
EXECUTIVE SUMMARY

Proper management of high-level radioactive wastes, including those resulting from the production of nuclear weapons and the operation of nuclear electric power plants, is vital for the protection of the public health and safety. It has been longstanding federal policy to dispose of these wastes underground in a mined geologic repository. The U.S. Department of Energy (DOE) is charged with the development and eventual operation of a repository. The U.S. Environmental Protection Agency (EPA) and the U.S. Nuclear Regulatory Commission (USNRC) share the responsibility for regulating the disposal program to ensure adequate protection of the health and safety of the public.

EPA promulgated its first standard for deep geologic disposal of high-level radioactive waste in 1985; this standard was challenged, litigated, and ultimately reissued in 40 CFR 191 in December 1993. Before EPA promulgated the new standard, however, Congress enacted the Energy Policy Act of 1992, which mandated a separate process for setting a standard specifically for the proposed repository at Yucca Mountain, Nevada. In Section 801 of the Act, Congress required EPA to arrange for an analysis by the National Academy of Sciences of the scientific basis for a standard to be applied at the Yucca

Mountain site and directed EPA," based upon and consistent with the finding and recommendations of the National Academy of Sciences, [to] promulgate, by rule, public health and safety standards for protection of the public from releases from radioactive materials stored in or disposed of in the repository at the Yucca Mountain site." This report responds to the charge of Section 801.

Implicit in setting a Yucca Mountain standard, is the assumption that EPA, USNRC, and DOE can, with some degree of confidence, assess the future performance of a repository system for time scales that are so long that experimental methods cannot be used to confirm directly predictions of the behavior of the system or even of its components. This premise raises the basic issue of whether scientifically justifiable analyses of repository behavior over many thousands of years in the future can be made. We conclude that such analyses are possible, within restrictions noted in this report. Nevertheless, these assessments of repository performance must contend with substantial uncertainties, and some areas — projecting the behavior of human society over very long periods, for example — are beyond the limits of scientific analysis. We have made explicit those instances, and have also pointed out where we believe it is appropriate to rely on informed judgments and reasonable assumptions to supplement scientific analysis.

In attempting to make the best use of the scientific understanding that is available, we have arrived at recommendations that differ in important ways from the approach followed by EPA in 40 CFR 191. In particular, we recommend:

- **The use of a standard that sets a limit on the risk to individuals of adverse health effects from releases from the repository. 40 CFR 191 contains an individual-dose standard, and it continues to rely on a containment requirement that limits the releases of radionuclides to the accessible environment. The stated goal of the containment requirement was to limit the number of health effects to the global population to 1,000 incremental fatalities over 10,000 years. We do not recommend that a release limit be adopted.**
- **That compliance with the standard be measured at the time of peak risk, whenever it occurs.⁵ The standard in 40 CFR 191 applies for a period of 10,000 years. Based on performance assessment calculations provided to us, it appears that peak risks might occur tens to hundreds of**

Within the limits imposed by the long-term stability of the geologic environment, which is on the order of one million years.

thousands of years or even farther into the future.

- **Against a risk-based calculation of the adverse effect of human intrusion into the repository. Under 40 CFR 191, an assessment must be made of the frequency and consequences of human intrusion for purposes of demonstrating compliance with containment requirements. In contrast, we conclude that it is not possible to assess the frequency of intrusion far into the future. We do recommend that the consequences of an intrusion be calculated to assess the resilience of the repository to intrusion.**

Finally, we have identified several instances where science cannot provide all of the guidance necessary to resolve an issue. This is particularly true in developing procedures for compliance assessment. Setting the standard, therefore, requires addressing policy questions as well as scientific ones. We recommend that resolution of policy issues be done through a rulemaking process that allows opportunity for wide-ranging input from all interested parties. In these cases, we have tried to suggest positions that could be used by the responsible agency in formulating a proposed rule. Other starting positions are possible, and of course the final rule could differ markedly from any of them.

Although we have taken a broad view of the scientific basis for the standard, we have not addressed the social, political, and economic issues that might have more effect on the repository program than the health standard. In particular, we have not recommended what levels of risk are acceptable; we have not considered whether the development of a permanent repository should proceed at this time; nor have we made a judgment about the potential for the Yucca Mountain site to comply with the standard eventually adopted.

PROTECTING HUMAN HEALTH

In Section 801, Congress directs that EPA set a standard for Yucca Mountain by specifying the maximum annual effective dose equivalent to individual members of the public. The first question posed in Section 801 is whether such a standard will provide a reasonable basis for protecting the health and safety of the general public. We recommend the use of a standard designed to limit individual risk, and describe how a standard might be structured on this basis. We then address the specific question of protection of public health in the context of the individual-risk standard and compare this standard to the one currently used by EPA. Based on this analysis, we conclude not only that the individual risk standard would protect the health of the general public, but also that it is a particularly appropriate

standard for the Yucca Mountain site in light of the characteristics of this site.

The risks to humans from exposures to low levels of radiation have been assessed in detail by national and international organizations. These assessments are fraught with uncertainty, but it has been possible to reach a reasonable consensus within the scientific community on the relationship of dose and health effects, which is generally considered to provide an acceptable basis for evaluating the risks attributable to a given dose or the degree of protection afforded by a given limitation of exposure. Additionally, a general consensus exists among national and international bodies on a framework for protecting the public health that provides a limit of 1 milliSievert (mSv) (100 millirem (mrem)) per year effective dose for continuous or frequent exposures from all anthropogenic sources of ionizing radiation other than medical exposures. A general consensus also appears to exist among national authorities in various countries to accept and use the principle of apportioning this total radiation dose limit among the respective anthropogenic sources of exposure, typically allocating to high-level waste disposal a range of 0.1 to 0.3 mSv (10 to 30 mrem) per year.

Elements of the Standard

A standard is a societally acceptable limit on some aspect of repository performance that should

not be exceeded if the repository is to be judged safe. We recommend the use of a standard that sets a limit on the risk to individuals of adverse health effects from releases from the repository. A risk-based standard would not have to be revised in subsequent rulemaking if advances in scientific knowledge reveal that the dose-response relationship is different from that envisaged today. Such changes have occurred frequently in the past, and can be expected to occur in the future. For example, ongoing revisions in estimates of the radiation doses received by atomic bomb survivors of Hiroshima and Nagasaki might significantly modify the apparent dose-response relationships for carcinogenic effects in this population, as have previous revisions in dosimetry (see Straume et al., 1992). Moreover, risks to human health from different sources, such as nuclear power plants and toxic chemicals can be compared in reasonably understandable terms.

It is essential to define specifically how to calculate risk, however, for otherwise it will not be clear what number to use to compare to the risk limit established in the standard. We define risk as the expected value of a probabilistic distribution of health effects. The first step in calculating risk is to develop a distribution of doses received by individuals. A probabilistic distribution of health effects can be developed as the product of each value of dose received and the health effect per unit dose.

Structuring of the individual-risk standard requires specifying what level of protection is to be

afforded, who is to be protected, and for how long. We acknowledge that determining what risk level is acceptable is not ultimately a question of science but of public policy. We note, however, that EPA has already used a dose limit equivalent to a risk level of 5×10^{-4} health effects in an average lifetime, or a little less than 10^{-5} effects per year assuming an average lifetime of 70 years, as an acceptable risk limit in its recently published 40 CFR 191. This limit is consistent with limits established by other federal nuclear regulations. In addition, the risk equivalent of the dose limits set by authorities outside the United States is also in the range of 10^{-5} to 10^{-6} per year (except for exposure to radon indoors or releases from mill tailings). This range is a reasonable starting point for EPA's rulemaking.

To determine whether a repository complies with the standard, it is necessary to calculate the risk to some individual or representative group of individuals and then to compare the result to the risk limit established in the standard. Therefore, the standard must specify the individual or individuals for whom the risk calculation is to be made. Although not strictly a scientific issue, we believe that the appropriate objective is to protect the vast majority of members of the public while also ensuring that the decision on the acceptability of a repository is not unduly influenced by the risks imposed on a very small number of individuals with unusual habits or sensitivities. The situation to be avoided, therefore, is an extreme case defined by unreasonable

assumptions regarding the factors affecting dose and risk, while meeting the objectives of protecting the vast majority of the public. An approach that is consistent with this objective, and is used extensively elsewhere in the world, is the critical-group approach. We recommend that the critical-group approach be used in the Yucca Mountain standards.

The critical group has been defined by the International Commission on Radiological Protection (ICRP) as a relatively homogeneous group of people whose location and habits are such that they are representative of those individuals expected to receive the highest doses⁶ as a result of the discharges of radionuclides. Therefore, as the ICRP notes, "because the actual doses in the entire population will constitute a distribution for which the critical group represents the extreme, this procedure is intended to ensure that no individual doses are unacceptably high." (ICRP, 1985a, at paragraph 46). In the context of an individual-risk standard, and using cautious, but reasonable, assumptions, the group would include the persons expected to be at highest risk, would be homogeneous in risk⁷, and would be

The ICRP defines critical group in dose terms. We use the ICRP terminology here to describe the concept as developed by the ICRP, and later adapt the concept to the risk framework.

That is, the difference between the highest and lowest risk faced by individuals in the group should be relatively small. Should a radiation dose occur, however, it may affect only a few members of the group. This is the difference between risk (the chance of an adverse health effect) and outcome

(continued...)

small in number. The critical-group risk calculated for purposes of comparison with the risk limit established in the standard would be the mean of the risks to the members of the group.

This definition requires specifying the persons who are likely to be at highest risk. In the present and near future, these persons are real; that is, they are the persons now living in the near vicinity of the repository and in the direction of the postulated flow of the plume of radionuclides. For the far future, however, it will be necessary to define hypothetical persons by making assumptions about lifestyle, location, eating habits, and other factors. The ICRP recommends use of present knowledge and cautious, but reasonable, assumptions.

The current EPA standard contains a time limit of 10,000 years for the purpose of assessing compliance. We find that there is no scientific basis for limiting the time period of an individual-risk standard in this way. We believe that compliance assessment is feasible for most physical and geologic aspects of repository performance on the time scale of the long-term stability of the fundamental geologic regime — a time scale that is on the order of 10^6 years at Yucca Mountain — and that at least some potentially important exposures might not occur until after several hundred thousand years. For these

(...continued)

(a cancer that actually develops). Risk can be homogeneous, even when outcomes are quite diverse.

reasons, we recommend that compliance assessment be conducted for the time when the greatest risk occurs, within the limits imposed by long-term stability of the geologic environment.

Another time-related regulatory concern, based on ethical principles, is that of intergenerational equity. A health-based risk standard could be specified to apply uniformly over time and generations. Such an approach would be consistent with the principle of intergenerational equity that requires that the risks to future generations be no greater than the risks that would be accepted today. Whether to adopt this or some other expression of the principle of intergenerational equity is a matter for social judgment.

Protection of the General Public

Congress has asked whether a standard intended to protect individuals would also protect the general public in the case of Yucca Mountain. **We conclude that an individual-risk standard would protect public health, given the particular characteristics of the site, provided that policy makers and the public are prepared to accept that very low radiation doses pose a negligibly small risk.**

The individual risk-standard that we recommend is intended to protect a critical group. In this context, the general public includes both global populations as well as local populations that lie

outside the critical group. Global populations might be affected because radionuclide releases from a repository can in theory be diffused throughout a very large and dispersed population. In the case of Yucca Mountain, the likely pathway leading to widely dispersed radionuclides is via the atmosphere beginning with release of carbon dioxide gas containing the carbon-14 (^{14}C) radioactive isotope which might escape from the waste canisters.

The risks of radiation produced by such wide, dispersion are likely to be several orders of magnitude below those of a local critical group. Great uncertainty exists about the number of health effects that would be imposed on the global population because of the difficulties in interpreting the risks associated with very small incremental doses of radiation. As noted in the BEIR V report (NRC, 1990a), the lower limit of the range of uncertainty in such risk estimates extends to zero (no effects). To address scenarios of widespread but extremely low-level doses, the radiation protection community has introduced the concept of negligible incremental dose (above background levels). For example, the National Council on Radiation Protection and Measurements (NCRP) has recommended a value of 0.01 mSv/yr (1mrem/yr) per radiation source or practice (NCRP 1993), which currently would correspond to a projected risk of about 5×10^{-7} /yr for fatal cancers, assuming the linear hypothesis. We believe that this concept can be extended to risk and can be applied to the establishment of a radiation standard at Yucca

Mountain. Defining the level of incremental risk that is negligible is a policy judgment. We suggest the risk equivalent of the negligible individual incremental dose recommended by the NCRP as a reasonable starting point for developing consensus.

Persons in some population outside the critical group may, however, still be exposed to risks in excess of the level of the negligible incremental risk but below the level of the critical group risk. The risks to these persons as individuals are, by definition, acceptable, but whether the effects on this population as a whole are acceptable remains a matter of judgment. Based on our review, we conclude that there is no technical basis for a population risk standard by which to make such a judgment.

ASSESSING COMPLIANCE

Any standard to protect individuals and the public after the proposed repository is closed will require assessments of performance at times so far in the future that a direct demonstration of compliance is out of the question. The only way to evaluate the risks of adverse health effects and to compare them with the standard is to assess the estimated potential future behavior of the entire repository system and its potential effects on humans. This procedure, involving modeling of processes and events that might lead to releases and exposures, is called performance assessment.

The technical feasibility of developing performance assessment calculations to evaluate compliance with a risk standard at Yucca Mountain depends on the feasibility of modeling the relevant events and processes (including their probabilities) specific to that site. By soliciting technical appraisals at our open meetings, reviewing solicited and unsolicited written contributions, and drawing on the available literature and our own experience and expertise, we have assessed the types, magnitudes, and time-dependencies of the uncertainties associated with potential radionuclide transport from a Yucca Mountain repository, the effects of potential natural and human modifiers of repository performance, and the pathways through the biosphere.

Physical and Geologic Processes

The properties and processes leading to transport of radionuclides away from the repository include release from the waste form, transport to the near-field zone, gas phase transport to the atmosphere above Yucca Mountain and its dispersal in the world atmosphere, and transport from the unsaturated zone to the water table and from the aquifer beneath the repository to other locations from which water might be extracted by humans. We conclude that these physical and geologic processes are sufficiently quantifiable and the related uncertainties sufficiently boundable that the

performance can be assessed over time frames during which the geologic system is relatively stable or varies in a boundable manner. The geologic record suggests that this time frame is on the order of 10^6 years. We further conclude that the probabilities and consequences of modifications by climate change, seismic activity, and volcanic eruptions at Yucca Mountain are sufficiently boundable that these factors can be included in performance assessments that extend over this time frame.

Exposure Scenarios

Performance assessment of physical and geologic processes will produce estimates of potential concentrations of radionuclides in ground water or air at different locations and times in the future. To proceed from these concentrations to calculations of risks to a critical group requires the development of an exposure scenario that specifies the pathways by which persons would be exposed to radionuclides released from the repository. Once an exposure scenario has been adopted, performance assessment calculations can be carried out with a degree of uncertainty comparable to the uncertainty associated with geologic processes and engineered systems.

Based upon our review of the literature, we conclude, however, that it is not possible to predict on the basis of scientific analyses the societal factors required for an exposure scenario. Specifying

exposure scenarios therefore requires a policy decision that is appropriately made in a rulemaking process conducted by EPA. We recommend against placing the burden of postulating and defending an exposure scenario on the applicant for the license.

As with other aspects of defining standards and demonstrating compliance that involve scientific knowledge but must ultimately rest on policy judgments, we considered what to suggest to EPA as a useful starting point for rulemaking on exposure scenarios. Reflecting the disagreement inherent in the literature, we have not reached complete consensus on this question. It is essential that the scenario that is ultimately selected be consistent with the critical-group concept that we have advanced. Additionally, EPA should rely on the guidance of ICRP that the critical group be defined using present-day knowledge with cautious, but reasonable, assumptions.

We considered two illustrative approaches to the design of an exposure scenario that EPA might propose to initiate the rulemaking process. The approaches have many elements in common but differ in their treatment of assumptions about the location and lifestyle of persons who might be exposed to releases from the repository, and in the method of calculating the average risk of the members of the critical group. A substantial majority of the committee members, but not all, considers one of the approaches to be more consistent with the foregoing criteria. This particular approach explicitly accounts

for how the physical characteristics of the site might influence population distribution and identifies the makeup of the critical group probabilistically.

HUMAN INTRUSION

Human activity that penetrates the repository (by drilling directly into it from the surface, for example) can cause or accelerate the release of radionuclides. Waste material could be brought to the surface and expose the intruder to high radiation doses, or the material could disperse into the biosphere. The second and third questions asked in Section 801 of the Energy Policy Act of 1992 concern the potential that at some time people might intrude into the repository.

With respect to the second question of Section 801, we conclude that it is not reasonable to assume that a system for post-closure oversight of the repository can be developed, based on active institutional controls, that will prevent an unreasonable risk of breaching the repository's engineered barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits. This conclusion is founded on the absence of any scientific basis for making projections over the long term of the social, institutional, or technological status of future societies. Additionally, there is no technical basis for making forecasts about

the long-term reliability of passive institutional controls, such as markers, monuments, and records.

With respect to the third question in Section 801, we conclude that it is not possible to make scientifically supportable predictions of the probability that a repository's engineered or geologic barriers will be breached as a result of human intrusion over a period of 10,000 years. We reach this conclusion because we cannot predict the probability that a future intrusion would occur in a given future time period or the probability that a future intrusion would be detected and remediated, either when it occurs or later. In addition, we cannot predict which resources will be discovered or will become valuable enough to be the objective of an intruder's activity. We cannot predict the characteristics of future technologies for resource exploration and extraction, although continued developments in current noninvasive geophysical techniques could substantially reduce the frequency of exploratory boreholes.

Although there is no scientific basis for judging whether active institutional controls can prevent an unreasonable risk of human intrusion, we think that, if the repository is built, such controls and other activities might be helpful in reducing the risk of intrusion, at least for some initial period of time after a repository is closed. Therefore, we believe that a collection of prescriptive requirements, including active institutional controls, record-keeping, and

passive barriers and markers would help to reduce the risk of human intrusion, at least in the near term.

Moreover, because it is not technically feasible to assess the probability of human intrusion into a repository over the long term, we do not believe that it is scientifically justified to incorporate alternative scenarios of human intrusion into a fully risk-based compliance assessment. We do, however, conclude that it is possible to carry out calculations of the consequences for particular types of intrusion events. The key performance issue is whether repository performance would be substantially degraded as a consequence of an intrusion of the type postulated. For this purpose, we have focused on the particular class of cases in which the intrusion is inadvertent and the intruder does not recognize that a hazardous situation has been created.

To provide for the broadest consideration of what human intrusion scenario or scenarios might be most appropriate, we recommend that EPA make this determination in its rulemaking to adopt a standard. For simplicity, we considered a stylized intrusion scenario consisting of one borehole of a specified diameter drilled from the surface through a canister of waste to the underlying aquifer. In our view, the performance of the repository, having been intruded upon, should be assessed using the same analytical methods and assumptions, including those about the biosphere and critical groups, used in the assessment of performance for the undisturbed case. We recommend that EPA require that the estimated risk

calculated from the assumed intrusion scenario be no greater than the risk limit adopted for the undisturbed-repository case because a repository that is suitable for safe long-term disposal should be able to continue to provide acceptable waste isolation after some type of intrusion. As with other policy-related aspects of our recommendations, we note that EPA might decide that some other risk level is appropriate.

IMPLICATIONS OF OUR CONCLUSIONS

Limits of the Scientific Basis

It might be possible that some of the current gaps in scientific knowledge and uncertainties that we have identified might be reduced by future research. It seems reasonable, therefore, to ask what gaps could be closed by taking time to obtain more scientific and technical knowledge on such matters as the nature of the waste, its potential use, the health effects of radionuclides, the value of waste products for later generations, and the security of retrievable storage containers. New information in these and other areas could improve the basis for setting the standards.

Whether the benefit of new information would be worth the additional time and resources required to obtain it is a matter of judgment. This judgment would be strengthened by a careful appraisal of the probable costs and risks of continuing the present temporary waste disposal practices and storage

facilities as compared to those attaching to the proposed repository. No such comprehensive appraisal is now available. Conducting such an appraisal, however, should not be seen as a reason to slow down ongoing research and development programs, including geologic site characterization, or the process of establishing a standard to protect public health.

Technology-Based Standards

Technology-based standards play an important role in regulations designed to protect the public health from the risks associated with nuclear facilities. We have examined three technological approaches in our study.

The "as low as reasonably achievable" (ALARA) principle is intended to be applied after threshold regulatory requirements have been met, and calls for additional measures to be taken to achieve further reduction in the calculated health effects. While ALARA continues to be widely recommended as a philosophically desirable goal, its applicability to geologic disposal of high-level waste is limited at best because the technological alternatives available for designing a geologic repository are quite limited. Further, the difficulties of demonstrating technical or legal compliance with any such requirement for the post-closure phase could well prove insuperable even if it were restricted to

engineering and design issues. We conclude that there is no scientific basis for incorporating the ALARA principle into the EPA standard or USNRC regulations for the repository.

If EPA issues standards based on individual risk, the USNRC would be required to revise its current regulations embodied in 10 CFR 60 to be consistent with such standards. One purpose of 10 CFR 60, which contains technology specifications, is to help ensure multiple barriers within the repository system. We conclude that because it is the performance of the total system in light of the risk-based standard that is crucial, imposing subsystem performance requirements might result in suboptimal repository design.

Finally, several persons suggested to our committee the use of a technology-based standard that would specify a strict release limit from an engineered barrier system during the early life of the repository. We find that such a limitation on early releases would have no effect on the results of compliance analysis over the long-term. Nonetheless some members of the committee believe that such a limitation might provide added assurance of safety in the near-term, and EPA might wish to consider this as a policy matter.

Administrative Consequences

Our recommendations, if adopted, imply the development of regulatory and analytical approaches for Yucca Mountain that are different from those employed in the past and from some approaches currently used elsewhere by EPA. The change in approach and the time required to develop a thorough and consistent regulatory proposal and to provide for full public participation in the rulemaking process will require considerable effort by EPA. This process probably will take more than the year, currently provided in statute, for EPA to complete development of a Yucca Mountain standard in a technically competent way. This does not mean that DOE's Yucca Mountain Site Characterization Project cannot proceed usefully in the interim.

INTRODUCTION

Proper management of high-level radioactive wastes, including those resulting from the production of nuclear weapons and the operation of nuclear electric power plants, is vital for the protection of public health and safety. In the United States, defense wastes from the nuclear weapons program have been accumulating for about 50 years and spent nuclear fuel from commercial power plants has been accumulating for almost 40 years.

Together defense nuclear wastes and spent nuclear fuel have been generated at almost 100 sites located throughout the country. At present, high-level defense wastes are in various physical and chemical forms and are stored—much of it in underground steel tanks—in several types of facilities, primarily at three U.S. Department of Energy (DOE) weapons-complex locations: Hanford site, WA; Savannah River site, SC; and the Idaho National Engineering Laboratory, ID (DOE, 1993a). The commercial spent nuclear fuel is stored in water pools and in above-ground dry-storage casks at more than 70 sites throughout the U.S.

There is therefore a need for a long-term strategy for disposal of these wastes that limits to an acceptable level the risks that they pose to public health and safety. By law, providing for "permanent disposal" of high-level radioactive waste is the responsibility of the federal government. It has been longstanding federal policy (see the Nuclear Waste Policy Act of 1982 (P.L. 97-425)) to dispose of these wastes in an underground mined geologic repository; the geologic disposal option has been examined and generally endorsed by the scientific community (National Research Council (NRC), 1957, 1983, 1990b).

The responsibility for high-level radioactive waste disposal is divided among three federal agencies. DOE is charged with the development and eventual operation of a geologic repository. It must locate an appropriate site; demonstrate the site's ability to meet regulatory requirements; obtain a license from the U.S. Nuclear Regulatory Commission (USNRC); and construct, operate, and maintain surveillance of the repository itself. The U.S. Environmental Protection Agency (EPA) and the USNRC share the

responsibility for regulating the disposal program to ensure adequate protection of the health and safety of the public. Operating under the authority of the Atomic Energy Act of 1954 (42 USC 2201(b)), EPA must establish generally applicable standards for protection of the environment from offsite releases from radioactive material in repositories (see 42 USC 1014(a), and the Nuclear Waste Policy Act of 1982 (P.L. 97-425)). The USNRC promulgates technical regulations that are consistent with the standards and considers license applications from DOE for any proposed repository, determining with reasonable assurance whether the EPA standard can be met. USNRC will have continued regulatory responsibilities to oversee the repository operation.

