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GAO

Report to the Honorable
Pete Domenici, U.S. Senate

June 2000

RADIATION STANDARDS

Scientific Basis Inconclusive, and EPA and NRC Disagreement Continues

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Abbreviations

DOE	Department of Energy
EPA	Environmental Protection Agency
GAO	General Accounting Office
NRC	Nuclear Regulatory Commission

United States General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

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June 30, 2000

The Honorable Pete Domenici
United States Senate

Dear Senator Domenici:

As the cold war came to a close, the United States shifted its focus from producing nuclear weapons to cleaning up its nuclear weapons production facilities. The Department of Energy (DOE), which manages the U.S. nuclear weapons program, is now cleaning up over a dozen major weapons production sites around the country. In addition, the nation's nuclear power industry is starting to decommission over 100 commercial nuclear power plants located in 31 states, a task that will continue during the coming decades. Furthermore, DOE is determining the feasibility of constructing an underground repository to provide for permanently disposing of much of the nation's highly radioactive waste at Yucca Mountain, Nevada. Until a repository is operational, federal facilities and nuclear power plants across the country will continue to store their highly radioactive waste on-site.

What standards should be used to protect the public from the risks of exposure to low-level radiation remaining at these sites after the nuclear materials and wastes have been removed—or, in the case of Yucca Mountain, to protect the public from exposure to the buried waste—is a question for which two federal agencies share primary responsibility. The Environmental Protection Agency (EPA) issues generally applicable public radiation protection standards and administers the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (Superfund), which governs cleanups of federal and nonfederal facilities. The Nuclear Regulatory Commission (NRC) issues implementing radiation protection standards as part of its mandate to regulate civilian sources of nuclear radiation, and it oversees the decommissioning of commercial nuclear facilities. The states may also be involved in radiation protection efforts under agreements with NRC for nuclear facilities within their jurisdictions. Finally, the National Academy of Sciences has a congressionally mandated role in recommending radiation protection standards for the Yucca Mountain repository.

Historically, EPA and NRC have sometimes differed over how restrictive U.S. radiation protection standards should be, as we reported in 1994.[1] These differences have implications for the pace and cost of federal facility cleanups and commercial decommissioning efforts, as well as for the design and potential development of the Yucca Mountain repository. Concerned about these issues, you asked us to examine the scientific basis for the agencies' radiation protection standards and the costs of implementing them. As agreed with your office, this report examines (1) whether the current U.S. radiation protection standards have a well-verified scientific basis, (2) whether federal agencies have come closer to agreeing on standards since we reported on this issue in 1994, and (3) how implementing these standards may affect the costs of nuclear waste cleanup and disposal activities. During our review, we examined many scientific studies and obtained the views of recognized scientists on the scientific basis of radiation standards. We focused mainly on differences in standards for Yucca Mountain and nuclear cleanup and decommissioning sites because they are prominent current examples of the debate about standards. In addition, the report includes a review, performed by a recognized expert in environmental radiation, of scientific research correlating naturally occurring (background) radiation levels in the United States and around the world with local cancer rates. This review was designed to determine whether the research results might have implications for setting radiation protection standards. (See app. I for a detailed discussion of our scope and methodology.)

Results in Brief

U.S. regulatory standards to protect the public from the potential health risks of nuclear radiation lack a conclusively verified scientific basis, according to a consensus of recognized scientists. In the absence of more conclusive data, scientists have assumed that even the smallest radiation exposure carries a risk. This assumption (called the "linear, no-threshold hypothesis" or model) extrapolates better-verified high-level radiation effects to lower, less well-verified levels and is the preferred theoretical basis for the current U.S. radiation standards. However, this assumption is controversial among many scientists. Some say that the model is overly conservative and that below certain exposure levels, there is no risk of cancer from radiation. Others say that the model may underestimate the risk. The research evidence is especially lacking at regulated public

[1] *Nuclear Health and Safety: Consensus on Acceptable Radiation Risk to the Public Is Lacking* (GAO/RCED-94-190, Sept. 19, 1994).

exposure levels—levels of 100 millirem a year and below from human-generated sources. Interest among scientists in obtaining a more conclusive understanding of the effects of low-level radiation has been evident in recent federally funded initiatives, including a reassessment by the National Academy of Sciences of the latest research evidence on the risks of low-level radiation, begun in the summer of 1998 and planned to conclude in 2001. Also, a 10-year DOE research program, begun in fiscal year 1999, has been specifically addressing the effects of low-level radiation within human cells, in part to help verify or disprove the linear model.

Lacking conclusive evidence of low-level radiation effects, U.S. regulators have in recent years set sometimes differing exposure limits. In particular, EPA and NRC have disagreed on exposure limits. Although we recommended as far back as 1994 that the two agencies take the lead in pursuing an interagency consensus on acceptable radiation risks to the public, they continue to disagree on two major regulatory applications: (1) the proposed disposal of high-level nuclear waste in a repository at Yucca Mountain and (2) the cleanup and decommissioning of nuclear facilities. Centrally at issue between the two agencies is groundwater protection. On the one hand, EPA applies community drinking water limits for radioactive substances to groundwater at nuclear sites, as a matter of water resource protection policy. Some of these limits are equivalent to fractions of a millirem a year. On the other hand, NRC includes groundwater and other potential contamination sources under a less restrictive limit of 25 millirem a year for all means of exposure,[2] an approach that conforms to internationally recommended radiation protection guidance. As applied in proposed standards for nuclear waste disposal at Yucca Mountain, EPA's groundwater approach has been criticized as technically unsupported by the National Academy of Sciences, which the Congress mandated to recommend standards for the repository. However, the Academy recognizes that EPA has the authority to establish a separate groundwater limit for Yucca Mountain, and EPA believes its groundwater protection approach for the repository to be technically justified. As applied to nuclear cleanup and decommissioning sites where both EPA and NRC may have jurisdiction, the two agencies' different regulatory approaches have sometimes raised questions of inefficient, conflicting, dual regulation. There has been little progress in finalizing a memorandum of

[2]These means of exposure, called "pathways" by specialists, include exposure through soil, water, and air.

understanding, encouraged by the House Appropriations Committee in August 1999, to resolve EPA's and NRC's conflict about cleanup standards. Given their historical differences, EPA and NRC may not easily agree on groundwater protection standards for Yucca Mountain or on their respective regulatory roles relating to nuclear cleanup and decommissioning sites. This report contains a matter for congressional consideration suggesting that, in such a situation, the Congress may wish to help resolve the agencies' disagreement.

