirected its program toward reducing the long-term risks posed by legacy wastes with initiatives such as closing tanks, pursuing supplemental technologies for tank waste processing, and pursuing risk-based end states. However, these efforts have apparently run afoul of EM's lack of use of risk management in the sense that it is normally understood (see NRC, 1983)—that is, as a process that defines the character and extent of the problems to be addressed, helps identify options to manage risks, and engages regulators and other stakeholders to balance risk considerations with other factors. As subsequent events (e.g., successful litigation concerning on-site disposition of tank heels; a RBES process that appears to be effectively stalled) have amply demonstrated, the absence of a real risk management process has been a substantial impediment to the cleanup and consequent risk reduction sought by EM.

Thus, the key ingredient of a needed program is precisely risk management, as defined by an earlier committee (NRC, 1983). Recognition must be given to the fact that some wastes cannot be cleaned up, that transgenerational risks will occur, and that long-term stewardship will be required into the indefinite future. These are the costs for this nation's choices during World War II and the Cold War.

Finding 10: The DOE risk assessments and decision processes examined by the committee do not exhibit all of the characteristics of an effective and credible risk-informed decision-making process, listed in Finding 8. Other bodies have made similar recommendations on how DOE should incorporate risk into environmental decision making, and DOE has made progress, but institutional factors appear to have interfered and perhaps undermined attempts to implement these approaches. This implies that changes at DOE are needed to address internal and external impediments to the risk-informed approach.

In its site visits and after, the committee requested that DOE present its best examples of risk assessment informing waste disposition or cleanup decisions. Through DOE's presentations to the committee and the committee's review of documents, the committee examined many risk assessments and decision processes. DOE and its contractors have performed technically complex risk assessments, and in many cases have performed risk assessments as part of regulatory processes that lead to cleanup decisions with stakeholder input. Yet the cases examined by the committee do not meet the needs identified and described in this report for the following reasons. The complex analyses were not decision oriented and were not carried out in a transparent manner needed for meaningful participation by those outside DOE. The actions supporting regulatory decisions in many cases also were lacking—the steps in the processes appeared to have been performed simply to meet procedural requirements and most did not appear to have taken the kind of cooperative approach that the committee sees as essential to reach credible decisions and to foster buy-in by other relevant parties.

That the risk assessments examined by the committee do not exhibit all of the characteristics of an effective and credible risk-informed decision-making process does not imply that DOE has been derelict. These are technically difficult cleanup problems being addressed in a complex political and social environment. DOE has stabilized into safe, although temporary, conditions the dangerous wastes and facilities at its sites, and in most cases has an enviable safety record in its cleanup program. Working toward effective and credible risk-informed decisions on these issues is very difficult. Further, many of the risk assessments examined by the committee were addressing smaller although significant problems, and so may not have warranted the effort recommended in this report. Also, the risk assessments were not necessarily aimed to fill the role described in this report. But on the latter point, the committee notes that numerous studies summarized in Appendixes A and B make recommendations consistent with those made in this report on how to incorporate risk into environmental decision making.

DOE has made progress, but approaches such as the one recommended by the committee still have not permeated DOE's decision-making apparatus. It appears that institutional factors both inside and outside DOE have impeded attempts to implement risk-informed approaches. These factors include a tradition of internal rather than open decision making, incentive structures that favor distorting or ignoring risk, and a public wariness or mistrust of DOE's use of risk assessment to justify proposed actions.

The committee's role is to help DOE to bring the best practices to bear on the challenges DOE is addressing on the nation's behalf. DOE's difficulty in adopting risk-based or risk-informed approaches recommended previously by other committees and observers implies that DOE needs to make changes. Moreover perhaps changes are needed more broadly in the nation's approach toward managing risks at DOE sites.

Recommendation 5: To address the challenges of implementation and acceptance, DOE should form an authoritative, credible, and reasonably independent group to revamp the way it goes about implementing risk-informed approaches applied to waste disposition decisions.

These are enormously complex problems with numerous parties involved and a great deal of institutional inertia (as evidenced by unsuccessful previous attempts to change). The committee sees a need to break out of old approaches. To this end DOE needs an action-oriented group that provides advice and identifies alternatives, but also assists with implementation and draws in major stakeholders to get buy-in. The group must be credible, and to be credible the group must be authoritative on the issues it addresses and independent so as to be unbiased and free of conflicts of interest. Before implementing this recommendation, it would be useful to consider the extensive experience of a variety of federal agencies with outside advisory committees, including the committees' roles and effectiveness.

6

Findings and Recommendations

The following principal findings and recommendations were reached from this study:

Finding 1: Deep geologic disposal is the default disposition option for HLW and TRU waste.

There is a long history of studies supporting deep geologic disposal of long-lived radioactive wastes. Deep geologic disposal remains the nation's approach for disposal of TRU and HLW.

Finding 2: Some waste currently classified as TRU or HLW may not warrant disposal in a deep geologic repository, either because (1) it is infeasible to recover and dispose of every last bit of waste that might conceivably be classified as TRU or HLW, or (2) the effort, exposures, and expense associated with retrieval, immobilization, and disposition in a repository may be out of proportion with the risk reduction achieved, if any.

Recovery of every last gram of TRU and HLW will be technically impractical and unnecessary. Recovery of some of the waste that is hardest to retrieve may result in little reduction in risk compared to disposing of it in situ while substantially increasing other risks, impacts, and costs. Further, processing and treatment methods can separate highly radioactive material from some wastes, which greatly reduces their hazards. But because of the definition of HLW found in the law, this latter waste, even if it contains very low concentrations of hazardous radionuclides, could also be classified as HLW and, therefore, require deep geologic disposal. Some of these wastes, then, may not warrant deep geologic disposal.

Finding 3: The committee makes no recommendation whether specific wastes should be approved for alternative disposal, but it has identified three waste types that contain waste streams that merit consideration: (1) HLW remaining in tanks (heels); (2) low-activity products from treatment of HLW; and (3) buried TRU waste (not buried in a manner that facilitates retrieval).

The nation must confront disposition decisions for each of the waste types listed. Each of these waste types spans a range of characteristics, from relatively low radioactivity and hazard to relatively high and volumes ranging from a few thousand liters to possibly billions of liters. The costs and risks of packaging and disposing of these wastes are very large. There is, then, the potential for a disproportion between the risk-reduction achieved and the costs and risks incurred for some wastes.

Finding 4: The nation needs a way to determine which of the wastes mentioned in Finding 3, if any, will be disposed in some manner other than deep geologic disposal.

Litigation over authority and agreements about waste disposition has left DOE's waste disposition program with substantial uncertainty concerning the path forward. Given the various disputes and the reality that not all of the waste will or can be recovered and disposed of in a deep geologic repository, an acceptable exemption process is needed.

Finding 5: Without a formal, well-structured, decision-making process, less desirable, ad hoc approaches will emerge.

Given the costs and difficulties of sending all waste that could be classified as HLW or TRU waste to a deep geologic repository, some approach will arise for deciding what waste gets geologic disposal and what does not. A formal, well-structured exemption process is needed regardless of the outcome of the various lawsuits and appeals concerning these wastes. The alternative to a reasoned, planned process is an ad hoc one, which could lead to inconsistent or poorly thought-out decisions that are not in the public interest.

Finding 6: Human health risk is a good basis or starting point for considering whether a waste stream should be granted an exemption, but it is not a sufficient basis for deciding these questions. At a minimum, costs, work-related risks, risks to ecosystems, technical feasibility, cultural and societal impacts, land use implications, preexisting agreements, and other, site-specific factors are also relevant in what is called a risk-informed approach.

Risk-informed approaches are necessary to include all valuable information in an exemption process. Human health risk is an essential consideration for exemptions because (1) risk reflects one of the basic values being protected—human health—and therefore is a sensible starting point; and (2) risk analysis is a powerful, structured, well-developed way of considering human health effects, and its strengths and weaknesses are well established. This report focuses on human health risk because it is of concern for all of the waste streams and because it has traditionally been studied in risk analysis. However, the committee does not mean to imply that other risks such as ecological or cultural are unimportant. A proper risk analysis should identify and consider all of the relevant risks at a given site. The process of performing a risk assessment is useful, too, because it draws attention to the critical assumptions and focuses thought on the most significant contributors to risks. The question of how such decisions should be reached, including the roles of these factors and ethical considerations, is critically important, but is entirely a policy question that is beyond the task statement of this technical committee.

Finding 7: The credibility of DOE's planning and decision making is reduced by the apparent conflict of interest created by DOE's authority both to propose and to approve disposition plans for radioactive waste.

The burden of proof for departing from the default disposition option must be on the petitioner seeking alternative disposition. Allocating the burden of proof to DOE is meaningful only if DOE is not also the decision maker. That is, the burden of proof would be weak indeed if it was simply a matter of DOE convincing itself that it is right. DOE's status as a self-regulating agency is problematic because of the perceived and real conflict of interest: DOE is both petitioner and decision maker. Outsiders might reasonably question whether DOE is able to separate these functions so that the agency is neutral in the latter role. Having DOE's application for exemption subject to the judgment of an independent arbiter would make the process more credible to skeptics, of which, in this area, there are many.

Therefore, the burden of proof implies, and the committee here makes it explicit, that a separate federal entity is needed as the regulatory decision maker for exemption purposes. DOE is, of course, regulated by a number of different federal and state entities. Persuasive arguments could be made for either the U.S. Environmental Protection Agency (U.S. EPA) or the U.S. Nuclear Regulatory Commission (U.S. NRC) as regulator, because both have significant expertise in the regulation of radioactive materials. The committee does not have a basis for making a recommendation for either agency but offers some observations on the merits of each for this role.

The U.S. EPA would appear to be the most obvious regulator for TRU waste, because it is already the decision maker identified by law and has worked extensively with such waste at the WIPP facility. U.S. EPA also has been the principal regulator for cleanup at the sites at which HLW and TRU waste is found and U.S. EPA has extensive experience with stakeholder interaction under several statutes; probably more experience than U.S. NRC has. The U.S. NRC, on the other hand, is the agency mentioned in the current definition of HLW. U.S. NRC will rule on DOE's license application for a HLW repository and is the regulator for the cleanup of waste, including HLW, at DOE's West Valley site, which is perhaps the experience that is technically most similar to the management and cleanup of HLW at Hanford, Savannah River, and INEEL. Also, U.S. NRC is legally an independent agency and has some distance from the administration in power. At the same time, however, U.S. NRC is perceived by some to be a captured regulator, serving the interests of the nuclear industry. Further, coming as it does from the same parent agency (the Atomic Energy Commission), U.S. NRC is perceived by some as being too close to DOE and therefore having an institutional bias for DOE.

Finally, the committee notes that it is desirable, but not essential, for the sake of efficiency and consistent application, that the same agency be the exemption decision maker for both HLW and TRU waste.

Recommendation 1: The nation should pursue a formal, well-structured, risk-informed approach to decide which specific waste streams within the waste types enumerated in Finding 3, if any, should be disposed in some manner other than deep geologic disposal.

The adoption of a formal, well-structured, risk-based approach cannot be the work of one institution alone. DOE must take the initiative, but it is constrained by legislation, the regulation of multiple federal agencies, state regulation, and formal and informal agreements with states, American Indian nations, and other stakeholders. Each of these has a role in the adoption and implementation of such an approach. The committee has recommended that DOE's exemption applications be reviewed and approved or rejected by an independent regulator (or decision maker). Where it is possible and appropriate to identify a particular actor who should be responsible for a particular part of the process described herein, the committee has done so. However, in several settings, the choice of a regulator and their authority is essentially a political one, and beyond the committee's mandate.

Recommendation 2: DOE should *not* attempt to adopt these changes unilaterally. Likewise, the exemption process that the committee recommends must be implemented in the context of DOE's existing or renegotiated compliance agreements.

Put another way, if DOE wants to renegotiate its compliance agreements, it must make a case for renegotiation that is informed by risk, sets out clear criteria for an exemption, comprehensively addresses health risks (including worker, transportation, and long-term risk), and follows a transparent process that allows and enables meaningful public input.

Recommendation 3: DOE and its regulators for HLW and TRU waste should adopt a six-step process for risk-informed decision making: (1) initiate the process, laying out viable options and potential decisions; (2) scope the information and analysis; (3) collect

data and refine models; (4) prepare refined risk assessment; (5) develop additional analyses and data collection, as needed, to support decisions; and (6) finalize the decision.

Finding 8: An effective and credible risk-informed-decision-making process has several characteristics. It is (1) participatory; (2) logical; (3) consistent with current scientific knowledge and practice; (4) transparent and traceable; (5) structured with reasonable independence of the decision authority from the petitioner; (6) subjected to thorough, independent peer review; (7) technically credible, with believable results; and (8) framed to address the needs of the decision process.

A risk-informed process that fails to meet any of these eight essential characteristics would likely be ineffective. In order to be effective, a risk-informed approach must be trusted. The eight characteristics listed above are intended not only to ensure a *result* that can be trusted, but *equally importantly* to create a process that can be trusted. For example, a technically credible risk-based approach that lacks participation or transparency would likely not be trusted and, therefore, would likely be ineffective in supporting a waste exemption process.

In summary, Findings 7 and 8 describe the key elements of a risk-informed approach as being a well-structured, participatory, and transparent process with an independent decision maker that uses current scientific knowledge and practice to address human health risk but also takes into account other impacts to reach a decision.

Finding 9: The biggest challenges to developing a meaningful risk-informed decision process, such as recommended herein, are minimizing disruption to existing laws, regulations, and agreements; creating buy-in to the approach; and enabling meaningful participation by participants who have few resources.

Disrupting existing laws, regulations, and agreements (e.g., changing the rules to allow potentially unsafe practices to proceed without due process) will tend to cause resistance and unintended consequences of an exemption process. Any meaningful decision process that involves stakeholders such as the risk-informed process recommended here will require finding ways to implement an exemption process in the least disruptive manner possible with regard to existing laws, regulations, and agreements. This process is difficult but important to maintain predictability, to create fewer unintended consequences, and to avoid destabilizing the policy equilibrium that has been reached as people have acted in reliance on the existing framework. The committee does not know how many exemptions DOE might seek or a regulator might approve. Assuming that the number will be relatively few, the committee has recommended exemptions because they can minimize disruption while preserving the desirable features of a risk-informed approach.

Recommendation 4: Congress, DOE, U.S. EPA, and U.S. NRC should take actions as necessary to enable DOE to implement effectively the risk-informed approach recommended here. Specifically, they should provide for a formal, well-structured exemption process, institute technical review of the risk analysis independent of the agency producing the analysis, give decision-making authority to an agency outside DOE, and ensure that sufficient resources are reliably available for regulators, American Indian nations, and stakeholders to participate meaningfully in the process from the outset.

The committee did not develop detailed actions for each entity/agency for the steps necessary to implement this recommendation. There are many possible distributions of responsibilities; what one agency might contribute toward implementation of the recommendations depends heavily on what others would contribute. The implementation of the recommendation should be achieved jointly by the entities involved, without attempting to define in advance of inter-agency discussions what each should contribute.

Finding 10: The DOE risk assessments and decision processes examined by the committee do not exhibit all of the characteristics of an effective and credible risk-informed decision-making process, listed in Finding 8. Other bodies have made similar recommendations on how DOE should incorporate risk into environmental decision making, and DOE has made progress, but institutional factors appear to have interfered and perhaps undermined attempts to implement these approaches. This implies that changes are needed at DOE to address internal and external impediments to the risk-informed approach.

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The committee's role is to help DOE to bring the best practices to bear on the challenges DOE is addressing on the nation's behalf. DOE's difficulty in adopting risk-based or risk-informed approaches recommended previously by other committees and observers implies that DOE needs to make changes and perhaps changes are needed more broadly in the nation's approach toward managing risks at DOE sites.

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References

Abraham, S. 2003. Letter from Secretary of Energy Spencer Abraham, U.S. Department of Energy to The Honorable J. Dennis Hastert, Speaker of the House, U.S. House of Representatives.

Andersson, J., and G. Grundteknik. 1999. Data and Data Uncertainties. SKB Technical Report TR-99-9,138. Stockholm, Sweden: Swedish Nuclear Fuel and Waste Management Company.

Apostolakis, G. E. 2004. How useful is quantitative risk assessment? Risk Analysis 24:515-520.

Applegate, J. S. 1995. A beginning and not an end in itself: The role of risk assessment in environmental decision making. University of Cincinnati Law Review 63:1643.

Applegate, J. S., and S. Dycus. 1998. Institutional controls or emperor's clothes? Long-term stewardship of the nuclear weapons complex. Environmental Law Reporter 28:10631.

Babich, A. 2003. Too much science in environmental law. The Columbia Journal of Environmental Law 28:119.