The process of selecting a deep geologic repository for high-level radioactive waste in the United States has been going on since at least 1975, although DOE has yet to apply for a license to build such a repository. In 1987, Congress directed DOE's Office of Civilian Radioactive Waste Management to concentrate only on the Yucca Mountain Site (Nuclear Waste Policy Act Amendments of 1987). DOE is currently studying the Yucca Mountain site by a process called "site characterization" to accumulate the information necessary to judge whether it will meet the standard to be set by EPA. If the site is deemed appropriate to be considered in the licensing process and a license application to USNRC is approved, DOE estimates that the earliest date for possible emplacement of high-level radioactive waste at Yucca Mountain would be the year 2010 (C. Gertz, DOE, personal communication, May 28, 1993). If the site is not deemed appropriate, Congress requires, in Section 113 of the Nuclear Waste Policy Act, recommendations from the Secretary of DOE to assure the safe, permanent disposal of spent nuclear fuel and high-level radioactive waste, including the need for new legislative authority.

This report deals with only one aspect of this long and complicated process — the standard that must be set to protect public health. The standard-setting process itself has extended over a period of nearly twenty years. EPA promulgated its first standard for deep geologic disposal of high-level radioactive waste (40 CFR 191) in 1985, after about a decade of study. Consistent with the

directive of its authorizing statute, EPA intended this standard to be generally applicable to any deep geologic disposal site. At the time, several repository sites were being considered for spent nuclear fuel and defense high-level waste, and the Waste Isolation Pilot Plant (WIPP) near Carlsbad, New Mexico, was being designed to accept transuranic waste from the defense nuclear program.⁸

Challenged by intervenors and state agencies, the standard was judicially reviewed, and in 1987 the U.S. Court of Appeals for the First Circuit remanded the standard to EPA for reconsideration of several of its provisions. Before EPA promulgated a new standard, however, Congress enacted the Energy Policy Act of 1992 (P.L. 102-486), which mandated a separate process for setting a standard specifically for the proposed repository at Yucca Mountain, Nevada. Through Section 801 of the Act, Congress severed the Yucca Mountain standard from coverage under the generally applicable standard in 40 CFR 191 and the Atomic Energy Act of 1954. In December 1993, EPA issued a final regulation (as 40 CFR 191) responding to the issues raised in the 1987 court remand, but this revised regulation does not apply to the proposed repository at Yucca Mountain.

In Section 801, Congress mandated that EPA arrange for an analysis by the National Academy of Sciences of the scientific basis for standards to be applied at the Yucca Mountain site and directed the agency, "based upon and consistent with the findings and recommendations of the National Academy of Sciences, [to] promulgate, by rule, public health and safety standards for protection of the public from releases from radioactive materials stored in or disposed of in the repository at the Yucca Mountain site." The first paragraph of Section 801(a) provides that the standard prescribe the maximum annual effective dose equivalent to individual members of the public from releases to the accessible environment. These standards will be the only ones for high-level radioactive waste disposal applicable to the Yucca Mountain site, and are to be promulgated within one year after the Academy submits its study.

According to the definition provided in 40 CFR 191, "transuranic waste" is waste that is contaminated with alpha-emitting radionuclides with atomic numbers greater than that of uranium (92), half-lives greater than 20 years, and concentrations greater than 1 ten-millionth of a curie per gram of waste.

USNRC then has one year to issue its specific regulations, requirements, and criteria to be consistent with the EPA Yucca Mountain standard.

This report responds to the charge made explicit in Section 801(a)(2), and in particular to the three questions that it posed:

1. Whether a health-based standard based upon doses to individual members of the public from releases to the accessible environment . . . will provide a reasonable standard for the protection of the health and safety of the general public.
2. Whether it is reasonable to assume that a system for post-closure oversight of the repository can be developed, based upon active institutional controls, that will prevent an unreasonable risk of breaching the repository's engineered barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits.
3. Whether it is possible to make scientifically supportable predictions of the probability that a repository's engineered or geologic barriers will be breached as a result of human intrusion over a period of 10,000 years.

The conference report accompanying Section 801 makes clear that Congress does not intend for our report to "establish specific standards for protection of the public but rather to provide expert scientific guidance on the issues involved in establishing those standards." (See Congressional Record, Oct. 8, 1992, pp. S17555 and H11399.) Furthermore, the conference report and subsequent correspondence, dated May 20, 1993, from the Chairman of the Senate Energy and Natural Resources Committee point out that our study is not precluded from addressing additional issues. (See Appendix B for the language of P.L. 102-486, the accompanying conference report, and the correspondence.) Accordingly, the scope of this report embraces a range of scientific questions about the Yucca Mountain standards and the process of demonstrating compliance with the standard.

SCOPE OF THE STUDY

The disposal of high-level radioactive waste in a geologic repository initially requires placing radionuclides in the repository at concentrations far in excess of natural levels. Some radionuclides decay quickly: for example cesium-137 has a half-life of 30 years and strontium-90 has a half-life of about 29 years. But some of the radionuclides have long half-lives: for example, the half-life of carbon-14 is 5,730 years and the half-life of iodine-129 is 17 million years. Others produce decay products that in turn persist for very long periods. The half-lives of plutonium-239 and neptunium-237 are 24,360 years and 2.2 million years, respectively.

The purpose of deep geologic disposal is to provide long-term barriers to the escape of these radionuclides into the biosphere⁹. Most of the original radioactive material placed in a repository is expected to have decayed to natural background levels while these barriers are effective. However, some of the longer-lived radionuclides involved will ultimately enter the biosphere, although it might take tens to hundreds of thousands of years or longer to do so. These releases will be "acceptable" in a regulatory sense if the adverse consequences for public health are sufficiently low. The health standard to be set by EPA and compliance with the standard will, in principle, determine whether the residual risks are acceptable.

Implicit in setting such a standard, and in demonstrating compliance with it, is the assumption that EPA, USNRC, and DOE can, with some degree of confidence, assess the future performance of a repository system for time scales that are so long that experimental methods cannot be used to confirm directly predictions of the behavior of the system or even of its components. This premise raises the basic issue of whether scientifically justifiable analyses of repository behavior over many thousands of years in the future can be made. Based on our evaluation of this issue and the state of

In this report, "biosphere" refers to the region of the earth in which environmental pathways for transfer of radionuclides to living organisms are located and by which radionuclides in air, ground water, and soil can reach humans to be inhaled, ingested, or absorbed through skin. Humans can also be exposed to direct irradiation from radionuclides in the environment.

scientific and technical understanding, we conclude that such analyses are indeed possible within limitations noted in this report. In such cases, these analyses can provide useful guidance for assessing compliance with required health standards, as Chapter 3 of this report will describe.

Even when scientifically useful analysis is possible, assessments of repository performance must contend with substantial uncertainties in information about, and understanding of, the basic physical processes that are important to judging the effectiveness of the repository system to isolate wastes. Although some of these uncertainties can be resolved by further research, not all of them can be. Some areas — projecting the behavior of human society over very long periods, for example — are beyond the limits of scientific analysis. For these reasons, we have attempted to be candid about the limits of scientific analysis in supporting the standard-setting process. We have made explicit those instances where, because there is no adequate scientific basis for an analysis, policy judgments are required.

Additionally, setting and assessing compliance with a standard must rely on informed judgments and reasonable assumptions based on scientific expertise when uncertainties and unknowns otherwise stand in the way of determinative analysis. There are no alternatives to relying on policy judgments and informed assumptions since some aspects of standard-setting and compliance analysis are not amenable to scientific analysis.

The processes of setting a standard and licensing a repository also raise social, political, and economic issues that would be difficult to resolve even if the scientific challenges were less formidable. Some of these issues might have more effect on the repository program than the health and safety standard itself. Although we have taken a broad view of our charge as related to the scientific basis for the standard, we have not addressed these other, potentially important, issues. The following discussion describes eight issues that we have not addressed.

1. *We have not recommended what levels of risk are acceptable.* A standard that serves as an objective for protection of public health must be stated in terms of some quantitative limit, such as acceptable dose, health

effects, or risk. The specific level of acceptable risk cannot be identified by scientific analysis, but must rather be the result of a societal decisionmaking process. Because we have no particular authority or expertise for judging the outcome of a properly constructed social decisionmaking process on acceptable risk, we have not attempted to make recommendations on this important question. However, many domestic and international bodies have reached carefully considered conclusions on this and related questions. We discuss these instances in Chapter 2 and note the cases where we believe that existing scientific, regulatory, and other expert opinions establish ranges within which lie useful starting points for consistent regulatory proposals.

2. *We have not considered whether the development of a permanent repository should proceed at this time. A central objective of the DOE program is to license and operate a repository as soon as possible. As individuals, we hold differing views on the urgency of meeting this objective. We were not asked and we did not attempt to address whether a repository is needed in the near future; nor did we compare the risks and benefits of proceeding with a repository now as opposed to those that might be realized by continued reliance on surface storage well into the next century. Accordingly, this report should not be interpreted as a recommendation for or against the development of a Yucca Mountain repository or even a judgment on whether any deep geologic repository should or should not be built at this time.*
3. *We have not made a judgment about the suitability of Yucca Mountain as a repository site, or on whether the proposed repository there would meet requirements of any standard consistent with our recommendations to EPA. Within our scope, we have not produced new scientific or technical data or made calculations that would add to the continuing assessment of the suitability of the site. Although we have reviewed the assessments currently underway, we have not evaluated either the quality or*

the results of the assessment program in a detailed, rigorous way. Finally, the question of site acceptability raises a variety of social, political, and economic issues that we have not examined because such issues are not within our mandate.

4. *We have not considered the effects of our recommendations on the future of nuclear power.* It has been argued that unless and until means for long-term disposal of spent fuels from commercial nuclear power plants are available, the future of nuclear power is in question. Some states and some foreign countries require by law or regulation that a means for disposing of waste be in place before additional plants are licensed. We did not, however, consider the effect on the future of nuclear power on the federal program for managing spent fuel from commercial nuclear power plants.
5. *We have not compared the basis for regulating high-level radioactive waste with the basis for regulating nonradioactive long-lived toxic substances, such as lead or cadmium.* Radioactive wastes are sometimes regulated on more stringent bases than nonradioactive wastes even though some nonradioactive substances are more persistent and can pose a greater hazard than many radionuclides. However, it is consistent with our charge in Section 801 to concern ourselves only with the radioactive constituents of the waste.
6. *We have not evaluated the standards applicable to the operational phase of the repository program.* This phase refers to the time before the approved repository is closed and includes the transportation of waste to the repository site and the steps taken at the site to prepare and emplace the waste in the repository. These operations are closely analogous to other nuclear activities regulated by EPA and USNRC. Even though some would argue that the health risk associated with these relatively transitory activities might be greater than those associated with the repository over geologic time, we have not addressed the issues because the clear

intent of Section 801 is that our report should focus on the post-operational performance of the repository over very long time-periods. Furthermore, the basis for regulating operating nuclear facilities is considerably better established.

7. *We have not considered the potential effects of the repository on nonhuman biota and ecosystem functions.* These effects might deserve attention, but the clear charge in Section 801 to focus on protection of public health has deterred us from going further. We are aware, of course, and have considered, that human health can be affected by exposure to radionuclides taken up by other organisms such as food crops.
8. *We have not considered the potential for chain reactions of fissile materials as part of a standard.* The possibility theoretically exists that circumstances might ultimately arise in which radioactive wastes containing fissile materials could undergo a chain reaction in a geologic repository. The potential is an important concern for engineering design that ultimately is likely to be the subject of regulation, perhaps by USNRC. This topic, however, requires specialized analysis that is sufficiently far from our primary focus that we left it for the consideration of others.

BACKGROUND AND APPROACH

A general description of the repository system, and of the ways that it may release radionuclides into the accessible environment, is essential background information for understanding our approach to this assignment. This description appears below, and is followed by discussions of the major issues to be considered in setting a health and safety standard, and of their implications for the study. A map showing the location of the Yucca Mountain region is shown in Figure 1.1. A schematic cross section of the potential Yucca Mountain repository is shown in Figure 1.2.

The Repository System

DOE plans to achieve containment and isolation of high-level radioactive waste in a proposed repository by using an engineered barrier system and locating the repository in the geologic setting of Yucca Mountain. The general repository design suggests that the waste would be emplaced in drifts (tunnels) about 300 meters (1,000 feet) beneath the land surface but above the water table of the uppermost aquifer, that is, in the unsaturated or vadose zone. By law the repository is conceptually designed to hold 70,000 metric tons of high-level radioactive waste. Under current policy, about 90% of this amount (63,000 metric tons) would be spent commercial fuel and the rest would be defense high-level waste. Up to 100 years after emplacement operations begin, the repository would be sealed

Figure 1.1 Map showing location of Yucca Mountain region adjacent to the Nevada Test Site in southern Nevada.
Source: Wilson et al., 1994.

Figure 1.2 Schematic cross section of the potential Yucca Mountain repository region showing location of the repository horizon and static water table with respect to the thermal/mechanical stratigraphic units defined by Ortiz et al. (1985). TCw: Tiva Canyon welded unit; PTn: Paintbrush nonwelded unit; TSw: Topopah Spring welded unit; CHn: Calico Hills nonwelded unit; PPw: Prow Pass welded unit; BFw: Bullfrog welded unit. Source: Wilson et al., 1994.

by backfilling the drifts, closing the opening to each emplacement drift, and sealing the entrance ramps and shafts.

The engineered barrier system would include the waste form (for example, reactor-fuel assemblies or high-level defense waste embedded in a glass matrix), internal stabilizers, the canister in which the waste is placed, and backfill between the canister and the adjacent host rock. The spent fuel assemblies include naturally radioactive uranium oxide containing fission products, as well as fuel cladding and support hardware, both of which will be radioactive due to activation or contamination. The defense waste consists of products resulting from physical and chemical processes associated with the separation of fissionable materials in weapons manufacture.

The engineered barrier system would be placed beneath Yucca Mountain in the unsaturated zone, which consists of layered units of welded and non-welded tuffs¹⁰. Some of these units are highly fractured — a characteristic that may influence the flow of water underground. The water table at Yucca Mountain occurs at depths of 600 meters to 800 meters below land surface, which would correspond to depths of 300 to 500 meters below the repository. The volume of rock below the water table contains two principal aquifer systems, one in the volcanic tuff and another at greater depth in carbonate rock. In the Yucca Mountain region, the regional ground water in the upper aquifer appears to flow generally southerly, from higher elevations north of the mountain to the Death Valley region to the southwest where it emerges at the surface (NRC, 1992).

Radionuclide releases from an undisturbed repository into the geologic environs can occur through the following sequence: degradation and failure of the waste canister through corrosion, relatively quick release of substances from the more mobile components of the radionuclide inventory, slow release of substances from the less soluble or less mobile components of the inventory, and movement of radionuclides from the waste package to the air and water in the pores and fissures of the host rock by gas phase and aqueous phase. Radionuclides can enter the environment accessible to humans by traveling down through the unsaturated zone and into the aquifer (the saturated zone), then through the aquifer to wells or

Tuff is consolidated volcanic ash.

springs where the water might be used for purposes such as drinking or agricultural irrigation. Releases might also occur in gaseous form, transported upward or laterally from the waste package through the rock to the atmosphere. Other pathways might develop if the site is disturbed, for example, by human intrusion or earthquakes.

More detailed information on the proposed repository and the inventory of radionuclides in the waste is presented in the 1993 total-system performance assessments for Yucca Mountain that were prepared for DOE (Andrews et al., 1994; Wilson et al., 1994).

Issues to Be Considered in Approaching the Study

The aim of this study is to provide guidance on the scientific basis for a standard that would protect the public health from the adverse effects of releases from a proposed repository for high-level radioactive waste at Yucca Mountain. There are two major considerations in providing this guidance. The first is how to make the best use of the scientific knowledge that is now or might soon be available. The second is how to make decisions when the scientific basis is deficient. We present below several examples that illustrate these two considerations, and then describe how we have addressed them in our approach to the study.

Large but improbable doses

It is important to define the standard in such a way that it is a useful measure of the degree to which the public is to be protected from releases from a repository. The nature of geologic disposal is to concentrate and isolate high-level radioactive wastes in a small area for a very long time. It is always possible to conceive of some circumstance that, however unlikely it may be, will result in someone at some time being exposed to an unacceptable radiation dose. Some of these scenarios are common to all geologic repositories; for example, it is always possible that a person will drill or otherwise intrude into any repository in such a way as to bring to the surface some amount of radioactive waste. Other such scenarios are dependent upon the characteristics of the repository site. In the case

of Yucca Mountain, human ingestion of radionuclides in ground water drawn from a well is an example of a site-specific scenario that, because of the limited amounts of water in a relatively isolated hydrologic basin, potentially could lead to radiation doses of a relatively high level to a few persons. The possibility that future volcanic activity in the region might seriously compromise the integrity of a repository at Yucca Mountain must also be evaluated. The challenge is to define a standard that specifies a high level of protection but that does not rule out an adequately sited and well-designed repository because of highly improbable events.

Demonstration of compliance

The feasibility of assessing compliance with the standard is another key issue. Quantitative performance assessment is the tool generally proposed for use in evaluating whether a repository is likely to meet the standard with a given level of assurance. Performance assessment requires analyzing the processes by which radionuclides might be released from the repository, the processes by which people might be exposed to them, and the health consequences of exposure. The first steps in the analysis are to model the degradation of waste packages and the migration of radionuclides through the engineered and geologic barriers of the repository and the adjacent host rock. Although this analysis involves important uncertainties, they can, in principle, be addressed by scientific methods. More difficult is the identification of the pathways through the biosphere that would result in exposure to humans. There are countless possible pathways for radionuclides but only a limited number of them need to be analyzed, that is, the ones most likely to yield the highest doses. Moreover, in principle, pathway and exposure analyses require specifying the state of human society many thousands of years into the future — where people might live, what they will eat and drink, what technologies will be available to detect and avoid radionuclides, and other factors. These difficulties cannot be ignored in setting a practical health-based standard, but dealing with them can depend as much, or perhaps more, on assumptions and informed judgment as on testable scientific hypotheses. The scientific basis for

performance assessment thus varies considerably among the steps in the analysis.

Fundamental vs. derived standards

To avoid explicitly using uncertain assumptions in compliance assessment, a derived standard is sometimes proposed rather than a fundamental one. A fundamental standard uses as its criterion the endpoint that the standard is intended to control. Thus, when adverse health effects are the outcome to be controlled, a fundamental standard would be stated in terms of limiting the number of adverse effects, the risks of developing an adverse health effect, or of some closely related parameter such as a dose rate. A derived standard translates the fundamental criterion into some other unit of measure, such as the total flux of radionuclides across a repository boundary, expressed for example in the cumulative amount of radioactivity released over a specified period of time.

The difference between the two is that the derived standard subsumes into its definition various assumptions, such as specifying the particular sets of pathways to human exposure, and a dose-response relationship, that would otherwise have to be made in compliance assessment for a fundamental standard. Because a derived standard might eliminate from the licensing process some of the calculations involved in specifying these pathways, it has the advantage of a simpler licensing decision (M. Federline, USNRC, personal communication, May 27, 1993). In choosing between a fundamental or a derived standard, a balance must be struck between clarity of purpose in the standard and complexity of the licensing process on the one hand, and complexity in the standard, but a clearer focus in the licensing process on the other.

Time scale

A final issue involves the time scale over which compliance with the standard should apply. The repository could release radionuclides over hundreds of thousands of years or more, but as performance assessments are extended into the future, the

uncertainties in some of the calculations that might be required could render further calculation scientifically meaningless. On the other hand, analyses that are uncertain at one time might not be so uncertain at a later time; for example, the uncertainties about cumulative releases to the biosphere that depend on the rate of failure of the waste packages are large in the near term but are smaller later, when enough time has passed that all of the packages will have failed. Selection of a time scale for the standard must therefore take into account the scientific basis for the performance assessment itself. Selection of a time scale also involves policy considerations. (For example, the level of protection that the standard affords to future generations is an important ethical question that must be considered. Limiting the time period covered by the standard could be inconsistent with a policy on long-term intergenerational equity.)

The remanded EPA standard — and the recently promulgated standard for radioactive waste repositories other than the proposed Yucca Mountain repository — places a time limit on performance assessment of 10,000 years. This time limit makes some aspects of the analysis more tractable by eliminating from consideration the uncertainties that increase at times beyond 10,000 years. In the case of Yucca Mountain, however, recent performance assessment calculations (Andrews et al., 1994) indicate that the likely time for some radionuclides, such as technetium-99, to reach the biosphere is longer than 10,000 years. If that time limit were to apply at the Yucca Mountain site, potential exposures occurring beyond 10,000 years would be excluded from the compliance analysis. The problem of the cumulative uncertainties must therefore be weighed against the need to consider the exposures when they actually are calculated to occur.

Choices Affecting the Bases of the Standard

The foregoing issues illustrate two considerations that we have had to balance in reaching our conclusions and recommendations. First, is the need to choose among the available options (for example, alternative forms of the standard and time scales) in a way that makes the best use of the scientific information that is available. For example, it might be intuitively attractive to state a standard in terms

of risk to human health. But as noted earlier, the demonstration of compliance with such a standard requires a model of the radionuclides and their pathways from the repository to the biosphere that is scientifically challenging to develop. This difficulty can be avoided by abandoning a health-based standard in favor of a limitation on releases from the repository, but doing so would obscure crucial information about the potential of the radionuclide releases for causing health effects. Similarly, selecting a time scale for analysis involves weighing how the scientific basis for analysis changes with time against the timing at which more numerous future health effects are likely to occur. We have tried to deal explicitly with these choices and to arrive at a basis for judging the form of standard that is best supported by the available scientific information taken as a whole.

The second consideration is how to provide, within the regulatory process, a system for making those choices for which scientific information is unavailable or insufficient. The regulatory process involves the two major steps of rulemaking and licensing. The rulemaking procedure allows extensive public participation and considerable administrative discretion in weighing and assimilating alternative points of view. Licensing is a quasi-judicial process that benefits from having clear-cut limits against which to judge an applicant's proposals. It is for the latter reason that several members of the USNRC staff have pointed out their reluctance to leave any speculation about the future of human society for the licensing process (which USNRC administers).

There are several choices to be made in designing the standard for which science cannot provide all the necessary guidance — defining the critical group to be protected or the radionuclide pathways to them through the biosphere, for example. Since these choices must be made, even in the absence of clear-cut scientific information, we recommend that such issues should be treated as part of the rulemaking process, since this process, as indicated earlier, allows a broader scope for discussing and weighing alternatives.

In the course of this study, we analyzed separately the scientific bases for setting a health-based standard, conducting compliance assessment, and dealing with human intrusion and episodic geologic processes, such as volcanoes and earthquakes. We adopted this procedure to help us understand the choices involved

among these different aspects of the problem, and to clarify where the scientific basis for choice was insufficient. We then weighed these considerations in making our final findings and recommendations, which are presented in the remaining chapters of our report.

PROTECTING HUMAN HEALTH

The primary objective of the proposed repository at Yucca Mountain is to dispose of high-level radioactive defense waste and spent nuclear fuel in a safe manner. To determine whether the repository can be designed to protect the public health from the risks associated with exposure to radiation from radionuclides that may be released from the repository, it is necessary to establish standards against which to judge whether the design of the repository is acceptable. This target will be embodied in a radiation protection standard to be issued by EPA.

In Section 801 of the Energy Policy Act of 1992, Congress directs that EPA set these standards by specifying the maximum annual effective dose equivalent to individual members of the public. In the same section, Congress also asks three questions, the first of which is:

whether a health-based standard based on doses to individual members of the public from radionuclide releases to the accessible environment . . . will provide a reasonable standard for the protection of the health and safety of the general public.

This chapter addresses this question. As background, we first present a synopsis of the health effects of ionizing radiation and outline the development of radiation protection standards on a national and international basis. This discussion will illustrate the current status of scientific investigation and consensus of expert judgment on which most efforts to establish a standard for high-level waste repositories are based.