The costs of implementing different radiation standards vary, depending on the standards' restrictiveness. Generally, the costs increase as the standards become more restrictive. Comprehensive estimates of overall costs to comply with current and prospective standards were unavailable, but these costs could be immense, considering that federal agencies expect to fund hundreds of billions of dollars in nuclear waste disposal and cleanup projects over many years in the future. According to DOE's and NRC's analyses of cleanup options for individual sites, costs per site can be many millions of dollars higher to comply with more restrictive standards than less restrictive standards, as might be expected. For example, a 1995 DOE analysis of cleanup options for plutonium-contaminated test ranges at the Nevada Test Site estimated $35 million in costs to achieve a 100-millirem-a-year-level, over three times as much to achieve a 25-millirem-a-year level, and over six times as much to achieve a 15-millirem-a-year level. Finally, the analysis showed costs that were over 28 times higher to achieve a 5-millirem-a-year level, illustrating that compliance costs accelerate rapidly to achieve the most restrictive protection levels.

We presented a draft of this report to NRC, DOE, and EPA for comment. NRC found the report to be fundamentally sound, and DOE found it to be factual and balanced. EPA disagreed with the report's conclusions, particularly our conclusion that there has been little progress on the finalization of a memorandum of understanding to resolve EPA's and NRC's conflict about cleanup standards. However, although the two agencies are developing such a memorandum, they have had long-standing differences, and we question whether their latest efforts will resolve these differences without congressional intervention. All three agencies provided technical comments on the report. In response to the comments received, we made some changes to the report's presentation.

Background

Nuclear radiation can be generally categorized as either low-level or high-level radiation. The low-level range includes exposures up to about 10,000 total millirem, [3] although the term commonly is used to refer to exposures of a few hundred millirem or less.[4] The lower portion of the low-level range includes natural background radiation levels, and the lowest portion of this range includes public exposure levels regulated under various U.S. radiation standards, as shown in appendix II.[5] Natural background radiation levels vary around the world, from below 100 millirem of exposure a year in some places to several hundred millirem a year in others, with even higher levels recorded in "hot spots." In the United States, average natural background radiation exposure is about 300 millirem a year. In addition, medical practices, such as X-rays and nuclear medicine, and industrial nuclear operations contribute average public exposures of about 50 millirem a year and 0.1 millirem a year, respectively. Radiation from within one's own body, largely from naturally present radioactive potassium, contributes almost 40 millirem a year, on average. As shown in appendix II, regulatory public exposure limits vary from a few millirem a year up to 100 millirem a year. At these levels, radiation is only one of many environmental and biological events (such as heat) that may alter (mutate) cell structure, and low-level radiation is commonly considered to be a relatively weak source of cancer risk.[6] To counter these cellular-level mutations, the human body has active repair processes, although these processes are not entirely error-free, and their relevance to human cancer risk remains unclear. Should a radiation-caused cancer develop in one or more cells, the process may take years, and the source of the cancer will be verifiable only in exceptional cases, given the current limited

[3]A millirem is a commonly used unit of measurement of the biological effect of radiation. The radiation from a routine chest X-ray is equivalent to about 6 millirem.

[4]Above about 30,000 total millirem, radiation exposure is a well-known cause of cancer. Instantaneous (or short-duration) exposures of about 200,000 total millirem can cause blood cell changes, infections, and temporary sterility. Short-duration exposures above about 400,000 total millirem can cause death within days or a few weeks and are associated with catastrophic nuclear accidents or atomic bomb blasts.

[5]U.S. worker protection standards limit annual exposures to 5,000 millirem. See app. II.

[6]About 187,000 spontaneous cell-altering events occur daily in each human cell. Low-level radiation exposures increase the number of such events by a small fraction—about 1 percent. There is evidence that the type of damage done by such radiation has a higher probability of resulting in DNA misrepair than the type of damage done by other normally occurring cell-altering events.

understanding of how cancer develops. Although nearly one in four persons in the United States dies of cancer from all causes, low-level radiation presumably accounts for a very small fraction of these cancers, if any. However, the fraction cannot be quantified.

Federal agencies, and in some instances states, administer U.S. radiation standards. EPA and NRC administer the majority of the federal standards. EPA issues environmental radiation protection standards as mandated under Presidential Reorganization Plan No. 3 of 1970. NRC issues standards as part of its mandate to regulate civilian sources of nuclear radiation, under the Atomic Energy Act. (Under the same act, DOE has issued public and worker exposure limits applicable on-site at the agency's nuclear installations.) Both EPA and NRC have regulatory roles related to nuclear waste disposal and nuclear site cleanup and decommissioning. For example, under the Energy Policy Act of 1992, both have roles at the proposed Yucca Mountain repository in southern Nevada. The proposed function of the repository is to receive and dispose of high-level waste from DOE sites and commercial power plants around the country. EPA has the role of issuing standards to protect the public from releases of radioactive materials from the facility, and NRC has the role of issuing technical requirements and criteria and licensing the facility. Under the act, exposure limits in NRC's final technical requirements and criteria are to be consistent with the limits in EPA's final public protection standards. DOE's role at Yucca Mountain will be as the developer and prospective operator of the repository, and the Department is pursuing the goal of deciding in 2001 whether to recommend the site to the President as suitable for nuclear waste disposal. Also involved in Yucca Mountain oversight are expert advisory bodies, including the Nuclear Waste Technical Review Board and the National Academy of Sciences, which was mandated under the Energy Policy Act of 1992 to recommend standards for the repository. In regard to nuclear cleanup and decommissioning activities, both EPA and NRC have mandated roles: EPA administers Superfund, the legislation that governs cleanups of federal and nonfederal facilities, and NRC regulates the decommissioning of over 100 active commercial nuclear power plants, as well as other commercial nuclear facilities, under the Atomic Energy Act.[7,8]