Barnes, C. M., C. B. Millet, and V. J. Johnson. 2004. Feed Composition for the Sodium-Bearing Waste Treatment Process. INEEL/EXT-2000-01378, Revision 4. Idaho National Engineering and Environmental Laboratory, Bechtel BWXT Idaho, LLC.

Bernero, R.M. 1989. Letter to A.J. Rizzo, Richland Operations Office, U.S. Department of Energy. Available through http://www.nrc.gov/reading-rm.html.

Bernero, R.M. 1993. Letter to J. Lytle, Office of Environmental Restoration and Waste Management, U.S. Department of Energy. March 2, 1993. Available through http://www.nrc.gov/reading-rm.html.

Bethke, C. M. 1992.The question of uniqueness in geochemical modeling. Geochimica et Cosmochimica Acta 56:4315-4320.

Bethke, C. M. 1996. Geochemical Reaction Modeling. New York: Oxford University Press, 397.

Bingaman, J. 2004. WIPP needs independent watchdog, not DOE lap dog. Albuquerque Journal, guest column. May 15.

Bjornstad, D. J., D. W. Jones, M. Russell, and C. L. Dümmer. 1998. Implementing Outcome-Oriented Risk Planning: An Overview. JIEE 98-02. October. Knoxville, Tenn.: Joint Institute for Energy and Environment.

Bredehoeft, J. D., A. W. England, D. B. Stewart, N. J. Trask, and I. J. Winograd. 1978. Geologic Disposal of High-Level Radioactive Wastes. Earth-Science Perspectives (Geological Survey Circular 779) 15. Washington, D.C.: U.S. Government Printing Office.

Bredehoeft, J. D., and L. F Konikow. 1993. Reply to comment by G. de Marsily, P. Combes, and P. Goblet on "Ground-water models cannot be validated." Advances in Water Resources 15:371-372.

Bredehoeft, J. D. 2003. From models to performance assessment: The conceptualization problem. Ground Water 41:571-577.

BRERA (Brownfields Revitalization and Environmental Restoration Act). 2002. Small Business Liability Relief and Brownfields Revitalization Act, Public Law 107-118, codified at 42 U.S.C. §§ 9601, 9607, 9622. Clean Water Act § 33 U.S.C. § 1311(n).

Browning, L., W. M. Murphy, C. Manepally, and R. Fedors. 2003. Reactive transport model for the ambient unsaturated hydrogeochemical system at Yucca Mountain, Nevada. Computers and Geosciences29:247-263.

Budnitz, R., R. C. Ewing, D. Moeller, J. Payer, C. Whipple, and P. Witherspoon. 1999. Peer Review of the Total System Performance Assessment-Viability Assessment Final Report, 145. Las Vegas, Nevada: Total System Performance Assessment Peer Review Panel.

Burger, J., C. Powers, M. Greenberg, and M. Gochfeld. 2003. The Role of Risk and Future Land Use in Cleanup at the Department of Energy. CRESP Report 03-001. March. Available at: *http://www.cresp.org/home.html*.

Burket, J. 2004. Changing the rules? *NRDC v. Abraham* and the reclassification of high level nuclear waste. Southeastern Environmental Law Journal 159.

Carnegie Commission on Science, Technology and Government. 1993. Risk and the Environment: Improving Regulatory Decision-Making. New York: Carnegie Corporation of New York.

CBO (Congressional Budget Office). 1994. Cleaning Up the Department of Energy's Nuclear Weapons Complex. Washington D.C.: CBO.

CERE (Consortium for Environmental Risk Evaluation). 1995. Health and Ecological Risk at the U.S. Department of Energy's Nuclear Weapons Complex: A Qualitative Evaluation. CERE Interim Risk Report. New Orleans, L.A.: Tulane University Medical Center.

CMA v. NRDC (Chemical Manufacturers Association v. Natural Resources Defense Council). 1985. 470 U.S. 116.

Cochran, T. B. 2003. United States District Court for the District of Idaho—Second Declaration of Dr. Thomas B. Cochran. Case No. 01-CV-413. April 15.

CRE (Center for Risk Excellence). No Date. Need/Opportunity. Available at: *http://www.ead.anl.gov/inetapp/ dsp_inetsum.cfm?appsumid=41*.

CRESP (Consortium for Risk Evaluation with Stakeholder Participation). 1996. CRESP National Review Panel Report: Review of Risk Data Sheet Information for FY 1998. Available at: *http://www.instrm.org/ cresp1/cresp1/nrp.pdf.*

CRESP. 1997. Improving DOE/EM Risk Information: Content and Format. Revised Version. January. Available at: *http://www.instrm.org/cresp1/ cresp1/ improve.pdf.*

CRESP. 1999. Peer Review of the U.S. Department of Energy's Use of Risk in its Prioritization Process. December 15. Available at: *http://www.instrm.org/cresp1/cresp1/home.html.*

CTUIR (Confederated Tribes of the Umatilla Indian Reservation). 1995. Scoping Report: Nuclear Risks in Tribal Communities. Umatilla Indian Reservation, Oreg.: Department of Natural Resources.

Curtis, C. 1995. DOE's Principles for Using Risk Analysis. Washington, D.C.: Department of Energy.

Davis, T.L., D.W. Tharin, D.W. Jones, and D.R. Lohr. 1977. History-Waste Tank 16 1959 Through 1974. DPSPU 77-11-17. E.I. du Pont de Nemours & Company. Savannah River Plant.

de Marsily, G., P. Combes, and P. Goblet. 1992. Comment on ground-water models cannot be validated by L. F. Konikow and J. D. Bredehoeft. Advances in Water Resources 15:367.

d'Entremont, P.D. and J.L. Thomas. 2002. Characterization of Tank 19 Residual Waste. WSRC-TR-2002-00052. Revision 1. November. Available at: *http://www.osti.gov/bridge.*

DOE (Department of Energy). 1988. Comprehensive Implementation Plan for the DOE Defense Buried TRU-Contaminated Waste Program. Joint Integration Office, Albuquerque.

DOE. 1995a. Closing the Circle on the Splitting of the Atom: The Environmental Legacy of Nuclear Weapons Production in the United States and What the Department of Energy is Doing About It. Office of Environmental Management, Washington, D.C.

DOE. 1995b. Office of Integrated Management. Available at: *http://web.em.doe.gov/irm/imr1.html*.

DOE. 1995c. Risks and the Risk Debate: Searching for Common Ground. The First Step. Washington, D.C.: DOE.

DOE. 1996. Implementation Plan for the Programmatic Environmental Impact Statement for the Department of Energy Environmental Restoration and Waste Management Program. Available at: *http://web.em.doe.gov/peis/*.

DOE. 1997a. Linking Legacies: Connecting the Cold War Nuclear Weapons Production Processes To Their Environmental Consequences DOE/EM-0319. Office of Environmental Management, Washington, D.C.

DOE. 1997b. Industrial Wastewater Closure Module for the High-Level Waste Tank 17 System, Revision 2, Savannah River Site.

DOE. 1997c. Final Waste Management Environmental Impact Statement for Managing Treatment, Storage, and Disposal of Radioactive and Hazardous Waste. DOE/EIS-0200-F. Washington, D.C.: DOE.

DOE. 1997c. 2006 Plan Update. Status of Environmental Management's 2006 Plan Vision and Status of Implementation. Washington, D.C.: DOE.

DOE. 1998a. Tanks Focus Area: Oak Ridge Reservation. Available at: *http://tech.inel.gov/documents/TEB/LDUA_Systems/html/ornl.html*

DOE. 1998b. Accelerating Cleanup: Paths to Closure. DOE/EM-0362. June. Washington, D.C.: DOE.

DOE. 1998c. Guidelines for Risk-Based Prioritization of DOE Activities. DOE-DP-STD-3023-98. April. Washington, D.C.: DOE.

DOE. 2000. Buried Transuranic-Contaminated Waste Information for U.S. Department of Energy Facilities. Office of Environmental Management. Washington, D.C.: DOE.

DOE. 2001. Summary Data on the Radioactive Waste, Spent Nuclear Fuel, and Contaminated Media Managed by the U.S. Department of Energy. Office of Environmental Management. Washington, D.C.: DOE.

DOE. 2002a. Waste Encapsulation and Storage Facility. U.S. Department of Energy Richland Operations Office Fact Sheet. REG-0275 1/02. Richland, Washington.

DOE. 2002b. Final Environmental Impact Statement for a Geologic Repository for the Disposal of Spent Nuclear Fuel and High-Level Radioactive Waste at Yucca Mountain, Nye County, Nevada, Volume II, Appendixes A through O. Office of Civilian Radioactive Waste Management DOE/EIS-0250. Available at: *http://www.ymp.gov/documents/feis_2/index.htm*.

DOE. 2002c. Idaho High-Level Waste and Facilities Disposition, Final Environmental Impact Statement. DOE/EIS-0287. Idaho Falls, Idaho: Department of Energy Idaho Operations Office.

DOE. 2002d. A review of the Environmental Management Program. Presented to the Assistant Secretary for Environmental Management by the Top-to-Bottom Review Team. February 4, 2002. Washington, D.C.: DOE.

DOE. 2003. DOE Policy 455.1. Use of Risk-Based End States. Approved July 15. Washington, D.C.: DOE.

DOE. 2004. Department of Energy FY 2005 Budget Request to Congress. Available at: *http://www.mbe.doe.gov/budget/05budget/*.

Duro, L., J. Bruno, S. Jordana, M. Grive, J. Pon, E. Castilier, C. Beaucaire, M. H. Faure, J. Peña, M. J. Gimeno, M. del Nero, C. Ayora, J. Salas, E. Ledoux, and B. Made. 2000. Blind Prediction Modeling (BPM) exercises in Oklo, Oklo working group. Proceedings of the Third and Final EC-CEA Workshop on Oklo—Phase II, held in Cadarache, France, D. Louvat, V. Michaud, and H. von Maravic, eds. Nuclear Science and Technology Report (EUR 19137 EN), 285.

Eide, S. A., J. L. Jones, and T. E. Wierman. 1998. Human Health Risk Comparisons for Environmental Management Baseline Programs and Integration Opportunities (Discussion Draft). INEEL/EXT-97-01253. Idaho Falls: Idaho National Engineering and Environmental Laboratory.

EMAB (Environmental Management Advisory Board). 1995. Letter from EMAB to Thomas P. Grumbly DOE Assistant Secretary for Environmental Management. August 25. Washington, D.C.: EMAB.

Ewing, R.C., M. S. Tierney, L. F. Konikow, and R. P. Rechard. 1999. Performance assessments of nuclear waste repositories: A dialogue on their value and limitations, Risk Analysis 19: 933-958.

FFERDC (Federal Facilities Environmental Restoration Dialogue Committee). 1993. Recommendations for Improving the Federal Facilities

Environmental Restoration Decision-Making and Priority-Setting Process. Washington, D.C.: U.S. Environmental Protection Agency.

FFERDC. 1996. The Final Report of the Federal Facilities Environmental Restoration Dialogue Committee: Consensus Precipices and Recommendations for Improving Federal Facilities Cleanup. Washington, D.C.: U.S. Environmental Protection Agency.

Fehringer, D. and R. Boyle. 1987. Status of NRC rulemaking for high-level radioactive waste disposal. Proceedings of the Waste Management '87: Waste Isolation in the U.S., Technical Programs and Public Education, Vol. 1. La Grange Park, Ill.: American Nuclear Society, pp. 315-317.

GAO (Government Accountability Office). 1995. Department of Energy: National Priorities Needed for Meeting Environmental Agreements. GAO/RCED-95-1. March. Washington, D.C.: GAO.

GAO. 2002. Waste Cleanup: Status and Implications of DOE's Compliance Agreements. GAO-02-567. May. Washington, D.C.: GAO.

GAO. 2004. Nuclear Waste: Absence of Key Management Reforms on Hanford's Cleanup Project Adds to Challenges of Achieving Cost and Schedule Goals. GAO-04-611. June. Washington, D.C.: GAO.

Garrick, B.J. and S. Kaplan. 1995. Radioactive and mixed waste—Risk as a basis for waste classification. NCRP Symposium, Proceedings No. 2. National Council on Radiation Protection and Measurements, Bethesda, Md., pp. 59-73.

Gephart, R. E. 2003. Hanford: A Conversation About Nuclear Waste and Cleanup. Columbus, Ohio: Battelle Press.

Greenberg M., K. Lowrie, M. Frisch, D. Lewis. 2002. Future economic history of the U.S. Department of Energy's major nuclear weapon site regions: National government policy options for contributing to regional economic stability. May 2002. New Brunswick, N.J.: Rutgers University.

Hamilton, L. D., S. Holtzman, A. F. Meinhold, S. C. Morris, M. D. Rowe, J. I. Daniels, D. W. Layton, and L. R. Anspaugh. 1993. Lessons Learned: Needs for Improving Human Health Risk Assessment at USDOE Sites. BNL-60157. Upton, N.Y.: Brookhaven National Laboratory.

Hanford FFA (Federal Facility Agreement). 2003. Hanford Federal Facility Agreement and Consent Order by Washington State Department of Ecology, United States Environmental Protection Agency, United States Department of Energy as amended through September 1, 2003. Available at: *http://www.hanford.gov/tpa/agreement-6/tpadoc.pdf*.

Harris, S., and B. Harper. 1999. Characterizing Risks: Can DOE Achieve Intersite Equity by 2006? Available at: *http://lts.apps.em.doe.gov/center/reports/doc12.html.*

Herrick C., and D. Sarewitz. 2000. Ex post evaluation: A more effective role for scientific assessments in environmental policy. Science, Technology and Human Values 25:309-330.

Hintze, D. 2004. Waste Disposition Project. Presentation to the National Academies Committee on Risk-Based Approaches for Disposition of Transuranic and High-Level Radioactive Waste. Augusta, Georgia. January 28. Available through the National Academies Office of News and Public Information.

Holdren, K. J., B. H. Becker, N. L. Hampton, L. D. Koeppen, S. O. Magnuson, T. J. Meyer, G. L. Olson, and A. J. Sondrup. 2002. Ancillary Basis for Risk Analysis of the Subsurface Disposal Area. INEEL/EXT-02-01125. September. Idaho Falls: Idaho National Engineering and Environmental Laboratory.

Hornstein, D. T. 1992. Reclaiming environmental law: A normative critique of comparative risk analysis. The Columbia Law Review. 92:562.

Howard, R.A. 1966. Decision Analysis: Applied Decision Theory. Pp. 55-71 in Proceedings of the Fourth International Conference on Operational Research, D. G. Hertz and J. Melese, eds. New York: Wiley-Interscience.

Hughson, D. L., L. Browning, W. M. Murphy, and R. T. Green. 2000. An archeological site at Akrotiri, Greece, as a natural analog for radionuclide transport: Implications for validity of performance assessments. Materials Research Society Symposium Proceedings 608:557-563.

Hulstrom, L.C. 2003. 618-10 and 618-11 Burial Ground Remedial Design Technical Workshop Summary Report. WMP-17684. Revision 0. September. Richland, Wash.: Fluor Hanford.

Hunter, R. L., D. W. Layton, and L. R. Anspaugh. 1994. Opportunities and impediments for risk-based standards: Some views from a workshop. Risk Analysis 14(5):863-868.

INEEL FFA (Idaho National Engineering and Environmental Laboratory, Federal Facility Agreement and Consent Order). December 9, 1991. The United States Environmental Protection Agency, Region 10, The State of Idaho, Department of Health And Welfare, and The United States Department of Energy. Available at: *http://web.em.doe.gov/2001_Agreements/Idaho/INEEL_FFA_CO_12-9-91.pdf.*

Jasanoff, S. 1990. The Fifth Branch: Science Advisors as Policymakers. Cambridge, Mass.: Harvard University Press.

Jenni, K. E., M. W. Merkhofer, and C. Williams. 1995. The rise and fall of a risk-based priority system: Lessons learned from DOE's Environmental Restoration Priority System. Risk Analysis 15(3):397-410.

Jensen, K. A., C. S. Palenik, and R. C. Ewing. 2002. U^{6+}-phases in the weathering zone of the Bangombe U-deposit: Observed and predicted mineralogy. Radiochimica Acta 90: 761-769.

Karkkainen, B. C. 2001. Information as environmental regulation: TRI and performance benchmarking, Precursor to a new paradigm? Georgetown Law Journal 89:257.

Konikow, L. F. 1986. Predictive accuracy of a ground-water model—Lessons from a postaudit. Ground Water 24:173-184.

Konikow, L. F. 1992. Discussion of the modeling process and model validation by Chin-Fu Tsang. Ground Water 30:622-23.

Konikow, L. F. 1995. The value of postaudits in groundwater model applications. Pp. 59-78 in Groundwater Models for Resources Analysis and Management. Boca Raton, Fla.: Lewis Publishers.