We then turn to the question of whether a standard for Yucca Mountain designed to protect individuals will, if met, also protect the general public. We conclude that the answer to this question is "yes," given the particular characteristics of the site and assuming that policy makers and the public are prepared to accept that very low radiation doses pose a negligible risk.

Because the current EPA standard for nuclear waste disposal in 40 CFR 191 takes an approach different from that required by Congress, however, addressing only the question posed in Section 801 is too narrow a response. Accordingly, we have expanded the discussion by recommending the use of a standard designed to limit individual risk rather than individual dose and by describing how a standard might be structured on this basis. We then address the specific question of protection of public health in the context of an individual-risk standard and compare this standard with the one currently used by EPA for sites other than Yucca Mountain. Based on this analysis, we conclude not only that an individual-risk standard would protect the health of the general public, but also that this form of standard is particularly appropriate for the Yucca Mountain site in light of the site's characteristics.

Finally, standards are only useful if it is possible to make meaningful assessments of future repository performance with which the standards can be compared. In Chapter 3, we discuss our conclusion that it is feasible to conduct such compliance assessments against an individual-risk standard. Doing so, however, requires using the rulemaking process to arrive at a regulatory decision about certain assumptions as part of the standard, for example, about future human behavior. In the following discussion of the standard, we have indicated the assumptions for which this is required.

THE HEALTH EFFECTS OF IONIZING RADIATION

Cell and gene damage can be caused in humans exposed to ionizing radiation (NRC, 1990a), (also referred to as the BEIR V report). Extremely high doses of radiation can lead to quick death, as seen, for example, in Nagasaki, Hiroshima, and Chernobyl. However, even much lower levels of radiation can affect health. International scientific bodies currently accept what is called the linear, or no-threshold hypothesis for the dose-response relationship. Most of what is known about effects of radiation on human health comes from studying people exposed to large doses of radiation. The empirical relationship between cancer induction and radiation dose

appears linear at the high doses received by the atomic bomb survivors. The linear hypothesis postulates that this dose-response relationship continues when extrapolated to very low doses. The no-threshold hypothesis holds that there is no dose, no matter how small, that does not have the potential for causing health effects. To explain this relationship of radiation to cancer, and other health effects, the following outlines the interaction between radiation and the human body.

Radiation that is sufficiently energetic to dislodge electrons from an atom is referred to as ionizing radiation. Impinging ionizing radiation, colliding with atoms and molecules in its path, gives rise to ions and free radicals that break chemical bonds and cause other molecular alterations in affected cells. Any molecule in the cell can be altered by radiation, but deoxyribonucleic acid (DNA), the double helix of base pairs that make up the genes to be passed on to the next generation, is the most critical molecular target because of the uniquely important genetic information it contains. Damage to a single gene, which might consist of thousands of base pairs, can profoundly alter or kill the cell. Although millions of changes in DNA are produced in the body of every person each year by exposure to natural background radiation and other influences, most of the changes are repairable. If unrepaired or misrepaired, however, the damage might be expressed in the form of permanent genetic changes or mutations, the frequency of which approximates 10^{-5} to 10^{-6} per gene per Sievert (Sv)¹¹. Because the mutation rate tends to change in direct proportion to the dose, it is inferred that the interaction of the gene with a single ionizing particle might suffice in principle to mutate the gene. Damage to the genetic apparatus of a cell can also cause changes in the number or structure of its chromosomes, the thread-like structures on which the genes are arranged. Such changes increase in frequency in proportion to the dose in the range below 1 Sv.

Radiation damage to genes, chromosomes, or other vital organelles can be lethal to affected cells, especially dividing cells, which are highly radiosensitive as a class. The survival of dividing cells, measured in terms of their capacity to grow and divide, tends

A unit of equivalent radiation dose, a Sievert is the product of the absorbed dose and the radiation weighting factor. 1 Sievert equals 100 rem.

to decrease exponentially with increasing dose, 1-2 Sv generally sufficing to reduce the surviving cell population by about 50% (NRC, 1990a). The killing of cells, if sufficiently extensive, can impair the function of the affected organ or tissue. In general, however, too few cells are killed by a dose below 0.5 Sv to cause clinically detectable impairment of function in most human organs other than those of the embryo. Because such effects on organ function are not produced unless the radiation dose exceeds an appreciable threshold, they are commonly viewed as nonstochastic (or deterministic) effects, in contradistinction to mutagenic effects of radiation, which are viewed as stochastic effects because they might have no thresholds (see Glossary). Carcinogenic effects of radiation, which can result from mutational changes in the affected cells, are likewise viewed as stochastic effects, the frequency of which is assumed to increase as a linear, no-threshold function of the dose, although the possible existence of a threshold for such effects cannot be excluded.

Natural background radiation is estimated by the National Council on Radiation Protection and Measurements (NCRP) to contribute 82% of the average annual radiation exposure to a United States citizen, and medical applications, an additional 15% (NCRP, 1987a). All other sources of radiation exposure together contribute approximately 3% (Table 2-1). All sources combined give an average dose of 3.6 mSv/yr (360 mrem/yr). Background radiation levels are not uniform. For example, the average difference in background radiation between Denver, CO and Washington, DC, is 0.3 mSv/yr (30 mrem/yr). One cross-country plane ride contributes approximately 0.025 mSv (2.5 mrem) (NCRP, 1987a,b).

At the low-dose rates characteristic of natural background radiation or occupational irradiation, the only health effects of radiation to be expected are stochastic effects; that is, mutagenic and carcinogenic effects. Although the risks of certain cancers have been significantly elevated in some cohorts of radiation workers, especially those employed in the era preceding modern safety standards, no definite or consistent evidence of carcinogenic effects has been observed in workers exposed within present maximum permissible dose limits or in populations residing in areas of high natural background radiation. Hence, assessment of any cancer risks attributable to irradiation in such populations must be based on extrapolation from observations of the effects of exposure at higher

dose levels. Because a statistically significant increase in heritable abnormalities is yet to be demonstrated in human beings at any dose level, assessment of the risks of such effects must be based on extrapolation from observations on laboratory animals. Because of the assumptions inherent in the extrapolations that are involved, assessments of the carcinogenic and mutagenic effects of low-level irradiation are highly uncertain. The uncertainties notwithstanding, it has been possible to reach a reasonable consensus within the scientific community on the relationship between doses and health effects, that is generally considered to provide an acceptable basis for evaluating the risks attributable to a given dose or the degree of protection afforded by a given limitation of exposure.

Within recent years, the risks attributable to low-level irradiation have been assessed in detail by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR, 1988), the National Research Council Committee on the Biological Effects of Ionizing Radiation (NRC, 1990a), and the International Commission on Radiological Protection (ICRP, 1991). The last of these assessments, which drew on and extended the previous two, arrived at risk assessments for carcinogenic effects and for heritable effects, which are shown in Table 2-2. Carcinogenic effects, which are expressed only in exposed individuals themselves, are estimated to account for the bulk (80%) of the overall risk of harm. The lifetime risk of developing a fatal cancer from irradiation is estimated to be $5 \times 10^{-2}/\text{Sv}$ for a member of the general population. Nonfatal cancers, although projected to be produced more frequently than fatal cancers, were judged to contribute less to the overall health impact of irradiation because of their lesser severity in affected individuals and were, therefore, weighted accordingly (Table 2-2). Of the total risk of heritable effects, about one-fourth is projected to be expressed in the first two generations alone, the remainder during subsequent scores of generations.

This table indicates that if 100 people were each to receive 1 Sv of radiation over their lifetimes, which is about 300 times greater than the overall average annual natural background level of radiation in the United States, five would be expected to die from cancer induced by that radiation. Since it accounts for the great bulk of the potential harm that might be attributed to low-level radiation, the above risk estimate for fatal cancer is often used to calculate the

expected number of fatalities attributable to low-dose irradiation in a population. For example, if one million persons were each exposed to a dose equivalent to that received from a transcontinental plane ride (0.025 mSv), the resulting collective dose (25 person-Sv) would be estimated to cause one extra fatal cancer in the population in addition to the 200,000 fatal cancers that would be expected to occur in the same population from all other causes combined. Because the added risk, if any, is calculated to be such a small fraction of the total cancer risk, it is not surprising that epidemiological data have revealed no significant differences in the rates of cancer or other diseases among populations exposed to far larger variations in natural background radiation levels (NRC 1990a).

Table 2-1 Average Amounts of Ionizing Radiation Received Yearly by a Member of the U.S. Population^a

Source	Dose ^b	
	(mSv/yr)	(%)
Natural		
Radon ^c	2.0	55
Cosmic	0.27	8
Terrestrial	0.28	8
Internal	0.39	11
Total Natural	3.0	82
Anthropogenic		
Medical		
X-ray diagnosis	0.39	11
Nuclear medicine	0.14	4
Consumer products	0.10	3
Occupational	< 0.01	< 0.3
Nuclear fuel cycle	< 0.01	< 0.03
Nuclear fallout	< 0.01	< 0.03
Miscellaneous ^d	< 0.01	< 0.03
Total anthropogenic	0.63	18
Total Natural and Anthropogenic	3.6	100

^a From NRC (1990a) and NCRP (1987a)

^b Average effective dose equivalent

^c Dose to bronchial epithelium alone

^d DOE facilities, smelters, transportation, etc.

Table 2-2 Estimated Frequencies of Radiation-Induced Fatal Cancers, Nonfatal Cancers, and Severe Hereditary Disorders, Weighted for the Severity of their Impacts on Affected Individuals^a

No. of cases per

Fatal cancers

5.0

PROTECTING HUMAN HEALTH

39

Nonfatal cancers

1.0

Severe heredity disorders

1.3

PROTECTING HUMAN HEALTH

39

Total

7.3

^aFrom ICRP (1991)

^b Numbers of cases, weighted for severity of their impacts on affected individuals over their lifetimes, attributable to low-level irradiation of a population of all ages.

DEVELOPMENT OF RADIATION PROTECTION STANDARDS

There is a worldwide interest in the development of radiation protection standards, including those for the disposal of high-level radioactive waste, and a considerable body of analysis and informed judgment exists from which to draw in formulating a standard for the proposed Yucca Mountain repository. EPA's process for setting the Yucca Mountain standard is presumably not bound by this experience, but a sound technical approach should include a review of other relevant work to date. Accordingly, we summarize below the status of relevant work on radiation protection standards both in the United States and abroad.

General Consensus in Radiation Protection Principles and Standards

A number of international and nongovernmental national bodies (such as the International Atomic Energy Agency (IAEA), ICRP and NCRP) have recommended radiation protection principles and standards. These recommendations, in turn, usually are considered by the national agencies that set radiation protection standards, which then are codified into pertinent rules and regulations. Of the international bodies, the International Commission on Radiological Protection (ICRP) is perhaps the most influential. Its counterpart in the U.S. is the National Council on Radiation Protection and Measurements (NCRP).

In the United States, several agencies establish radiation protection standards in their areas of responsibility. Among them are the following: the U.S. Environmental Protection Agency (EPA), the U.S. Nuclear Regulatory Commission (USNRC), and the U.S.

Department of Energy (DOE). These three agencies play key roles in programs involving public health and safety, environmental protection, health and safety in the nuclear industry, and radioactive waste management and disposal.

Recommendations for radiation standards to protect the public health and safety are frequently based on the analyses of radiation risks developed by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the ICRP on the international level and by the Committees on Biological Effects of Ionizing Radiation (BEIR) in the United States. The most recent analyses are presented in the UNSCEAR (1988) and NRC (1990a) reports, respectively.

Concurrent with the development of radiation protection concepts internationally and in this country, a consensus has emerged among the organizations involved in performing analyses and making recommendations (ICRP, NCRP, NRC's BEIR V, and UNSCEAR) and those that promulgate regulations (EPA, USNRC, and DOE). This coalescence of views and resulting consensus can be seen in the general uniformity in the system of radiation dose limitation, fundamental units and terminology, health effects factors, occupational and public dose limits, dose apportionment, and use of the critical-group concept. The latter two concepts are defined and discussed later in this chapter.

Consistent with the current understanding of the related consequences, ICRP, NCRP, IAEA, UNSCEAR, and others have recommended that radiation doses above background levels to members of the public not exceed 1 mSv/yr (100 mrem/yr) effective dose for continuous or frequent exposure from radiation sources other than medical exposures. Countries that have considered national radiation protection standards in this area have endorsed the ICRP recommendation of 1 mSv per year radiation dose limit above natural background radiation for members of the public. In the United States, DOE, in Order 5400.5, and USNRC, in 10 CFR 20, have set the dose standard for public exposure to ionizing radiation at 1 mSv per year above natural background level. EPA is in the process of developing similar guidance for all U.S. federal agencies (EPA, 1993).

This framework, with an effective dose limit of 1 mSv per year, is used as a basis for protecting the public health from routine

or expected anthropogenic sources of ionizing radiation (i.e., resulting from human activity) other than medical exposures. It includes any exposures to the public derived from the management and storage of high-level radioactive defense waste and spent nuclear fuel. We note that guidance to date has been for expected exposures from actual routine practices. There is little guidance on potential exposures in the far distant future.

ICRP (1985a) proposed apportionment of the total allowable radiation dose from all anthropogenic sources of radiation, excluding medical exposures. Thus, for radioactive waste management, including high-level radioactive defense waste and spent nuclear fuel, the national authorities could apportion, or allocate, a fraction of the 1 mSv per year to establish an exposure limit for high-level waste facilities. EPA in 40 CFR 191 noted that its requirement for the WIPP transuranic waste facility, at a level of 0.15 mSv/yr (15 mrem/yr), is consistent with ICRP's concept of apportionment.

Most other countries also have endorsed the principle of apportionment of the total allowed radiation dose. Apportionment values that have been established by various countries for high-level radioactive waste range from 5% to 30%, corresponding to radiation doses ranging from 0.05 mSv (5 mrem) per year to 0.3 mSv (30 mrem) per year.

Table 2-3 presents the limits established by various countries on individual exposure from high-level waste disposal facilities. The information in this table suggests a general consensus among national authorities and agencies to accept and use the principle of radiation dose apportionment.

THE FORM OF THE STANDARD

A standard is a societally acceptable limit on some aspect of repository performance that should not be exceeded if the repository is to be judged safe. There is, however, a variety of ways in which this limit can be formulated. It can, for example, be imposed at several points in the chain of events that might ultimately lead to adverse effects on public health. Thus, the limit could apply to the amount of radionuclides released from the repository, to the radiation doses to persons resulting from those releases, to the number of

health effects associated with the doses, or to the level of risk. Risk, dose, or health effect limits can be stated for individuals or for populations.

We recommend the use of a standard that sets a limit on the risk to individuals of adverse health effects from releases from the repository. In this context, risk is the probability of an individual receiving an adverse health effect. It is essential to define specifically how to calculate this risk, however, for otherwise it will not be clear what number to use to compare with the risk limit established in the standards.

From the scientific perspective, the calculation of health risks should take into account all of the uncertainties involved in analyzing repository performance over very long time periods. Because many of the elements of the calculation are not well known, they must be dealt with by using distributions that represent the analysts's state-of-knowledge. The first step in calculating risk is therefore to develop a distribution of doses received by individuals, taking into account all of the events that go into determining whether a dose is received.¹² A probabilistic distribution of the health effects associated with these doses can then be developed as the product of each value of dose received and the health effects per unit dose. In this report, we choose to define risk as the expected value of the probabilistic distribution of health effects.¹³

This does not mean that every event needs to be treated probabilistically; some might be represented by a single bounding estimate, for example. The definition does require, however, that all of the parameters that determine the dose be considered in developing the probabilistic distribution of dose.

It is both easier and common practice to calculate doses received over an individual lifetime. One reason is that the effects of radiation might not appear until years after the dose is received. The lifetime calculation can be annualized by dividing by the duration of an average lifetime. Since this annualized risk is often more convenient for comparison to other risks, we recommend it be used.

Table 2-3 Quantitative High-Level Waste Disposal Objectives/Criteria at International Level and in OECD Countries^a

Organization/Country	Main Objective/Criteria	Other Main Feature(s)	Comments
NEA (1984)	Max. indiv. risk objective $10^{-5}/\text{yr}$ (all sources)	Individual risk/dose = best criterion to judge long-term acceptability	No consensus on ALARA/optimization
ICRP Publication 46 (1985)	1 mSv/yr (normal evolution scenarios) $10^{-5}/\text{yr}$ (probabilistic scenarios) for individuals (all sources)	Both prob. and doses should be taken into account in ALARA	ALARA useful, notably to compare alternatives, but might not be the most important siting factor
IAEA Safety Series 99 (1989)	ICRP Publication 46		Also includes qualitative technical criteria on disposal system features and role of safety analysis and quality assurance
CANADA AECB regul. Document R.104 (1987)	Max. indiv. risk obj. $10^{-6}/\text{yr}$	Period of time for demonstrating 10^4yr No sudden and dramatic increase for times $> 10^4\text{yr}$	Additional qualitative, nonprescriptive requirement and guidelines in regulatory documents No explicit optimization required

FRANCE	Under development ^b : Ref. to ICRP Publication 46		Technical criteria for siting established in 1987
GERMANY Section 45, para 1 of Radiation Protection Ordinance (1989)	Individual dose < 0.3 mSv/yr for all reasonable scenarios	Calculation of individual doses limited to 10 ⁴ yr but isolation potential beyond 10 ⁴ yr might be assessed	Additional qualitative technical criteria in guidelines and regulatory documents
THE NORDIC COUNTRIES Consultative document (1989)	Individual dose < 0.1 mSv/yr (normal scenarios) Individual risk < 10 ⁻⁶ /yr (disruptive events)	Additional criterion on "total activity inflow" limiting releases to biosphere, based on inflow of natural alpha radionuclides	Under revision following broad consultation Includes other qualitative criteria
SPAIN Statement by Nuclear Safety Council, 1987	Individual dose < 0.1 mSv/yr Individual risk < 10 ⁻⁶ /yr in any situation		Further development under study
SWITZERLAND Regulatory Document R-21 (1980)	Individual dose < 0.1 mSv/yr at any time for reasonably probable scenarios; individual risk < 10 ⁻⁶ /yr for sources with lower probability	Repository must be designed in such a way that it can at any time be sealed within a few years without the need for institutional control (for all times)	Flexibility to amend dose and risk limits depending on numbers exposed

UNITED KINGDOM	No specific criteria for HLW but likely application of principles similar to existing objectives for L/ILW: 10^6/yr target for individual risk from a single facility	No time-frame for quantitative assessment specified	ALARA to be used to the extent practical and reasonable
U.S. EPA 40 CFR 191 (1985)	Limits on projected radionuclides releases to the accessible environment for 10^4 yr, based on objective to limit serious health effects to less than 10 in the first, 10^4 yr after disposal for each 1,000 metric tons of heavy metal or other unit of waste	Individual dose (over 1000 yr) ≤ 0.25 mSv/yr Other requirements on drinking water contamination	1985 EPA standard was vacated in 1987 and most of its provisions adopted into law in 1992
U.S. EPA 40 CFR 191 (1993)	Same as in 1985 standard	10,000 year period Individual dose from all environmental pathways ≤ 0.15 mSv/yr Requirements to protect underground sources of drinking water to the maximum contaminant level	Not applicable to Yucca Mountain Same as 1985 standard except for individual dose and ground water provisions

<p>U.S. NRC 10 CFR 60</p>	<p>Minimum levels of performance: Waste package ("substantially complete" containment for 300- 1000y) Engineered barrier system (releases <10⁵/yr of the inventory at 1000 yr after repository closure) Pre-waste-emplacment ground water travel time between "disturbed zone" and "accessible" environment >100y</p>		<p>NRC subsystem requirements are intended to help achieve compliance with the EPA standard and alternative criteria may be approved if appropriate</p>
-------------------------------	--	--	---

^a This table was established by the OECD/Nuclear Energy Agency (NEA) Secretariat, based on national presentations made at a Joint Radioactive Waste Management Committee and Committee on Radiation Protection and Public Health Workshop on Radiation Protection and Safety Criteria for the Disposal of High-Level Waste, Paris, Nov. 5-7, 1990. It presents national criteria in a very simplified form, and should always be read in conjunction with the descriptions reproduced in the Workshop Proceedings published by NEA. Despite apparent differences, all criteria share the same common basis and aim at a relatively uniform safety level.

^b France has since adopted a limit of 0.25 mSv/yr. (Dejonghe, 1993).

^c The UK National Radiological Protection Board has made recommendations for changes in this regard (Barraclough, 1992). As of June 1, 1995, these recommendations are under considerations by the government.

To illustrate, current scientific understanding indicates that the lifetime risk of developing a fatal cancer (based on the dose-response relationship shown in Table 2-2) is 5×10^{-2} per Sv. Thus, if the expected value of the lifetime dose that an individual receives, calculated from a probabilistic distribution of dose, is 1×10^{-4} Sv, then that person's lifetime risk of a fatal cancer is 5×10^{-6} (1×10^{-4} Sv \times 5×10^{-2} fatal cancers per Sv).

We recognize that our recommendation to use an individual-risk standard differs from the form of standard set by EPA in 40 CFR 191 and is a refinement of the form of the effective-dose standard required by Section 801. At the end of this chapter, we discuss our reasons for preferring the risk-based approach.

ELEMENTS OF AN INDIVIDUAL-RISK STANDARD

We now turn to a discussion of how the key elements of an individual-risk standard for Yucca Mountain might be structured. In particular, it is necessary to specify what level of protection is to be afforded, who is to be protected, and for how long. Establishing this structure is prerequisite to assessing whether the individual-risk standard will protect the health of the general public.

As background for this discussion, it is useful to review some of the relevant characteristics of the Yucca Mountain site. The proposed repository would be located in volcanic tuff several hundred meters above the local water table. When materials are released from the waste packages in the repository, they will be transported downward through an unsaturated zone toward the underlying aquifer by water that infiltrates from the surface. The amount of infiltration or recharge depends on climatic conditions. In the absence of fast transit pathways such as faults, fractures, or drill holes, current understanding suggests that transit times to the water table will be long, perhaps 10,000 to 100,000 years (DOE, 1988).

Once radionuclides reach the aquifer, they would be transported away from the vicinity of the repository in the direction of ground-water flow, which is generally to the southwest from the site. Thus, within the aquifer, there would be a plume of contaminated ground water stretching away from the vicinity of the repository. Near Yucca Mountain, there is no flowing surface water

that might serve as a source in preference to ground water. From what currently is known about the aquifer and its low recharge rate, it seems likely that at some times in the future the concentrations of radionuclides in this plume could be relatively high compared with concentrations that would result if the ground water were discharged into a body of flowing surface water (NRC, 1983).¹⁴

According to current understanding, there are three potential routes by which radionuclides in the ground-water plume could expose humans to radiation. One is through withdrawal of contaminated ground water via wells for local use. Another is through contact where the ground water eventually emerges at the surface. A third would occur if ground water were withdrawn and transported away from the region for use elsewhere. In the judgment of most analysts to date, the most probable route for exposing humans to radiation via ground water at Yucca Mountain is via wells.

In addition to exposure via ground water, humans could also be exposed as a result of gaseous emissions from the Yucca Mountain site. Because the proposed repository is above the local water table, some carbon-14 (¹⁴C), the radioactive isotope of carbon, will be emitted as gaseous carbon dioxide, which can migrate through the overlying rock to the surface. Once in the atmosphere, the radioactive carbon dioxide will eventually be distributed across the globe in times relatively short compared with the half-life of ¹⁴C. Current understanding suggests that the major pathway for exposure of ¹⁴C to humans is through food crops.

What Level of Protection?

The level of protection established by a standard is a statement of the level of risk that is acceptable to society. We acknowledge that determining what is acceptable is not ultimately a question of science but of public policy. Whether posed as "How safe

The concentrations of radionuclides in undiluted ground water are likely to be high in the vicinity of almost any repository at some times in the future. A distinguishing feature of the Yucca Mountain site is that there are no surface water sources that would dilute the concentrations of radionuclides if the ground water were discharged to them.

is safe enough" or as "What is an acceptable level of risk?", the question is not solvable by science alone. The rulemaking process, directly involving public comment to which an agency must respond, is an appropriate method of addressing the question of an appropriate level of protection. Accordingly, we do not directly recommend a level of acceptable risk. We do, however, describe the spectrum of regulations already promulgated that imply a level of risk, all of which are consistent with recommendations from authoritative radiation protection bodies.