Our September 1994 report on radiation protection issues found that U.S. radiation standards reflected a lack of federal agency consensus on acceptable radiation risk to the public, as well as a lack of interagency coordination on standards. Among the reasons we found for the lack of consensus were differences in agencies' historical missions and legislative mandates, as well as differences in agencies' regulatory strategies, particularly in those of EPA and NRC. For example, EPA has historically in many cases implemented a risk-based radiation protection approach, under which the agency addresses individual contamination sources, coregulates chemicals and radioactive substances, and protects both human health and environmental resources.[9] In accordance with its tradition of regulating chemicals, EPA has generally set a risk of 1 in a million that an individual will develop cancer in a lifetime as a goal for remediation and has considered a risk of greater than 1 in 10,000 to be potentially excessive. EPA's approach has been described as "bottom up," setting a relatively restrictive risk goal to be pursued through the best available technology—but allowing less restrictive limits in site-specific situations. In contrast, NRC favors a dose-based, radiation-specific protection approach that focuses on human health protection.[10] NRC's protection strategy has been

[7]Superfund regulations call for, among other steps, the development of cleanup alternatives through a remedial investigation, the finalization of applicable cleanup requirements, and a formal record of decision on an agreed cleanup level, after which cleanup is conducted. Decommissioning involves the removal of all radioactive components and materials from the facility and the cleanup of radionuclides to NRC's standards (10 C.F.R. 20).

[8]The coordination of federal radiation protection issues is the responsibility of the federal Interagency Steering Committee on Radiation Standards, and coordination among states is the responsibility of the Conference of Radiation Control Program Directors. In addition, authoritative national and international technical organizations make recommendations on radiation protection issues, including the congressionally chartered U.S. National Council on Radiation Protection and Measurements, the International Commission on Radiological Protection, and the United Nations Scientific Committee on the Effects of Atomic Radiation.

[9]EPA's protection approach draws, in part, on experience with regulating thousands of different chemicals, many of which pose risks that are generally thought to be even less well understood than radiation risks. These chemicals may or may not exist naturally in the environment.

[10]NRC's approach (with which DOE generally concurs) draws on experience in estimating radiation-specific risks, within an internationally recommended radiation dose limitation and risk assessment framework. The framework takes into account that radiation exists naturally in the worldwide environment.

described as a “top down” approach. Compared with EPA, NRC sets a relatively less restrictive dose limit but reduces doses (and risks) well below the limit in site-specific situations where the reductions are “reasonably achievable.”[11]

U.S. Public Radiation Protection Standards Lack a Conclusive Scientific Basis

The standards administered by EPA and NRC to protect the public from low-level radiation exposure do not have a conclusive scientific basis, despite decades of research. These standards are based on a hypothetical model of low-level radiation effects. The model, derived from studies of large populations (in the tens of thousands) exposed to radiation, extrapolates better-verified high-level radiation effects to lower, less well-verified levels. The standards protect at annual millirem levels considerably lower than the better-verified levels. According to a consensus of scientists, there is a lack of conclusive evidence of low-level radiation effects below total exposures of about 5,000 to 10,000 millirem. The model under which these effects are assumed, lacking conclusive evidence, is called the “linear, no-threshold” hypothesis or model. According to this model, even the smallest radiation exposure carries a quantifiable cancer risk. The model, which has been endorsed by national and international radiation protection organizations and used for many years as a preferred model in regulating low-level radiation, is a fundamental basis for U.S. radiation standards. There is interest among scientists in obtaining more conclusive evidence of radiation effects, and a DOE research program that is examining cellular low-level radiation effects may eventually help to develop a better understanding of the cellular processes of radiation cancer causation.

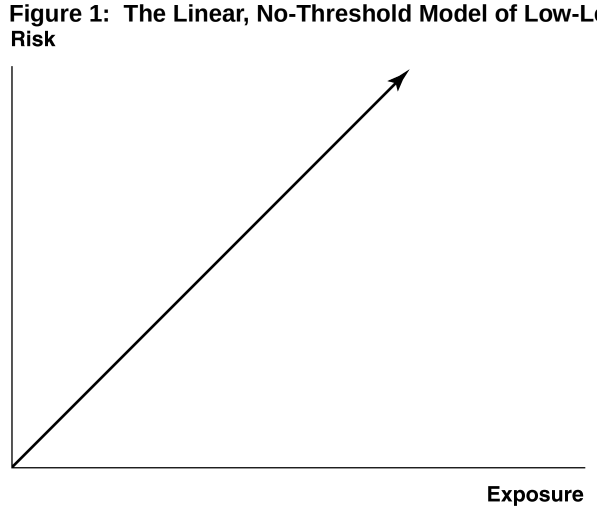
Low-Level Radiation Effects Are Assumed for Regulatory Purposes

Conclusive evidence of radiation effects is lacking below a total of about 5,000 to 10,000 millirem, according to the scientific literature we examined and a consensus of scientists whose views we obtained. At these

[11]NRC’s 25-millirem-a-year dose limit is equivalent to 1 chance in about 1,000 of a fatal cancer over a 70-year lifetime, using a commonly accepted dose-risk conversion factor and assuming the linear model of radiation effects holds.

levels, authoritative bodies have estimated radiation risks through complex modeling of the available data,[12] and regulators have assumed that even the smallest radiation exposure carries a risk. This assumption is commonly referred to as the linear, no-threshold hypothesis or model. Extrapolated mainly from high-dose effects reported for Hiroshima and Nagasaki survivors, the linear model assumes that radiation health effects are proportional to exposure. As figure 1 shows, the model uses a straight line to extrapolate risks all the way down to zero. From zero upward, the model assumes that as exposure doubles, risk doubles, and that no entirely risk-free exposure level or threshold exists.