Konikow, L. F., and J. D. Bredehoeft. 1992. Ground-water models cannot be validated. Advances in Water Resources 15:75-83.

Lichtner, P. C., C. I. Steefel, and E. H. Oelkers. 1996. Reactive transport in porous media. Reviews in Mineralogy. 34:438.

Long, J. C. S. and R. C. Ewing. 2004. Yucca Mountain: Earth science issues at a geologic repository for high-level nuclear waste. Annual Reviews in Earth and Planetary Science 32:363-401.

Madé, B., E. Ledoux, C. Ayora, and J. Salas. 2000. Coupled chemical transport modeling of uranium around the reaction zone at Bangombé, Oklo, Gabon. Oklo working group. Proceedings of the Third and Final EC-CEA workshop on Oklo—Phase II, held in Cadarache, France, D. Louvat, V. Michaud, and H. von Maravic, eds. Nuclear Science and Technology Report (EUR 19137 EN) 307.

Mears, D. K., and J. Ruple. 2004. Natural Resources Defense Council v. Abraham: Preventing the Department of Energy from defining away high-level waste. Journal of Land Resources and Environmental Law 24:77-112.

Morgan, M. G., and M. Henrion. 1990. Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis. Cambridge, U.K.: Cambridge University Press.

Morrison, R. D. 2004. Richland Operations Office. Personal correspondence with H. Brownell. U.S. EPA Region X, October 5.

NCRP (National Council on Radiation Protection and Measurements). 2002. Risk-Based Classification of Radioactive and Hazardous Chemical Wastes. NCRP Report No. 139. Bethesda, Md.: NCRP.

NEJAC (National Environmental Justice Advisory Council). 2004. Cumulative Risk/Impacts Workgroup Report. Washington, D.C.: U.S. EPA.

Nordstrom, D. K. 2004. Modeling low-temperature geochemical processes. Pp. 37-72 in Treatise on Geochemistry, H. D. Holland and K. K. Turekian, eds. Vol. 5, Surface and Ground Water, Weathering, and Soils, J. I. Drever, ed., Amsterdam: Elsevier Pergamon.

NNMCAB (Northern New Mexico Citizen's Advisory Board). 2004. Recommendation to the Department of Energy No. 2004-3. Regarding DOE's Commitment to Public Participation. Approved July 28. Santa Fe, N.Mex. Available at: *http://www.nnmcab.org/recommendations/board-recommendations.htm*.

NRC (National Research Council). 1957. The Disposal of Radioactive Waste on Land. Washington, D.C. National Academy Press.

NRC. 1983. Risk Assessment in the Federal Government: Managing the Process. Washington, D.C.: National Academy Press.

NRC. 1989a. Review Comments on Predecisional Draft II of DOE's Environmental Restoration and Waste Management Five-Year Plan. August 3. Washington, D.C.: National Research Council.

NRC. 1989b. The Nuclear Weapons Complex: Management for Health, Safety, and the Environment. Washington, D.C.: National Academy Press.

NRC. 1990. Rethinking High-Level Radioactive Waste Disposal: A Position Statement of the Board on Radioactive Waste Management. Washington, D.C.: National Academy Press.

NRC. 1994a. Science and Judgment in Risk Assessment. Washington, D.C.: National Academy Press.

NRC. 1994b. Ranking Hazardous Waste Sites for Remedial Action. Washington, D.C.: National Academy Press.

NRC. 1994c. Building Consensus Through Risk Assessment and Management of the Department of Energy's Environmental Remediation Program. Washington, D.C.: National Academy Press.

NRC. 1995a. Nuclear Wastes: Technologies for Separations and Transmutation. Washington, D.C.: National Academy Press.

NRC. 1995b. Improving the Environment: An Evaluation of DOE's Environmental Management Program. Washington, D.C.: National Academy Press.

NRC. 1996. Understanding Risk: Informing Decisions in a Democratic Society. Washington, D.C.: National Academy Press.

NRC. 1999. Disposition of High-Level Radioactive Waste Through Geologic Isolation. Development, Current Status, and Technical and Policy Challenges. Washington, D.C.: National Academy Press.

NRC. 2000a. Alternatives for High-Level Waste Salt Processing at the Savannah River Site. Washington, D.C.: National Academy Press.

NRC. 2000b. Long-Term Institutional Management of U.S. Department of Energy Legacy Waste Sites. Washington, D.C.: National Academy Press.

NRC. 2001a. Science and Technology for Environmental Cleanup at Hanford. Washington, D.C.: National Academy Press.

NRC. 2001b. Disposition of High-Level Waste and Spent Nuclear Fuel. Washington, D.C.: National Academy Press.

NRC. 2001c. Basic Research Opportunities in Earth Science. Washington, D.C.: National Academy Press.

NRC. 2004. Valuing Ecosystem Services: Toward Better Environmental Decision-Making. Washington, D.C.: National Academies Press.

NRDC (Natural Resources Defense Council), Snake River Alliance, and the Confederated Tribes and Bands of the Yakama Nation v. Abraham. 2002. Complaint for declaratory and injunctive relief. Case 01-413. U.S. District Court for the District of Idaho.

NRDC, Snake River Alliance, and the Confederated Tribes and Banks of the Yakama Nation v. Abraham. 2003. Memorandum Decision. Civ. No. 01-0413-S-BLW. U.S. District Court for the District of Idaho. 271 F. Supp. 2d 1260. July 2.

Oreskes, N., and K. Belitz. 2001. Philosophical issues in model assessment. Pp. 23-41 in Model Validation: Perspectives in Hydrological Science, M. G. Anderson and P. D. Bates, eds. New York: John Wiley and Sons, Ltd.

Oreskes, N., K. Shrader-Frechette, and K. Belitz. 1994. Verification, validation, and confirmation of numerical models in the earth sciences. Science 263:641-46.

ORNL (Oak Ridge National Laboratory). 1982. Proceedings of Alpha-Contaminated Waste Management Workshop, Gaithersburg, MD, 10-13 Aug 1982 (CONF-820845).

Passell, H. D., V. C. Tidwell, S.H. Conrad, R.P. Thomas, and J. Roach. 2003. Cooperative Water Resources Modeling in the Middle Rio Grande Basin. SAND2003-3653. Sandia National Laboratories. December. Available at: *http://www.sandia.gov/water/rdocs.htm.*

Perge, A. 1982. Historical Overview. Proceedings of Alpha-Contaminated Waste Management Workshop. 1982. CONF-820945. Gaithersburg, MD, 10-13 Aug 1982.

PCCRARM (Presidential/Congressional Commission on Risk Assessment and Risk Management). 1997a. Framework for Risk Assessment: Final Report, Volume 1. Available at: http://www.riskworld.com/Nreports/1996/risk_rpt/Rr6me001.htm

PCCRARM. 1997b. Risk Assessment and Risk Management in Regulatory Decision-Making: Final Report, Volume 2. Available at: http://www.riskworld.com/Nreports/1996/risk_rpt/Rr6me001.htm

Probst, K. N., and A. I. Lowe. 2000. Cleaning Up the Nuclear Weapons Complex: "Does Anybody Care?" Center for Risk Management. Washington, D.C.: Resources for the Future.

Raffensperger, C., and J. Tickner, eds. 1999. Protecting Public Health and the Environment: Implementing the Precautionary Principle. Washington, D.C.: Island Press.

Rasmussen, N. C. 1975. Reactor Safety Study: An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants. NUREG-75/014, WASH-1400. October. Washington, D.C.: U.S. Nuclear Regulatory Commission.

Rechard, R. P. 1999. Historical relationship between performance assessment for radioactive waste disposal and other types of risk assessment. Risk Analysis19:763-807.

Rizzo, A.J. 1989. Letter to Robert Bernero, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission. March 6, 1989. Available through http://www.nrc.gov/reading-rm.html.

Roberson, J. 2003a. Guidance to Support Implementation of DOE Policy 455.1 for a Site-Specific Risk-Based End State (RBES) Vision Document. Washington, D.C.: DOE.

Roberson, J. 2003b. Risk Based End States Vision Document. Memorandum. December 9. Washington, D.C.: DOE.

Russell, M. 1997. Toward a Productive Divorce: Separating DOE Cleanups from Transition Assistance. JIEE 97-03. Knoxville, Tenn.: The Joint Institute for Energy and Environment.

Russell, M. 2000. Reducing the Nuclear Legacy Burden: DOE Environmental Management Strategy and Implementation. JIEE/2000-01.Knoxville, Tenn.: The Joint Institute for Energy and Environment.

Schmitt, E. 2003. Risk Based End States Guidance Clarification. Memorandum. December 23. Washington, D.C.: DOE.

Shapiro, S. A., and R. L. Glicksman. 2003. Risk Regulation at Risk: Restoring a Pragmatic Approach. Palo Alto, Calif.: Stanford University Press.

Smith, C. 1982. A Review of the Risk Assessments for Defining the Alpha-Contaminated Wastes. Proceedings of Alpha-Contaminated Waste Management Workshop. 1982. CONF-820945. Gaithersburg, MD, 10-13 Aug 1982.

SNL (Sandia National Laboratories). 2004. Greater Confinement Disposal Project. Available at: *http://www.nwer.sandia.gov/wlp factsheets/gcd.pdf.* Accessed September 22, 2004.

SRS FFA (Federal Facility Agreement for the Savannah River Site). 1993. Administrative Document Number 89-05-FF. WSRC-OS-94-42. Effective Date: August 16. Available at: *http://www.srs.gov/general/enviro/erd/ffa/ffaa.pdf.*

Tal, A. 1997. Assessing the environmental movement's attitudes toward risk assessment, Environmental Science and Technology 31:470a-476a.

Thompson, K.M. 2004. Impacts of residual radioactive waste on Hanford groundwater. Presentation to the National Academies Committee on Risk-Based Approaches for Disposition of Transuranic and High-Level Radioactive Waste. Richland, Wash.. March 9. Available through the National Academies Office of News and Public Information.

U.S. EPA (U.S. Environmental Protection Agency). 1986. Guidelines for Carcinogen Risk Assessment. Federal Register 51(185):33992-34003.

U.S. EPA. 1989. Risk Assessment Guidance for Superfund (RAGS). Human Health Evaluation Manual (HHEM), Part A, Baseline Risk Assessment, Volume I. Interim Final. EPA/540/1-89/002. NTIS PB90-155581. Washington, D.C.: Office of Emergency and Remedial Response.

U.S. EPA. 1990a. Guidance for Data Useability in Risk Assessment, Part A, Final. OSWER Directive 9285.7-09A. NTIS PB92-963356. Washington, D.C.: Office of Emergency and Remedial Response.

U.S. EPA. 1990b. Guidance for Data Useability in Risk Assessment, Part B, Final. OSWER Directive 9285.7-09B. NTIS PB92-963362. Washington, D.C.: Office of Emergency and Remedial Response.

U.S. EPA. 1991a. Risk Assessment Guidance for Superfund (RAGS): Volume I, Human Health Evaluation Manual (HHEM) (Part B, Development of Risk-Based Preliminary Remediation Goals). EPA/540/R-92/003. OSWER Directive 9285.7-01B. NTIS PB92-

963333. Washington, D.C.: Office of Emergency and Remedial Response.

U.S. EPA. 1991b. Risk Assessment Guidance for Superfund (RAGS) Volume I: Human Health Evaluation Manual (HHEM) (Part C, Risk Evaluation of Remedial Alternatives). Interim. EPA/540/R-92/004. OSWER Directive 9285.7-01C. NTIS PB92-963334. Washington, D.C.: Office of Emergency and Remedial Response.

U.S. EPA. 1991c. Risk Assessment Guidance for Superfund (RAGS): Volume I—Human Health Evaluation Manual Supplemental Guidance: Standard Default Exposure Factors. Interim Final. OSWER Directive 9285.6-03. Washington, D.C.: Office of Emergency and Remedial Response.

U.S. EPA. 1991d. Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions. OSWER Directive 9355.0-30. Washington, D.C.: Office of Solid Waste and Emergency Response.

U.S. EPA. 1992. Guidelines for Exposure Assessment. Federal Register Notice. 57(104): 22888-22938.

U.S. EPA. 1998. Final Guidelines for Ecological Risk Assessment. Risk Assessment Forum. EPA/630/R-95/002F. Federal Register 63(93): 26846-26924.

U.S. EPA. 2000 Guidance for the Data Quality Objectives Process. EPA QA/G-4. EPA/600/G-96/055. Washington, D.C.: Office of Environmental Information.

U.S. EPA. 2001a. Guidance for Characterizing Background Chemicals in Soil at Superfund Sites. OSWER Directive 9285.7-41. Washington, D.C.: Office of Emergency and Remedial Response.

U.S. EPA. 2001b. Risk Assessment Guidance for Superfund: Volume III, Part A, Process for Conducting Probabilistic Risk Assessments. OSWER Directive 9285.7-45. Washington, D.C.: Office of Emergency and Remedial Response.

U.S. EPA. 2002. Framework for Cumulative Risk Assessment. EPA/630/P-02/ 001A. Washington, D.C.: Office of Research and Development, National Center for Environmental Assessment.

U.S. EPA. 2003. RCRA Orientation Manual. EPA530-R-02-016. Washington, D.C.: Office of Solid Waste and Emergency Response.

U.S. NRC (U.S. Nuclear Regulatory Commission). 2000. A Performance Assessment Methodology for Low-Level Radioactive Waste Disposal Facilities. Recommendations of NRC's Performance Assessment Working Group. NUREG-1573. Washington, DC.: Division of Waste Management, Office of Nuclear Material Safety and Safeguards.

van den Belt, M. 2004. Mediated Modeling. A System Dynamics Approach to Environmental Consensus Building. Washington, D.C.: Island Press.

Wagner, W. E. 1995. The science charade in toxic risk regulation. Columbia Law Review 95:1613.

Wang, Y. F., C. Bryan, H. F. Xu, and H. Z. Gao. 2003. Nanogeochemistry: Geochemical reactions and mass transfers in nanopores. Geology 31:387-90.

Weinberg, A. 1971. Letter to the editor. Science 174:546.

Weinberg, A. 1972. Science and trans-science. Minerva 10:209.

Wiegman, S. 2004. Office of River Protection. Presentation to the National Academies Committee on Risk-Based Approaches for Disposition of Transuranic and High-Level Radioactive Waste. Richland, Washington. March 9. Available through the National Academies Office of News and Public Information.

WIPPLWA (Waste Isolation Pilot Plant Land Withdrawal Act). 1992. Public Law 102-579, 106 Stat. 4777, as amended October 30.

WSRC (Westinghouse Savannah River Company, Inc.). 2001. HLW-STE-2001-00508. 29801. Cited in Langton, C. A. and G. M. Iversen. Stabilization of Tank 33 and 35 Aqueous PUREX Waste. WSRC-TR-2001-00546. Revision 0. December 4., Aiken, South Carolina.

WSRC. 2004. Annual Radioactive Waste Tank Inspection Program—2003. WSRC-TR-2004-00167. Aiken, South Carolina.

Zitnik, J. F., A .T. Armstrong, B. K. Corb, M. H. Edens, D. B. Holsten, P. M. O'Flaherty, J. Rodriguez, R. L. Treat, W. Schofield, and K. L. Sykes. 2002. Preliminary Evaluation of Remedial Alternatives for the Subsurface Disposal Area. INEEL/EXT-02-01258. Revision 0. Idaho Falls: Idaho National Engineering and Environmental Laboratory.

Appendixes

Appendix A

Overview: Risk Assessment

Risk assessment can be described as an approach to problem analysis that uses available scientific data (often of varying quality) to characterize the nature of the adverse effects of a substance or activity on human health. It is designed to produce quantitative estimates of the probability that an individual will suffer disease or death as a result of exposure to a substance, expressed in terms of population or individual mortality or morbidity (Carnegie Commission, 1993). Risk management is the process of evaluating policy alternatives and selecting the most appropriate action, integrating the results of risk assessment with social, environmental, economic, and political concerns. Risk assessments are frequently employed by risk managers to help make decisions about regulating substances. Risk assessments are intended to provide risk managers with scientifically credible information that is useful for decisionmaking (NRC, 1983).

In addition to producing quantitative estimates, the risk assessment and risk management *processes* are useful for at least two other reasons. First, they serve as a way to collect, organize, and evaluate the data surrounding the hazardous effects of a toxin or activity. Second, when practiced as analytical-deliberative exercises, they can assist interested parties and decision makers in establishing a dialogue about the hazard in question and create a neutral framework for discussion and deliberation.