For example, EPA has already used a risk level of 5×10^{-4} health effects in an average lifetime, or a little less than 10^{-5} effects per year, assuming an average lifetime of 70 years, as an acceptable risk limit in its recently published 40 CFR 191. This limit is consistent with other limits established by other U.S. nuclear regulations, as shown in Table 2-4. In addition, the risk equivalent of the dose limits set by authorities outside the United States (shown in Table 2-3) is also in the range of 10^{-5} to 10^{-6} /yr (except for exposure to radon indoors or releases from mill tailings). This range could therefore be used as a reasonable starting point in EPA's rulemaking.

Who Is Protected?

To determine whether a repository complies with the standard, it is necessary to calculate the risk to some individual or group of individuals and then to compare that number with the risk limit established in the

Table 2-4 Comparison of the Annual Individual Risks Associated with USNRC and EPA Standards
 Adapted from: Kitty Dragonette, USNRC, personal communication, June 16, 1993 and 40 CFR 191.

Standard	Limit	Annualized Individual Risk ^a
Indoor Radon	4 pCi/l (0.1 Bq/l)	4x10 ⁻⁴
40 CFR 192 (Mill Tails)	20 pCi/M ² s (0.7 Bq/m ² s) 5 pCi ²²⁶ Ra/g (0.2 Bq/g)	1x10 ⁻⁶ 3x10 ⁻⁴
10 CFR 61 (Low Level Waste) ^b	25 mrem/yr (0.25 mSv/yr)	1.25x10 ⁻⁵
40 CFR 190 (Uranium Fuel Cycle)	25 mrem/yr (0.25 mSv/yr)	1x10 ⁻⁵
40 CFR 191.03 (Repository Operations)	25 mrem/yr (0.25 mSv/yr)	1x10 ⁻⁵
40 CFR 191.15 (High-Level Waste Individual Protection Standards)	1985: 25 mrem/yr (0.25 mSv/yr)	1x10 ⁻⁵
	1993: 15 mrem/yr (0.15 mSv/yr)	7.5x10 ⁻⁶
40 CFR 61 (National Emission Standards for Hazardous Air Pollutants)	10 mrem/yr (0.1 mSv/yr)	5x10 ⁻⁶
40 CFR 191.16 (Ground Water Protection Standards) ^c	1985: 4 mrem/yr (0.04 mSv/yr)	2x10 ⁻⁶
	1993: Safe Drinking Water Act	2x10 ⁻⁶
40 CFR 300 (Superfund)	General 5 pCi ²²⁶ Ra/g (0.2 Bq/g) ^d	10 ⁻⁶ to 10 ^{-8e} 3 x 10 ⁻⁴

^a Assumes a lifetime risk of 5x10⁻² per Sievert (5x10⁻⁴ per rem). With two exceptions, the risks in this table are those allowed for an assumed maximally exposed individual.

One exception is the reactor safety goal, which is based on average risks experienced by the population potentially affected by the facility. Translation from average maximum individual risks (or vice versa) is not possible without specific demographic information about the exposed population. Another exception is 40 CFR 191.13 which is based on collective-dose considerations.

^b Neglects consideration of ALARA radiation protection measures; actual doses to members of the public from all pathways are generally far below the dose limit.

^c These levels of the standard are consistent with EPA's ground water protection strategy.

^d The Superfund requirements address the risk of fatal and nonfatal cancer over a lifetime. In order to present risk values on a consistent basis in the table, the risk is expressed in terms of fatal cancers per year assuming a 70-year lifetime and a ratio of 1.5 for total cancer incidence to fatal cancer incidence. Depending upon exposure pathways, radionuclide, total inventory, and site characteristics, the ratio of 1.5 could be off by a factor of 2.

^e As applied at selected Superfund sites with ²²⁶Ra contamination, for example Montclair, NJ, Denver, CO.

standard. Therefore, the standard must specify the individual or individuals for whom the risk calculations are to be made. The issue is how to define who is to be protected among the persons having the highest risk of health effects due to releases from a repository, since by definition all other persons face a lower risk.

The choice of those to be protected can obviously have a significant effect on the calculated risk and, therefore, on whether the calculated performance meets the standard. For example, some groups of persons are particularly sensitive to exposure due to factors such as pregnancy, age, or existing health problems. Similarly, it is possible to construct scenarios in which an individual could receive a very high dose of radiation, even though only one or two people might ever receive such doses.

There is an obviously sensitive issue involved here, since the definition of the person or persons to be protected directly affects the outcome of the risk calculation. Although not a purely scientific issue, we believe that a reasonable and practicable objective is to protect the vast majority of members of the public while also

ensuring that the decision on the acceptability of a repository is not prejudiced by the risks imposed on a very small number of individuals with unusual habits or sensitivities. The situation to be avoided, therefore, is an extreme case defined by unreasonable assumptions regarding the factors affecting dose and risk, while meeting the objectives of protecting the vast majority of the public. An approach consistent with this objective that is used extensively elsewhere in the world is to define and protect a critical group; we recommend this approach for the Yucca Mountain standards.

The critical group has been defined by the ICRP (1977, 1985b) as a relatively homogeneous group of people whose location and habits are such that they are representative of those individuals expected to receive the highest doses¹⁵ as a result of the discharges of radionuclides. Therefore, as the ICRP notes, "because the actual doses in the entire population will constitute a distribution for which the critical group represents the extreme, this procedure is intended to ensure that no individual doses are unacceptably high." (ICRP 1985a, at paragraph 46). In the case of Yucca Mountain, these individuals presumably would live in the near vicinity of the site and would potentially be exposed to radiation through the use of contaminated ground water.

The critical-group dose is defined as that dose received by an average member of the critical group. Using the average member of the group as the basis for comparison with the limit established by the standard avoids the problem of the outcome being unduly influenced by the habits of a few persons. To ensure that this calculation is nevertheless representative of the persons who receive the highest doses, the ICRP definition of the critical group requires that:

1. The persons calculated to receive the highest doses based on cautious, but reasonable, assumptions be included in the group.
2. The group be homogeneous in dose; that is, there should be a relatively small difference between those receiving

The ICRP defines critical group in terms of dose. We use the ICRP terminology here to describe the concept as developed by the ICRP, and later adapt the concept to the risk framework.

the highest and lowest doses in the group (ICRP, 1991). In its Publication 43, the ICRP (1985b) suggests that if the ratio of the calculated average critical-group dose to the regulatory limit is less than one-tenth, then the critical group should be considered homogeneous if the distribution of individual doses lies substantially within a total range of a factor of ten, or a factor of three on either side of the average. At ratios greater than one-tenth, homogeneity requires a smaller range.

3. The group be relatively small. The ICRP recommends that it should typically include a few to a few tens of persons. Normally a critical group would not consist of a single individual but rather a few tens of individuals. On the other hand, homogeneity implies that the group should not be too large.

In the context of an individual-risk standard, similar conditions would apply for the same reasons. Based on cautious, but reasonable, assumptions, the group would include the persons expected to be at highest risk, would be homogeneous in risk¹⁶, and would be relatively small. The critical-group risk calculated for purposes of comparison with the risk limit established in the standard would be the mean of the risks of the members of the group.

More specifically, we recommend the following definition of the critical group for use with the individual-risk standard:

The critical group for risk should be representative of those individuals in the population who, based on cautious, but reasonable, assumptions, have the highest risk resulting from repository releases. The group should be small enough to be relatively homogeneous with respect to diet and other

That is, the difference between the highest and lowest risk faced by individuals in the group should be relatively small. Should a radiation dose occur, however, it may affect only a few members of the group. This is the difference between risk (the probability of an adverse health effect) and outcome (a cancer that actually develops). Risk can be homogeneous, even when outcomes are quite diverse.

aspects of behavior that affect risks. The critical group includes the individuals at maximum risk and is homogeneous with respect to risk. A group can be considered homogeneous if the distribution of individual risk within the group lies within a total range of a factor of ten and the ratio of the mean of individual risks in the group to the standard is less than or equal to one-tenth. If the ratio of the mean group risk to the standard is greater than or equal to one, the range of risk within the group must be within a factor of 3 for the group to be considered homogeneous. For groups with ratios of mean group risk to the standard between one-tenth and one, homogeneity requires a range of risk interpolated between these limits.

This definition requires specifying the persons who are likely to be at highest risk. In the present and near future, these persons are real; that is, they are the persons now living in the near vicinity of the repository that lies in the direction of the flow of the ground water plume of radionuclides that would occur far in the future. The expected containment capability of an undisturbed repository at Yucca Mountain means, however, that no significant risks would likely arise until at least thousands of years in the future. At such times, it will be necessary to define hypothetical persons by making assumptions about lifestyle, location, eating habits, and other factors. ICRP recommends use of present knowledge and cautious, but reasonable, assumptions in making projections far into the future. These assumptions are part of the exposure scenarios¹⁷ that must be defined as a basis for determining whether the repository performance is judged to comply with the standard. Exposure scenarios are discussed further in the next chapter.

There are multiple release pathways from the repository, and each might have its own exposure scenario and critical group. However, only one of these critical groups will contain the person or persons that face the highest risk.

For How Long?

As noted earlier, the current EPA standard contains a time limit of 10,000 years for the purpose of assessing compliance. There are three possible reasons for setting such a time limit. One would be to set a policy that beyond a set interval of time, it would not be necessary to protect public health. We will not address this reason, but only the other two, which have a technical basis.

The first technically based reason is the argument that beyond that limit the uncertainties in compliance assessment become too large. We consider this issue in Chapter 3, and conclude that assessment is feasible for many aspects of repository performance for much longer times and that the ultimate restriction on time scale is determined by the long-term stability of the fundamental geologic regime — a time scale that is on the order of 10^6 years at Yucca Mountain. In the case of human activity, as discussed in Chapters 3 and 4, there is no scientific basis for prediction of future states, and the limit of our ability to extrapolate with reasonable confidence is measured in decades or, at most, a few hundreds of years.

The other technically based reason for limiting the time of analysis is if there are likely to be no significant health effects after a specified time. In the case of Yucca Mountain, at least, some potentially important exposures might not occur until after several hundred thousand years. For example, the half-life of some of the radionuclides contained in the repository is millions of years, and for some scenarios the travel time of these materials to the accessible environment is in the range of tens of thousands to hundreds of thousands of years.

For these reasons, we believe that there is no scientific basis for limiting the time period of the individual-risk standard to 10,000 years or any other value. We recommend in Chapter 3 that compliance assessment be conducted for the time when the greatest risk occurs, within the limits imposed by long-term predictability of both the geologic environment and the distribution of local and global populations.

Indeed, the 10,000-year limitation might be inconsistent with protection of public health. For example, as noted in a previous National Research Council study, "EPA's 10,000-year time limit, evidently adopted in USNRC's rationale, makes compliance rather

easy. This we do not support because . . . we see no valid justification for this time limit . . . The USNRC-EPA calculational approach may seem to simplify licensing, but we do not understand how such an exercise can support the finding, required in licensing, that there be no unreasonable risk to the health and safety of the public" (NRC, 1983, at p. 236).

As described, we have recommended that the standard for individual risk should apply at times when the peak potential risks might occur. We recognize that there are significant uncertainties in the supporting calculations and that the uncertainties increase as the time at which peak risk occurs increases. However, we see no technical basis for limiting the period of concern to a period that is short compared to the time of peak risk or the anticipated travel time.

Nevertheless, we note that although the selection of a time period of applicability has scientific elements, it also has policy aspects that we have not addressed. For example, EPA might choose to establish consistent policies for managing risks from disposal of both long-lived hazardous nonradioactive materials and radioactive materials.

Another time-related regulatory concern can affect the formulation of the safety standard. This is based on ethical principles, and is the issue of intergenerational equity (Berkovitz, 1992; Holdren, 1992; Okrent, 1994). Whether and how best to be fair to future generations is an important societal question. Although current generations are assumed to have benefited from activities, such as electricity production or national defense programs that have caused radioactive wastes to accumulate, far future generations will not benefit directly, but might be exposed to risks when any radioactive materials eventually escape the proposed repository. In drafting standards, EPA should as a matter of policy address whether future generations should have less, greater, or equivalent protection.

The responsible institutions have considered the question of the protection to be afforded future generations. For example, in her presentation to us, Margaret Federline (USNRC, personal communication, May 27, 1993) spoke about a "societal pledge to future generations" that would "provide future societies with the same protection from radiation we would expect for ourselves." The

IAEA document, *Safety Principles and Technical Criteria for HLW Disposal*, Safety Series 99, has as one objective the “responsibility to future generations.” Under this responsibility to future generations, IAEA recommends that “the degree of isolation of high-level radioactive waste shall be such so there are no predictable future risks to human health or effects on the environment that would not be acceptable today.” In this IAEA establishes that “[t]he level of protection to be afforded to future individuals should not be less than that provided today.”

A health-based risk standard could be specified to apply uniformly over time and generations. Such an approach would be consistent with the principle of intergenerational equity that requires that the risks to future generations be no greater than the risks that would be accepted today. Whether to adopt this or some other expression of the principle of intergenerational equity is a matter for social judgment.

PROTECTING THE GENERAL PUBLIC

Earlier in this chapter, we recommend the form for a Yucca Mountain standard based on individual risk. Congress has asked whether standards intended to protect individuals would also protect the general public in the case of Yucca Mountain. We conclude that the form of the standards we have recommended would do so, provided that policy makers and the public are prepared to accept that very low radiation doses pose a negligibly small risk. This latter requirement exists for all forms of the standards, including that in 40 CFR 191. We recommend addressing this problem by adopting the principle of negligible incremental risk to individuals.

The question posed by Congress is important because limiting individual dose or risk does not automatically guarantee that adequate protection is provided to the general public for all possible repository sites or for the Yucca Mountain site in particular. As described in the previous section, the individual-risk standard should be constructed explicitly to protect a critical group that is composed of a few persons most at risk from releases from the repository. The standards are then set to limit the risk to the average member of that group. Larger populations outside the critical group might also be

exposed to a lower, but still significant, risk. It is possible that a higher level of protection for this population represented by a lower level of risk than the one established by the standards might be considered.

For purposes of this discussion, the "general public" can be thought of as including global (hemispheric or continental) populations that might receive very small risks from repository releases, as well as local populations that lie outside the critical group but that might still be exposed to risks not much lower than those imposed on the critical group. The issues are different for these two types of populations, and we discuss them separately.

PROTECTING THE GLOBAL POPULATION

Radiation releases from a repository can in principle be distributed to a global, or other large and dispersed population, in several ways. For example, food contaminated by radionuclides could be shipped to regions far from the repository area, or contaminated ground water could enter a major river and the drinking water supplies that it serves. The global distribution of releases from a repository is assumed as the exposure scenario for the containment requirements in EPA's regulation 40 CFR 191. In the case of Yucca Mountain, there would be no releases to major rivers, and therefore the most likely pathways for global distribution are gaseous releases of carbon dioxide containing the radioactive isotope of carbon, ^{14}C , that eventually will escape from the waste canisters, or by widespread distribution of foodstuffs grown with contaminated water.

In general, the risks of radiation produced by such wide dispersion are likely to be several orders of magnitude below those to a local critical group. As noted earlier in this chapter, however, the "linear hypothesis" implies that even very small increments to background doses might cause effects from cancer induction in the same ratio ($5 \times 10^{-2}/\text{Sv}$) as larger doses. Using the linear hypothesis to calculate the effects of very low doses on large populations requires multiplying this factor by the cumulative dose imposed on populations numbered in the trillions over the life of the repository.

There are, however, important cautions to be noted with this procedure. With respect to small increments to natural background radiation levels, the BEIR V report (NRC 1990a) states that:

Finally, it must be recognized that derivation of risk estimates for low doses and dose rates through the use of any type of risk model involves assumptions that remain to be validated. At low doses, a model dependent interpolation is involved between the spontaneous incidence and the incidence at the lowest doses for which data are available. Since the committee's preferred risk models are a linear function of dose, little uncertainty should be introduced on this account, but departure from linearity cannot be excluded at low doses below the range of observation. Such departures could be in the direction of either an increased or decreased risk. Moreover, epidemiologic data cannot rigorously exclude the existence of a threshold in the millisievert dose range. Thus the possibility that there may be no risks from exposures comparable to external natural background radiation cannot be ruled out. At such low doses and dose rates, it must be acknowledged that the lower limit of the range of uncertainty in the risk estimates extends to zero.¹⁸

The doses to global populations involved in gaseous release from Yucca Mountain are likely to be well below the mSv range noted in BEIR V. For example, let us assume that the repository inventory of 91,000 Ci (3.37×10^{15} Bq) (Wilson et al., 1994) of ^{14}C is released into the air over 10,000 years. Using EPA's dose conversion factor 1.1×10^{-10} Sv/Bq (EPA, 1992), the population dose over 10,000 years would be 3.7×10^5 person-Sv, or an average of 37 person-Sv/year over the 10,000-year period (Nygaard et al., 1993). Assuming that the ^{14}C is well mixed with air over the globe, and for an average global population of 12 billion people during this period, the

In this paragraph "low doses" applies to very small increments to the dose from the natural background.

corresponding average individual dose rate is 3.1×10^{-9} Sv/yr (3.1×10^{-4} mrem/yr). For comparison, the dose set by EPA in 40 CFR 191 is 1.5×10^{-4} Sv/yr (15 mrem/yr), and this is the limit to be applied for the persons likely to receive the highest doses from the repository. Therefore, there is great uncertainty about the number of health effects that would be imposed on the global population because of the difficulties in interpreting the risks associated with such small incremental risks from ^{14}C releases at Yucca Mountain.

NEGLIGIBLE INCREMENTAL RISK

To address scenarios of widespread but extremely low-level doses, the radiation protection community has introduced the concept of negligible individual dose. The negligible individual dose is defined as a level of effective dose that can, for radiation protection purposes, be dismissed from consideration. NCRP has recommended a value of 0.01 mSv/yr (1 mrem/yr) per radiation source or practice (NCRP, 1993), which currently would correspond to a projected risk of about 5×10^{-7} /yr for fatal cancers, assuming the linear hypothesis. In its considerations, NCRP decided on this level of dose or risk taking into account risk in relation to:

1. Natural risk of the same health effects;
2. Risk to which people are accustomed;
3. Estimated risk for the mean and variance of natural background radiation exposure levels;
4. Perception of, and behavioral response to, risk levels; and
5. Difficulty in detection and measurement of dose and health effects.

Others over the years have advocated the use of a negligible dose or risk level (Comar, 1979; Eisenbud, 1981; Schiager et al., 1986)¹⁹. The general consensus of these authorities was that a

Where authors use "negligible dose" or "negligible risk" the terms should be understood as increments to the unavoidable background radiation. In life,
(continued...)

negligible value would be useful in many applications. Federal and state approaches for the regulation of chemical carcinogens are in keeping with this view, which generally take a 10^{-6} lifetime risk as an acceptable level (Travis et al., 1987; EPA, 1991), as are the exposure limits for radioactive waste adopted by most nations in the Organization for Economic Cooperation and Development (OECD) (Dejonghe, 1993). The Federal German Radiation Protection Commission, for example, has recommended ignoring individual doses of less than 0.003 mSv per year (Smith and Hodgkinson, 1988).²⁰

We believe that the concept of a negligible incremental dose can be extended to risk and can be applied to Yucca Mountain. Defining the level of incremental risk that is negligible is a policy judgment. We suggest the risk equivalent of the negligible incremental dose recommended by the NCRP as a reasonable starting point for developing consensus in a rulemaking process. For example, the average dose to a member of the global population from exposure to ^{14}C from the repository is estimated to be about 3×10^{-9} Sv/yr, corresponding to a risk of fatal cancer of 1.5×10^{-10} /yr or about 10^{-8} per lifetime. As indicated earlier, NCRP has recommended a negligible incremental dose that corresponds to a risk of 5×10^{-7} /yr (NCRP, 1993). Therefore, if the NCRP recommendation were adopted, the effects of gaseous ^{14}C releases on individuals in the global population would be considered negligible.

PROTECTING LOCAL POPULATIONS

Persons in some populations outside the critical group might be exposed to risk from repository releases in excess of the level of negligible incremental risk. As individuals, these persons would be (by definition and in practice) exposed to less risk than the risk limit established by the standard for the critical group. If many persons were exposed to this individual risk, however, the total number of

(...continued)

there is no zero dose and no zero risk.

Note that this is equivalent to an annual risk of fatal cancer of about 1.5×10^{-7} /yr.

health effects that could occur might be relatively large, particularly if integrated over a very long period of time.

We know of no analysis that has addressed the spatial distribution of radiation doses and risks near Yucca Mountain at the distant future times when individual doses and risks would be at their maximum. It should be feasible to determine a spatial distribution of potential concentrations in ground water or air and a spatial distribution of individual doses and risks, employing the same types of exposure assumptions used for calculating doses and risks to members of a critical group (see Chapter 3). However, the total number of fatal cancers cannot be known without knowledge of the number of future persons residing in the Yucca Mountain vicinity. This number is obviously unknowable. Even if EPA were to define it arbitrarily through a rulemaking process, comparing the total population risk against some defined figure-of-merit in order thereby to decide on whether to accept or reject a repository seems too arbitrary to be useful.

Population-Risk Standard

As an example of the difficulty of framing an absolute population-risk standard, we considered normalizing the population risks as a means to avoid the difficulty of not having a technical basis for knowing the total population at risk. Such a regulatory scheme might require that the integrated population risk over a given period (one generation, for example) be limited to some fractional risk in the affected population. A specific hypothetical example would be to require that the integrated population risk must produce fewer than x health effects per N people during a defined interval of time.

Framed this way, however, the standard looks very much like an individual-protection standard: each person outside the critical group would have an individual lifetime risk limited to x/N . As a matter of policy, it is certainly legitimate to desire to protect a smaller group (the critical group) by limiting individual risk to a certain level, and also to protect a larger group (the nearby population) with a different but still meaningful risk limit. However, this approach is not a collective-risk protection scheme — it is merely a two-tiered individual-risk protection scheme.

Spatial Gradient in Risk

An alternative approach that does have a technical basis is consideration of the spatial distribution of individual risks near the critical group, at the distant future time when the critical-group risk is highest. Such a spatial distribution has a technical significance because it depends on the characteristics not only of the Yucca Mountain physical site but also of the waste form and the engineered and geologic barriers of the repository design.

Furthermore, a risk distribution with a steep spatial gradient — that is, a distribution in which the individual risks become smaller relatively quickly with increasing distance from the location of the highest individual risks — seems obviously preferable to a distribution with a more gradual spatial gradient, all other things being equal. This is because a steeper spatial gradient implies smaller integrated population risks than does a more gradual gradient for the same spatial distribution of population.

This observation cannot provide information for discriminating between an "acceptable" repository and an "unacceptable" one without an acceptable level of risk for comparison purposes. However, we have not been able to identify a technically based figure-of-merit that could be used to judge the compliance acceptability of a given spatial risk gradient. To use the gradient in an absolute sense, one is faced with not only selecting a time interval of concern, which is arbitrary, but also defining the future nearby population. For the simpler task of adequately characterizing the exposure scenarios leading to calculation of risks to a critical group, we have concluded that a feasible procedure can be developed using known distributions of physical and chemical parameters and defensible assumptions on lifestyles; in other words, there is a reasonable technical basis for a critical-group calculation. For identifying the size, the distribution and the varied lifestyles of a larger population, more assumptions of greater uncertainty would be required. The resulting data for a risk assessment would become so arbitrary that no adequate decision basis would result. We therefore conclude that there is no technical basis for establishing a population-risk standard that would limit the risk to the nearby population for a Yucca Mountain repository.

PREFERRED FORM OF THE STANDARD

Although we have couched the discussion of the last two sections in terms of an individual-risk standard, we noted in an earlier section of this report that there are several possible forms of standard that could be used. We end this chapter by explaining why we conclude that the individual-risk form has scientific advantages over the others.

Release Limits. It is possible to state the standard in terms of a limitation on the amount of radionuclides crossing an imaginary boundary that encloses the repository. The limit generally would be placed on cumulative release over a specified time period. This is the approach used by EPA in 40 CFR 191, which relies primarily on a table of maximum allowable cumulative radioactive releases to the accessible environment for a period of 10,000 years.