Figure 1: The Linear, No-Threshold Model of Low-Level Radiation Effects



Radiation protection organizations such as the National Council on Radiation Protection and Measurements and the International Commission on Radiological Protection have historically endorsed the model, and U.S. regulators have used it as a preferred, plausible model, but it is controversial. On the one hand, the model is widely considered to be a useful, relatively mathematically simple working hypothesis that may be

[12]For example, a 1990 study by a National Academy of Sciences committee, called BEIR V, estimated that, at the 90-percent statistical confidence interval, out of 100,000 adults exposed to 100 millirem a year of radiation over a lifetime, anywhere from 410 to 980 men and 500 to 930 women might die of cancer caused by the exposure. This confidence interval assumes the validity of the linear model and reflects the uncertainty of inputs to the model.

conservative—that is, it may not underestimate risks. Regulators make use of the model in doing risk assessments, regulatory impact analyses, cost-benefit analyses, and other studies to support their decision-making. In using the model, they are able to estimate risk reductions and hypothetical lives saved from regulating at a given exposure level. On the other hand, many scientists question the validity of the model. The consensus view we encountered is that the research data on low-level radiation effects are inadequate either to establish a safety threshold or to exclude the possibility of no effects. Scientists we contacted and scientific literature we examined generally did not indicate that any one model clearly best fit the overall data. Instead, there was evidence that any of several models may "fit." (See app. III.) Some researchers also said low-level radiation effects are likely too complicated and variable to be expressed in a single model. There is evidence that the relationship may vary in individuals, and with the type of radiation, type of cancer, body organs exposed, sex, and/or age at exposure. We also found considerable agreement among regulators and scientists that the linear model may be a conservative "fit" to the data, unlikely to underestimate risks. However, some said the data support the existence of a safety threshold below which there are no risks, and others said low levels of radiation can be beneficial to health. This is a highly controversial theory, called hormesis, which is in part based on the documented ability of the body to repair cell damage—referred to as adaptive response. However, other scientists pointed to studies indicating the linear model may actually understate radiation risks, especially to fetuses and children.[13]

Authoritative radiation protection organizations and committees have given the linear model a qualified endorsement. For example, in 1990, a committee of the National Academy of Sciences, the Biological Effects of Ionizing Radiation Committee (BEIR V), reported that the linear model was not inconsistent with the available research data. According to the committee's report, at low radiation exposures, risks either less or greater than linearity—and the existence of a threshold in the low-level dose range—cannot be excluded, and "the possibility that there may be no risks from exposures comparable to external natural background radiation cannot be ruled out. At such low doses, it must be acknowledged that the lower limit of the range of uncertainty in the risk estimates extends to zero." In addition, a 1994 report of the United Nations Scientific Committee

[13]There is evidence of mental retardation linked to fetal exposure to low-level radiation. Age at time of exposure appears to be an important determinant of cancer risk from radiation.

on the Effects of Atomic Radiation (UNSCEAR) stated that "there are theoretical reasons based solely on the nature of DNA damage and repair to expect that cancer can occur at the lowest doses without a threshold in the response, although this effect would perhaps not be statistically demonstrable."[14] Despite the linear model's unproven and controversial status among scientists, some scientists said the model is so well accepted that it could only be superseded on the basis of overwhelming contrary evidence.

Research Efforts to Verify Low-Level Radiation Effects Are Ongoing

Two types of important research into low-level radiation effects have been conducted. One type of study painstakingly follows the long-term health of individuals in large populations exposed to radiation, seeking statistically significant patterns of elevated cancer risks from the radiation exposures. These are called epidemiological studies. Another type of study subjects animals or tissue or cell cultures to radiation, seeking biological evidence of radiation effects. These are called radiobiological studies.

Epidemiological studies may never conclusively prove or disprove the linear model, according to some scientists. Epidemiological studies have been a key basis for the linear model, including the research evidence accumulated on over 85,000 Japanese survivors of the Hiroshima and Nagasaki bomb blasts. The study, conducted by the international Radiation Effects Research Foundation, has well established the effects of radiation at high exposure levels, and scientists have extrapolated this relationship to the low-level radiation range as well—with considerable inherent uncertainty.[15] However, some scientists have questioned the project's results, asserting among other concerns that the basic estimates of the Hiroshima and Nagasaki doses (and their neutron component, for example) still need to be reevaluated, even after decades of effort devoted to determining these doses.

As noted, epidemiological studies require large study populations for the research results to be statistically powerful. Epidemiologists consider two

[14]The British National Radiation Protection Board similarly maintains, in consideration of relevant cellular and molecular data, that the weight of evidence falls decisively in favor of the thesis that for a majority of common human tumors, low-dose and low-dose-rate cancer risk rises as a simple function of dose with no threshold.

[15]According to one expert, extrapolating effects from high exposures to low exposures equivalent to natural background radiation levels is more guesswork than science.

types of epidemiological studies—analytic or ecologic. Analytic studies either compare individuals who have been exposed to radiation to individuals who have not been exposed and determine if there are subsequent differences in their health status (cohort studies) or compare individuals who have a disease to those who do not to determine if there were differences in the past exposures of the two groups (case control studies). Ecologic studies rely on regional data on disease and radiation levels, instead of individual data, and are considered to be less reliable than analytic studies. Analytic and ecologic studies have attempted to correlate regional natural background radiation levels with regional cancer rates at locations in the United States, Europe, Asia, Brazil, Iran, and other places. A premise related to such studies is that, if the linear model holds, cancer rates should be higher at locations where natural background radiation levels are significantly higher. With the help of an expert consultant, we examined 82 studies, which generally found little or no evidence of elevated cancer risks from high natural background radiation levels. A large number of studies reported a lack of evidence of cancer risks, some others reported evidence of slightly elevated risks, and some others reported evidence of slightly reduced risks. Overall, the studies' results are inconclusive, but they suggest that at exposure levels of a few hundred millirem a year and below, the cancer risks from radiation may be either very small or nonexistent. (See app. IV.)