The practice of risk assessment has evolved for decades and can encompass important non-health outcomes, such as ecological impacts (U.S. EPA, 1998; NRC, 1996), but this discussion focuses mostly on human health risk. In 1983, the practice was codified in a formal way by the National Research Council (NRC) with the publication of *Risk Assessment in the Federal Government: Managing the Process*, more commonly known as the Red Book (NRC, 1983). The Red Book divided risk assessment into four steps: (1) hazard identification—determination of whether a compound is causally linked to particular health outcomes; (2) dose-response assessment—determination of the relationship between magnitude of exposure and probability of occurrence of adverse health effects; (3) exposure assessment—determination of the extent of human exposure to the substance; and (4) risk characterization—a description of the nature and magnitude of human risk, including attendant uncertainty. The Red Book explains that the basic problem in risk assessment is the sparseness and uncertainty of scientific knowledge, a problem that has no readily available solution. In each of these steps, the report notes that there are a number of decision points at which risk can only be inferred from available information. In some circumstances, scientific judgment and/or science policy choices may be applied to select from among possible inferences.

Among the recommendations in the Red Book was the suggestion that regulatory agencies maintain and establish a clear conceptual distinction between risk assessment and risk management. Scientific findings and policy judgments embodied in risk assessments should be distinguished from political, economic, and social considerations that affect regulatory choices. This conceptual distinction allows for interactions and iterations between risk assessment and risk management, but not confusion of the two. The report also states that regulatory agencies should develop a set of inference guidelines to structure the interpretation of scientific and technical information. The goal of these guidelines is to promote clarity, completeness, and consistency. The guidelines should also help maintain the distinction between risk assessment and risk management.

The U.S. Environmental Protection Agency (U.S. EPA), the U.S. Nuclear Regulatory Commission (U.S. NRC), and other executive agencies and departments have published inference rules covering carcinogenicity, mutagenicity, developmental toxicity, exposure, and effects of chemical mixtures (see, e.g., U.S. EPA, 1986, 1992). These guidelines, some of which have been updated and reissued over the years, seek to preserve flexibility while building consistency and clarity in the risk evaluation process. Many aspects of these guidelines have been controversial (NRC, 1994a).

As risk assessment practice has matured and lessons from the Red Book and inference guidelines have been institutionalized, various criticisms have arisen. These concerns include (1) the lack of scientific data quantitatively linking chemical exposures to health risks; (2) the lack of uniformity in the type and manner of reporting research results, making it difficult to compare data from different laboratories and different studies; (3) the uncertainties associated with modeling, which is generally used where direct measurement is not possible (including predictions of how systems will behave in the future); (4) the use of conservative default options (i.e., those more likely to overstate, rather than understate, human risk) and when these options should be abandoned in favor of new information; and (5) the qualification and quantification of variability and uncertainty (NRC, 1994a).

To address these and other issues and to fulfill a statutory requirement of the Clean Air Act Amendments of 1990, the NRC again established a review committee to study risk assessment protocols, specifically those employed by U.S. EPA (NRC, 1994a). After extensive discussion, the review committee confirmed that the Red Book model was an effective risk assessment paradigm. It also concluded that U.S. EPA had acted reasonably in formulating default guidelines. The report suggested that U.S. EPA consider a methodology to assess cumulative risk—multiple risks from multiple sources—and advised the agency to adopt principles for choosing default options and for judging when and how to depart from them. The NRC committee elaborated on two issues that were discussed briefly in the Red Book: variability and uncertainty, recommending further research and better treatment of both issues (NRC, 1994a).

In the mid-1990s, two influential publications investigated risk assessment and risk management and offered recommendations to improve their application and credibility. In *Understanding Risk: Informing Decisions in a Democratic Society* (NRC, 1996), the NRC focuses on the complex and controversial nature of risk characterization, recasting it as an analytic-deliberative process. The report offers criteria for evaluating the analytic-deliberative process that leads to risk characterization. The criteria, which are set out in Table A.1, can be used to develop realistic goals for the process. The message of the *Understanding Risk* report is important for the risk analyst, who must be cognizant of the fact that his or her work product will be relied upon to make regulatory decisions. As such, it must be responsive to the problem, reflective of the strengths and weaknesses of the science, and robust enough to withstand critical peer scrutiny. In addition, *Understanding Risk* emphasizes that to conduct risk assessment and risk management processes well, scientists and technical experts must interact and work with the public meaningfully (NRC, 1996). Responding to public concerns and questions, and changing course if necessary based on stakeholder input, are linchpins of the analytic-deliberative models.

The Presidential-Congressional Commission on Risk Assessment and Risk Management (1997a, 1997b) issued a two-volume report containing 71 recommendations aimed at improving federal agencies' approaches to environmental and public health threats. These recommendations rest on a framework for risk management that, like the *Understanding Risk* report, emphasizes the need for a comprehensive, problem-solving, iterative approach to risk management. The commission suggests that federal agencies move from a one-pollutant-at-a-time approach to a multimedia, multisource, multichemical risk assessment methodology that integrates information about many pollutants and diverse endpoints (PCCRARM, 1997a, 1997b).

As the use of risk-based decision making has spread, the practice of risk assessment and risk management has continued to advance in the directions set out in Understanding Risks and the Presidential-Congressional Commission reports. Recent efforts have called for even greater citizen and community interaction and challenged risk analysts to tackle cumulative risks and aggregate exposure. The U.S. EPA has published a *Framework for Cumulative Risk Assessment* (2002), which it sees as the first step in a long-term strategy to develop cumulative risk assessment guidelines. The framework defines cumulative risk assessment as an analysis, characterization, and possible quantification of the combined risks to human health and the environment from multiple agents or stressors. It recognizes that within communities there are multiple contributors to health and differential susceptibility within populations at risk. The centerpieces of a cumulative risk approach are a focus on a specific, “flesh-and-blood” community; involvement of that community from the start in the assessment process; and a full and detailed vulnerability analysis for that community.

Table A.1. Criteria of Risk Characterization

Criterion	Measurement procedure
Getting the science right	Ask risk analytic experts who represent the spectrum of interested parties to judge the technical adequacy of the risk-analytic effort
Getting the right science	Ask representatives of the interested and affected parties how well their concerns were addressed by the scientific work that informed the decision
Getting the right participation	Ask public officials and representatives of the interested and affected parties if there were other parties that should have been involved
Getting the participation right	Ask representatives of the parties whether they were adequately consulted during the process; if there were specific points when they could have contributed but did not have the opportunity
Developing accurate, balanced, and informative synthesis	Ask representatives of the parties how well they understand the bases for the decision; whether they perceived any bias in the information coming from the responsible organization

Source: NRC, 1996.

The U.S. EPA framework adopts a three-phase process for risk-based decision making (see Figure A.1). The process begins with a problem analysis, or scoping and planning phase. The framework points out that at this initial stage a risk assessment team should be organized. The team should include technical experts, members of the community or communities, and others. Scientists can play an important role in this phase by collecting, organizing and presenting data for all of the involved parties. However, planning, scoping, and screening also require the input of societal values and stakeholder participation. While scientists can help identify and characterize risks, they are not uniquely qualified to set priorities among them.

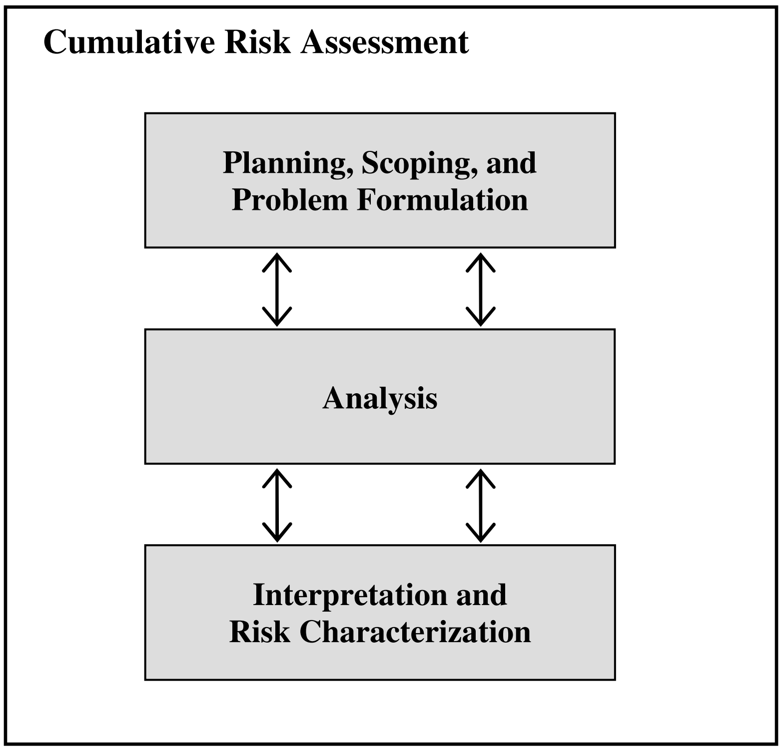

FIGURE A.1 Three-phase process for risk-based decision-making. SOURCE: U.S. EPA, 2002.

Appendix B

Summary of Previous Studies and Programs Aimed at Incorporating Risk into DOE Environmental Management Decision Making

1988-1989 PROGRAM OPTIMIZATION SYSTEM

In response to a congressional directive, the Program Optimization System (POS) was developed by the Department of Energy (DOE) to establish a prioritization system for funding environmental restoration. The DOE Defense Programs unit was responsible for developing the program because cleanup activities at nuclear weapons facilities were not yet organizationally separate from other units. The goal of POS was to use a bottom-up approach in which facility managers specified where and how funding cuts would be made and estimated the consequences of those cuts. This system was used in late 1988 to help plan the FY 1990 budget request and six months later as a basis for determining allocations among field offices. The POS suggestions for radical changes to the allocation of funds across the complex had little impact on fund allocations, but DOE headquarters supported the system because it provided them with detailed documentation regarding cleanup problems at the field offices (Jenni et al., 1995).

External Review Group

The DOE design team responsible for developing and implementing a risk-based priority system met with representatives from states, American Indian nations, national environmental groups, and the U.S. Environmental Protection Agency (U.S. EPA) through an External Review Group. Meetings were held from the fall of 1989 through the final meeting in February 1991. The design team presented the POS that DOE had developed for prioritizing environmental restoration activities to the External Review Group as an example of one type of system. The External Review Group raised concerns about the system and, in a February 1990 consensus statement, declared that they opposed "DOE's unilateral application of any prioritization system" (Jenni et al., 1995, p. 404). In response to this and other External Review Group concerns, the DOE design team created a hierarchy of criteria, including several that had not been included within the POS, such as uncertainty reduction and socioeconomic criteria. DOE also created a three-tiered screening component to address External Review Group concerns that any prioritization system give human health and the environment the highest priority and that DOE comply fully with all legal agreements. DOE developed plans for public involvement but did not specify how personnel in the field should carry out these plans. The system that was developed from the POS was called the Environmental Restoration Priority System, which is discussed in more detail below (Jenni et al., 1995).

Creation of the Environmental Management Program

The House Armed Services Committee's Subcommittee on Procurement and Military Nuclear Systems held a hearing in February 1989 on the priority-setting process used by DOE in conducting environmental restoration activities at its nuclear weapons facilities. In April 1989, the governors of ten states sent Secretary of Energy James Watkins a letter calling for federal action on the establishment of a comprehensive national program for cleanup of all DOE facilities. The governors suggested the need for a national priority system for ensuring that the appropriate priorities for DOE cleanups were established (FFERDC, 1996, Appendix C).

In July 1989, DOE reorganized to create the Office of Environmental Restoration and Waste Management, later renamed Environmental Management (EM), to oversee and manage environmental activities at all

DOE sites. Specific goals of the program included managing and eliminating urgent risks throughout the nuclear weapons complex, emphasizing the health and safety of workers and the public, and establishing stronger partnerships between DOE and its stakeholders.

1989 BRWM Letter Report

In 1989, at the request of Secretary of Energy Watkins, the Board on Radioactive Waste Management (BRWM) of the National Research Council (NRC) issued a letter report reviewing DOE's Predecisional Draft II of the Environmental Restoration and Waste Management Five-Year Plan. The DOE draft plan describes a 30-year cleanup program for ensuring that risks to human health and safety and the environment posed by DOE's past, current, and future activities are either eliminated or reduced to safe levels (NRC, 1989a). In its report, the BRWM agrees with DOE that the development of a priority ranking system with input from affected parties is of crucial importance. The letter report states that DOE plans for a National Priority System to provide the basis for subsequent resource allocations could serve as a demonstration of DOE's new openness by involving stakeholders in its development. The letter report emphasizes that the National Priority System will be useful only if it is developed through a credible process and recommends that DOE put in place a broadly supported allocation system negotiated among DOE, regulators, the states, American Indian nations, local governments, and interest groups during the program start-up, rather than later, when it may no longer be possible. The letter report also notes that DOE's time frame for developing the system for setting priorities did not allow enough time to do it right, with an iterative process of public participation. The letter report endorses DOE's goal of "striving toward 'technically sound, risk-based standards' with the observation that what is meant is really risk-based environmental requirements rather than 'standards'" (NRC, 1989a).

1989 NATIONAL RESEARCH COUNCIL REPORT ON THE NUCLEAR WEAPONS COMPLEX

In 1989, Secretary of Energy Watkins, in response to a congressional directive asked the NRC to provide recommendations concerning the health, safety, and environmental issues arising throughout the nuclear weapons complex and the steps that would enhance the safety of operations at the facilities. In the NRC report entitled, *The Nuclear Weapons Complex: Management for Health, Safety, and the Environment*, (NRC, 1989b), the NRC committee[1] suggested that the evaluation of cleanup actions be guided by the consideration of contamination risks to human health and the environment. The NRC committee concluded that DOE needed to develop and apply a scientifically credible scheme to aid decision making about appropriate cleanup standards and priorities for remediation activities under resource constraints (NRC, 1989b).

The committee reviewed the DOE Environmental Restoration and Waste Management Five-Year Plan that the BRWM reviewed in a letter report (see above) and suggested that DOE use risk-based methodologies to the extent permissible by law to guide it in setting priorities. The committee recommended that DOE seek to achieve site-specific cleanup standards. It also recommended that consistent risk assessment methodologies be used to bring scientific information into decisions regarding the extent of cleanup, cleanup methodologies, and priorities for environmental restoration. The committee noted that in order to ensure public acceptance of its cleanup decisions, DOE had to significantly increase public and state involvement in activities related to environmental issues at the sites (NRC, 1989b).

1990-1994 OPPORTUNITIES AND IMPEDIMENTS FOR RISK-BASED STANDARDS

In January 1990, the Environmental and Occupational/Public Health Standards Steering Group "was established by the directors of 13 DOE laboratories to organize a broad long-term education and outreach and research program focused on better scientific and public understanding of the risk associated with hazardous agents in the environment and workplace" (Hunter et al., 1994, p. 864). The Steering Group was interested in environmental restoration at the DOE labs and sites, and supported risk-based standards for remediation as a logical way to manage risks to public health and the environment caused by contamination at DOE facilities. In July 1991, the Steering Group held a workshop to

[1] The NRC formed a different ad hoc committee for each of the studies listed in this appendix. For simplicity, the same term (NRC committee) is used to refer to each of them.

evaluate the use of risk assessment as a principal mechanism for guiding the management of hazardous materials and site remediation across the United States. The Steering Group concluded that risk assessment techniques are a useful tool for decision making, but cautioned that risk analysis itself cannot determine the best course of action for an agency or an individual site. The Steering Group determined that effective risk management requires both scientific risk assessment and responsive consideration to public risk perceptions. It also concluded that the following are areas for additional effort in risk analysis: developing methods to reduce uncertainties in risk analysis; determining how quantitative data collected are used in decision making, such as whether risk managers should consider cost-benefit analyses in their decisions; and most importantly, making sure that decision makers and the public are able to comprehend the meaning of risk information communicated to them (Hunter et al., 1994).

1991 EVOLUTION OF THE ENVIRONMENTAL RESTORATION PRIORITY SYSTEM FROM THE PROGRAM OPTIMIZATION SYSTEM

The External Review Group mentioned at the beginning of this appendix was created to participate in the DOE development of a risk-based priority system. The review group met twice with the DOE design team and commented on the Program Optimization System (see above). Evolution from the POS to the Environmental Restoration Priority System was influenced by the controversy that arose when DOE officials decided to use the POS to help plan for the FY 1992 budget without external involvement, as requested by the External Review Group. DOE's response to the negative reaction of the External Review Group was to modify the POS and develop what was called an Environmental Restoration Priority System with three major differences: (1) it included socioeconomic criteria, activity screening, and information analysis; (2) it was not limited to DOE Defense Program facilities; and (3) it was to serve as an external tool, with outside involvement. (CRESP, 1999; Jenni et al., 1995). The quality of information available to support the scoring process differed dramatically across the complex, so scorers were directed to use the best possible information (Jenni et al., 1995).