A release limit has the appearance of simplicity because it focuses on the amount of radionuclides released from the repository across some specified boundary. This form of standard does not provide any information about how these releases affect public health, however, and so is incomplete unless coupled with a calculation of individual (or population) risk (or dose or health effects). If one is interested in this information on public health for a specific site, it is good scientific practice to incorporate specific data about the site into the calculation. If that is done, essentially all of the calculations described in Chapter 3 are required. The advantage of our recommendation is that these calculations are to be done using a methodology approved by a rulemaking, with all calculations explicit to the public. Hence, we conclude that a release limit for a site-specific standard does not reduce scientific complexity or uncertainty. Without calculations of dose or risk, a release standard appears arbitrary.

Other than the appearance of simplicity, there seem to be no other advantages to a release-limit form of the standards. It does not produce information that is easy to understand or to compare with other risks. Note that no other standard listed in either Table 2-3 or 2-4 is expressed as a release limit.

A population standard²¹, such as the one that appears to be the basis for the release limit in 40 CFR 191, establishes a total number of health effects permitted over some time period — 1,000 in 10,000 years, in the case of 40 CFR 191. This form of standard does not provide a basis for assessing the risk to the individuals in the critical group, or for local populations nearby. Therefore, a population standard alone is insufficient to protect the population most at risk and, probably for this reason, 40 CFR 191 contains a parallel individual standard.

Also, as discussed earlier in this chapter, assessing compliance with a standard designed to protect the global population involves highly uncertain calculations because of the extremely low incremental doses to which large numbers of persons may be exposed. We have recommended the use of the concept of negligible incremental risk to individuals as a preferable way of dealing with these uncertainties at the outset.

An *individual standard* is needed, however, and the issue is whether to state it in terms of dose, health effects, or risk. In Section 801, Congress directs EPA to use individual dose. As mentioned above, we recommend using the risk form for the following reasons:

1. A risk-based standard would not have to be revised in subsequent rulemaking if advances in scientific knowledge reveal that the dose-response relationship is different from that envisaged today. Such changes have occurred frequently in the past, and can be expected to occur in the future. For example, ongoing revisions in estimates of the radiation doses received by atomic bomb survivors of Hiroshima and Nagasaki may significantly modify the apparent dose-response relationships for carcinogenic effects in this population, as have previous revisions in dosimetry (see Straume et al., 1992).
2. Risks to human health from different sources, such as nuclear power plants, waste repositories, or toxic chemicals, can be compared in reasonably

Or, equivalently, a cumulative dose standard.

understandable terms. Doses or releases have to be stated in radiation units Sieverts or Becquerels that are not easily understood by the general public and that can only be compared conveniently with other sources of radiation or radioactivity.

Although we recommend a risk-based standard rather than the dose-based standard in Section 801, they are closely related. We define risk as the expected value of the probabilistic distribution of health effects. The distribution of health effects is derived from a distribution of dose and the expected health effects per unit dose.

Consequently, in answer to congressional question No. 1, we believe that a health-based individual standard will provide a reasonable standard for protection of the general public. However, we recommend that this be a risk-based, rather than a dose-based standard.³

ASSESSING COMPLIANCE

INTRODUCTION

In the preceding chapter, we described our conclusion that the form of a Yucca Mountain standard should be based on limiting individual risk as measured by the average risk to individuals in a critical group. This group is defined as being composed of persons likely to be at highest risk from radionuclides released from the repository. Our judgment is that limiting individual risk in this way is also likely to provide adequate radiological protection for all relevant populations that might be exposed to radiation from radionuclides released from the proposed repository at Yucca Mountain (see Chapter 2). The period over which this level of protection should be assessed should extend over the period of duration of hazard potential of the repository, that is, until the time at which the highest critical group risk is calculated to occur, within the limits imposed by the long-term stability of the geologic environment at Yucca Mountain, which is on the order of 10^6 years.

In this chapter, we discuss the analyses that must be undertaken to judge compliance with such a standard. Important questions to be answered are:

1. Whether the scientific understanding of the relevant events and processes potentially leading to releases is sufficient to allow a quantitative estimate of future repository behaviors.
2. Whether adequate analytical methods and numerical tools exist to incorporate this understanding into quantitative assessments of compliance.
3. Whether the current scientific understanding and analytic methods are sufficient to evaluate performance with sufficient confidence to assess compliance over the long time periods required.
4. Whether the results of the analyses required to assess repository performance can be combined into an estimated risk for comparison with the standards in the licensing process. In particular, the estimated risk is defined as the mean risk of members in the critical group. Risk is defined as the expected value of the probabilistic distribution of health effects experienced by an individual member of the critical group.

The main tool used to assess compliance is quantitative performance assessment, which relies upon mathematical modeling. We have evaluated the degree of confidence that can be placed today in such assessments. We have also made a systematic analysis of the application of this methodology to the Yucca Mountain site. Based on these analyses, we conclude that:

1. For those aspects of repository and waste behavior that depend on physical and geologic properties and processes, enough of the important aspects can be known within reasonable limits of uncertainty, and these properties and processes are sufficiently understood and stable over the long time scales of interest to make

calculations possible and meaningful. These properties and processes include the radionuclide content of the waste (which changes over time due to radioactive decay), the influx of water through the site and its effect on waste package integrity and other engineered barriers, the migration of wastes to ground water after waste packages have lost their integrity, and the subsequent dispersion and migration of wastes in ground water. While these factors cannot be calculated precisely, we believe that there is a substantial scientific basis for making such calculations, taking uncertainties and natural variabilities into account, to estimate, for example, the concentration of wastes in ground water at different locations and the times of gaseous releases.

One critical gap in our understanding is with respect to future human behavior. Since there is no scientific basis for predicting human behavior, we recommend that policy decisions be made to specify default (or reference) scenarios to be used to incorporate assumed future human behavior into compliance assessment calculations.

2. Available mathematical and numerical tools are neither perfect nor complete. Nevertheless, the currently available tools plus additional tools that we believe can be developed as part of the standard-setting and compliance assessment efforts, or through other research, should be adequate for the analyses required to evaluate repository performance.
3. So long as the geologic regime remains relatively stable, it should be possible to assess the maximum risks with reasonable assurance. The time scales of long term geologic processes at Yucca Mountain are on the order of 10^6 years. Other processes that operate on short time scales, such as seismic activity, can also be accommodated in performance assessment if the maximum risks associated with these processes depend

- more on whether an event is likely to occur (at any time) than on the specific timing of the event.
4. Established procedures of risk analysis should enable the combination of the results of all repository system simulations into a single estimated risk to be compared with the standard. (Human intrusion is excluded from such a combination. See Chapter 4.) An element of judgment is contained in many of the conceptual assumptions to be made, and those assumptions, methods, and the reference data will have to be specified. Similarly, reference exposure scenarios must be established clearly. This transparency in the use of assumptions is critical to evaluating the calculated risk.

Because some readers might be unfamiliar with the technical aspects of a repository performance assessment, it is appropriate to provide an overview of the methodology, as we do in Part I of this chapter. We then consider the scientific basis for making an assessment of Yucca Mountain. We have found it useful to separate this evaluation into two parts, one dealing with the physical properties and geologic processes relevant to the behavior of the wastes and the other with those aspects of performance assessment that deal with assumptions about where and how people live, how they might be exposed through the food and water they consume, and other factors that could affect exposures to radioactive wastes. We shall refer to this latter collection of factors that must be considered as exposure scenarios. The reason for separating these two elements of performance assessment is that the nature of calculations in each is substantially different. We discuss these in Parts II and III.

PART I: OVERVIEW OF PERFORMANCE ASSESSMENT

Any standard to protect individuals and the public after the proposed repository is closed would require assessments of performance at times so far in the future that a direct evaluation of compliance (for example by physical monitoring of system behavior) is out of the question. The only way to evaluate the risks of adverse health effects and to compare them with the standard is to assess the estimated potential future behavior of the entire repository system

and its potential impact on humans. This procedure, involving modeling of processes and events that might lead to releases and exposures, is called performance assessment. It involves computer calculations using quantitative models of physical, chemical, geologic, and biological processes, taking uncertainties into account.

Modeling repository performance is a challenging task because the rates of geochemical transformation and transport of the radionuclides are generally very slow and the times at which points distant from the repository become significantly affected by radionuclide releases will be in the far future. Thus, to assess these effects requires projection of geochemical, hydrodynamic, and other processes over long time periods within rock masses whose properties are imperfectly known. Factors describing how humans can be exposed to radionuclides from the wastes are even more imperfectly known and these factors, including the future state of technology and medicine, might be more changeable over time than are the physical processes.

Reasonable Confidence

One possible response to these difficulties is to conclude that they render any assessments of the ultimate fate of the waste materials too uncertain to be useful. However, we believe that such analyses do provide information for judging the quality of a disposal site. Even if the uncertainties involved are large, some options for the disposition of the wastes can clearly be shown to result in worse consequences than other options would produce.

The results of compliance analysis should not, however, be interpreted as accurate predictions of the expected behavior of a geologic repository. No analysis of compliance will ever constitute an absolute proof; the objective instead is a reasonable level of confidence in analyses that indicates whether limits established by the standard will be exceeded. Both the USNRC and EPA have explicitly recognized this objective. For example, EPA states in 40 CFR 191 that "unequivocal numeric proof of compliance is neither necessary nor likely to be obtained." In regulation 10 CFR 60, USNRC acknowledges that "it is not expected that complete assurance that [performance objectives] will be met can be presented." The USNRC

requires instead "reasonable assurance, making allowances for the time period, hazards, and uncertainties involved." EPA's required level of proof in 40 CFR 191 is "reasonable expectation."

Time scale

One commonly expressed concern regarding the performance assessment modeling is that it requires simulating performance at such distant times in the future that no confidence can be placed in the results. Of course, the level of confidence for some predictions might decrease with time. This argument has been used to support the concept of a 10,000 year cutoff (DOE, 1992). We do not, however, believe that there is a scientific basis for limiting the analysis in this way.

One of the major reasons for selecting geologic disposal was to place the wastes in as stable an environment as many scientists consider possible. The deep subsurface fulfills this condition very well (NRC, 1957). In comparison with many other fields of science, earth scientists are accustomed to dealing with physical phenomena over long time scales. In this perspective even the longest times considered for repository performance models are not excessive. Furthermore, even changes in climate at the surface would probably have little effect on repository performance deep below the ground. We recommend calculation of the maximum risks of radiation releases whenever they occur as long as the geologic characteristics of the repository environment do not change significantly. The time scale for long-term geologic processes at Yucca Mountain is on the order of approximately one million years. After the geologic environment has changed, of course, the scientific basis for performance assessment is substantially eroded and little useful information can be developed.

Because there is a continuing increase in uncertainty about most of the parameters describing the repository system farther in the distant future, it might be expected that compliance of the repository in the near term could be assessed with more confidence. This is not necessarily true. Many of the uncertainties in parameters describing the geologic system are due not to temporal extrapolation but rather to difficulties in spatial interpolation of site characteristics.

These spatial difficulties will be present at all times. Accordingly, even in the initial phase of the repository lifetime, a compliance decision must be based on a reasonable level of confidence in the predicted behavior rather than any absolute proof. Under some circumstances, use of a shorter period for analysis could in fact introduce additional uncertainties into the calculation. For example, uncertainties in waste canister lifetimes might have a more significant effect on assessing performance in the initial 10,000 years than in performance in the range of 100,000 years.

Probabilistic Analysis of Risk

To judge compliance against a risk-based standard of the type proposed, a risk analysis including treatment of all scenarios that might lead to releases from the repository and to radiation exposures is, in principle, required. To include them in a standard risk analysis, all these scenarios need to be quantified with respect to the probabilities of *scenario occurrence* and the probability distribution of their *consequences* to humans, such as health effects of radiation doses. In subsequent sections we specifically note that for some events or processes either the probability of occurrence or the estimated consequences become very difficult to specify with confidence. Events caused by human activity are usually of this type. Incorporation of such events or processes into the formalized risk analysis sometimes is not justified on a scientific basis. Instead, how to deal with these events should be decided as a matter of policy.

This approach implies a departure in part from common analytical techniques to assess risks and the introduction of more pragmatic procedures needed to provide an adequate decision basis. It is important, therefore, that the "rules" for the compliance assessment be established in advance of the licensing process; that is, that the scenarios that might be excluded from the integrated risk analysis be identified. Human intrusion is an example of one scenario that we judge to be not amenable to incorporation in the risk assessment framework; this is discussed further in Chapter 4.

We believe that performance assessment using numerical models of physical and chemical processes and quantitative estimates of probabilities is the key approach to assessing compliance.

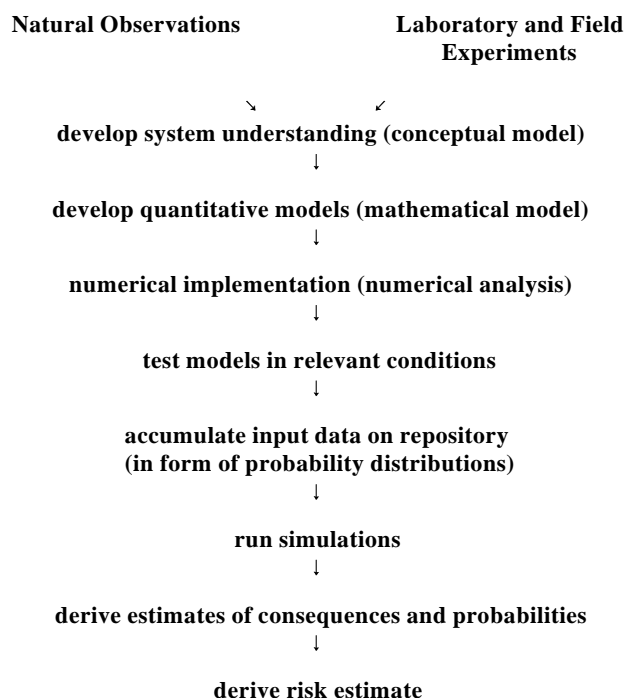
However, the confidence that can be placed in such analyses is also a key part of the compliance issues. To some extent, this degree of confidence can be quantified, for example, by performing rigorous uncertainty analyses that propagate uncertainties in parameter values through the analysis to produce estimates of uncertainties in estimated risks. Uncertainties due to modeling approaches can also be assessed by comparing the results of assessments using various alternative models, or by comparing model results with data collected in experiments or in observations. In other cases, less rigorous but useful evidence of the adequacy of models or data can be obtained by, for example, comparisons with relevant natural analog systems.

A final, important point to note is that performance assessments of the type summarized above are not likely to be performed only on a single occasion preparatory to licensing. Assessments will likely be performed iteratively during system design, construction and operation of a geologic repository, and finally at the time the repository is sealed, following decades of experience in which additional data on the performance of system components can be gathered.

QUANTITATIVE CALCULATION OF REPOSITORY PERFORMANCE

In this section, we summarize general aspects of performance assessment modeling and sources of uncertainty in the modeling process before moving in subsequent sections to issues more specific to Yucca Mountain. The main thrust of performance assessment involves developing a quantitative understanding of system behavior, assembling a sufficient database of parameters describing the system, and producing simulations of possible future system behavior allowing as fully as possible for uncertainties in understanding or in databases. Figure 3.1 schematically illustrates the generic modeling process described in more detail below.

Figure 3.1 The Basic Steps in Performance Assessment



Elements of Performance Assessment

Conceptual model

The conceptual model reflects the scientists' understanding of how the important aspects of the system work. It answers questions such as: What are the limits of the system? What are the geometry and composition of the system? What are the significant physical processes? It is the conceptual model that dictates the selection of the mathematical formalisms that enable quantitative calculations to be performed.

One special type of conceptual model frequently employed in performance assessment is the scenario. In this context, a scenario means a description of how radionuclides might migrate from the repository and affect humans. For example, "the wastes are dissolved in ground water, which is transported by natural processes to an

agricultural area, where it is pumped out of the ground and used to irrigate crops and ingested by humans" is a possible scenario for the Yucca Mountain repository. Quantitative performance assessment based on this scenario would then have to employ detailed conceptual models of release and transport processes specifying, among other things, how and where the ground water flows and exposure scenario models specifying where farmers live, what technologies they use and their patterns of consumption of food and water. The scenario thus constitutes a kind of master conceptual model that guides the selection of more detailed and specific conceptual models for each step of the process.

The conceptual models are potentially the source of the most significant uncertainties regarding the outcome of the analysis. If the nature of the system has not been properly assessed, or the most important processes have not been included in the conceptual model, the mathematical model based on the conceptual model will not properly simulate the behavior of the system regardless of how adequately the other elements of the analysis might be quantified.

Inadequacies in conceptual models are a particularly worrisome aspect of the performance assessment process because a major error could invalidate the entire exercise, yet be difficult or impossible to detect. Although, it is important to realize that this limitation is an aspect of all human problem-solving activities, it is particularly important for radioactive waste repository performance assessment computations because of their long-term considerations. The best way to guard against errors of this nature is to provide for multiple, rigorous, independent reviews of conceptual models that are clearly documented and widely disseminated.

Mathematical model

By mathematical model we mean the mathematical relationships that are used to describe the physical system quantitatively. The system of equations that is incorporated in the mathematical model usually represents a simplification of the selected conceptual model. Mathematical simplification might be required because it is not possible to find adequate descriptions of all the phenomena considered important, or because incorporation of all

relevant equations would result in a mathematical system too cumbersome to solve, or because the data available do not justify the most complete description of the system that might be possible. Mathematical simplifications reduce the realism of the outcome of the model, but the degree to which the results are affected can be assessed by means of mathematical techniques, such as sensitivity analyses of numerical results.

Numerical analysis

Most mathematical models consist of sets of coupled differential equations. For the cases of interest to performance assessment, it is often difficult to solve such complex systems of equations analytically, or exactly, in which case approximate numerical methods are employed. Selection of appropriate numerical methods is important because more efficient numerical techniques can permit more complex (and thus, presumably, more realistic) physical models to be solved, and because inappropriate numerical schemes can introduce significant errors into results. However, numerical inaccuracies are rarely a major source of error in properly conducted modeling because well-established methods exist for assessing the accuracy of numerical schemes. Further, if one approach is found to introduce unacceptable error, it can either be replaced or modified to achieve the desired accuracy.

Model parameters

Physical and chemical models require the specification of the physical properties of the system to be modeled. These properties are referred to as parameters. The parameters are represented by numerical functions or values in the mathematical models. Models of the type commonly used in performance assessment describe the behavior of the system as a function of both space and time. Spatially heterogeneous models of systems incorporate the spatial variations of the parameters throughout the physical domain that is being modeled. The need to provide numerical values for parameters is another source of uncertainty in mathematical modeling. It is a goal

of geologic disposal of nuclear wastes to emplace them in an environment that is deep, remote, and difficult to access. These same repository properties make it difficult to obtain data on the spatial variations of physical parameters in the system. Furthermore, the very procedures necessary to collect the data, such as drilling exploratory holes to extract samples of rock might compromise the integrity of the geologic barriers.

Boundary conditions

Performance assessment models have both spatial and temporal boundaries, that is, times of the beginning and ending of simulations. In general, both mass and energy can flow across these boundaries. Thus, to perform model calculations it is necessary to specify the conditions at the spatial and temporal boundaries (the model calculates parameter values within the model domain). Specification of the "boundary conditions" is subject to many of the same types of uncertainty that are involved in specifying parameter values, and they are usually dealt with in a similar fashion.

In general, spatial boundary conditions of regional scale subsurface flow models are considered to be constant over time. There is at least one important exception to this generalization. The upper boundary to the geologic environment around the repository is the atmosphere. The average of atmospheric conditions is the climate, and it is well known that climate can vary significantly over geologic periods of time. Although the typical nature of past climate changes is well known, it is obviously impossible to predict in detail either the nature or the timing of future climate change. This fact adds to the uncertainty of the model predictions.

During the past 150,000 years, the climate has fluctuated between glacial and interglacial status. Although the range of climatic conditions has been wide, paleoclimatic research shows that the bounding conditions, the envelope encompassing the total climatic range have been fairly stable (Jannik et al., 1991; Winograd et al., 1992; Dansgaard et al., 1993). Recent research has indicated that the past 10,000 years are probably the only sustained period of stable climate in the past 80,000 years (Dansgaard et al., 1993). Based on this record, it seems plausible that the climate will fluctuate between

glacial and interglacial states during the period suggested for the performance assessment calculations. Thus, the specified upper boundary, or the physical top boundary of the modeled system, should be able to reflect these variations (especially in terms of ground water recharge).

Treatment of Uncertainty

The description above has emphasized sources of uncertainty in performance assessment. Uncertainties in scenario and detailed conceptual models are among the most important, but are difficult to quantify. Parameter uncertainty is also obviously important, but can be more rigorously treated. Compliance with a health standard can be judged acceptable only if the calculated behavior — even allowing for uncertainties in the analyses — is acceptable. Hence, the standard must require that estimates of technical uncertainties be provided even if it does not explicitly state in advance the permissible level of uncertainty. Some of the main issues in treating uncertainty are discussed below.

Probabilistic modeling

A number of statistical approaches exist to account for the effects of uncertainty in modeling the transport of radionuclides. A method used to help implement statistical distributions of a parameter in performance assessment is the Monte Carlo method. In this method, data on the frequency distributions of parameter values are sampled to provide input to the equations. These distributions are used to describe parameters where there is inherent variability or where the precise value is uncertain. The model is then run a number of times using parameter values randomly selected from the specified distributions. When a sufficient number of simulations have been performed, the statistics of the results are used to estimate the uncertainty imparted to the result by the uncertainty in the input parameters (Henley and Kumamoto, 1992).

The main problem for technical analyses of this type for compliance purposes might be developing consensus on the input

statistical distributions of parameter values for the assessments. Because of the requirements for spatial resolution or the infrequency of particular events, deriving the distributions from measurement programs or from observations might not be feasible for defining the parameter distributions. This means that a large element of informed judgment will often be involved. A further drawback of complex probabilistic modeling is that the results are not very transparent or easily understood.

Bounding estimates

Analyses using pessimistic scenarios and parameter values are more easily understood than Monte Carlo analysis. The results of these conservative calculations are then no longer estimates of likely behavior but rather bounding estimates. Bounding estimates can be criticized for compounding conservative assumptions, since they can easily produce consequences that are highly improbable. On the other hand, if compliance can be shown with a bounding estimate, then there is no need for a more complex analysis. Bounding estimates can thus be very useful, but care should be given as to how one could combine the robust, bounding-estimate type of assessment with a probabilistic analysis.

Alternative conceptual models

In the case of uncertainty arising from the choices in conceptual models, even more difficult questions arise. It is sometimes tempting to treat alternative, physically exclusive conceptualizations of a particular process, such as unsaturated flow together in a combined probabilistic analysis by allocating to each concept some, possibly arbitrary, probability of being correct. This approach is hard to defend, although it is being used by some groups that are analyzing repositories. Alternatives include separate treatment as two scenarios, agreement on the most likely case, or concentrating on the more conservative case. In any event, explicit recognition of differences in expert opinions is unavoidable.

When all reasonable steps have been taken to reduce technical uncertainties by, for example, performing site characterization and material testing programs, there still remains a residual, unquantifiable uncertainty. It can never be totally ruled out that the best analytic conclusions might be affected by some hitherto unknown or overlooked process or event. This is not a situation unique to waste disposal; it occurs in other licensing arenas. The only defense against it is to rely on informed judgment. The formulation of any disposal standard and of corresponding compliance requirements should explicitly acknowledge that this is the case. Unfulfillable expectations can thus be avoided and a more defensible approach to licensing procedures might be possible.

Summary

This section has described a methodology for assessing the performance of nuclear waste repositories. The description has emphasized sources of uncertainty in the analysis, the most important of which are uncertainties in scenarios, detailed conceptual models, and parameters. These assessments can provide both analyses of the future performance of the repository and estimates of the uncertainty in the performance assessments. Further, both of these results have additional uncertainty due to factors, such as conceptual model uncertainty that might not have been properly quantified or for which quantification is not possible. The issue is whether the methods and data available today are capable of producing assessments of behavior (or else bounding estimates) adequate for indicating whether standards can be met.

This question has been addressed in international circles. Following a major conference on safety assessment in 1990, a Collective Opinion was prepared by the Radioactive Waste Management Committee of the Nuclear Energy Agency of the Organization for Economic Cooperation and Development. The general conclusions drawn were, first, that appropriate performance assessment tools are currently available for producing results of the quality required for a decision on compliance and, second, that the final quality of the results is restricted primarily by the availability

of site-specific data for the analyses. We concur with these two conclusions.