Radiobiological studies, particularly molecular studies, may eventually develop more conclusive scientific evidence of low-level radiation effects than epidemiological studies, according to scientists. Past radiobiological research has helped to establish, among other evidence, the genetic effects of radiation and its effects on individual body organs. Recently, there has been interest in research into the cellular processes through which radiation causes cancer, in part in relation to progress in human genome research in the 1990s.[16] Researchers have been obtaining a better understanding of specific phenomena such as DNA damage and repair, chromosomal instability, so-called "bystander" effects on neighboring cells, and cellular adaptation to exposures. Researchers are looking into such cellular processes for biological signs (or "biomarkers") of radiation cancer causation. Several stages are apparent in the development of radiation-caused cancer: DNA damage, misrepair, cancer initiation, cell proliferation, and tumor promotion (with subsequent malignant transformation). To date, the first stage in the process is better understood than the long-term second

[16]Such research focuses on cells' nuclei, where DNA is located.

stage. Since fiscal year 1999, DOE has funded a research program targeting the biological effects of low-level radiation at the cellular level, with total funding of almost $220 million projected over 10 years. The program is considered unique in that it is designed specifically to better validate the effects of very low levels of radiation in areas such as cells' response to radiation damage, thresholds for low-dose radiation effects, and features distinguishing radiation-caused cell damage from damage from causes internal to the cell. Many scientists and regulators we interviewed said this type of research could eventually help to determine more conclusively the effects of low-level radiation and their potential link to cancer causation.

In October 1998, the National Academy of Sciences contracted to reassess the linear model and risk estimates for low-level radiation, at the request of U.S. regulators, including EPA, NRC, and DOE. The regulators, acting through the Interagency Steering Committee on Radiation Standards, concluded that enough research progress had been made in the 1990s to warrant the study. The Academy last did such an assessment in 1990, called BEIR V. The latest assessment, called BEIR VII, is to be completed by 2001.[17] High expectations have been set for the BEIR VII committee, reflecting the scientific controversy surrounding the linear model and low-level radiation effects. For example, in requesting the effort, EPA, DOE, and NRC asked the committee to focus on areas the agencies do not believe were emphasized in the previous BEIR V effort. EPA asked the committee to provide a clear indication of the weight of evidence for risks at low doses and dose rates and to carefully assess the sources of any inconsistencies in the results from different epidemiological studies. DOE asked BEIR VII to consider epidemiological studies on nuclear workers, and NRC asked the committee to focus especially on evidence of radiation effects at the lowest portion of the low-level radiation range, at levels where regulators set radiation standards, and to consider evidence of hormesis. Also, the committee is committed to fully assessing all pertinent research data, not just the data that have been traditionally influential, such as the Hiroshima and Nagasaki data. Because of its broad focus, the BEIR VII assessment could produce instructive results, but some agency officials and scientists said the amount of new research data available might not be sufficient to lead the committee to either fully validate or disprove the linear model. An EPA official said he expected the BEIR VII work to support the continued use of the linear model for regulatory purposes.

[17]BEIR VI was a 1999 Academy assessment of risks from radon.

EPA and NRC Continue to Disagree on Major Radiation Standards for Public Protection

We reported in 1994 that federal agencies' radiation standards reflected a lack of consensus on acceptable risk to the public. Today, this situation persists, and EPA and NRC, the principal federal radiation standard-setting agencies, continue to disagree significantly on regulatory approaches and standards related to groundwater protection. Two major instances of their disagreement are proposed standards for the prospective Yucca Mountain high-level-waste repository and standards for the cleanup and decommissioning of federal and commercial nuclear facilities. For these applications, EPA favors both (1) a public protection limit of 15 millirem a year from all radiation sources through all means of exposure—called "all pathway" protection by specialists—and (2) extra protection of groundwater resources under sites, at limits originally set for community drinking water systems, equivalent to 4 millirem a year. Alternatively, NRC favors a single 25-millirem-a-year all-pathway public protection limit, within which groundwater is a potential pathway.[18] This disagreement has complicated planning for the prospective Yucca Mountain high-level waste repository, on which a national decision is to be made in 2001, as well as day-to-day planning for facility decommissioning by commercial nuclear operators licensed by NRC. In both of these cases, it remains to be seen whether EPA and NRC can resolve their differences or whether the Congress will need to intervene.

EPA and NRC Have Proposed Different High-Level-Waste Disposal Standards

The disagreement between EPA and NRC on groundwater protection is reflected in differences in the radiation standards set by the two agencies but appears most notably in the debate over proposed draft standards for the Yucca Mountain, Nevada, high-level-waste repository. Radiation standards are an important part of the ongoing debate about the future of the planned facility. Both EPA and NRC issued proposed radiation protection standards for the repository in 1999, NRC in February and EPA in August. The agencies differ on proposed all-pathway limits (15 millirem a year versus 25 millirem a year), and especially on extra groundwater protection. The groundwater issue at Yucca Mountain relates to differences in the two agencies' overall resource protection policies, as well as technical details. EPA's approach reflects its attempt to implement a

[18]EPA's approach includes various levels of acceptable risk, from 1 chance in about 2,000 to less than 1 chance in about a million of a fatal cancer over a 70-year lifetime. NRC's all-pathway approach involves a level of acceptable risk of 1 chance in about 1,000 of a fatal cancer over a lifetime. These calculated risks are based on a commonly used dose-risk conversion factor, assuming the linear model holds.