The Environmental Restoration Priority System (ERPS) was reviewed in 1991 by the Technical Review Group (TRG), an ad hoc peer committee. The TRG stated that the system was useful for ordering priorities, but was inappropriate for determining the budget for environmental restoration. The TRG recommended that the ERPS be used only to allocate funds among the DOE facilities. The TRG also noted that the system conflicted with regulatory requirements such as compliance agreements. DOE heard these same concerns again at a national workshop it held in October (Jenni et al., 1995; NRC, 1994b).

1991-1994 RANKING HAZARDOUS WASTE SITES FOR REMEDIAL ACTION

The NRC Committee on Remedial Action Priorities for Hazardous Waste Sites examined how priority setting was being used or considered by federal and state agencies to rank hazardous waste sites for remedial priority. The project was sponsored by the Department of Defense (DOD), the U.S. EPA, DOE, the American Petroleum Institute, Monsanto, and the Coalition on Superfund (NRC, 1994b).

The committee compared DOE, DOD, and U.S. EPA programs and determined that none had developed an overall priority-setting process that was explicit, adequately documented, and sufficiently open to scientific and public scrutiny. The committee found that the formal mathematical models developed to aid in the priority-setting process played little role in determining which sites were ultimately remediated. It noted that site-ranking models would play a greater role in priority-setting processes if they incorporated social and economic values to a greater extent, and if users and the public were more confident in the model outcomes (NRC, 1994b).

The committee reviewed DOE's Environmental Restoration Priority System (ERPS) and although there was not enough information to make a credible evaluation of the system as an objective ranking of sites for remediation, the committee noted that such a model would greatly assist in addressing conflicts by providing a more objective evaluation of the sites that should be cleaned up first and the degree of cleanup desired. The committee noted, as had others, that DOE had many preexisting compliance agreements that would override the relative evaluations of sites provided by the priority system. In 1993 the committee learned that DOE had decided not to use the system, (Jenni et al., 1995; NRC, 1994b) and Assistant Secretary for Environmental Management Thomas Grumbly announced that technical problems combined with a lack of involvement by regulators or the public led to the postponement of the system's implementation (Jenni et al., 1995).

1991-1996 KEYSTONE DIALOGUE AND KEYSTONE REPORT

In 1991, the Keystone Center, at the request of U.S. EPA convened meetings on the National Policy Dialogue on Federal Facility Environmental Management. Meeting participants included representatives from American Indian governments, local citizen groups, DOD, DOE, and U.S. EPA. The group discussed the role of health assessments and the consideration of risk in setting priorities for federal facility cleanup; how American Indian cultural issues should be factored into the priority-setting process; and the role that various governmental and nongovernmental entities should play in setting priorities for federal facility cleanups (FFERDC, 1996).

In February 1993, the Federal Facilities Environmental Restoration Dialogue Committee (FFERDC) published an interim report entitled *Recommendations for Improving the Federal Facilities Environmental Restoration Decision-Making and Priority-Setting Process* (FFERDC, 1993), known as the Keystone Report. This report established a "fair-share" process for setting funding priorities for remediation activities among different facilities in the event of insufficient funds. Risk reduction was included among the factors to be considered in the fair-share process (FFERDC, 1993).

In 1996, the FFERDC set forth its consensus recommendations in *The Final Report of the Federal Facilities Environmental Restoration Dialogue Committee: Consensus Precipices and Recommendations for Improving Federal Facilities Cleanup* (FFERDC, 1996). The FFERDC recommended that priority setting at the facility level not be limited to prioritizing the relative risks posed by site contamination but instead go further to include prioritizing the activities that are designed to clean up the contamination. It noted that relative risks will have a bearing on the setting of priorities for cleanup activities but should not become the de facto priorities. The FFERDC supported the use of "risk plus other factors," in which risk to human health and the environment and other factors[2] are carefully considered in advance of the need to make priority-

[2] Cultural, social, and economic factors, including environmental justice considerations; potential or future land use; ecological impacts of contamination and the proposed action to address it; regulator, American Indian nations, and other stakeholder acceptance of actions; statutory requirements and legal agreements; life-cycle costs; taking into consideration the ability to execute cleanup projects in a given year and the feasibility of carrying out the activity in relation to other

setting decisions at site-specific and national levels. The FFERDC noted that the priorities used in risk-based decision making for cleanup budgets should be set with the agreement of regulators and in consultation with stakeholders (FFERDC, 1996).

The FFERDC recommended that all key decision makers adhere to the following when using risk assessments: (1) scientific uncertainties and data limitations should be delineated clearly in laymen's terms as part of the analysis of risk; (2) stakeholders should be involved at the front end in the analysis of risk and risk reduction potential, and risk management and broader priority setting decisions based upon the analyses; and (3) communicate the assumptions used in conducting risk assessments should be communicated at the front end so that the results may be better understood (FFERDC, 1996).

1993 BROOKHAVEN NATIONAL LABORATORY AND LAWRENCE LIVERMORE NATIONAL LABORATORY PILOT STUDY

The DOE Office of Environmental Restoration and Waste Management funded a study by researchers at Brookhaven National Laboratory and the Lawrence Livermore National Laboratory. In 1993, a report documenting the results of a pilot study involving the Savannah River Site, Fernald Environmental Management Project, and Nevada Test Site was released. The report focused on lessons learned in human health risk assessments and was meant to demonstrate realistic risk assessments; produce estimates for the problems studied; and provide suggestions for changing the way in which risk assessments were conducted at DOE facilities. The authors recommended "the initiation of a systematic approach to identify, prioritize, and reduce sources of uncertainty in risk assessments at DOE facilities" (Hamilton et al., 1993, p. 26). The authors stated that in choosing remediation options, identifying acceptable contamination levels, and in prioritizing sites for cleanup resources, DOE must also consider the amount of risk reduction to workers and the public that could be achieved by using particular remedies. The authors noted a need for the development of data, assumptions, and methods to assess the risk reductions associated with the remedies likely to be selected for DOE facilities (Hamilton et. al., 1993).

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activities at the facility; overall cost and effectiveness of a proposed activity; and actual and anticipated funding availability.

1993-1994 NRC REPORT ON BUILDING CONSENSUS

In September 1993, DOE Assistant Secretary for Environmental Restoration and Waste Management Grumbly, asked the National Research Council to help him "focus on whether a risk-based approach to evaluating the consequences of alternative [cleanup] actions is feasible and desirable" and how public credibility of the process can be improved (NRC, 1994c). The NRC committee noted that to be most effective and useful, the procedures and institutions adopted for risk assessment should satisfy several objectives: (1) they must be credible to stakeholders and the general public; (2) they must operate expeditiously without threatening scientific validity; (3) they should consider the full range of risks of concern to stakeholders in the light of social, religious, historical, political, land use, and cultural values and needs; and (4) they should be efficient and cost-effective and should produce results that contribute to the identification of remedies and priorities that are themselves efficient and cost-effective. The NRC committee stated that the first and likely the most important step in effective risk assessment and risk management is to establish broad public participation that involves all stakeholders (NRC, 1994c).

The NRC committee also recommended that DOE establish a culture receptive to the adoption of risk-based thinking as a component of making remediation decisions. The committee noted that DOE's decentralized management approach allowed the creation of many different perspectives on, and applications of, risk assessment, which led to lack of communication across sites in the complex (NRC, 1994c).

To ensure credibility, the NRC committee suggested the creation of two boards: (1) a national stakeholder oversight board with representatives from various groups; and, (2) a national scientific board that could help to maintain consistently high standards in risk assessment by reviewing drafts of risk assessments, providing broad advice about methodological consistency, and helping to ensure national consistency in the plans (NRC, 1994c).

1994 CONGRESSIONAL BUDGET OFFICE STUDY

At the request of the chairman of the Defense Nuclear Facilities Panel of the House Committee on Armed Services, the Congressional Budget Office (CBO) conducted an examination of the central issues accounting for the potential costs of DOE's cleanup program. The CBO stated that in order to make informed decisions, DOE needed better information about the risks posed by wastes in the nuclear weapons complex. CBO noted that DOE's lack of comprehensive risk measures for facility contamination hampered its planning efforts because the information collected by various sites and offices had not been coordinated into a unified framework that would facilitate comparisons. CBO also noted that a better understanding of risks would allow for informed debate among interested and affected stakeholders about how much risk is acceptable and how soon cleanup levels should be reached. Understanding risks enables the identification of trade-offs between risks and costs to assist policy makers in setting the appropriate goals and priorities for cleanup. CBO stated that in situations involving budgetary constraints, DOE will have to decide, in consultation with regulators, stakeholders, and Congress, which cleanup activities to defer. CBO also noted that before DOE makes choices about how to conduct cleanup projects it should determine final land uses in conjunction with stakeholders (CBO, 1994).

1994-1995 RISK REPORT TO CONGRESS

In response to concerns about DOE's ability to meet certain compliance goals and schedules for cleanup, Public Law 103-126, enacted on October 28, 1993, required the secretary of energy to submit by June 30, 1995, "a report to the Committees on Appropriations evaluating the risks to the public health and safety posed by the conditions at weapons complex facilities that are addressed by the compliance agreement requirements" (U.S. Congress, cited in CERE, 1995, pp. 1-2). Congress did not request an exhaustive, formal risk assessment; instead it directed DOE to "estimate the risk addressed by cleanup requirements on the basis of the best scientific evidence available" (U.S. Congress, cited in CERE, 1995, pp. 1-2).

In 1994, the EM Office of Integrated Risk Management was created to respond to the congressional mandate for a report evaluating the risks of the nuclear weapons complex to human health and the environment. The office mission was to develop policy, requirements, and guidance for ensuring coherent risk-based environmental decision-making processes and involving concerned and affected stakeholders in developing risk management decisions (DOE, 1995b).

In March 1995, the Consortium for Environmental Risk Evaluation (CERE) interim report to DOE entitled *Health and Ecological Risks at the U.S. Department of Energy's Nuclear Weapons Complex: A Qualita-*

tive Evaluation was released (CERE, 1995). CERE prepared this interim report to assist the DOE Office of Integrated Risk Management in fulfilling the congressional request for a report on risks. The report was intended to provide an independent qualitative evaluation of risks to the health and safety of the public, American Indian nations, workers, and the environment. The report was also to identify important information gaps, key uncertainties, and issues of concern to interested and affected parties (CERE, 1995, p. ES-1).

CERE's findings confirmed that DOE should continue to manage previously identified risks involving contaminated areas and facilities and the storage of radioactive and toxic waste materials. The CERE interim report concluded that there were no significant risks to the public, American Indian tribal health, workers, or the ecosystem as long as continued facility management, limits to human access, and site remediation existed (CERE, 1995).

The CERE noted that its

> …findings and conclusions do not provide a stand-alone basis for revision of plans or budget levels, either within an installation, or between installations. The usefulness of CERE's investigation is in providing an overview of risks that may serve as one input among many in the deliberations on future EM funding…CERE's work should not be considered as providing definitive answers to the difficult and complex questions of assessing the risks at the six DOE installations

Limitations of the report as noted by the CERE (1995) and others (CTUIR, 1995; EMAB, 1995) are discussed in the summaries below.

NUCLEAR RISKS IN TRIBAL COMMUNITIES

In March 1995 the Confederated Tribes of the Umatilla Indian Reservation (CTUIR) issued a report for DOE entitled *Scoping Report: Nuclear Risks in Tribal Communities* to "advocate reform of current risk assessment practice in order to make risk assessment a more effective tool for public policy and environmental management decision making" (CTUIR, 1995, p. 1). The report states that issues of importance to American Indian nations were not being addressed by risk assessment. These issues include the unique and multiple use of treaty-reserved rights and resources for subsistence, ceremonial, cultural, or religious practices; the multiple exposure pathways that result from cultural resource uses that are not included in typical exposure scenarios; how tribal community life-styles result in disproportionately greater-than-average exposure potential; the value that American Indians place on future generations; environmental justice issues, and the need for input from affected communities; and consideration of intangibles such as equity, peace of mind, and aesthetics (CTUIR, 1995).

The CTUIR suggested the following data sources to provide a more comprehensive risk evaluation: (1) site-monitoring data; (2) a comprehensive literature search; (3) a review of extensive tribal and public comments submitted in response to DOE documents, work plans, records of decision, and so forth; (4) public health surveys; (5) worker observations; (6) chemical and toxicity profiles; (7) analyses of worst-case scenarios; and (8) analyses of environmental impacts and alternatives to proposed actions (CTUIR, 1995).

The CTUIR stated that without considering such information sources, CERE failed to provide a comprehensive or credible evaluation of risks at any DOE sites. Additionally, by not including meaningful involvement by American Indian nations or other members of the public throughout the evaluation process, there was an overdependence on risk experts and their values and judgments, rather than creating a balance by directly including affected communities (CTUIR, 1995).

GENERAL ACCOUNTING OFFICE REPORT

In March 1995, the General Accounting Office (GAO) issued a report evaluating the progress made by DOE in cleaning up the nuclear weapons complex and provided recommendations to Secretary of Energy Hazel O'Leary for enhancing the effectiveness of DOE's cleanup strategy. The GAO stated that future progress for DOE's cleanup strategy depended on adopting a national risk-based strategy. It noted a need for a more comprehensive, risk-based cleanup strategy for establishing baselines, rather than numerous separately negotiated compliance agreements that were not well suited to setting priorities among the sites under severe budgetary constraints. The GAO suggested that the results of the forthcoming DOE risk report to Congress be used to set priorities across, as well as within sites, and to further develop a national cleanup strategy for targeting the available resources to the highest priorities. The GAO noted that as DOE moved from developing to implementing a national cleanup strategy at individual facilities, it would have to retain the involvement of stakeholders, or they may view the DOE strategy as an attempt to circumvent existing compliance agreements (GAO, 1995).

DOE RISK REPORT TO CONGRESS

In June 1995, DOE issued its report to Congress entitled *Risks and the Risk Debate: Searching for Common Ground, "The First Step"* (DOE, 1995c). DOE stated that the report "captured the spectrum of risks" associated with EM activities, it "linked the risks in a qualitative fashion to compliance and the budget," and experienced field managers categorized the work. To prepare the risk report, DOE estimated risks by assessing compliance requirements, reviewing documents related to EM risk, performing a qualitative evaluation of EM activities and costs, and involving the public.

Based on its analysis, DOE found that without containment and limited public access to DOE's inventory of hazardous and radioactive materials, the sites and facilities would pose much greater risks. DOE found that it is difficult to integrate risk assessment methods and cultural and social values to produce meaningful priorities. The report stated that this is particularly true for American Indian nations and for minority and low-income populations affected by DOE activities. DOE found that public involvement of interested and affected communities was essential to developing a comprehensive, credible risk management process, as noted by CTUIR (see above). DOE also found that the regulatory process and compliance agreements had uneven results in the way they addressed categories of risks across DOE's hazardous material inventories, sites, and facilities (DOE, 1995c).

DOE's preliminary conclusion of the complex-wide analysis was that the majority of EM's budget did address high and medium risks. DOE stated that its next steps would be to expand stakeholder involvement and discuss with stakeholders whether it is accurately identifying and estimating risks to the pubic, workers, and the environment. DOE also stated that it would have to identify the degree to which risks should be reduced at each site and whether these risks should be the same across the complex. DOE added that it needed to put additional effort into developing a consistent understanding and framework for comparing multiple risks and hazards across the weapons complex. DOE also found that it would be necessary to improve the data collection process in order to better capture the risks to public health, worker safety, and the environment, and their life-cycle costs, and to develop a targeted research agenda to reduce uncertainties in the data (DOE, 1995c).

Environmental Management Advisory Board Review

In an August 25, 1995, letter to Thomas P. Grumbly, DOE assistant secretary for environmental management, the Environmental Management Advisory Board (EMAB, 1995) issued its recommendations to DOE on the draft risk report to Congress (see above); the CERE interim report to DOE (see above); and the interim Principles for Using Risks Analysis issued by Under Secretary of Energy Charles Curtis (Curtis, 1995).

The full EMAB accepted the following recommendations and findings of its Risk Committee: (1) The risk process started by DOE was an important first step for relating risks to the budget and compliance information. DOE had to improve the quality of information collected throughout the process by identifying assumptions used during information gathering and to develop accurate, credible, and consistent information and data through public, and peer review. (2) DOE should be more specific about its criteria for future land use, because risks to the public, workers, and the environment differ based on assumptions of future land use. (3) DOE should improve the way it integrates its understanding of risks with other long-term cost projections and future land use planning into the budget and other decision-making processes. (4) DOE should use creative approaches to engage stakeholders in the risk process in order to improve both the quality of information and the credibility of the process. To be effective, DOE would have to improve its communication with the public (EMAB, 1995).