PATHWAYS AND PROCESSES FOR PERFORMANCE ASSESSMENT AT YUCCA MOUNTAIN

We now turn to more specific consideration of factors that would enter into compliance calculations for a repository at Yucca Mountain. Comparisons of potential repository performance to a standard expressed in the form of individual risk require estimating the probabilistic distribution of doses to a critical group as well as a conversion from doses to health effects. Estimating the probabilistic distribution of doses requires identification of the potential pathways of radionuclides from the repository to the biosphere, which comprises the air, water, food and other components of the landscape that are accessible to humans as well as the humans themselves; estimates of the concentrations that will be present in air, water, food, and other materials with which humans might come into contact; and estimates of the probabilities that humans will be exposed to contaminated air, water, food, or other materials leading to a radiation dose.

The major pathways from a repository at Yucca Mountain to humans are illustrated schematically in Figure 3.2. In this figure, major reservoirs that can contain radionuclides at various times after closure of a repository are shown as rectangles. These include (1) the canisters or other waste forms in the repository horizon; (2) the backfill, disturbed rock and other materials of the near-field zone in the vicinity of the waste; (3) the rock, air and water of the unsaturated zone (rock and pores above the water table); (4) the local atmosphere above Yucca Mountain; (5) the world atmosphere; (6) the water table aquifer immediately beneath the repository; (7) the aquifer downgradient of the repository (away from the repository along the direction of ground water flow) from which water may be withdrawn via wells for human use; and (8) the regional discharge zone of the ground water flow system where water exits the ground as discharge to surface water bodies or through evapotranspiration. It should be noted that in most cases these reservoirs are not

physically distinct at their boundaries but rather form a continuum with the next reservoir in the pathway.

Figure 3.2 Schematic illustration of the major pathways from a repository at Yucca Mountain to humans

Solid arrows drawn on the figure from one box to another represent the processes by which radionuclides are transported from one reservoir to the next. The relative lengths of these arrows are meant to suggest, in a very qualitative sense, the relative times involved in these transport processes. For example, release of gaseous radionuclides from waste packages and their transport through the unsaturated zone to the atmosphere above Yucca Mountain is thought to be a relatively rapid process compared to dissolution of radionuclides and their transport in solution through the unsaturated zone to the water table.

Exposure pathways from the atmosphere or from ground water to humans are represented by jagged arrows. These arrows represent not only factors that affect human exposures, such as geographic location and eating and drinking habits, but also the human response to radiation doses. Releases to the atmosphere directly above or adjacent to Yucca Mountain can cause exposure by inhalation to the people who might be present in the immediate vicinity and who constitute a potential critical group. Atmospheric circulation, which will dilute concentrations many orders of magnitude from those at the mountain, can lead to worldwide exposures of the world population. Exploitation of ground water by some potential critical group downgradient from the repository can lead to exposure via food, water, or other contact with contaminated water. If radionuclides are transported through the entire ground water flow system to the regional discharge area, they or their radioactive or stable daughters might accumulate in soil, water, plants, leading to possible exposures in yet another potential critical group.

Several gradual and episodic natural processes, specifically global-climate change, volcanic eruptions, and seismic activity, have the potential to modify the properties of the reservoirs and the processes by which radionuclides are transported through these reservoirs to the biosphere. These are shown on the figure as diamonds connected by dashed lines to the reservoirs upon which they are likely to have the most significant effects. Intrusion by humans into the repository also has the potential to modify properties of the repository as well as of the near-field and unsaturated zones in the vicinity of the intrusion. Human intrusion is represented as a diamond similar to those for the natural processes that could modify

repository performance. Human intrusion could also lead directly or indirectly to human exposures, an issue that is addressed in Chapter 4. The exposure pathways resulting from human intrusion are not depicted on Figure 3.2.

Given that the important pathways that could lead from the repository to human exposure have been identified, in a general sense, the technical feasibility of developing performance assessment calculations to evaluate compliance with a risk standard for Yucca Mountain depends on the feasibility of modeling the relevant processes that lead to transport, accompanied by dilution or concentration along these pathways. It also depends on the feasibility of quantifying the probabilities associated with any processes that cannot be predicted in a purely deterministic fashion. As discussed in the preceding section of this chapter, uncertainties can be associated with conceptual, mathematical, and numerical models of processes. Uncertainties in parameters and in boundary conditions also necessitate a probabilistic treatment. In some cases, reasonable estimates can be made only of the bounds of probability of occurrence. In other cases, only the consequences of a process can be estimated or bounded in a quantitative manner. Some uncertainties could be such that the probabilities of occurrence or consequences are not quantifiable. The time frame over which models must be applied also influences the level of uncertainty.

By soliciting the opinions of knowledgeable scientists at our meetings, through review of solicited and unsolicited written contributions, and drawing on the available literature and our own expertise, we attempted to assess the types, magnitudes, and time-dependencies of uncertainties associated with (1) transport from a Yucca Mountain repository through the various reservoirs shown in Figure 3.2; (2) the effects of potential natural and human modifiers to repository performance; and (3) the exposure pathways through the biosphere. Part II below summarizes our conclusions regarding the feasibility of including the geologic and physical factors in a quantitative performance assessment. The inclusion of human behavior and other exposure factors are discussed in Part III of this chapter. In carrying out this evaluation of the feasibility of quantitative performance assessment of a repository, we did not attempt to evaluate the performance of a repository at Yucca Mountain.

PART II: EARTH SCIENCE AND ENGINEERING FACTORS IN PERFORMANCE ASSESSMENT AT YUCCA MOUNTAIN

Our conclusions about the feasibility of using quantitative performance assessment at Yucca Mountain rely on a systematic analysis of the application of the methodology to this specific site.

Transport Among Reservoirs

For the processes leading to transport among the reservoirs identified in Figure 3.2, we conclude that the processes are sufficiently quantifiable and that the uncertainties are sufficiently boundable that they can be included in performance assessments that extend over time frames corresponding to those over which the geologic system is relatively stable or varies in a boundable manner. The geologic record suggests that this time frame is on the order of about 10^6 years. Some of the important considerations for the reservoirs and associated transport processes are summarized below.

Release from the waste form

Calculations of release rates from the waste-packages require information on waste composition, waste-package properties, and the thermal, chemical and hydrologic processes that can lead to deterioration and failure of canisters. If the two major waste sources are spent fuel from light-water power reactors and borosilicate glass containing defense waste, it would appear that the necessary engineering parameters relating to the waste form could be reasonably well specified. Specification of waste properties will be more complicated if large amounts of waste with more heterogeneous properties are included. Time-dependent temperatures, porosity and humidity in the vicinity of the canisters, required for estimates of waste package failure, are currently being calculated using models of two-phase convective flow in the near-field unsaturated zone induced by thermal loading of the repository. Detailed estimates of time for

canister failure are less important for much longer-term estimates of individual dose or risk.

Simplifications in predictive models of waste package failure, as currently employed for the Yucca Mountain project, do not account for diffusive impedance of penetrations.²² Recent studies show that diffusive impedance from penetrations results in release rates being insensitive to water flow rates near the waste package, at least for some period of time. These results suggest that uncertainties in release-rates resulting from uncertainties in water flow rate might be small even for sites with pore water velocities much greater than those expected at Yucca Mountain. Further refinements in release-rate predictions can be made if the time-dependent failure characteristics of waste containers and of Zircaloy cladding on spent fuel can be estimated.

Transport from canisters to the near-field unsaturated zone

Inflow of air through failed canisters and oxidation of waste prior to infiltration of water can affect the time-dependent release rates of gaseous radionuclides as well as the later release of dissolved radionuclides. This process would probably affect estimates of 10,000-year cumulative releases more than estimates of longer-term doses and risks. Once a waste canister has been penetrated, release of soluble radionuclides will be affected by the size of canister penetration, diffusion coefficients, rates of oxidative alteration of spent fuel and hydration or alteration of borosilicate glass defense waste. Water content and porosity of the surrounding rock or backfill can affect rates of air and water ingress that can contribute to oxidation and hydration of the waste. Release rates of solubility-limited elements such as thorium, uranium, neptunium, plutonium and americium depend on the chemical environment within the waste canister as well as on the physical properties that affect more soluble species. A conservative release model for low solubility species can be strongly affected by the local flow rate of unsaturated water because

Canisters are likely to fail initially at small local openings through which water might enter, but out of which the diffusion of dissolved wastes will be slow until the canister is grossly breached.

all water flowing past the waste is assumed to become saturated with solubility-limited species. This leads to predicted cumulative releases being sensitive to water flow rate in the vicinity of the waste. In contrast, the moist-continuum model used in recent Yucca Mountain assessments predicts that release rates will be dominated by molecular diffusion, with little dependence on water flow rate at the low pore velocities in the vicinity of the waste packages.

Colloid formation has the potential to increase bulk concentration of radionuclides in water adjacent to the waste-form surface. The Yucca Mountain project has not yet implemented analyses of colloid formation and transport affected by filtration and interactions with radioactive solutes. Sorption in backfill and rock surrounding the waste package could substantially retard diffusion of radionuclides away from the waste canister. Analysis of diffusion for unsaturated zone sites such as Yucca Mountain, with or without sorptive retardation, is currently limited by knowledge of the effective diffusion coefficients in unsaturated backfill and tuff. In principle, however, these processes are amenable to the type of quantitative modeling required for performance assessment.

Gas phase transport from the unsaturated zone to the atmosphere above Yucca Mountain

Some radionuclides released from the waste forms, of which carbon-14 (^{14}C) is probably the most important, can be mobile in the gas phase of the unsaturated zone. Gas phase transport can lead directly to releases to the biosphere when the gas flows out of the mountain into the near-surface atmosphere. Diffusive and convective transport in the gas phase are both likely to reduce concentrations within the unsaturated zone as contaminated and uncontaminated air mix during transport through the mountain. Further mixing and concentration reductions will occur once the air is released from the unsaturated zone to the atmosphere. These mixing processes can have significant effects on individual doses and risk since they will control the concentrations to which humans are exposed, largely through the consumption of ^{14}C in plants. Concentrations will be reduced by radioactive decay only if time elapsed from emplacement

in the repository to release at the land surface is long compared to the half-life of the radionuclide.

The major sources of uncertainty in the calculation of local exposures from gaseous releases of ^{14}C from Yucca Mountain are canister life, time distribution of canister failure, the fraction of ^{14}C initially released when a canister and the fuel rods it contains are breached, the release rate of the ^{14}C contained in the ceramic matrix, and the dispersion of the ^{14}C when it is released into the air at Yucca Mountain. The mechanisms of gas phase transport are fairly well understood, and the available evidence suggests that travel times from the repository, once ^{14}C is released from the waste canisters, are comparatively short.

Atmospheric circulation leading to dispersal of gaseous radionuclides in the world atmosphere

An estimate of radionuclide concentrations in air resulting from releases at Yucca Mountain can be made assuming that radionuclides are distributed uniformly through the world atmosphere. However, this case provides a global average estimate for individual exposures, and would not indicate whether higher exposures might occur at specific locations. More sophisticated models are also available and have been applied to Yucca Mountain release scenarios (see calculations presented in Chapter 2). Calculations of this type have been used to assess potential population doses of ^{14}C and compare these with a negligible incremental dose limit. Such calculations would be directly applicable to quantitative assessments of compliance with a population-risk standard. In addition to the analysis of local individual exposures that might result from gaseous releases at Yucca Mountain, there have been numerous studies of the global effects of such releases (Nysaard et al., 1993). For ^{14}C , the dominant pathway is through the uptake of ^{14}C by plants and the ingestion of those plants by humans. If the level of health risk is as these studies suggest, the average global exposures that would result would be classified as negligible individual doses, as described in Chapter 2. The standard that we recommend would include local risks from ^{14}C in its analysis. If those risks were found

to be significant, they would be included against the risk limit we propose.

Aqueous phase transport from the unsaturated zone to the water table

Mechanisms of aqueous phase transport of dissolved radionuclides in the unsaturated zone at Yucca Mountain are less well understood than those of gas phase transport. The porous flow and dual porosity models employed to date in performance assessment exercises for Yucca Mountain have been criticized (L. Lehman, L. Lehman and Associates, personal communication, Dec. 16, 1993) for not incorporating adequate representations of the controlling features, particularly episodic flow through fractures. This is an example of uncertainty in the underlying conceptual model. DOE and its contractors recognize some of the limitations of the current models and are evaluating alternative unsaturated zone flow and transport codes as part of site characterization activities (Reeves et al., 1994). According to Reeves et al., none of the existing codes identified has the adequate capabilities to simulate the nonequilibrium fracture-matrix flow that might arise during unsteady infiltration in the unsaturated zone at Yucca Mountain. However, we have been presented with results from detailed analyses by Nitao et al., (1993) that do consider episodic nonequilibrium fracture-matrix flow.

Uncertainties in unsaturated zone travel time estimates are most significant for standards that are applicable over a limited time frame. For an individual-risk standard, the significance of these travel time estimates is that they determine the time available for radioactive decay. Long travel times would allow for significant decay and, as a result of the decay, reduction in radionuclide fluxes to the water table. Unsaturated zone travel times for some radionuclides can be increased by sorptive retardation. Uncertainties in retardation estimates stem from the limited amount of data on sorption isotherms of the radionuclides with the various rock units at Yucca Mountain. This uncertainty can be reduced through additional laboratory studies to measure these isotherms. If unsaturated zone transport occurs primarily by episodic, rapid flow through fractures, it is possible that sorption isotherms might

overestimate sorptive retardation, at least during the period of fracture flow. Solution phase complexation and sorption to mobile colloids would also serve to limit retardation. Conservative bounding calculations in such cases would be those that consider the radionuclide to behave as a nonsorbing solute.

Although considerable uncertainty currently exists regarding the mechanism and rates of aqueous phase transport in the unsaturated zone, these uncertainties do not preclude incorporation of this transport in a quantitative performance assessment. Site characterization activities currently underway are designed to elucidate the processes and provide improved estimates of the relevant parameters. Even if these efforts are of limited success in reducing uncertainties, bounding estimates can be incorporated into a performance assessment designed to evaluate compliance with an individual risk standard.

Saturated zone transport from the aquifer beneath the repository to other locations from which water may be extracted by humans or ultimately reach the surface in a regional discharge area

The time at which inhabitants downgradient from a Yucca Mountain repository could be exposed to radionuclides depends on the rates of advective transport in the saturated zone and on modifications to that rate resulting from geochemical processes such as sorption. Rates of advective transport in the saturated zone can be estimated using existing models that require quantification of the hydraulic properties of the rock and of the hydraulic gradient. Modification in transport rates by geochemical processes depends on the rate and extent of chemical interactions between the dissolved radionuclides and the aquifer solids. Geochemical processes can also modify concentrations of radionuclides in ground water. Concentrations can also be modified by radioactive decay, by diffusion, and by dispersive mixing of contaminated and uncontaminated water. Thermal gradients induced by the repository could generate additional convective mixing that would reduce peak concentrations beneath the repository.

The important processes of saturated zone transport are understood at a conceptual level, and mathematical models are

available to represent these processes to some extent. Because of the fractured nature of the tuff aquifer below Yucca Mountain, some uncertainty exists regarding the appropriate mathematical and numerical models required to simulate advective transport. This issue can be addressed through the site-characterization activities and through sensitivity modeling. Major uncertainties regarding the values of hydraulic and geochemical parameters required as input to these models are likely to remain even at the end of extensive site characterization due to the inherently heterogeneous nature of the aquifer. However, even with residual uncertainties, it should be possible to generate quantitative (possibly bounding) estimates of radionuclide travel times and spatial distributions and concentrations of plumes accessible to a potential critical group.

Gradual and Episodic Natural Modifiers

Several gradual and episodic natural processes or events have the potential to modify the properties of the reservoirs and the processes by which radionuclides are transported among them. We conclude that the probabilities and consequences of modifications generated by climate change, seismic activity, and volcanic eruptions at Yucca Mountain are sufficiently boundable so that these factors can be included in performance assessments that extend over periods on the order of about 10^6 years. Each of these three possible modifiers of repository performance is discussed in more detail below.

Climate change

At present the earth is in an interglacial phase. Our knowledge of past climate transitions indicates that a transition to a glacial climate during the next few hundred years is highly unlikely but not impossible. Such a transition during the next 10,000 years is probable, but not assured. Over a million-year time scale, however, the global climate regime is virtually certain to pass through several glacial-interglacial cycles, with the majority of the time probably spent in the glacial state. Given that a deep geologic repository is

relatively shielded from the large changes in surface conditions, there are three main potential effects of climate change on repository performance. The first of these is that increases in erosion might significantly decrease the burial depth of the repository. Site-specific studies of erosion rates at Yucca Mountain (DOE 1993b) indicate that an increase in erosion to the extent necessary to expose the repository (even over a million-year time scale) is extremely unlikely.

Change to a cooler, wetter climate at Yucca Mountain would likely result in greater fluxes of water through the unsaturated zone, which could affect rates of radionuclide release from waste-forms and transport to the water table. Little effort has been put into quantifying the magnitude of this response, but a doubling of the effective wetness, defined as the ratio of precipitation to potential evapotranspiration, might cause a significant increase in recharge. An increase in recharge could raise the water table, increasing saturated zone fluxes. There is a reasonable data base from which to infer past changes in the water table at Yucca Mountain. Although past increases under wetter climates are evidenced, a water-table rise to the point that the repository would be flooded appears unlikely (Winograd and Szabo, 1988; NRC, 1992; Szabo et al., 1994). Additional site characterization activities and studies of infiltration at Yucca Mountain should help improve estimates of the bounds of potential hydrologic responses to climate change. It should also be noted that the subsurface location of the repository would provide a temporal filter for climate change effects on hydrologic processes. The time required for unsaturated-zone flux changes to propagate down to the repository and then to the water table is probably in the range of hundreds to thousands of years. The time required for saturated flow-system responses is probably even longer. For this reason, climate changes on the time scale of hundreds of years would probably have little if any effect on repository performance, and the effects of climate changes on the deep hydrogeology can be assessed over much longer time scales.

The third type of change that might result from climate change is a shift in the distribution and activities of human populations. In the vicinity of Yucca Mountain, a wetter, cooler climate would provide a more hospitable environment and could result in population increases. This could change the composition of the critical group by exposing more people to potential risks from the

repository. However, even at the present time, the available ground-water supply could sustain a substantially larger population than that presently in the area. Thus, there is no simple relation between future climatic conditions and future population. This unpredictability of human behavior is common to the issue of estimating pathways through the biosphere and will be addressed later in Part III.

Seismicity

Seismic displacement along faults is one type of episodic event that must be considered in estimating the long-term safety of a repository at Yucca Mountain. The adverse effects of seismicity can be assessed in terms of canister failure or an increase in fluid conductivity in the saturated or unsaturated zone. Yucca Mountain is within a region of Quaternary (from 2 million years ago to the present) seismic activity, of which the Little Skull Mountain earthquake of June 29, 1993, with a Richter magnitude 5.6, is the most notable recent example. Measured slip rates on faults in the region vary from approximately 0.001 mm/yr to 0.02 mm/yr with recurrence intervals of 20,000 to 100,000 years (Whitney, 1994). Also, according to Whitney, no significant faults, that is, faults with more than 5 cm displacement over the last 100,000 years have been found at the proposed repository site. Seismicity is an episodic process, appearing to be essentially a fractal activity involving frequent releases of small amounts of strain energy and progressively less frequent releases of larger amounts of energy. It is possible through careful examination of the geologic record to establish a chronological history of the activity over millions of years. Estimates of activity over similar periods into the future can be made by extrapolation from the past activity.

Seismic effects are important both during the repository operational or pre-closure phase and the post-closure phase. The effect of a seismic event on underground excavations, such as repositories is usually less severe than the effects on a surface facility. Numerical models are available to assess the effect of seismicity on displacements along fractures and faults in rock. It would appear that, with good engineering, the probability of adverse effects on

repository isolation capabilities due to seismic loading at Yucca Mountain could be reduced sufficiently to result in boundable and probably very low risk.

Specifically, with respect to the effects of seismicity on canisters, the rock mass at Yucca Mountain is extensively fractured so the future seismic displacements are likely to occur along existing fractures rather than on new ones. Risks could be further reduced through the practice of "fault avoidance," whereby no canisters would be placed within or immediately adjacent to a known underground fault (which should be readily apparent during excavation of repository drifts and canister emplacement holes). Similarly, in-drift placement of canisters surrounded by a buffer backfill, such as bentonite-sand could essentially isolate canisters from the effects of seismicity.

With respect to the effects of seismicity on the hydrologic regime, the possibility of adverse effects due to displacements along existing fractures cannot be overlooked. It would seem that the hydrologic regime has been conditioned by many similar seismic events over geologic time. In consequence, such displacements have an equal probability of favorably changing the hydrologic regime, so that the effect of seismicity on the hydrologic regime could probably be bounded.

Studies have been made of the possibility that a seismic event could produce transient changes in the water table at Yucca Mountain sufficient to bring ground water through the repository to the surface (NRC, 1992). Results indicate a probable maximum transient rise on the order of 20 m or less. In summary, although the timing of seismic events is unpredictable, the consequences of these events are boundable for the purpose of assessing repository performance.

Volcanism

A volcanic intrusion into the proposed repository could be catastrophic, releasing a major part of the repository inventory directly into the biosphere. However, the overall risk might be very low, because it is also a very unlikely event. Like seismicity, volcanism is episodic. The two phenomena could also be linked, in

that some seismic activity can be triggered during periods of volcanic activity. Unlike seismicity, volcanism in the Yucca Mountain region involves intermittent concentrated activity separated by long repose periods. Even so, like seismicity, estimates of future volcanic activity can be based on analysis of the geologic record, with the assumption that the same pattern of events will hold in the future.

The risk from volcanism at Yucca Mountain is being examined using a probabilistic approach. According to Crowe et al. (1994), current studies are designed to establish three components of an overall probability of magmatic disruption of a repository:

1. Future recurrence rate of volcanic events, such as volcanic centers or volcanic clusters;
2. The probability that a future event will intersect a specified area, such as the repository or a controlled area beyond the repository;
3. The probability that an event occurring within the specified area will release radionuclides into the biosphere.

The probability of occurrence of the second component depends upon the probability of the first component, and the overall probability of radionuclide release due to volcanism in the Yucca Mountain region depends on the combined probability of all three components. Emphasis is being given to estimating the combination of the first and second components to determine the combined probability that a future event will intersect a specified area. This analysis is based on extrapolations into the future of volcanic activity from the historic record, and on assumptions about the spatial distribution of future volcanic eruptions in the Yucca Mountain region. Crowe suggests that a probability of $10^{-8}/\text{yr}$, which is a 1 in 10,000 possibility of a disruption over 10,000 years or 1 in 1,000 possibility in 100,000 years) or less might be sufficiently low to constitute a negligible risk. If the combined probability of the first two components can be shown to be below this level, then it might not be necessary to consider the third component.

Efforts are underway to refine the intrusion distribution models by incorporating geologic structure constraints. It is noted, for example, that the volcanic eruptions in Crater Flat appear to be

aligned in the northeast direction of the extensional faulting (across the Yucca Mountain site). If this constraint is confirmed and included in the distribution, the probability of a future event intersecting the repository site might fall below 10^{-8} per year.

While acknowledging the complexity of estimating the release of radionuclides to the biosphere, it seems possible, given the knowledge of material ejected from various types of volcanic eruptions and study of the cinder cones in the region, to develop reasonable estimates of the health consequences from radionuclides released by a volcanic eruption through a repository at Yucca Mountain. Thus, it is believed that the radiological health risk from volcanism can and should be subject to the overall health risk standard to be required for a repository at Yucca Mountain.

PART III: EXPOSURE SCENARIOS IN PERFORMANCE ASSESSMENT

As noted above, we believe that it is feasible to calculate, to within reasonable limits of certainty, potential, defined as possible but not necessarily probable concentrations of radionuclides in ground water and air at different locations and times in the future. To proceed from the calculation of radionuclide concentrations to calculations of risks that would result from a repository, many additional factors or assumptions about the nature of the human society at or near the repository site must be considered. These factors must be included in an exposure scenario that specifies the pathways by which persons are exposed to radionuclides released from the repository.