consistent policy, across various standards, of protecting groundwater as a national resource, in line with community drinking water standards established in regulations under the Safe Drinking Water Act. (According to EPA, the policy is based on preventing pollution before it occurs. If pollution has occurred, the polluter should be responsible for the costs of cleanup.) On the other hand, NRC believes its all-pathway approach is fully protective of human health at Yucca Mountain and elsewhere. In the Commission's view, EPA's drinking water standards were not originally intended for an application such as Yucca Mountain, and the Commission questions EPA's technical basis for proposing extra groundwater protection.[19,20]

NRC has been joined in its views by DOE and some others who have commented on EPA's proposed Yucca Mountain standards, including the National Academy of Sciences. The Academy has questioned the technical basis for EPA's extra groundwater protection approach. Specifically, the Academy, together with NRC, DOE, and other commenters, has asserted, first, that EPA has not provided a technical rationale for its approach. By contrast, according to these commenters, NRC has a technically based rationale for its approach that is in accord with internationally recommended radiation protection practices. Second, the Academy and others have pointed out that the drinking water concentration limits to be applied to groundwater at the repository are outdated, reflecting doses and risks that are inconsistent. These limits consist of dozens of numerical maximum contaminant levels for radionuclides, expressed in picocuries per liter, which reflected consistent doses and risks when they were

[19]The agencies also disagreed on low-level waste disposal standards in the mid-1990s. Current low-level waste standards consist of NRC's 25-millirem-a-year all-pathway limits that date from 1983. In 1994, EPA considered issuing its own standards, reflecting 15-millirem-a-year all-pathway protection, plus extra groundwater protection to drinking water standards. At the time, DOE estimated over $300 million in added annual costs if its disposal sites and commercial disposal sites were required to comply with the approach EPA was considering.

[20]In addition, in 1994, EPA issued transuranic waste disposal standards for the Waste Isolation Pilot Project in southeastern New Mexico (40 C.F.R. 191) that include 15-millirem-a-year all-pathway limits, plus extra groundwater protection to drinking water standards. NRC expressed concerns about the groundwater protection standards but concurred with them because on-site groundwater was not an issue in EPA's project certification process—the aquifer was brine. Transuranic waste is tools, rags, laboratory equipment, and other items contaminated with radioactive elements, mostly plutonium.

established in regulations implementing the Safe Drinking Water Act of 1976.[21] These limits are outdated under the latest risk estimation methods.

In particular, the Academy, in its congressionally-mandated role of recommending reasonable standards for protecting health and safety at the repository, has questioned EPA's groundwater protection approach for Yucca Mountain. The Academy did not propose separate groundwater protection standards for the repository in its own technical recommendations for the facility, which were issued in 1995. The Academy's November 1999 comments on EPA's draft standards directly opposed such an approach, calling it "scientifically unsupported," adding little or no public health benefit.[22] According to the Academy, EPA has the authority to establish a separate groundwater limit for Yucca Mountain but has not presented a technical rationale for doing so. In addition, NRC and DOE have commented that EPA has not done a comprehensive analysis of the health benefits and costs of its groundwater approach for Yucca Mountain. EPA has issued a draft regulatory impact analysis to accompany its draft Yucca Mountain standards, in accordance with Executive Order 12866, which calls for such an analysis if the regulatory action is significant (for example, raises novel legal or policy issues). However, the draft regulatory impact analysis was limited in scope (stating that data were lacking for a fuller discussion), and the document did not analyze the specific impact of EPA's groundwater protection approach for the repository.

EPA recognizes that the drinking water contamination limits that are to be applied at the repository are not scientifically up to date. They are based on 1970s-era methods of radiation dose estimation, which have been superseded. The limits were originally intended to be equivalent to 4 millirem a year of exposure. However, under updated dose estimation methods, they no longer reflect 4 millirem a year. Instead, using a commonly accepted dose conversion factor, they reflect varying annual millirem levels and acceptable risks, and some reflect millirem levels up to a thousand times lower than average U.S. natural background radiation levels. A few of the limits are equivalent to well above 4 millirem a year, but

[21]Under 40 C.F.R. 141, annual concentrations of beta particle and photon activity sources are limited to no more than a total body or internal organ dose equivalent of 4 millirem a year. See app. II.

[22]On the other hand, the Academy found the magnitude of EPA's proposed 15-millirem-a-year all-pathway limit to be consistent with the Academy's own recommendations.

many are equivalent to fractions of a millirem a year.[23] NRC has commented that because groundwater is expected to be the dominant exposure pathway at Yucca Mountain, these limits will be the de facto overall protection standards for the repository.

According to EPA officials, the agency's proposed standards and groundwater protection approach for Yucca Mountain are justified on policy grounds and are technically justifiable as well. The agency has applied drinking water standards to groundwater at the repository, EPA officials said, because it desires to protect groundwater as an environmental resource (for drinking water and irrigation needs) in a region where the population has been growing quickly. In addition, the agency has a general policy of coregulating chemicals and radionuclides in groundwater, and EPA officials said the standards for Yucca Mountain should be in accord with this policy. EPA officials agreed that the agency has not done a comprehensive analysis of the health benefits and costs of the agency's groundwater approach for Yucca Mountain, but they believe their regulatory approach has fully addressed the pertinent overall technical issues related to setting radiation protection standards for the site. They said they are developing an expanded regulatory impact analysis to accompany their final standards, which will not constitute a specific technical rationale for their extra groundwater protection approach but will address technical and cost issues related to the implementation of their standards, as the Academy recommended.