The Risk Committee was also tasked with meeting with members of CERE to discuss the interim risk report to DOE and to make recommendations on the report. The Risk Committee stated that the CERE interim report provided an extensive baseline collection and summary of more than 1600 publicly available risk documents for 6 of the 17 DOE sites. However, the report did not provide answers—nor did it claim to—about the real issues that the EM program had to address in order to arrive at credible and cost-effective decision-making choices. The CERE findings did not define what actions DOE should or should not take to avoid unnecessary increases in costs and risks to the public, workers, and the environment. The report findings also did not provide a basis for budget allocation decisions among DOE weapons sites. The Risk Committee also stated that the report did not provide a framework for comparisons among DOE sites and did not examine important issues such as natural resource damage, off-site transportation, equitable distribution of risk, collective risk to populations, and intergenerational risk. The Risk Committee stated that focusing only on individual risks could lead decision makers to make poor choices regarding cleanup priorities. The Risk Committee concluded that the CERE report did "not provide the basis for a sensible, broad-based approach to risk-management decision making" (EMAB, 1995, Attachment 1-B, p. 3). In the letter to Assistant Secretary Grumbly, the full EMAB committee accepted the recommendations of the Risk Committee and acknowledged the contribution of the CERE report in improving access to and evaluation of information regarding the hazards, risks, and public concerns at the six DOE sites included in the study (EMAB, 1995).

The EMAB also generally endorsed DOE's Principles for Using Risks Analysis (Curtis, 1995). These principles were grouped according to general, risk assessment, risk management, risk communication, and priority setting using risk analysis. The Risk Committee suggested that the principles could be used for priority setting in phases, first on a site-specific basis then, and, if successful, across the entire complex (EMAB, 1995).

1995-1997 RISK DATA SHEET SCORING SYSTEM

The Risk Data Sheet scoring system was initially developed for the risk report to Congress as a priority-setting tool for using risk information in making management decisions. Categories of analysis were site personnel safety and public health and safety; environmental impacts; worker risk; social, cultural, political, and economic impacts; stakeholder concerns; public perception; and stakeholder involvement. Categories were described by impacts leading to different levels of severity and by the levels of likelihood (high, medium, low) to represent the ranges of annual probability and expectations for the frequency of activities occurring in order to assess risk reduction. Categories were not weighed against each other in order to allow for qualitative analysis. A Risk Data Sheet was established for each activity or group of similar activities with the same risk, and data were provided to the field offices as a basis for their qualitative evaluation. The sheets were completed by the sites and forwarded to headquarters where the field information was aggregated and summarized to provide summary information by field office, by program, and for the overall EM program (DOE, 1995b, Appendix C).

CRESP Review of the Risk Data Sheets

The Consortium for Risk Evaluation with Stakeholder Participation (CRESP) was asked by EM to conduct an independent review of the quality, completeness, and utility of the Risk Data Sheets it used to describe risks for the report to Congress. On May 14, 1996, the CRESP Risk Data Sheet National Review Panel issued a final report. The panel unanimously viewed the process as a powerful tool that presented highly relevant information to the EM planning and decision-making process (CRESP, 1996, p. 1). However, the panel found inconsistent, incorrect, or incomplete information contained in Risk Data Sheets as well as a lack of cross-site consistency for several activities. It stated, however, that there were some Risk Data Sheets with sufficient quantities of high-quality and relevant information. The panel noted that the clear majority of the Risk Data Sheets were not completed according to DOE guidance. The panel suggested that there was a correlation between the quality of Risk Data Sheets and the level of interaction with external stakeholders. It noted that the Risk Data Sheets would be useful for internal budget activities but were not of high enough quality to withstand scrutiny by outside groups or to serve as support for budget requests to either Congress or the Office of Management and Budget (OMB). Reviewers also stressed that transparency was lost due to the inadequate narratives contained in many of the Risk Data Sheets, which would impact public confidence in the decision-making processes used. Among the panel recommendations was that a two-tiered ranking system be implemented to improve assessments of activities related to the overall project. The overall project Risk Data Sheets could be prepared with detailed examinations of impact categories; then specific activity Risks Data Sheets could be evaluated in relation to their importance to the overall project (CRESP, 1996).

NRC REPORT EVALUATING DOE'S ENVIRONMENTAL MANAGEMENT PROGRAM

On January 11, 1995, Assistant Secretary Grumbly requested assistance from the NRC in addressing remedial action and waste management problems throughout the nuclear weapons complex. In response, the NRC established a committee that produced the 1995 report, *Improving the Environment: An Evaluation of DOE's Environmental Management Program* (NRC, 1995b). As part of its study, the committee evaluated EM's priority-setting system and issued principal recommendations that included the following. A priority-setting system should be used consistently for a number of years in order to gain the acceptance of future administrations, or it will be discarded. The committee also noted that Congress has a key role in determining the longevity of the system because without predictable funding, "there can be no priority-setting system that implements a long-term strategy aimed at the highest possible cost-effectiveness" (NRC, 1995b, p. 19). The committee also stated that there should be coherence throughout the complex, regular evaluation of the priority-setting tools, clarity and transparency, and stakeholder participation (NRC, 1995b).

The NRC committee suggested that DOE look to the extensive list of evaluation criteria developed for the ERPS model (mentioned above) in setting priorities for environmental management activities, noting that the two criteria that would probably retain preeminence in any priority-setting system are risk and regulatory considerations. The NRC committee stated that true priority-setting techniques provide enough information to assess whether to take action and what types of action to take. They are able to assist in identifying reasonable trade-offs across sites and activities. Thus, the tools needed for priority setting require activity-specific information; incremental information on risks associated with an action; and explicit recognition of the goals that DOE is trying to address (NRC, 1995b).

1995-1997 WASTE MANAGEMENT PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT

In October 1990, DOE issued a notice of intent to prepare a programmatic environmental impact statement (PEIS) on the proposed integrated EM program (DOE, 1996). The implementation plan for the waste management (WM) PEIS was issued in January 1994, identifying the proposed action of formulating and implementing "an integrated environmental restoration and waste management program in a safe and environmentally sound manner and in compliance with applicable laws, regulations and standards" (DOE, 1997b, p. 3; see also DOE, 1996). In January 1995, DOE issued a *Federal Register* notice proposing to modify the scope of the PEIS to eliminate the environmental restoration activities analyses. DOE had determined that environmental restoration decisions are site specific rather than program-wide and should focus on local conditions and communities. In September 1995, DOE released the draft WM PEIS and invited public comments. A controversial and oft-repeated issue raised during the public comment period was the potential human health impacts of treatment, storage, and disposal of wastes. Specific concerns were raised about risk assessment methodologies used in the analysis; risks to minority, low-income, and densely populated areas; risks associated with subsistence fishing in some communities; impacts on future generations; and impacts of additional exposures on populations affected by other DOE activities. Of the changes that DOE made in the WM PEIS to respond to comments about risk, the environmental justice analysis was modified to better determine whether disproportionately high and adverse health impacts on minority or low-income communities could occur, and the chapter on cumulative impacts was revised to provide a more comprehensive evaluation of other DOE actions that may affect the sites (DOE, 1997b; see also Harris and Harper, 1999).

1997-1998 HUMAN HEALTH RISK COMPARISONS FOR ENVIRONMENTAL MANAGEMENT BASELINE PROGRAMS AND INTEGRATION OPPORTUNITIES

In May 1997, a contractor team issued a report on its analysis of the complex-wide baseline programs and alternatives. A separate report was issued in February 1998, documenting the human health risk models developed for the baselines and alternatives (Eide et al., 1998). A simplified risk model was developed to provide a consistent, comprehensive, and quantitative human health risk picture for the baseline activities and their alternatives; to evaluate the alternative program risks relative to the baseline program risks; and to provide a model that could be used to answer stakeholder questions about risk. The risk model was used for human health and safety risk from normal, incident- free operations and accidents, and did not include programmatic or environmental impact risks. The risk model was developed for activities involving high-level waste, transuranic waste, low-level waste, mixed-level waste, and spent nuclear fuel. A typical risk model analysis consists of the following steps: (1) information collection, (2) development of a system flow diagram (disposition map), (3) breakdown of the system flow diagram into more basic risk states (e.g., disposal and specific material storage), (4) characterization of the curie and/or chemical flows through the system, (5) development of risk matrices, (6) combining individual risk matrix results into system risk results, and (7) if more detailed analyses are available, comparing them with simplified risk model's risk estimates (Eide et al., 1998).

1997 PROJECT BASELINE SUMMARIES AND THE 2006 CLEANUP PLAN

In July 1996, DOE Assistant Secretary Alm "articulated a vision for the EM program of completing as much cleanup as possible by 2006" by accelerating the cleanup of EM sites and reducing the overall life-cycle costs of the EM program while staying in compliance with applicable environmental and legal requirements (DOE, 1997c, p. 1). As part of this national cleanup plan, by the fall of 1997 each field office was required to submit a project baseline summary to headquarters for every project approved. Risk was to be considered in setting priorities at and across sites, sequencing project work, measuring progress, and showing that EM was addressing the most urgent risks first. Project managers were required to perform a qualitative evaluation of risks to workers, the public, and the environment associated with each project, following a screening evaluation to determine the need and appropriate level of detail for risk evaluation. The risk evaluation was intended to build upon previous evaluations and to address the interest and concerns of regulators, stakeholders, and American Indian nations. For each applicable risk category of public, worker, and environment, the level of risk was defined by the intersection of two qualitatively assessed parameters (i.e., impact and likelihood), and the risk was classified as urgent, high, medium, low, or not applicable (CRESP, 1999).

1997 CRESP REVIEW OF DOE-EM RISK INFORMATION

In 1997, Assistant Secretary Alm endorsed two meetings convened by CRESP to discuss how to improve the content and format of the risk elements in DOE's risk database. CRESP recommended that EM continue to consider risks to workers, the public, and the environment and pay greater attention to how risks to workers and the public may arise from remediation activities. The group suggested that DOE revise the current EM risk database format and pilot-test the revised risk matrix to evaluate projects prior to final submission to headquarters. CRESP also recommended screening the revised database to identify circumstances in which further risk assessment is not needed. Finally, CRESP recommended including site personnel with the training and experience necessary to help in devising a credible database of risk information (CRESP, 1997).

1998 ACCELERATING CLEANUP: PATHS TO CLOSURE

Released in June 1998, *Accelerating Cleanup: Paths to Closure* (DOE, 1998b) provided a vision for completing site cleanup at 53 DOE sites by 2006, with the remaining 10 sites, including 5 of the largest sites continuing treatment for legacy waste streams. Each field office was required to provide information in the form of the project baseline summaries (see above), which were management tools intended for the development of detailed projections of scope, schedule, and cost (baselines) for each site, based on the aggregation of logical, discrete units of work (DOE, 1998b, p. 2-3). According to the report, the project baseline summaries were the main source of site information for headquarters and provided detailed information about each project's programmatic risks, technical approaches, end states, life-cycle performance measurements, annual performance targets, and other information such as data on risk, health, and safety. However, the main focus of this report was on programmatic risk, which DOE describes as associated with project cost, schedule, and performance, rather than risks to workers, the public, or the environment. The categories of risk defined in the report are technology, scope, and intersite dependence (DOE, 1998b).

CRESP Review of Project Baseline Summaries and Paths to Closure

The Peer Review Committee of CRESP (1999) stated that the Project Baseline Summary program failed because DOE did not have a clear basis for understanding or classifying risks, there were inconsistencies in implementation, assessments were inadequate and not well documented, and the summaries were not accepted by field offices. As defined in the national 2006 cleanup plan, the risk assessments did not require adequate evaluation of the exposure receptors of concern or of the toxicity of constituents of concern, which are of fundamental importance to any risk characterization. This management tool did not prove useful for comparing risks across sites; instead it was useful for comparing the value of projects at a single site. Without a clear and transparent definition of the basis for classifying risks and without consistent application of the process across all sites and projects, it would be difficult to track project progress adequately and make it credible and acceptable to stakeholders (CRESP, 1999; see also Gephart, 2003). After 1998, risk information for this program was no longer developed (GAO, 2002).

As the CRESP peer review of *Paths to Closure* notes, risks in the report focus on the risks to cost, schedule, and technical performance resulting from failure to complete a given activity or schedule. The peer review committee states that with "no specific reference in the report to reduction of risks to health and the environment," it gives the appearance that risks to health and the environment have been incorporated into the planning of projects and thus do not have to be mentioned or are unimportant (CRESP, 1999, p. 32). The CRESP review committee notes that it is significant that traditional questions about risks to human health and the environment, risk reduction, and the allocation of funds across the complex to address risks were not included more directly in the report (CRESP, 1999).

1997-1999 CENTER FOR RISK EXCELLENCE AND RISK PROFILES

The DOE Center for Risk Excellence (CRE) was created by EM to support the development of integrated risk programs and risk-based decision making. The CRE, which operated through 2002, provided an online resource for evaluation of EM risk guidelines, requirements, and policies, and was intended as a focal point for integrating science-based information for risk practitioners and others interested in risk analysis and for facilitating involvement by stakeholders, including other agencies, in the risk evaluation process (CRE, no date).

The CRESP review committee reported that the risk profiles were presented in a 1999 draft report entitled *Results and Status of Environmental Management Site Risk Profiles: Public Hazard Management at Ten DOE Field Offices* (CRE, 1999, cited in CRESP, 1999). This report resulted from a collaborative effort of CRE, the 10 field offices, and the EM Office of Science and Risk Policy to characterize the risks addressed by EM activities. The five stated objectives of the risk profiles are (1) to provide broad site-level risk information; (2) to make effective use of existing data from the sites; (3) to present clear information to a variety of audiences in support of the budget process and in response to outside requests for summary risk information; (4) to develop and follow an objective and repeatable evaluation of EM progress over time; and (5) to seek and incorporate extensive site and stakeholder input. CRESP reviewed the report and states that, in general, the report does not meet its stated objectives. The reviewers state that the report should be construed as a hazard profile, rather than a risk profile report. It was found that although the report contains detailed volume and waste-type information for each site, essential information for evaluating the associated risks is not consistently and adequately documented. The terms risk and hazard are used interchangeably and inconsistently throughout the report, causing confusion and ambiguity. Graphs in the report depicting relative change in site hazard or risk over time for each waste type do not answer the fundamental question of how and to what extent a given reduction in hazard corresponds to a reduction in risk. The report also failed to address ecological or occupational risks (CRESP, 1999, p. 34). In 2001, DOE eliminated the support group responsible for assisting the sites with this effort, and the risk profiles were generally no longer developed (CRESP, 1999).

1998 DOE GUIDELINES FOR RISK-BASED PRIORITIZATION OF DOE ACTIVITIES

These guidelines were issued as a Defense Programs standard approved for use by all DOE "components" (offices and programs) and their contractors. These guidelines suggest that the most important first steps in risk-based prioritization may be the initial structuring and formulation of the problem and decision to be made, the decision objectives or goals to be reached, and any available options or alternatives for reaching these goals. The use of multiattribute utility theory is suggested because it is a quantitative-based decision analysis technique and management tool that provides a demonstrated way to combine quantitatively dissimilar measures of costs, risks, and benefits, along with decision-maker preferences, into high-level aggregated measures that can be used to evaluate alternatives. The risk-based prioritization is intended as an analysis of the predicted costs, risks, and benefits of various activities as a method for aiding decision makers with resource allocation, planning, and scheduling decisions. The guidelines state that the following characteristics are to be used for evaluating the quality of a prioritization system: (1) logical soundness, (2) completeness, (3) accuracy, (4) acceptability, (5) practicality, (6) effectiveness, (7) defensibility, and (8) quantification of costs and benefits (DOE, 1998c).

The risk-based prioritization standard provides guidance to decision makers for developing a clear understanding of how policy issues will be addressed in structuring prioritization efforts. One recommendation is for decision makers to be prepared to reprioritize each time new information is introduced, by either preparing contingency plans in the eventuality that the factors driving the preferred decision may change before the decision is fully carried out or planning for a "living schedule" in which new information is processed regularly in an ongoing prioritization, so activities or allocations always reflect the most up-to-date information. Decision makers should make a determination of the threshold guidance for whether risk-based prioritization and the standard should be implemented, how a graded approach should be employed for the decisions made, and how the approach should be adapted to the decision context (DOE, 1998c).