As we note in Chapter 4 with regard to the feasibility of making projections of future human intrusion into a repository, based on our review of the literature we believe that no scientific basis exists to make projections of the nature of future human societies to within reasonable limits of certainty. Therefore, unlike our conclusion about the earth science and geologic engineering factors described in Part II of this chapter, we believe that it is not possible to predict on the basis of scientific analyses the societal factors that must be specified in a far-future exposure scenario. There are an unlimited number of possible human futures, some of

which would involve risks from a repository and others that would not.

Although the nature of future societies cannot be predicted, it is possible, at least conceptually, to consider several characteristics of future society that would indicate whether a repository is likely to pose a risk to people. A repository would be unlikely to pose significant risks to future societies: if the area near the repository were not occupied, if future societies do not use ground water from the contaminated region, or if future societies routinely monitor ground-water quality and either treat or avoid use of contaminated sources. Conversely, exposures would result if water wells were drilled into the contaminated areas and the water consumed by people or used to irrigate crops. As far as we are able to determine, there is no sound basis for quantifying the likelihood of future scenarios in which exposures do or do not occur; about all that can be said is that both are possible.

It is our view, however, that once exposure scenarios have been adopted, performance assessment calculations can be carried out for the specified scenarios with a degree of uncertainty comparable to the uncertainty associated with geologic processes and engineered systems. The more difficult task is the specification of reasonable scenarios for evaluation. Any particular scenario about the future of human society near Yucca Mountain that might be adopted for purposes of calculation is likely to be arbitrary, and should not be interpreted as reflecting conditions that eventually will occur. Although we recognize the burden on regulators to avoid regulations that are arbitrary, we know of no scientific method for identifying these scenarios.

Selection of Exposure Scenarios for Performance Assessment Calculations

Any approach to assessing compliance with the standard must make assumptions about the nature of the human activities and lifestyles that provide pathways for exposure. For example, people could drink water containing radionuclides, irrigate crops with the water, eat these crops, and bathe in the water. Quantification of the doses received from the various pathways requires detailed data on these pathways. For the example above, the average amount of water

ingested per day (not including other beverages constituted with uncontaminated water) should be known, as should the type of crops grown, the amount eaten, and the frequency of bathing. The set of circumstances that affects the dose received, such as where people live, what they eat and drink, and other lifestyle characteristics including the state of agricultural technology, are part of what we refer to as the exposure scenario.

Unfortunately, many human behavior factors important to assessing repository performance vary over periods that are short in comparison with those that should be considered for a repository. The past several centuries (or even decades) have seen radical changes in human technology and behavior, many or most of which were not reasonably predictable. For example, within the past one hundred years, our society has evolved from one in which drilling and pumping technology did not exist for production of water from the depths of ground water at Yucca Mountain to a level of technology where such production is feasible. Within this same time period, we have seen U.S. demographic patterns shift from a time where a majority of U.S. residents were engaged in farming and grew their own food to the present day in which only a few percent of the work force is employed in farming, and in which most people's diet includes food produced outside their local area.

Given this potential for rapid change, it is unknowable what patterns of human activity might exist 10,000 or 100,000 years from now. Indeed, the period during which repository performance might be relevant, on the order of a million years, is sufficiently long that any number of different societies might reside near the repository site. Several glacial periods probably will have occurred, making estimates of human society even more difficult. Given the unknowable nature of the state of future human societies, it is tempting to seek to avoid the use of such assumptions in performance assessment calculations. In our view, however, it is not possible for a reasonable standard for the protection of human health to avoid use of some specified assumptions about future populations, patterns, and lifestyles around a proposed repository site. Even regulatory standards stated in terms of geologic and engineering factors are not independent of assumptions about future exposure scenarios. For example, the containment requirements of 40 CFR 191 were

apparently developed based on consideration of a global release scenario in which average doses to large populations were considered.

The problem is how to pick an exposure scenario to be used for compliance assessment purposes. Given the lack of a scientific basis for doing so, we believe that it is appropriate for the regulator to make this policy decision. One specific recommendation we make is to avoid placing the burden of postulating and defending assumptions about exposure scenarios on the applicant for a license. The regulator appears to be better situated than the applicant to carry the responsibility because of the perception that any future scenario developed by the applicant could have been chosen to give the desired outcome. On the other hand, the results of calculations from a scenario specified by the regulator in an open process designed to consider the views of all the interested parties might be seen as a fair test of the suitability of a site and design.

In addition, we recommend against an approach under which a large number of future scenarios are specified for compliance assessment, since such an approach could be seen as putting both the regulator and the applicant in the indefensible position of claiming to have considered a sufficient number of scenarios and that all reasonable future situations are represented in the analysis. The purpose of making exposure scenario assumptions is not to identify possible futures, but to provide a framework for the analysis and evaluation of repository performance for the protection of public health.²³

Specification of the exposure scenario assumptions to be used in performance assessment at Yucca Mountain will greatly influence whether the site and design can comply or not. The selection of exposure scenarios is perhaps the most challenging and contentious aspect of risk and compliance assessment. For example, EPA guidelines for exposure assessment reflect a philosophical disagreement over the question of when and how to depart from the

Another argument for using a large number of scenarios is that iterative analysis of repository performance will lead to the most cost-effective repository design. This might be true, but we believe that the regulator must in the end assess compliance with a single level of protection as defined in the standard. Therefore, one (or at most a few) exposure scenarios must be specified for compliance assessment purposes.

theoretical upper bound estimate of exposure and to employ probabilistic techniques (Federal Register 57 [May 29, 1992]: 22888-22938). These questions, which are at the interface between science and policy judgment, are also addressed in *Science and Judgment in Risk Assessment* (NRC, 1994). For these reasons, we strongly recommend that the decision be made through a public rulemaking process. This process will provide a more complete analysis of the advantages and disadvantages of alternative scenarios than we have been able to perform, and do so with the benefit of full public participation.²⁴

As with other aspects of defining the standards and demonstrating compliance that involve scientific knowledge but must ultimately rest on policy judgments, we considered what to suggest to EPA as a useful starting point for rulemaking on exposure scenarios. Reflecting the disagreement inherent in the literature, we have not reached complete consensus on this question.

We do agree, however, that the exposure scenario used to test compliance should not be based on an individual defined by unreasonable assumptions regarding habits and sensitivities affecting risk. It is essential that the exposure scenario that is ultimately selected be consistent with the critical-group concept that we advanced in Chapter 2. The purpose of using a critical group is to avoid using the standard to protect a person with unusual habits or sensitivities. The critical-group approach does this by using the average risk in the group for testing compliance. To ensure that this average risk nevertheless affords a high level of protection to most persons, the group must contain the persons at highest risk within the group and must be homogeneous in risk. An exposure scenario selected for compliance assessment should produce a critical group with these characteristics.

This rulemaking need not be done before the promulgation of an individual-risk standard that we recommended in Chapter 2. Indeed, we would not want the selection of that standard to be colored by foreknowledge of the assumptions incorporated in the exposure scenario.

Additionally, we note that the ICRP (1985a) recommends that the critical group be defined using present knowledge²⁵ and cautious, but reasonable, assumptions. Although this guidance was originally intended for the regulation of dose limits, we believe that it is generally appropriate in applying the critical-group concept to risk, as we have recommended. EPA should rely on this guidance when choosing the assumptions for the exposure scenario to be used for performance assessment.

Finally, we have considered the design of an exposure scenario that EPA might propose when it initiates the rulemaking process. We have considered two illustrative approaches for this purpose. We describe the two approaches in Appendixes C and D, and summarize their important characteristics below.

A substantial majority of the committee considers that the approach outlined in Appendix C is more clearly consistent with the foregoing criteria for selecting an exposure scenario than is the alternative in Appendix D, and therefore believes that EPA should propose an approach along the lines of Appendix C. Of course, other methods might also meet these criteria, and some of the methods might be less complex than the method illustrated in Appendix C.

Although the following discussion highlights differences between the two approaches, we wish to stress that the approaches are similar in many ways.

The approach in Appendix C makes use of information that can be collected on the factors that influence human behavior in the present. Assumptions about factors such as the source of food would be based on the source of food for today's population near the repository site. The Appendix C approach bases the exposure scenario on a population distribution derived from observed statistical associations between environmental parameters and the population distribution of actual population groups. For example, such parameters could include depth to water, soil type and depth, land slope, and growing season. This approach uses statistical

We understand "present knowledge" to mean any knowledge that is available today, and so should be read as an injunction against making assumptions about knowledge that might exist in the future. For example, assuming that future societies will have found a cure or prevention for cancer would not be present-day knowledge.

techniques to compute a critical group for each of a large number of simulations of the contaminated ground-water plume and then averages over these calculations to identify the average critical group for compliance purposes.

Important characteristics of this approach include the following. First, it extends the probabilistic methods that have been applied to simulations of physical processes (such as transport of ground-water contaminants) to analysis of the factors affecting exposure. Second, although mathematically complex, the model is based on currently observable data and does not require assumptions regarding specific values of parameters, only ranges within which the parameters might fall. Third, the degree to which conservatism is incorporated is determined not only by the analyst in selecting the ranges of parameters that describe farming lifestyles but also by the regulator when the standard is set. Fourth, it requires that the probability that persons occupy specific parcels of land for farming be determined statistically by the relevant characteristics of the land, ground water, and technology that influence farming, avoiding the potential that the standard could be influenced by a situation in which the maximum dose occurred at a place that was uninhabitable or otherwise unsuitable for farming.

The approach in Appendix D specifies *a priori* one or more subsistence farmers as the critical group and makes assumptions designed to define the farmer at maximum risk to be included in the critical group. The subsistence farmer would be a person with eating habits and with response to doses of radiation that are normal for present-day humans. All food eaten over the lifetime of the subsistence farmer would be grown with water drawn from an underground aquifer contaminated with radioactivity from the repository. The water would be withdrawn at a location outside the footprint of the repository and near that maximum potential concentration of the most critical radioactive contaminant in the ground water so that the scenario describes the maximum dose and risk. All of the farmer's drinking water would come from that same source. For compliance assessment purposes, it is assumed that the homogeneity criterion (see the definition of critical group in Chapter 2) applies and that the risk to the average member of the critical group is about one-third that of the subsistence farmer.

The important features of the subsistence-farmer model include the following. First, it has been used extensively in radioactive waste management programs in the United States and other countries, so a body of experience with it exists on which to draw. Second, it is straightforward and relatively simple to understand and calculate. Third, while it incorporates a series of assumptions about the lifestyle of the hypothetical farmer, any degree of conservatism can be built into the model by choices among alternative assumptions, which can be based on current conditions in the Amorgosa Valley; these assumptions need not be constrained by the characteristics of the current population of the region. Fourth, it makes the most conservative assumption that wherever and whenever the maximum concentration of radionuclides occurs in a ground water plume accessible from the surface, a farmer will be there to access it.

These approaches have many elements in common. Most important, both rely on probabilistic methods of estimating the distribution of radionuclides in the environment. Both also incorporate knowledge of the natural geologic features of the environment that influence the potential for exposure and both are intended to incorporate cautious, but reasonable, assumptions about lifestyles of the affected populations that the EPA might propose in a rulemaking. For example, both assume eating habits and response to radiation doses that are normal for present-day humans.

Despite these similarities between the approaches, two major issues that differentiate them have emerged from our consideration. These issues are summarized below:

- Assumptions about the location and lifestyle of persons who might be exposed to radionuclides released from the repository are crucially important because they affect the identification of the person at highest risk that must be contained in the critical group. The two approaches differ in their treatment of these assumptions. For example, the approach in Appendix D specifies *a priori* that a person will be present at the time and place of highest nuclide concentrations in ground water and will have such habits as to be exposed to the highest concentration of radiation in the environment.

This person is assumed to define the upper limit of risk in the critical group. Appendix C treats the distribution of potential farmers probabilistically based on current technical understanding of farming in the region. Because the person at highest risk might not be the same under the two approaches, the critical group selected for compliance assessment could be different.

- **The second difference involves the method of calculating the average risk of the members of the critical group. Appendix C uses detailed statistical analysis to define the critical group. Specifically, it identifies a "critical subgroup" for each of a large number of Monte Carlo realizations of the contamination plume. The critical group risk is determined by averaging over the average risks to each of these subgroups. In contrast, the Appendix D approach approximates the average critical group risk at about one-third of the risk faced by the person at highest risk, since the requirement that the critical group be homogeneous in risk implies that the overall range of risks in the critical group be limited to about a factor of ten. If the distribution of risk among members of the critical group is not relatively uniform, these approaches could produce different averages.**

As noted earlier, we agree that unrealistic assumptions are inappropriate. Our divergence of view is on the extent to which the alternative sets of assumptions embodied in Appendixes C and D are cautious, but reasonable. The approach of Appendix C has the advantages of explicitly accounting for how the physical characteristics of the site might influence population distribution and of identifying the makeup of the critical group probabilistically. Most of the committee regard these as desirable features of exposure scenarios that are intended to be consistent with the critical-group concept. We emphasize, however, that specification of exposure-scenario assumptions is a matter for policy decision.

Exclusion Zone

The original standard, 40 CFR 191, contained a provision for an exclusion zone in the immediate vicinity of the repository. The purpose was to provide a boundary for calculating releases.

In light of our conclusion in Chapter 4 that there is no scientific basis for assuming that institutional controls can be maintained for more than a few centuries, we also conclude that there is no scientific basis for assuming that human activity can be prevented from occurring in an exclusion zone or that defining such a zone will provide protection to future generations from exposures in the vicinity of the repository.

The question remains whether an exclusion zone serves a useful purpose for compliance assessment. In our analysis, we have assumed that some human activities, such as drilling into or through the repository, should be treated as special cases of human intrusion (see Chapter 4). If, as we recommend, human intrusion is treated separately from the performance of an undisturbed repository, it is reasonable in our view to define a region in which human activities are to be regarded as intrusion and to exclude that region from calculation of the undisturbed repository performance. For example, if we assume that all drilling for water wells is vertical, the area directly above the repository plan (or footprint) would be considered an exclusion zone for purpose of calculating compliance with that part of the standard that applies to undisturbed performance. Drilling in that zone would be a case of human intrusion.

Beyond the repository footprint, however, there seems to be no practical purpose for defining a larger exclusion zone for the form of the standard we recommend. Without either a release limit or a time limit for the standard for undisturbed performance, an arbitrary boundary serves no purpose. In the approach we recommend, an objective of performance assessment calculations is to determine the time in the future when risks from exposure to radionuclides released from the repository are greatest and to base the regulatory judgment about compliance on a comparison of the risks at that time to the standard. Furthermore, neither of the alternatives for treating the critical group requires an exclusion zone larger than the repository footprint.

HUMAN INTRUSION AND INSTITUTIONAL CONTROLS

INTRODUCTION

In Section 801(a)(2) of the Energy Policy Act of 1992, Congress asked three specific questions. The first question, about the use of individual dose as a criterion for protecting the public, was addressed in Chapter 2. The second and third questions concern the potential that at some future time people might intrude into the repository, thereby defeating its geologic and engineered barriers. We were asked to examine the scientific basis for predicting human intrusion and the potential for protecting against it, specifically:

Question 2. Whether it is reasonable to assume that a system for post-closure oversight of the repository can be developed, based on active institutional controls, that will prevent an unreasonable risk of breaching the repository's engineered barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits.

Question 3. Whether it is reasonable to make scientifically supportable predictions of the probability that a repository's engineered or geologic barriers will be breached as a result of human intrusion over a period of 10,000 years.

Briefly, we conclude that the answer to both questions is "no" for the reasons outlined below.

Human activity that penetrates the repository, such as by drilling into it from the surface, can cause or accelerate the release of radionuclides. Waste material might be brought to the surface and expose the intruder to high radiation doses, or the material might disperse into the biosphere. Even if this does not occur, a borehole could go through the repository and open a pathway by which radionuclides more readily reach the ground water.

Over the years, DOE has developed a considerable literature on human intrusion and on active and passive controls to prevent it (von Winterfeldt, 1994). For example, some studies have examined resource potential and historical exploration activity and used current understanding and rates of drilling to project future activity. Other studies have detailed examples of monuments and inscriptions that have survived from long ago. Still others have speculated on the characteristics of signs and markers that might improve their long-term effectiveness at delivering a message to future generations. Based on our understanding of this literature, however, we conclude that there is no technical basis for predicting either the nature or the frequency of occurrence of intrusions.

For some initial period, human intrusion could be managed through active or passive controls. As long as they are in place, active institutional controls such as guards could prevent intruders from coming near the repository. We conclude, however, that there is no scientific basis for making projections over the long term of either the social, institutional, or technological status of future societies. Relying on active controls implies requiring future generations to dedicate resources to the effort. There is, however, no scientific basis from which to project the durability of governmental institutions over the period of interest, which exceeds that of all recorded human history. On this time scale, human institutions have come and gone. We might expect some degree of continuity of institutions, and hence of the potential for active institutional controls, into the future, but there is no basis in experience for such an assumption beyond a time scale of centuries.

Similarly, there is no scientific basis for assuming the long-term effectiveness of active institutional controls to protect against human intrusion. Although it may be reasonable to assume that a system of post-closure oversight can be developed and relied on for some initial period of time, there is no defensible basis for assuming that such a system can be relied on for times far into the future. Between these limits, the ability to rely on such active institutional systems presumably diminishes in a way that is intrinsically unknowable. We have seen no evidence to support a claim to the contrary. People might disagree, of course, on their predictions for how long into the future active institutional controls might survive and remain effective.

The situation is not qualitatively different for passive institutional controls. As long as they are recognized and heeded, passive controls such as markers, barriers, and archival records could serve to warn potential intruders away. Passive controls, too, may be of limited duration, requiring future generations to renew them. While many historical markers, monuments, and records have survived for long periods of time, up to thousands of years, most presumably have not. Those records that have survived might not represent records for which the local social knowledge was continuous. We cannot know those that did not survive to our time. Further, languages have changed over periods of centuries so that old documents and inscriptions might be difficult for any but scholars to interpret. Even though technologies for making markers and monuments will improve and even though modern global telecommunications might slow the rate of change of languages, the time span of concern for a high-level waste repository far exceeds experience, so there is no technical basis for making forecasts about the reliability of such passive institutional controls.

Just as there is no basis for assuming the effectiveness of either active or passive institutional controls to reduce the risk of human intrusion, we also conclude that there is no scientific basis for estimating the probability of intrusion at far-future times. Several types of intrusion can be considered: inadvertent intrusion into the repository in the process of exploring for or producing other resources in the vicinity, intrusion driven by curiosity about the markers and what might lie below them, or intentional intrusion for malicious purposes or to recover the repository contents. (The malicious intrusion might be by a hostile nation or subnational group assuming a societal or institutional presence.) In our view, there is simply no scientific basis for estimating the probability of inadvertent, willful, or malicious human action.

Estimating the probability of inadvertent intrusion as a consequence of exploration or production of resources might seem more plausible than for the cases of willful or malicious intrusion. Doing so, however, requires knowledge of which materials at or near the site will be regarded as resources in the future and the technologies that will exist for exploration and production. We cannot predict future economic conditions that help to define what is a valuable resource nor can we forecast future exploration technology, although we can observe that, if the past is an adequate guide, economic conditions and technology will change rapidly in the future. It might very well be, for example, that

subsurface exploration technology in the future could be based on remote sensing so that penetration of the surface is no longer required. We therefore do not think that it is feasible to make meaningful predictions about the probability of advertent or inadvertent intrusion.

Based on these findings, we make two observations about how to deal with human intrusion in the Yucca Mountain standard. First, although there is no scientific basis for judging whether active institutional controls can prevent an unreasonable risk from human intrusion, we think that if the repository is built such controls and other activities can be helpful in reducing the risk of intrusion, at least for some initial period of time after a repository is closed. Therefore, although it cannot be proven, we believe that if a repository is built at Yucca Mountain, a collection of prescriptive requirements, including active institutional controls, record-keeping, and passive barriers and markers, will help to reduce the risk of human intrusion, at least in the near term. The degree of benefit is likely to decrease over time. Further, once other knowledge of the repository is lost, passive markers could attract the curious and actually increase the risk of intrusion. Nonetheless, we conclude that the benefits of passive markers outweigh their disadvantages, at least in the near term.

Second, because it is not technically feasible to assess the probability of human intrusion into a repository over the long term, we do not believe that it is scientifically justified to incorporate alternative scenarios of human intrusion into a fully risk-based compliance assessment that requires knowledge of the character and frequency of various intrusion scenarios. We do however conclude that it is possible to carry out calculations of the consequences for particular types of intrusion events, for example drilling one or more boreholes into and through the repository. We also believe that calculations of this type might be informative in the sense that they can provide useful insight into the degree to which the ability of a repository to protect public health would be degraded by intrusion.

For these reasons, to address the human intrusion issue on an adequate basis, we recommend that the repository developer should be required to provide a reasonable system of active and passive controls to reduce the risk of intrusion in the near term and that EPA should specify in its standard a typical intrusion scenario to be analyzed for its consequences on the performance of the repository. Such an analysis will provide useful quantitative information that can be meaningful in the licensing process, as described later in this chapter. Because the assumed

intrusion scenario is arbitrary and the probability of its occurrence cannot be assessed, the result of the analysis should not be integrated into an assessment of repository performance based on risk, but rather should be considered separately. The purpose of this consequence analysis is to evaluate the resilience of the repository to intrusion.

Although we believe that a requirement based on analyses of intrusion consequences is useful in assessing repository performance at Yucca Mountain, such analyses are likely to be more meaningful in selecting among alternative sites (such as by avoiding sites that have potentially valuable mineral, energy, or ground-water resources) than in assessing the performance of a particular site and design. However, Yucca Mountain has already been selected for evaluation as a potential repository site, so the value of analyses of the consequences of human intrusion at Yucca Mountain is limited. Consideration of analytic approaches that would discriminate among alternative sites with greater or lesser likelihood or consequences of intrusion is beyond our charge.

In the remainder of this chapter, we present our argument for the usefulness of an analysis of consequences of a simple intrusion scenario; and provide additional detail on the factors we considered in arriving at our conclusions.

The Consequences of Intrusion

As noted earlier, the consideration of human intrusion cannot be integrated into a fully risk-based standard because the results of any analysis of increased risk as a consequence of intrusion events would be driven mainly by unknowable factors. We reach this conclusion specifically because the numerical value of the risk of adverse health effects due to intrusion is always the product of two factors, the frequency of an intrusion scenario and the measure of consequence. However, the frequency of an intrusion scenario in the distant future is indeterminate.

Technical basis

Some factors affecting an analysis of the consequences of human intrusion can be assessed from a technical base, and some cannot. The

historical record of intrusion in the region of the site, including both rate and characteristics (drill depth, hole size, etc.) and the characterization of known mineral and other current resources near the site, can be assessed very well. However, the relevance of the historical record is doubtful. The physical consequences, in terms of the release and probable dispersion of radioactive materials, which is conditional on a defined intrusion scenario — either benevolent or malevolent in purpose — (such as the timing and physical characteristics of the intrusion and whether the intrusion is recognized and remediated), can be assessed moderately well within limits imposed by the level of detail contained in the modeling. Adverse consequences from a specified type of intrusion to a specified local society can also be assessed moderately well, but this assessment for the distant future requires making assumptions about many aspects of the future society, including its sources and technologies for distributing drinking water and food, the ability to detect contamination of food or water, locations of future populations, etc. which cannot be accurately predicted. These assumptions, discussed in Chapters 2 and 3, are inherent in any health-based standard, and we have recommended that for the purposes of compliance analysis they be made explicit through the rulemaking process.

Factors that cannot be technically assessed include the likelihood that institutional controls will persist and succeed over time, or that markers or barriers would persist, be understood, and deter intrusion; the probability that a future intrusion would occur in a given future time period such as in any one year; and the probability that a future intrusion would be detected and remediated, either when it occurs or later. In addition, we cannot predict which resources will be discovered or will become valuable enough to be the objective of an intruder's activity. We cannot predict the characteristics of future technologies for resource exploration and extraction or whether future practice will include sealing of physical intrusions such as boreholes. Continued developments in current non-invasive geophysical techniques, for example, could substantially reduce the frequency of exploratory boreholes.