While recognizing that the drinking water concentration limits to be applied at Yucca Mountain are out of date, reflecting inconsistent doses and risks, EPA officials said the agency is in the process of updating the limits and expects to complete this effort by the fall of 2000. They said that if the final Yucca Mountain standards are issued before then, the updated limits will be incorporated into them. The officials noted that under a "no backsliding" provision of the 1996 Safe Drinking Water Act Amendments, any updated drinking water standards for radionuclides must maintain

[23]For example, the limit for Iodine 129, considered a benchmark among the various limits for Yucca Mountain, is 1 picocurie per liter, or about 0.2 millirem a year; the limit for Nickel 63 is 50 picocuries per liter, or about 0.02 millirem a year, and the limit for Tritium is 20,000 picocuries per liter, or about 0.9 millirem a year. In addition, the limits reflect acceptable lifetime risks ranging anywhere from less than 1 chance in a million to more than 1 chance in 2,000 of a person dying from the exposure, using a commonly accepted dose-risk conversion factor and assuming the linear model holds. EPA points out that most limits fall within its acceptable risk range of 1 chance in about 10,000 to 1 chance in about a million of a person getting cancer from the exposure.

equal or greater levels of public health protection. According to EPA, this provision precludes the agency from raising any of the concentration limits, even in attempting to achieve greater uniformity in doses or risks.[24] A draft version of the proposed new limits indicates that EPA may not change any of the limits.[25]

As EPA and NRC prepare to issue final standards for Yucca Mountain, it is not evident that the two agencies and the Academy will agree on appropriate groundwater protection standards for the repository. If they do not agree, EPA's final Yucca Mountain standards, expected to be issued in the summer of 2000, will lack a degree of technical consensus that would add to their credibility and acceptability. Aware of the conflict between EPA and NRC over standards for Yucca Mountain, the Congress, in March 2000, passed legislation retaining EPA's standard-setting authority while (1) allowing the Academy and NRC to report to the Congress any major disagreements they may have with EPA's final standards and (2) delaying the issuance of final standards for Yucca Mountain until June 2001. On April 25, 2000, the President vetoed the bill, in part because it would have limited EPA's authority to issue radiation standards, and on May 2, 2000, the Senate upheld the veto.

EPA and NRC Have Issued Different Standards and Guidance for Nuclear Site Cleanup and Decommissioning

Both EPA and NRC developed nuclear site cleanup and decommissioning standards in the 1990s, attempting to facilitate the massive national effort to clean up nuclear contamination at many federal and commercial nuclear sites—including DOE's nuclear weapons complex and commercial nuclear power plants licensed by NRC —that are closing down after decades of operations. In 1995, EPA drafted cleanup standards reflecting the agency's groundwater protection approach, which includes 15-millirem-a-year all-pathway protection, plus separate groundwater protection to drinking water standards. However, the agency withdrew these standards in 1996, before they were finalized, after other agencies objected to them. Subsequently, in 1997, EPA implemented the same approach through

[24]Another technically related groundwater issue is EPA's prospective choice of a groundwater scenario for Yucca Mountain, including the point of enforcement (at or how near to the repository boundary) and appropriate estimated groundwater flow volume. DOE and NRC officials said a very conservative scenario could severely complicate DOE's efforts to do detailed, refined groundwater analysis for the site.

[25]According to EPA, the new limits are to be based on acceptable risks instead of the current dose basis of 4 millirem a year.

nonbinding Superfund guidance. Also in 1997, NRC finalized its own cleanup standards—decommissioning standards for its licensees—reflecting 25-millirem-a-year all-pathway protection.[26] In correspondence with NRC, EPA has objected to NRC's standard as potentially not protective in all cases.[27] In some cases, both EPA's and NRC's approaches have both been applied to the same site, raising questions about potential dual regulation.

EPA and NRC have long disagreed on standards for cleaning up and decommissioning the nation's nuclear sites. As far back as 1992, the two agencies signed a memorandum of understanding, agreeing to avoid unnecessary duplication of regulatory requirements. In 1994, we reported that EPA and NRC were involved in potentially costly dual regulation of NRC's licensees. Our previous report's recommendation that the agencies pursue consensus on acceptable risk was a factor in the establishment in 1995 of the Interagency Steering Committee on Radiation Standards, which is cochaired by EPA and NRC. However, despite numerous staff initiatives and some progress in cooperation, this committee has not resolved major issues between the two agencies. The two agencies have continued to use separate approaches in setting standards for cleaning up and decommissioning nuclear sites, especially when groundwater protection is involved. Consequently, perceived dual regulation by EPA and NRC continues to complicate the cleanup and decommissioning process at some sites where both agencies' standards may apply, potentially causing duplication of effort and regulatory delays, adding to facilities' compliance costs, and raising public questions about what cleanup levels are appropriate and safe.[28]

[26]In addition, DOE has issued public protection orders for its nuclear installations that generally conform to NRC's approach, including all-pathway protection without extra groundwater protection, as well as dose reductions to levels as low as reasonably achievable. DOE has proposed to convert its order into a regulatory standard, but EPA has opposed the draft standard as inconsistent with Superfund requirements.

[27]In 1994, NRC considered standards comparable to EPA's—15 millirem a year, with separate groundwater protection to drinking water standards—but changed to an all-pathway, 25-millirem-a-year approach after further analysis and public comments on the proposed rule.

[28]Also, over the years, differences between EPA and DOE concerning standards and acceptable risks for cleanups at DOE sites have contributed to regulatory delays and higher regulatory and cleanup costs while raising public questions about what cleanup levels are appropriate. See Nuclear Cleanup: Completion of Standards and Effectiveness of Land-Use Planning Are Uncertain (GAO/RCED-94-144, Aug. 26, 1994).