1998 OUTCOME-ORIENTED RISK PLANNING

Supported by the EM Office of Science and Risk Policy, the Joint Institute for Energy and Environment (JIEE) produced a series of reports directed toward DOE management that focused on a process for outcome-oriented risk planning as an alternative to the EM status quo and aimed to stimulate dialogue about implementing the lowest-cost, risk-based cleanup that is realistic about restrictions imposed by regulatory requirements and technical uncertainties. The authors suggest that in order for EM to lead arbitration over budgets, timeframes, endstates, and long-term stewardship, it must be able to place issues within a common framework and relate them to other relevant aspects of cleanup. EM must also be able to demonstrate the trade-offs associated with alternatives and the impacts they will have on the cleanup process. The authors state that this means "defining the process that will lead to program decisions and not to making the decisions themselves" (Bjornstad et al., 1998, p. 4).

The authors suggest a series of seven steps for achieving outcome-oriented risk planning; (1) separate community desires for additional funding from community desires for effective cleanup; (2) reorient cleanup from inputs to outputs—a logical output is the reduction and management of risks that result from the wastes and materials being cleaned up; (3) build the already existing risk principles, databases describing physical attributes of the wastes, established uses of risk for project prioritization, and risk material developed by other agencies; (4) create a risk-planning system tailored to DOE cleanup needs by combining the risk principles with the particular attributes of the EM mission; (5) conduct a demonstration phase before formal implementation of a new risk-planning system that could serve to both anticipate possible analytical pitfalls and overcome EM inertia; (6) systematically begin to integrate the risk planning into the EM management system; and (7) reorient cleanup from hazard elimination to risk management and from partnering waste inventories with best available technologies to associating inventories with the appropriate risk levels (Bjornstad et al., 1998, pp. 4-10).

1999-2000 INTEGRATOR OPERABLE UNIT AND COMPOSITE ANALYSES

The 1999 CRESP review committee observed a gap between DOE Environmental Management activities that are necessary to comply with various environmental statutes and regulations and those generated by a risk evaluation across the complex. The review committee noted that successful accomplishment of DOE's environmental management mission at large sites containing multiple sources of contamination will require that interim measures necessitated by relevant regulatory requirements be appropriately linked to the long-term goal of completing the overall cleanup process and ensuring lasting protection against risks from any residual hazards that may remain at a given site. Conducting source-by-source analysis and cleanup only, is inefficient at large sites and may not adequately capture the full scope of current and potential risks (CRESP, 1999). The integrator operable units and composite analyses were an attempt to link risk concepts with regulatory innovations.

2002 GAO REVIEW OF DOE'S COMPLIANCE AGREEMENTS

The General Accounting Office reviewed DOE's compliance agreements from July 2001 through May 2002 (GAO, 2002). The GAO found that DOE's compliance agreements are site specific and are not intended as a way to manage environmental risks across the DOE complex. DOE had not developed a comprehensive, relative ranking of the risks that it faces across its sites and, as a result could not systematically make decisions among sites based on risk. The compliance agreements do not include information on risks being addressed, nor do they provide a means of prioritizing among sites; therefore, they do not provide a basis for decision making across all sites. Instead, DOE was providing relatively stable funding to its sites each year and generally allowed local stakeholders to determine site priorities for sequencing work. The GAO discussed DOE's current initiative to improve the cleanup program and how accelerated risk reduction was identified as a central theme of the top-to-bottom review of the EM program, which is discussed below (DOE, 2002d). GAO identified "following through on its plan to develop and implement a risk-based method to prioritize its various cleanup activities" as one of the two main challenges for DOE going forward with its initiative to accelerate risk reduction and reduce cleanup costs (GAO, 2002, p. 27).

2002 DOE REVIEW OF THE ENVIRONMENTAL MANAGEMENT PROGRAM

In August 2001, DOE Assistant Secretary for Environmental Management Jessie Roberson, created the Top-to-Bottom Review Team, which was tasked with conducting a programmatic review of EM and its management systems, with the goal of making recommendations for how to improve program performance quickly and significantly. On February 2, 2002, the top-to-bottom review of the Environmental Management Program was released (DOE, 2002d). One of the major findings of the review was that the EM complex-wide cleanup strategy is not based on a coherent, comprehensive, technically supported prioritization of risks. Many wastes are managed according to their origins, rather than risks. This approach has resulted in expensive waste management and disposition strategies that are not proportional to risks posed to human health and the environment. The review team recommended that DOE move EM to an accelerated, risk-based cleanup strategy by initiating an effort to examine how current DOE orders, requirements, and regulatory agreements are addressing risk reduction, and that it begin conversations with regulators to work toward achieving regulatory agreements that reduce risk based on technical risk evaluation. The following steps were suggested for incorporating this new strategy: (1) cleanup work should be prioritized to achieve the greatest risk reduction at an accelerated rate; (2) realistic approaches to cleanup and waste management should be based on technical risk evaluation, with consideration given to anticipated future land uses, points of compliance, and points of evaluation; (3) cleanup agreements should be assessed for their contribution to reducing risk to workers, the public, and the environment; and (4) waste acceptance criteria at facilities for permanent disposal should be reevaluated to identify other waste streams that could be sent to these facilities without increasing risk to workers, the public, or the environment (DOE, 2002d, p. ES-4).

2003 THE ROLE OF RISK AND FUTURE LAND USE IN CLEANUP AT THE DEPARTMENT OF ENERGY

Following the EM top-to-bottom review, DOE project teams were set up to implement some of the review's recommendations. The team examining "risk-based end states" asked 36 DOE sites to complete a self-assessment questionnaire. Based on the results, the authors concluded that although there are some "laws and regulations that take risk into account, the lack of site-specific data on exposures and risk scenarios, and the lack of attention to future land use or end states has potentially resulted in a disconnect between risk and cleanup, risk and final end states, and the cleanup levels and end state or subsequent land use" (Burger et al., 2003, p. 10). Considering the final end state before and during cleanup can ensure that risk and other factors inform the decisions (Burger et al., 2003).

The authors provide the following recommendations to DOE: (1) risk balancing should occur consistently at all cleanup sites and should involve regulators, state and tribal governments, and other stakeholders; (2) risk balancing should occur among remediation sites, methods, and schedules (balance risks of acting now against those of delaying until better technologies are available); (3) risk balancing should occur among DOE facilities to address environmental management in a consistent pattern (understand risks before making budget decisions; consider site-wide tradeoffs, and include the participation of American Indian and local government officials, regulators, and other stakeholders); (4) risk, remediation decisions, and future land use designations should be consistent; (5) types of stakeholder participation and information transfer categories should be consistent; (6) tools to meld risk, cleanup goals, and end states should be available to all DOE sites; and, (7) decision-matrix tools for risk balancing should be further developed and made available to all sites (Burger et al., 2003, pp. 11-13).

2003 DOE POLICY ON THE USE OF RISK-BASED END STATES

DOE Policy 455.1 on the use of risk-based end states was approved on July 15, 2003. The goal of this policy is the reevaluation of DOE's cleanup activities to ensure that DOE actions are appropriate for, and aligned with, the end state conditions it aims to achieve. This policy requires each site to formulate a risk-based end state vision "in cooperation with regulators, and in consultation with affected governments and American Indian nations, and stakeholders (as appropriate)" (DOE, 2003, p. 2). After the vision document is developed, sites should create an implementation plan that assesses current cleanup strategies and baselines at each site, to bring them into line with the end state vision. As needed, sites will work with regulators to modify site cleanup strategies, agreements, and baselines and will then update the baselines and performance plans to be consistent with the end state strategy. Sites are required to incorporate the following elements in their efforts to achieve risk-based end states: base the end states on integrated site-wide perspectives, including current and future land use, rather than isolated operable units or release sites. Use the end states as the basis for exposure scenarios developed in the baseline risk assessments that help establish acceptable exposure levels for developing remediation alternatives. Cleanup strategies and decision documents should include risk reduction measures, life-cycle costs, uncertainties, and other relevant policy factors. When remedies result in long-term stewardship, risk control concepts should include institutional controls that are layered, redundant, and commensurate with the risks to maintain protection of human health and the environment. All federal, state, and treaty requirements must be complied with, and when the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) is the governing statute, all nine CERCLA remedy selection criteria must be evaluated. Site managers should establish communication plans for working with stakeholders through all phases of preparation of the site vision. Once the end state is achieved, DOE will address how it plans to manage "the impacts of future risks, uncertainties, and vulnerabilities, including the creation of contingency plans and the identification of responsible parties in the event that site conditions change after cleanup is completed" (DOE, 2003, p. 3).

Guidance to Support Implementation of DOE Policy 455.1

On September 22, 2003, EM issued guidance to assist sites in developing the draft risk-based end state (RBES) vision documents. This guidance provides the steps that sites must use for RBES documents. Historically, land use plans, site maps, and conceptual site models, were generated by the sites using a variety of tools and procedures. In contrast, the guidance uses a standardized approach for generating and using site maps and conceptual site models. The guidance requests site maps that present and allow comparisons between current and future land use and enable graphical depictions of hazards and the associated risks, as well as the affected receptors or populations. The maps should serve as a tool to aid in management decisions at the sites and headquarters. They should also be used for communication and risk assessment tools for discussions with state and federal regulators and with the public about cleanup activities, requirements, and future land use. Conceptual site models, which provide information on hazards, pathways, receptors, and barriers between hazards and receptors, are integral to the RBES approach since they are used as an additional means for communicating risk information to DOE managers, regulators, and the general public (Roberson, 2003a).

On December 9, 2003, at the request of site managers, Assistant Secretary Roberson extended the deadlines for submitting the draft RBES documents to headquarters from October 31, 2003, to February 1, 2004, and the final RBES vision document to March 30, 2004 (Roberson, 2003b).

On December 23, 2003, Gene Schmitt, the DOE deputy assistant secretary for environmental cleanup and acceleration, issued an RBES guidance clarification to respond to the RBES vision documents received at headquarters up to that date. There appeared to be confusion and misinterpretation of the intent of the guidance. Therefore, the guidance clarification document explained that the RBES vision documents were intended as a means for sites to communicate to readers the current state of cleanup progress at the site and alternative end states. Thus, it was expected that the documents would be used to examine future actions based on alternative scenarios associated with land use plans, hazard information, and risk assessments, rather than only to describe current and planned cleanup actions (Schmitt, 2003).

Appendix C

Information-Gathering Meetings

Below is a list of presentations the committee received during information gathering meetings. These were open to the public and included opportunities for public comment.

C.1 MEETING 1: SEPTEMBER 15-16, 2003, WASHINGTON, D.C.

- *U.S. Department of Energy, Office of Environmental Management* (DOE-EM), study sponsor, Patrice Bubar, Associate Deputy Assistant Secretary for Integration and Disposition
- *DOE-EM Corporate Project on Risk-Based End States*, David Geiser, Director, Office of Long-Term Stewardship
- *U.S. Environmental Protection Agency: Risk in EPA Regulations*, Betsy Forinash, Office of Radiation
- *HLW and TRU Issues at Hanford: How We Got Where We Are Today* (videoconference), Roy Gephart, Pacific Northwest National Laboratory

C.2 MEETING 2: DECEMBER 2-4, 2003, IDAHO NATIONAL ENGINEERING AND ENVIRONMENTAL LABORATORY (INEEL), IDAHO FALLS, ID

- *Tour of Idaho Nuclear Technology and Engineering Center and Radioactive Waste Management Complex*
- *Welcome to Idaho Falls and Idaho National Engineering and Environmental Laboratory (INEEL),* Lisa Green, U.S. Department of Energy, Idaho Operations Office (DOE-ID)
- *Overview of INEEL, Discussion of Types and Locations of INEEL Waste Streams,* Keith Lockie, DOE-ID
- *INEEL Risk-Based End State Project*, Bill Leake, DOE-ID

High-Level Waste (HLW) and Sodium Bearing Waste (SBW) Discussion

- *Overview of Waste Streams,* Keith Lockie, DOE-ID
- *Treatment and Disposal of SBW,* Keith Lockie, DOE-ID; Arlin Olson, Lockheed Martin Idaho Technologies Company (LMITC); and Baird McNaught, Bechtel B&W Idaho, LLC (BBWI)
- *Treatment and Disposal Options for Calcine HLW,* Greg Duggan, DOE-ID
- *Discussion of Risks, Costs, and Schedules for SBW, and Calcine Treatment, and Disposal,* Richard Kimmel, DOE-ID
- *HLW Tank Closure Planning,* Keith Lockie, DOE-ID

Transuranic (TRU) Waste Discussion

- *Origin of TRU Waste Located at INEEL,* Jerry Wells, DOE-ID
- *Buried Waste,* Jeff Perry, DOE-ID
- *Stored Remote Handled-TRU Waste,* Tom Clements BBWI TRU Waste Management
- *Stored Contact-Handled TRU Waste,* Brian Edgerton, DOE-ID
- *Regulatory Perspectives,* Kathleen Trever, INEEL Oversight Board, Idaho Department of Environmental Quality and Rick Poeten, U.S. Environmental Protection Agency, Region 10

- *Discussion of Environmental Management Corporate HLW Risk Reduction Project,* Joel Case, DOE-ID, HLW Project Manager (by telephone)

C.3 MEETING 3: JANUARY 27-29, 2004, SAVANNAH RIVER SITE (SRS), AUGUSTA, GA

- *Tour of LLW Disposal Area, TRU Waste Area, F Tank Farm, H Tank Farm, Defense Waste Processing Facility, Glass Waste Storage Building, and Saltstone Facility*
- *Accelerating EM Cleanup at SRS,* Doug Hintze, DOE Savannah River Operations Office (DOE-SR)
- *Waste Disposition Program at SRS,* Doug Hintze, DOE-SR
- *Low Level Waste,* Elmer Wilhite, Savannah River Technology Center (SRTC)
- *Transuranic Waste,* W.T. "Sonny" Goldston, Westinghouse Savannah River Company (WSRC)
- *High-Level Waste,* Joe Carter, WSRC
- *Progress on the risk-based end-state vision,* Tony Polk, DOE-SR
- *Incorporating Risk in DOE's Cleanup Decisions,* Chuck Powers, Consortium for Risk Evaluation with Stakeholder Participation (CRESP II)
- *Regulatory Issues Panel Discussion,* David Wilson, South Carolina Department of Health and Environmental Control (SCDHEC), Ben Rusche, South Carolina Governor Advisory Board, and Jon Richards, U.S. Environmental Protection Agency (EPA)
- *Risk Considerations in Waste Incidental to Reprocessing (WIR) Determinations,* David Esh and Anna Bradford, U.S. Nuclear Regulatory Commission

C.4 MEETING 4: MARCH 9-11, 2004, HANFORD SITE, RICHLAND, WA

- *Overview of Hanford*, Keith Klein, Manager, Richland Operations Office (DOE-RL)
- *Types of Risk at Hanford: Groundwater, Subsurface, Surface* John Morse, Senior Technical Advisor for Groundwater, DOE-RL

- *Impacts of Residual Radioactive Waste on Hanford Groundwater*, Mike Thompson, Physical Scientist, Groundwater Project, DOE-RL
- *How We Assess Risk System Assessment Capability, Composite Risk Modeling*, Doug Hildebrand, Environmental Scientist, Waste Operations Team, DOE-RL, Charles Kincaid, Scientist Level Five, Pacific Northwest National Laboratory
- *How We Use Risk in Decision Making (How does Hanford determine what lower hazard wastes to leave in place based on risk)* John Morse, Senior Geotechnical Environmental Advisory, DOE-RL
- *Looking at Risk to People and Natural Resources over the Long Term,* Russell Jim, Confederated Tribes and Bands of the Yakama Nation
- *Overview of Tank Waste Remediation*, Steve Wiegman, Senior Technical Advisor, DOE, Office of River Protection (ORP)
- *Discussion of Risk-Based End State (RBES) Strategies for the Hanford Tank Farms,* Bob Popielarczyk, Director, and Tony Knepp, River Protection Project Integration, CH2M HILL Hanford Group, Inc.
- *Hanford's RBES Vision*, Shirley Olinger, Assistant Manager for Safety and Engineering, DOE-RL
- *Remarks from Entities with Consultation or Regulatory Status*, Stuart Harris, Confederated Tribes of the Umatilla Indian Reservation; Gabriel Bohnee, Nez Perce Tribe; John Price and Suzanne Dahl, Washington State Department of Ecology; Nick Ceto, Hanford Project Manager, U.S. Environmental Protection Agency, Region 10; and Dirk Dunning, Nuclear Safety Division, Oregon Department of Energy
- *Discussion of How Risk Factors into Planning for the U Plant Waste Sites*, John Price and Suzanne Dahl, Washington State Department of Ecology; Nick Ceto, U.S. Environmental Protection Agency, Region 10; and Dirk Dunning, Oregon Department of Energy

C.5 MEETING 5: MAY 19-21, 2004, WASHINGTON, D.C.