Consequence-based analysis

Although it would be desirable if the risks associated with the disturbances to a repository by human intrusion could be integrated into a risk assessment of the undisturbed repository performance, technically it is not appropriate to do so. Rather than a complete risk analysis, one alternative is to examine the site- and design-related aspects of repository performance under an assumed intrusion scenario to inform a qualitative judgment. In this approach, the objective would be to perform a consequences-only analysis without attempting to determine an associated probability for the analyzed scenario. We recommend that the Yucca Mountain standard require such an analysis.

We considered at some length the question of whether the calculation of consequences for one or more specified human intrusion scenarios, absent their associated probabilities, could form a useful basis for evaluating a proposed repository site and design. We conclude that the calculations of consequences would provide useful information about how well a repository might perform after an intrusion occurs. The key performance issue is whether the repository would continue to be able to isolate wastes from the biosphere, or if its performance would be substantially degraded as a consequence of an intrusion of the type postulated.

Because the form and frequency of intrusions cannot be predicted, certain assumptions must be made in order to assess the resilience of the repository to intrusion. As in the case of adopting a model of the biosphere and identifying critical groups, selecting an intrusion scenario for analysis entails judgment. To provide for the broadest consideration of what scenario or scenarios might be most appropriate, we recommend that EPA make this determination in its rulemaking to adopt a standard. In this regard, we suggest the following starting point.

For simplicity, we considered a stylized intrusion scenario consisting of one borehole of a specified diameter drilled from the surface through a canister of waste to the underlying aquifer. One can always conceive of worse cases, such as multiple boreholes with each penetrating a canister, but this single-borehole scenario seems to us to hold the

promise of providing considerable insight into repository performance with the minimum complication.²⁶

An example of a scenario that we believe provides a reasonable basis for evaluation would postulate current drilling technology but assume sloppy practice, such as not plugging the hole carefully when abandoning it, after which natural processes would gradually modify the hole. Although the time at which the intrusion occurs in the future is arbitrary in any hypothetical scenario, we believe it is useful to assume that the intrusion occurs during a period when some of the canisters will have failed but the released materials would not otherwise have had time to reach the ground water. This assumption places emphasis in the consequence analysis on the creation of enhanced pathways to the environment (both to the atmosphere and to the aquifer) as opposed to emphasis on the intrusion's breaching of the canister, which will happen eventually even without human intrusion.

Having defined the reference scenario, the principal questions are what consequence should be assessed and how the result should be interpreted. In our view, the performance of the repository, having been intruded upon, should be assessed using the same analytical methods and assumptions, including those about the biosphere and critical groups, used in the assessment of the performance for the undisturbed case. This analysis should be carried out to determine how the hypothesized intrusion event affects the risk to the appropriate critical groups. We propose that the figure-of-merit for this calculation should be the same as in the undisturbed case, because a repository that is suitable for safe, long-term disposal should be able to continue to provide acceptable waste isolation after some type of intrusion.

The result of this calculation, however, would be a conditional risk: that is, a risk assuming that the hypothesized intrusion occurs. Because the probability is inherently unknowable, we are led to the conclusion that the most useful purpose of this type of analysis is to identify the incremental effects from the assumed scenario. As indicated earlier, we believe that since human intrusion of some type might be

Under many conditions, the effect of multiple boreholes presumably would be the sum of the effects of each taken separately, but circumstances when this assumption is invalid can easily be conceived. Because construction of scenarios is arbitrary, we would argue for the simplest case that tests the repository.

likely at some time in the future, a repository should be resilient to at least modest inadvertent intrusions. Because whether and how frequently intrusion events might occur are unknowable, how important these effects are for our expectation that the repository will protect the public can also only be a matter of judgment. Our recommendation is that EPA should require that the conditional risk as a result of the assumed intrusion scenario should be no greater than the risk levels that would be acceptable for the undisturbed-repository case. The conditional risk calculation would not include risks to the intruder or those arising from the material brought directly to the surface as a consequence of the intrusion. As with other policy-related aspects of our recommendations, we note that EPA might decide that some other risk level is appropriate.

Finally, we wish to reiterate that the single borehole scenario that we have discussed should not be interpreted as an estimate of the likely form or frequency of intrusion. A calculation of consequences for such an intrusion removes from consideration a number of imponderables, each of which would otherwise need to be treated separately, including the probability that an intrusion borehole would intersect a waste canister, the probabilities of detection and remediation, and the effectiveness of institutional controls and markers to prevent intrusion. This scenario should not be interpreted as either an optimistic or pessimistic estimate of what might actually occur, because there might be no boreholes that intercept canisters, or there might be more than one. We believe that the simplest scenario that provides a measure of the ability of the repository to isolate waste and thereby protect the public health is the most appropriate scenario to use for this purpose.

ADDITIONAL BASES FOR OUR RECOMMENDATION

In this section we discuss two additional aspects of the human intrusion question that underlie our thinking: the various categories of future human intrusion scenarios and the categories of hazards that could result from a typical borehole intrusion.

Categories of Future Human Intrusion Events

For the purposes of considering how to deal with human intrusion in the context of standard-setting and licensing, we have focused on the particular class of cases in which the intrusion is inadvertent and the intruder does not recognize that a hazardous situation has been created.

We considered several other categories of intrusive events. One case is when the intrusion is inadvertent, but the intruder recognizes that a radioactive waste repository has been disrupted and takes corrective actions. On the assumption that the corrective measures taken are effective and the repository is sealed, this class is not of concern. If, however, corrective actions are not taken or are ineffective, this type of intrusion is operationally the same as the inadvertent intrusion that is not recognized as hazardous, which is the class of cases on which we have focused.

We also considered intentional intrusion for either beneficial or malicious purposes, but concluded that it makes no sense — indeed it is presumptuous — to try to protect against the risks arising from the conscious activities of future human societies. Given the potential energy value of the wastes intended for Yucca Mountain, however, this category of intrusion scenarios might be likely.

Categories of Hazards Resulting From an Intrusion

We have identified three broad types of hazards from radioactive material that could occur as a result of an intrusion into the repository of the type characterized by borehole scenarios. The categories are:

- Hazards to the intruders themselves (the drillers, miners, or handlers of material previously in the undisturbed repository).
- Hazards to the public from any material brought directly to the surface by the intrusive activity. These hazards would arise because such material, now no longer at depth within the repository, would now be mobile in the biosphere, and the public (in addition to the intruders) can be exposed to the material.

- Hazards that arise because the integrity of the repository's engineered or geologic barriers have been compromised by the intrusion.

In the first and second instances, we concluded that analyzing the risks to the intrusion crew and the risks from any material brought directly to the surface as a consequence of intrusion is unlikely to provide useful information about a specific repository site or design and therefore should not provide a basis for judging the resilience of the proposed repository to intrusion. Whenever highly dangerous materials are gathered into one location and an intruder inadvertently breaks in, that intruder runs an inevitable risk. This is not unique to a deep geologic repository, and all deep geologic repositories have this feature. In particular, for inadvertent human intrusion, we believe that it would not be feasible to take regulatory actions today to protect the intrusion crew itself against the risks of its actions, except that requirements identified above associated with active or passive institutional controls might be helpful in this regard.

However, it is possible that an inadvertent intruder would not recognize or would irresponsibly ignore the hazard and would leave the cuttings on the surface so that further exposures would occur. This is the second category of hazards listed above. Our view is that the amount of such future cuttings might not be very different from one repository site or design to another, especially given the unknown nature of an intrusion. Analysis of this hazard too, therefore does not provide information that is useful for judging the ability of the particular repository site and design to protect the public. In this case, we also believe that it is not feasible to take regulatory actions today to alter the repository design to minimize these risks.

We therefore, recommend that the compliance analysis should concentrate on the third category of hazard posed by human intrusion, the one resulting from modification of the repository's barriers and the consequences of these modifications for the ability of the repository to perform its intended function.

Early in this study, we were asked by EPA to provide a description of how the form of the standard that we recommend differs from that of the current EPA standard for high-level radioactive waste in 40 CFR 191 and, where there were significant differences, to provide an explanation of the basis for the differences. We have tried to do so in the detailed discussions of Chapters 2, 3, and 4. The purpose of this chapter is to provide a comparison of our recommended approach with 40 CFR 191, including both common elements and differences. It is our intention that this chapter provide a concise summary of what we propose should be done differently and what elements of the 40 CFR 191 approach we recommend be retained.

In addition, we discuss the approach recommended here and that of technology-based standards such as the USNRC's 10 CFR 60. Because our approach is risk-based, it is not useful to make a direct comparison with 10 CFR 60. We do discuss here some aspects of technology-based standards, including ALARA and technology requirements to minimize early releases. Finally, we note some possible administrative consequences of our recommendations.

COMPARISON WITH 40 CFR 191

40 CFR 191 applies to the Waste Isolation Pilot Plant (WIPP) not to the proposed Yucca Mountain repository. Whether some other future repository would be subject to 40 CFR 191 depends on the legislative means taken to initiate it. The 40 CFR 191 standard has three major elements: containment requirements, individual dose limits, and groundwater protection requirements. Section 801 of the Energy Policy Act of 1992 directs EPA to issue a standard to protect the public from radionuclide releases at Yucca Mountain, and requires that the standard be stated in terms of the maximum annual dose equivalent to individual members of the public.

Considerations

We believe that there are two major considerations that give rise to differences between our recommendations and 40 CFR 191.

Generic vs. site-specific standards

By law, EPA is charged with issuing generally applicable standards for protection of health and the environment, and for that reason, 40 CFR 191 is a generic standard. This means that 40 CFR 191 contains provisions applicable for all conceivable terrestrial deep geologic repository sites and types. In addition, at the time that 40 CFR 191 was drafted, the major effort towards establishing a repository was site selection, and 40 CFR 191 was developed to give guidance regarding the feasibility of different types of sites. In contrast, our recommendations concern a standard for the proposed repository at Yucca Mountain. Consequently, we have not addressed site selection, nor have we emphasized potential elements of a standard that would be operationally insignificant at Yucca Mountain. For example, our finding that a containment requirement or release limit is inappropriate is a finding specific to a Yucca Mountain repository; for another geologic setting, we might or might not have reached a different conclusion. The distinction between a generic standard and a site-specific one should be noted as our recommendations are compared with 40 CFR 191.

Dose vs. risk

40 CFR 191 limits individual doses from the undisturbed performance of a repository to 0.15 mSv per year (15 mrem per year). In contrast, we have recommended an approach based on individual-risk limits. Among the reasons why we have chosen risk as the regulatory basis rather than dose, two are important for this discussion. The first is that changes in our understanding of radiation health risks can be accommodated without revision of the level of the standard. If, in the future, scientific evidence becomes available indicating that radiation is

more or less hazardous than our current scientific understanding suggests, the framework we propose would incorporate that new information without a required revision to the level of the standard. The second reason that we have recommended a risk basis is that the probabilities associated with various elements of the exposure calculation can be considered. Our recommended approach is a risk limit based on the probabilistic distribution of a dose and the probability of health effects associated with that dose.

Because the individual dose requirements of 40 CFR 191 have not been implemented, it is not possible to tell whether or how probabilities would be incorporated into estimation of dose. Because the effort at EPA with 40 CFR 191 implementation is now focused on WIPP, and because the individual dose limit is not a particularly important component of the standard for WIPP, it is not clear to us how EPA will interpret its dose limit. In any event, our proposal is clear with respect to our intention that the standard should include consideration of the probabilistic aspect of future exposures.

Differences From 40 CFR 191

What follows is a brief summary of the differences between our recommendations and 40 CFR 191.

Time period

Perhaps the most significant difference between our recommendations and 40 CFR 191 concerns the time period over which the standard is applicable. In 40 CFR 191, the standard applies for a period of 10,000 years. In our proposal, we have specified that the basis for the standard should be the peak risk, whenever it occurs²⁷. Based on performance assessment calculations provided to us, it appears that for some reasonable combinations of parameters, peak risks are likely to occur after 10,000 years.

Within the limits imposed by the long-term stability of the geologic environment.

Population health effects and release limits

A major element of 40 CFR 191 is its containment requirement, which limits releases of radionuclides to the accessible environment during the first 10,000 years of operation. The stated goal of the release limit was to limit cancer deaths to the general population to 1,000 over 10,000 years. This requirement was to be implemented through a comparison of calculated releases of radionuclides with a table of allowable release limits for each radionuclide. For reasons stated in Chapter 2, we do not think that such a requirement would provide additional protection over that provided by the individual-risk limit for a repository at Yucca Mountain, and we do not recommend that a release limit be adopted.

A related topic is our recommendation in Chapter 2 to employ the concept of a negligible incremental risk, which is the level of risk that can, for radiation protection purposes, be dismissed from consideration. Persons in some local populations outside of the critical group at Yucca Mountain might be exposed to risk from repository releases in excess of the level of negligible incremental risk. However, as individuals, these persons would be exposed to less risk than the risk limit established by the standard for the critical group. On a collective basis, the risks to future local populations are unknowable. We conclude that there is no technical basis for establishing a collective population-risk standard that would limit risk to the nearby population of the proposed Yucca Mountain repository.

Radiation releases from a Yucca Mountain repository can, in principle, be distributed beyond a local population to a global population. In general, the risks of radiation produced by such wide dispersion are likely to be several orders of magnitude below those to a local critical group.

Human intrusion

Under 40 CFR 191, an assessment must be made of the frequency and consequences of human intrusion for purposes of demonstrating compliance with the containment requirements. Human intrusion is not a consideration for compliance with the individual dose limits of ground-water protection requirements. In recognition of the substantial uncertainties involved, EPA has provided detailed guidance for analysis

of human intrusion risks and is proposing a reference biosphere be used for the implementation of 40 CFR 191 at WIPP that incorporates an assumption that the future biosphere is much like the present. The EPA requirement includes releases due to drilling cuttings brought to the surface and also includes increases in other radionuclide releases that might occur, for example, through accelerated releases to ground water.

In contrast, we conclude that it is not possible to assess the probability of human intrusion into a repository over the long term, and we do not believe that it is scientifically justified to incorporate alternative scenarios of human intrusion into a risk-based compliance assessment. We do, however, conclude that it is possible to carry out calculations of the consequences for particular types of intrusion events. The key performance issue is whether repository performance would be substantially degraded as a consequence of an inadvertent intrusion for which the intruder does not recognize that a hazardous situation has been created. This consequence assessment is to be done separately from the calculation of compliance with the risk limit from other events and processes, and is to exclude exposures to drillers or to members of the public due to cuttings. We recommend that EPA should require that the conditional risk as a result of the assumed intrusion scenario be no greater than the risk limits adopted for the undisturbed-repository case.

Ground-water protection

40 CFR 191 includes a provision to protect ground water from contamination with radioactive materials that is separate from the 40 CFR 191 individual-dose limits. These provisions have been added to 40 CFR 191 to bring it into conformity with the Safe Drinking Water Act, and have the goal of protecting ground water as a resource. We make no such recommendation, and have based our recommendations on those requirements necessary to limit risks to individuals.

Common Elements With 40 CFR 191

Although our recommendations differ from 40 CFR 191, there are also important similarities in approach.

Dose apportionment

In the recently revised 40 CFR 191, EPA has endorsed the dose limit and dose-apportionment recommendations of the ICRP. We support this approach.

Reference biosphere

In view of the almost unlimited possible future states of society and of the significance of these states to future risk and dose, both EPA and we have recommended that a particular set of assumptions be used about the biosphere (including, for example, how and from where people get their food and water) for compliance calculations. Both EPA and we recommend the use of assumptions that reflect current technologies and living patterns.

Exclusion zone

The original standard, 40 CFR 191, contained a provision for an exclusion zone in the immediate vicinity of the repository. The purpose was to provide a boundary for calculating releases. The zone was presumably to be protected from human activity.

In light of our conclusion in Chapter 4 that it is not reasonable to assume that institutional controls can be maintained for more than a few centuries, we also conclude that there is no scientific basis for assuming that human activity can be prevented from occurring in an exclusion zone or that defining such a zone will provide protection to future generations from exposures in the vicinity of the repository. If, as we recommend, human intrusion is treated separately from the performance of an undisturbed repository, it is reasonable in our view to define a region in which human activities are to be regarded as intrusion and to exclude that region from calculation of the undisturbed repository performance. Beyond the repository footprint, however, there seems to be no practical purpose for defining a larger exclusion zone for the form of the standard we recommend. Without either a release limit or a time limit for the standard for undisturbed performance, an arbitrary boundary serves no purpose.

Use of mean values

We recommend that the mean values of calculations be the basis for comparison with our recommended standards.

LIMITS OF THE SCIENTIFIC BASIS

Our assignment has been to assess the scientific bases for a standard to protect the public health from radiation exposures that might result from radionuclide releases associated with a high-level waste repository at Yucca Mountain. In so doing, we have concluded that for some decisions there presently exists a limited scientific basis required to set and administer such a standard. We have explicitly noted these issues in the preceding chapters, and have indicated that they must be decided on a policy, rather than a scientific, basis. This interplay of scientific and policy issues in the standard has two major implications.

First, where we have identified policy issues, we have recommended that sound public policy would have these issues addressed in rulemaking by the appropriate federal agency, EPA or USNRC. The process of addressing these issues by rulemaking or an equivalent procedure must provide a full opportunity for public participation, especially by the citizens of the affected jurisdictions, and allow the agency the flexibility to take a broad range of public opinion into account in its final public policy judgments. We regard these characteristics as essential for the policy judgments that are required in formulating the standard. In contrast, the licensing process is not suited to this policy-making role, but rather is the arena in which compliance with the standard can be tested.

Several times we have identified possible positions that could be used by the responsible agency in formulating a proposed rule, which is often the initial step in the process. Other starting positions are possible, and of course the final rule might differ markedly from the one proposed. We have tried only to illustrate by reference to other authorities or by example that there seems to be a reasonable policy position from which to begin.

The second implication of the limitations that we have identified is that since they represent current gaps in scientific knowledge, it might be possible that some of these gaps and uncertainties might be reduced by additional research. It seems reasonable, therefore, to ask what gaps could be closed by taking time to obtain more scientific and technical knowledge on such matters as the nature of the waste, its potential use, the health effects of radionuclides, the value of waste products for later generations, and the security of retrievable storage containers. New information in these and other areas could improve the basis for setting the standards if, for example, this information reduced the uncertainty about the effects of very low doses of radiation.

Whether the benefit of new information would be worth the additional time and resources required to obtain it is a matter of judgment. This judgment would be strengthened by a careful appraisal of the probable costs and risks of continuing the present temporary waste disposal practices and use of storage facilities as compared with those attaching to the proposed repository. No such comprehensive appraisal is now available. Conducting such an appraisal, however, should not be seen as a reason to slow down ongoing research and development programs, including geologic site characterization or the process of establishing a standard to protect public health.

TECHNOLOGY-BASED STANDARDS

Technology-based standards play an important role in regulations designed to protect the public health from the risks associated with nuclear facilities. The purpose of these standards is typically to help ensure protection by employing the best available technology, considering cost and other factors. Three issues involving technological approaches have been raised in our study, and we comment on them below.

The ALARA Principle

The "as low as reasonably achievable" (ALARA) principle has been a basic feature of radiation protection for nearly 30 years. It is intended to be applied after threshold regulatory limits have been met, and calls for additional measures to be taken to achieve further reduction in

the calculated health effects resulting from radiation exposure of workers or of a population so that final exposures are "as low as reasonably achievable taking account of economic and social factors." ALARA requires a balancing of costs and benefits.

While ALARA continues to be widely recommended as a philosophically desirable goal, its applicability to geologic disposal of high-level wastes is limited at best because the technological alternatives available for designing a geologic repository are quite limited (IAEA, 1989). Further, the difficulties of demonstrating technical or legal compliance with any such requirement for the post-closure phase could well prove insuperable even if it were restricted to engineering and design issues. We conclude that there is no scientific basis for incorporating the ALARA principle into the EPA standard or USNRC regulations for the repository. However, it is nothing other than sound engineering practice to consider whether reductions in radiation dose or risk can be achieved through engineering measures that can be implemented in a cost-effective manner.

10 CFR 60

If EPA issues a standard based on individual risk, USNRC is required to revise its current regulations embodied in 10 CFR 60 to be consistent with such a standard. One purpose of the existing USNRC regulations is to help ensure multiple barriers within the repository system. The concept of multiple barriers, implemented through subsystem requirements, has its origin in the Nuclear Waste Policy Act of 1982. Recognizing this origin, we nonetheless conclude that because it is the performance of the total system in light of the risk-based standard that is crucial, imposing subsystem performance requirements might result in a suboptimal repository design. Care should be taken to ensure that any subsystem requirements for Yucca Mountain do not foreclose design options that ensure the best long-term repository performance.

For example, in 10 CFR 60, there is a subsystem requirement that "the geologic repository shall be located so that the preemplacement ground water travel time along the fastest path of likely radionuclide travel from the disturbed zone to the accessible environment shall be at least 1,000 years. . ." This regulation was written with the presumption that the repository would be located in a saturated zone. At Yucca

Mountain, the repository is being considered for location in the unsaturated zone where there is a direct pathway to the atmosphere. This subsystem requirement has focused attention on the ground water and away from the gaseous pathway.

As an explicit example of suboptimization, it could be that in a specific geologic setting the requirement to keep ground water travel times to the accessible environment above 1,000 years, as required by 10 CFR 60, might have next to no effect on future individual risks. However, such a requirement could force the repository design team to alter the specific location of the emplaced waste to a location that, although it could meet the travel-time requirement, would be less optimal. That is, it could imply greater future individual risks — due to other factors such as, for example, a less optimal gaseous pathway or a different geochemical setting that would lead to higher radionuclide solubilities or lower retardation.

Minimum Early Release

Several persons suggested to our committee the use of a technology-based standard that would specify a strict release limit from an engineered barrier system during the early life of the repository. A representative proposal of this type would permit the release of less than 1 part in 100,000 per year of the radionuclides present at 1,000 years after repository closure. It was suggested that this proposal would be consistent with the essentially complete containment concept of 10 CFR 60, and would result in essentially no public health impact for an initial period of time of 300 to 1,000 years, during which the integrity of the engineered barrier system could be assured with a high level of confidence.

We find that such a limitation on early releases from the repository would have no effect on the results of compliance analysis over the long term. Nevertheless, some members of the committee believe that such a limitation might provide added assurance of safety in the near term. Whether to provide such assurance by using a limitation on early releases is a policy decision that EPA might wish to consider.

**ADMINISTRATIVE CONSEQUENCES FOR EPA, USNRC,
AND DOE**

Our recommendations, if adopted, will imply the development of regulatory and analytical approaches for Yucca Mountain that are different from those employed in the past and from some approaches currently used elsewhere by EPA. We further note that several parameters important in risk-based assessment require determination by rulemaking. Both the change in approach and the time required to develop a thorough and consistent regulatory proposal and to provide for full public participation in the rulemaking process, particularly in devising the biosphere models, identifying the critical groups, and defining intrusion scenarios, will require considerable effort by EPA.

Indeed, this process probably will take more than the year, that is currently provided for in the statute, for EPA to complete development of a Yucca Mountain standard in a technically competent way. Although it is important to obtain a timely result, we also believe it is important that EPA take sufficient time to produce a thorough, competent, and consistent standard. A similar duty is imposed on USNRC to assure that its regulation implementing the EPA standard is not compromised by time constraints.

Although a new standard and its implementing regulations might not be available within the two years envisioned in the Energy Policy Act of 1992, that does not mean that DOE's Yucca Mountain Site Characterization Project cannot proceed usefully in the interim. The site-characterization and iterative-performance assessment efforts can continue in the absence of a promulgated standard. DOE has, in fact, been making progress consistent with our recommendations with its series of total-system performance assessments (TSPAs) and we hope that progress will continue. For example, the TSPA-1993 reports from the Sandia National Laboratory (Wilson et al., 1994) and Intera, Inc. (Andrews et al., 1994) examined the performance measure of radiation dose to a maximally exposed individual, in addition to consideration of normalized cumulative releases as defined by EPA in 40 CFR 191.13. The TSPA has also reported on repository performance for a period of one million years as well as for the 10,000-year period. Both the dose calculation and extension of the time period move in the direction of our recommendations. On the other hand, progress for some aspects of DOE's program might depend on the nature of EPA's promulgated standard. For

example, the potential risks to a critical group living near Yucca Mountain cannot readily be assessed until the rules for identifying the critical group are defined.