- *What Would Be Useful to DOE in the Committee's Final Report?*, Gene Schmitt, Department of Energy Office of Environmental Management (DOE-EM)

- *Current Status and Understanding of Risk-Based End States Project,* John Lehr, DOE-EM
- *Risk in Decision Making for a Model Comprehensive Environmental Response Record of Decision, CERCLA ROD: MacKenzie Chemical Works Superfund Site in Central Islip, Suffolk County, New York*, Charles Nace, U.S. Environmental Protection Agency Region 2

Appendix D

Glossary

ACTINIDES. A family of chemically similar elements with atomic numbers 90 to 103. Uranium and plutonium are in this group.

ALTERNATIVE DISPOSAL. Disposal in a manner other than deep-geologic disposal.

ARAR. Applicable or Relevant and Appropriate Requirements to be considered under CERCLA (see below).

BURIED TRU. Waste buried prior to compliance with the 1969 directive to store transuranic waste retrievably that nonetheless meets the definition of TRU waste.

CERCLA. The Comprehensive Environmental Response, Compensation, and Liability Act.

CLASS C LIMIT. The concentration limits under U.S. Nuclear Regulatory Commission regulations for disposal of low-level radioactive waste in a near-surface facility.

COMPLIANCE AGREEMENT. An agreement reached to comply with decisions regarding a Federal Facility Agreement.

CRIBS. Shallow, subsurface drainage structures for filtering liquid waste into soil.

CURIE. A unit of radioactivity equal to 37 billion decays per second.

DECAY PRODUCT. An atom resulting from the decay of a radioactive atom.

DWPF. The Defense Waste Processing Facility at the Savannah River Site.

FEDERAL FACILITY AGREEMENT. An agreement among the U.S. Department of Energy, the U.S. Environmental Protection Agency, and the relevant state regulator for a U.S. Department of Energy site that lays out how the site will comply with environmental laws and regulations.

FISSION PRODUCT. An atom resulting from the splitting or fission of a heavier atom.

GROUNDWATER TRAVEL TIME. The time for a contaminant to travel a given distance through groundwater.

HALF-LIFE. The time required for half of the atoms of a radioactive isotope to decay.

HANFORD. The Hanford Site along the Columbia River in south-central Washington State was claimed and developed by the federal government to produce plutonium for nuclear weapons as part of the Manhattan Project. After 50 years of operation, the site is now primarily a cleanup site.

HIGH-LEVEL RADIOACTIVE WASTE (HLW). "(A) The highly radioactive waste material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such liquid waste that contains fission products in sufficient concentrations; and (B) other highly radioactive material that the Commission, consistent with existing law, determines by rule to require permanent isolation." (U.S. Code, Title 42, Section 10101).

IDAHO NATIONAL ENGINEERING AND ENVIRONMENTAL LABORATORY (INEEL). A large reservation near Idaho Falls, Idaho, that has been used for research and test reactors, operations to support the Naval Nuclear Propulsion Program, and other research. The site has HLW from chemical processing of naval spent nuclear fuel and has TRU waste from its own operations and the Rocky Flats Plant.

IMMOBILIZED. Bound up in a solid to isolate from environmental release or transport.

INTEC. Idaho Nuclear Technology & Engineering Center at INEEL.

LONG-LIVED. With a half-life that is long compared to human history. For example, technetium-99 with its 215,000-year half-life is long-lived.

LOW-LEVEL RADIOACTIVE WASTE. Radioactive waste not classified as HLW-TRU waste, spent nuclear fuel, or by-product material as defined in section 11e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste).

NPL. National Priority List.

NRC. The National Research Council of the National Academies.

NWPA. The Nuclear Waste Policy Act of 1982.

PERFORMANCE ASSESSMENT. Estimates the potential behavior of a system or system component under a given set of conditions. It includes estimates of the effects of uncertainties in data and modeling. In the context of radioactive waste, performance assessment is a systematic method for a repository risk assessment.

PROBABILISTIC RISK ASSESSMENT (PRA). A systematic approach for transforming failures into risk profiles. PRA allows both qualitative and quantitative evaluation of reliability, availability, and accident scenarios. The results of the PRA provide the probability and magnitude of each risk.

RADIATION. Energetic emissions. In this report, radiation is energy emitted from radioactive decay and may be in the form of gamma rays (high-energy electromagnetic emissions), beta particles (mostly electrons), or alpha particles (bare helium nuclei).

RADIOACTIVITY. The property of some materials to undergo internal changes (decays) that change the nuclear configuration or composition of the material and emit or absorb energy or particles.

RCRA. The Resource Conservation and Recovery Act.

RISK ANALYSIS. A detailed examination including risk assessment, risk characterization, risk communication, and risk management performed to understand the nature of unwanted, negative consequences to human life, health, property, or the environment (Society for Risk Analysis [SRS] Available at: *http://www.sra.org/).*

RISK ASSESSMENT. The scientific evaluation of known or potential adverse health effects resulting from exposure to hazards. It is a process of establishing information regarding the acceptable levels of risk for an individual, group, society, or the environment. The process consists of the following steps: (1) hazard identification, (2) hazard characterization, (3) exposure assessment, and (4) risk characterization. The definition includes quantitative risk assessment, and also qualitative expressions of risk, as well as an indication of the attendant uncertainties (NRC, 1983; 1986). See Appendix A for a more detailed discussion of risk assessment.

RISK MANAGEMENT. The policy process involving the balancing of risk, other impacts, and cost.

RBES. Risk-Based End States.

RISK-INFORMED APPROACH. An approach in which risk is the starting point but still only one among several factors in a decision process.

SALTCAKE. The crystalline salt that forms in high-level radioactive waste tanks and contains much of the cesium and some of the actinides in the waste.

SALTSTONE. The cementitious waste form used at Savannah River Site to immobilize liquid waste from processing HLW that is being sent to the vitrification plant.

SAVANNAH RIVER SITE (SRS). The nation's second site developed for the production of plutonium, SRS still carries out missions for the nuclear weapons program. Located in southern South Carolina, the site has closed two HLW tanks and disposed of low-activity waste on-site.

SHORT-LIVED. With a half-life that is short compared to human history. For example, cesium-137 with its 30.2-year half-life is short-lived.

SLUDGE. Insoluble wetted particles.

SUPERNATE. The fluid above a sediment or precipitate.

SWPF. The Salt Waste Processing Facility under development at SRS.

TANK HEEL. The waste remaining in the bottom of a waste tank after substantial removal of the bulk waste. The heel may be liquid, loose or encrusted solids, or all of these.

TRANSURANIC ISOTOPE. An isotope of an element with more protons than uranium (i.e., atomic number greater than 92).

TRANSURANIC (TRU) WASTE. Waste containing more than 100 nanocuries of alpha-emitting TRU isotopes (atomic number greater than 92) per gram of waste, with half-lives greater than 20 years, except for

- High-level radioactive waste.
- Waste that the Secretary [of Energy] has determined, with the concurrence of the Administrator [of the Environmental Protection Agency], does not need the degree of isolation required by the disposal regulations; or
- Waste that the Nuclear Regulatory Commission has approved for disposal on a case-by-case basis in accordance with part 61 of title 10, Code of Federal Regulations." (P.L. 102-579)

TRI-PARTY AGREEMENT. Federal Facility Agreement.

U.S. EPA. The U.S. Environmental Protection Agency.

U.S. NRC. The U.S. Nuclear Regulatory Commission.

VADOSE ZONE. The zone between the earth's surface and the top of the water table, also called the unsaturated zone.

VITRIFIED. Immobilized in glass.

Appendix E

Biographical Sketches of Committee Members

David E. Daniel, *Chair*, is an expert in the performance of engineered disposal cells and barriers to contaminant migration. He is dean of the College of Engineering and Gutgsell Professor of Civil Engineering at the University of Illinois at Urbana-Champaign. His research has focused on engineered containment systems for waste disposal and on the cleanup of contaminated waste disposal sites. Prior to his appointments at the University of Illinois, Dr. Daniel was L.B. Meaders Professor of Engineering at the University of Texas, where he taught for 15 years. He has won several awards from the American Society of Civil Engineers and the American Society for Testing and Materials. He is currently a member of the National Research Council's (NRC's) Board on Radioactive Waste Management. He has also served on the NRC's Board on Energy and Environmental Systems and Geotechnical Board. Dr. Daniel received his B.S., M.S., and Ph.D. degrees in civil engineering, all from the University of Texas. He was elected to the National Academy of Engineering in 2000.

John S. Applegate, *Vice Chair,* is the associate dean for academic affairs and Walter W. Foskett Professor of Law at the Indiana University School of Law-Bloomington. He teaches and writes about environmental law, regulation of hazardous substances, risk, and environmental remediation. Mr. Applegate is chair of the Risk Science and Law Specialty Group of the Society for Risk Analysis. He co-chaired the Long-Term Stewardship and Accelerated Cleanup Subcommittees of the Department of Energy's (DOE's) Environmental Management Advisory Board. He was previously the James B. Helmer, Jr., Professor of Law at the University of Cincinnati College of Law; chair of the Fernald Citizens Advisory Board; visiting professor at Vanderbilt University Law School; a judicial clerk to the United States Court of Appeals for the Federal Circuit; and an attorney in private practice. He is the author, coauthor, or editor of more than 20 articles and two books on risk and environmental law. Mr. Applegate received his B.A. in English from Haverford College and his J.D. from Harvard Law School.

Lynn Anspaugh is a research professor in the Division of Radiobiology of the School of Medicine at the University of Utah, Salt Lake City. Dr. Anspaugh is an internationally recognized expert in dose reconstruction, leading an effort to assess doses due to environmental releases of radionuclides from the first nuclear weapons production plant in Russia. He held several leadership positions at the Lawrence Livermore National Laboratory, including division leader of the Environmental Sciences Division and director of the Risk Sciences Center. His research has included the environmental effects of utilizing geothermal energy, reconstruction of radiation doses from early fallout of nuclear weapons tests, and calculation of radiation doses from nuclear reactor accidents. Dr. Anspaugh received his B.A. in physics from Nebraska Wesleyan University, Lincoln; and his M. Bioradiology (health physics) and Ph.D. (biophysics), both from the University of California at Berkeley.

Allen G. Croff retired in 2003 as manager of Environmental Quality R&D Program Development in the Biological and Environmental Sciences Directorate at the Oak Ridge National Laboratory (ORNL). From when he joined ORNL in 1974, he was involved in numerous technical studies that have focused on waste management and nuclear fuel cycles. He recently chaired the National Council on Radiation Protection and Measurements committee that produced the 2002 report titled *Risk-Based Classification of Radioactive and Hazardous Chemical Wastes.* He is now vice chair of the U.S. Nuclear Regulatory Commission's Advisory Committee on Nuclear Waste. Mr. Croff has served on several NRC committees, and is currently a member of the NRC's Board on Radioactive Waste Management. He holds a B.S. in chemical engineering from Michigan State University, a nuclear engineering degree from the Massachusetts Institute of Technology, and an M.B.A. from the University of Tennessee.

Rodney C. Ewing is an expert in mineralogy and materials science. His research interests include the long-term durability of radioactive waste forms. He is a professor in the Department of Geological Sciences, with joint appointments in the Departments of Nuclear Engineering and Radiological Sciences and Materials Science and Engineering, at the University of Michigan. Dr. Ewing previously served for 23 years as a professor in the Department of Earth and Planetary Sciences at the University of New Mexico. He has served on several NRC committees, and is currently a member of the Board on Radioactive Waste Management. He is a past president of the International Union of Materials Research Societies and of the Mineralogical Society of America. Dr. Ewing received M.S. and Ph.D. degrees in geology from Stanford University.

Paul A. Locke, a public health scientist and attorney, is a faculty member at the Johns Hopkins University Bloomberg School of Public Health. Previously, he was general counsel and deputy director of Trust for America's Health, a not-for-profit public health advocacy organization; deputy director of the Pew Environmental Health Commission at the Johns Hopkins School of Public Health; and director of the Center for Public Health and Law at the Environmental Law Institute in Washington, D.C. He has worked extensively on environmental health and policy issues, including radiation protection, indoor air quality, alternatives to animal testing, and risk assessment. Dr. Locke was chair of the American Public Health Association's (APHA) environment section in 2001 and is currently secretary of the APHA Intersectional Council Steering Committee. He is a member of the editorial board of *Risk Analysis: An International Journal,* and is a past councilor and past member of the executive committee of the Society for Risk Analysis. Dr. Locke currently serves as a member of the NRC's Board on Radioactive Waste Management. He holds an M.P.H. from Yale University School of Medicine and a Dr.P.H. from the Johns Hopkins University Bloomberg School of Public Health. He is also a graduate of Vanderbilt University School of Law and is licensed to practice before the bars of the States of New York and New Jersey, the District of Columbia, and the United States Supreme Court.

Patricia A. Maurice is a professor of civil engineering and geological sciences at the University of Notre Dame and director of the university's interdisciplinary Center for Environmental Science and Technology. Dr. Maurice's research focuses on microbial, trace metal, and organic interactions with mineral surfaces from the atomic scale to the scale of entire watersheds. Her research encompasses the hydrology and biogeochemistry of freshwater wetlands and mineral-water interactions, the remediation of metal contamination, and global climate change. Dr. Maurice received her B.A. in earth and planetary sciences from the Johns Hopkins University, her M.S. in geology from Dartmouth College, and her Ph.D. in aqueous and surface geochemistry from Stanford University.

Robin Rogers is an expert in separations chemistry and does research on prevention or chemical treatment of waste streams. He is professor of chemistry and director of the Center for Green Manufacturing at the University of Alabama. Dr. Rogers' research interests include green-sustainable separation science and technology, aqueous biphasic systems, room- temperature ionic liquids, environmentally benign polymer resins, crystal engineering, and radiochemistry. Dr. Rogers is the editor of the American Chemical Society journal *Crystal Growth & Design*. He served on a NRC study on research needs for high-level radioactive waste. Dr. Rogers received his B.S. and Ph.D., both in chemistry, from the University of Alabama, and he reached the rank of presidential research professor at Northern Illinois University before returning to Alabama.

Anne E. Smith is a vice president of Charles River Associates (CRA), an economics consulting firm. Prior to joining CRA, Dr. Smith was a vice president of Decision Focus Incorporated and served as an economist in the Office of Policy Planning and Evaluation of the U.S. Environmental Protection Agency. Dr. Smith specializes in the integrated assessment of environmental and energy policy decisions, including risk management, decision analysis, benefit-cost analysis, and economic modeling. She has applied these techniques to many types of policy decisions, including contaminated site cleanup, nuclear waste management, global climate change, air quality, and food safety. Dr. Smith has developed and reviewed decision support tools for risk-based ranking of contaminated sites and for making risk trade-offs in selecting remediation alternatives. She led an assessment of human and environmental risks at the DOE's Fernald site that was part of a larger effort to report to the U.S. Congress on risks posed by U.S. nuclear weapons facilities. She has served on several NRC committees reviewing issues involving risk management within DOE's Environmental Management program. Dr. Smith received her B.A. in economics from Duke University and her M.A. and Ph.D. degrees in economics from Stanford University. She also completed a Ph.D. minor in engineering-economic systems at Stanford University.

Theofanis G. Theofanous is an expert in risk analysis and safety. He is a professor in the Department of Chemical Engineering with a joint appointment in the Department of Mechanical and Environmental Engineering, and is the director of the Center for Risk Studies and Safety at the University of California, Santa Barbara. His current technical interests are risk assessment and management in complex technological and environmental systems. Dr. Theofanous has done innovative work analyzing and enhancing the safety of nuclear reactors, including development of a new methodology for accident analysis. He has received several commendations from the U.S. Nuclear Regulatory Commission, as well as the Department of Energy's E.O. Lawrence Medal in Nuclear Technology. Dr. Theofanous received his B.S. in chemical engineering from the National Technical University, Athens, Greece, and his Ph.D. in chemical engineering from the University of Minnesota. He was elected to the National Academy of Engineering in 1998.

Jeffrey Wong is the deputy director for science, pollution prevention and technology development for the California Department of Toxic Substances Control (DTSC). His office is engaged in environmental measurements, biological and exposure monitoring, toxicology and risk assessment, pollution prevention and waste minimization, and verification and evaluation of technologies involved in hazardous waste detection, containment, treatment, disposal, or cleanup. Before his current appointment, Dr. Wong served as chief of DTSC's Human and Ecological Risk Division since the early 1990s. In that position, he directed the scientific organization that gathers site characterization data and performs risk assessments in support of the state's hazardous waste and site remediation programs. Dr. Wong has served on several NRC committees on issues related to hazardous waste and site cleanup, peer review teams examining DOE's cleanup of the nuclear weapons complex, and programs on risk EPA assessment. He served by presidential appointment on the U.S. Nuclear Waste Technical Review Board from 1996 until 2002. Dr. Wong received his B.A. in bacteriology, his M.S. in food science and technology, and his Ph.D. in pharmacology and toxicology, all from the University of California at Davis.