For example, in individual situations at NRC-licensed sites, EPA has indicated that it might not view cleanups performed to NRC's standards as adequately protective under its Superfund guidance. EPA considers such potentially conflicting situations to be exceptions, not the rule. EPA raised the matter of the standards' adequacy twice in 1999 in connection with nuclear power plants in Maine and Connecticut where the decommissioning process is under way, and again in connection with the West Valley, New York, nuclear site, a DOE-operated facility where NRC has a legislatively mandated regulatory role. In such situations, the licensee may construe EPA's involvement as a warning that EPA could reevaluate the adequacy of a cleanup that has met NRC's requirements. In the New England cases, the licensee has thus far responded to the prospect of dual regulation by proceeding with its decommissioning plans, assuming that it will be able to comply with both agencies' standards.[29] In the West Valley case, it remains to be seen whether NRC's or EPA's approach will finally be chosen for the site.

Our 1994 report found that U.S. radiation standards reflected a lack of federal agency consensus on acceptable radiation risk to the public, particularly between EPA and NRC. We recommended that the two agencies take the lead in pursuing interagency consensus on acceptable radiation risks to the public. In succeeding years, EPA and NRC have attempted to resolve their conflict over cleanup standards by means of a memorandum of understanding that would clarify their potentially conflicting, dual regulation of NRC-licensed sites. In August 1999, the House Appropriations Committee strongly encouraged the two agencies to develop such a memorandum and directed them to report to the Congress by May 1, 2000, on the status of their efforts to do so.

In early May 2000, EPA and NRC informed the Committee by separate letters that they are developing such a memorandum, although a jointly drafted version of the memorandum does not yet exist. To date, EPA officials see such a memorandum as providing an outline of consultation procedures for EPA and NRC to use during NRC's decommissioning process when NRC requests EPA's assistance. It is unclear whether the memorandum will consider whether EPA should retain its authority to conduct a Superfund evaluation of an NRC-licensed or -decommissioned

[29]The licensee has stated that it can meet more stringent standards of 10 millirem a year, plus extra groundwater protection to the equivalent of 4 millirem a year, as imposed by the state of Maine.

facility when a stakeholder requests such an evaluation. EPA believes it should retain this authority and has provided guidance to its regional offices on how to proceed when a stakeholder asks for an evaluation. According to this guidance, EPA believes that at the vast majority of NRC-licensed sites, cleanups that meet NRC's standards will also meet Superfund standards. An NRC draft version of the memorandum assumes that EPA will defer to NRC's radiological cleanup and decommissioning standards and regulations and will exempt most NRC-regulated sites from the application of the Safe Drinking Water Act and Superfund. NRC's version reflects the Commission's view that clearly delineated jurisdictions for the two agencies are needed.

Costs Vary to Comply With Different Radiation Standards

Long-term costs related to complying with current and prospective U.S. radiation standards have generally not been comprehensively estimated, but these costs will be immense, likely in the hundreds of billions of dollars.[30] The potential size of these costs is reflected in DOE's long-term funding estimates for high-level waste disposal and nuclear cleanup projects. These estimates total more than $200 billion over many decades and could increase, according to DOE. In addition, DOE's, NRC's, and EPA's analyses of individual nuclear sites' cleanup options show that site-specific compliance costs can vary significantly depending on the restrictiveness of the standards. As might be expected, the analyses show that compliance with more restrictive standards—for example, exposure limits of a few millirem a year—costs considerably more than compliance with less restrictive standards—for example, limits of 100 millirem a year. Site-specific DOE analyses estimate multimillion-dollar cost differences between less restrictive and more restrictive protection levels, in some cases. These analyses further show faster rising costs to achieve the most restrictive protection levels.

[30]Annual costs and benefits of environmental regulations have been estimated to total many billions of dollars annually. For example, see R. Hahn, and J. Hird, "The Costs and Benefits of Regulations," Yale Journal on Regulation, vol. 8 (1991), pp. 233-78.

Costs of Implementing High-Level Waste Standards

To comply with high-level waste standards, DOE has projected multibillion dollar costs, whether or not the Yucca Mountain repository is developed. Radiation protection standards for Yucca Mountain have not been finalized,[31] but DOE has estimated funding of over $43 billion (in 1998 dollars) for the total repository system to 2116, in large part to help ensure that the public is protected from exposure to the waste stored there. According to DOE's latest estimates, long-term funding for the repository could go over $55 billion. Alternatively, if the repository is not built, DOE has estimated expenditures of about $52 billion to $57 billion to store high-level waste for 100 years at existing sites around the country. From the enactment of the Nuclear Waste Policy Act of 1982 through fiscal year 1998, DOE spent about $7 billion (in 1998 dollars) for its repository program.[32]

EPA, NRC, and DOE have not estimated the total difference in compliance costs under the conflicting standards proposed by EPA and NRC for Yucca Mountain. DOE officials said that most of the projected increases in the repository's costs can be associated with design changes resulting from the combination of EPA's proposed groundwater standards, the need to provide the level of confidence in the repository's performance required for a rigorous NRC licensing process,[33] and the influence of external oversight advisory bodies and peer review panels. DOE estimated that cost increases have totaled over $10 billion since 1993 to achieve added confidence that restrictive performance and radiation protection requirements can be met over thousands of years. For example, in 1993 a repository-performance-related increase of $7 billion (in 1999 dollars) came from a design change involving the use of more robust, cylindrical waste containers. Furthermore, DOE is considering an additional cost of $3.7 billion (in 1999 dollars) for water-diverting titanium drip shields (over the waste

[31]DOE officials said that since the 1990s, they have been designing the repository to more than meet prospective radiation standards that EPA and NRC might issue.

[32] At another nuclear waste disposal facility that is already in operation, the Waste Isolation Pilot Project, where EPA's transuranic waste disposal standards are operative, DOE projects funding to 2070 at $7.7 billion. In addition, state compacts and unaffiliated states have to date incurred almost $600 million in costs for planning and developing potential low-level waste disposal sites, although no sites have been built. See *Low Level Radioactive Wastes: States Are Not Developing Disposal Facilities* (GAO/RCED-99-238, Sept. 17, 1999).

[33]According to DOE and EPA, NRC's proposed "reasonable assurance" performance objective for the repository may be more stringent and costly to implement than the "reasonable expectation" compliance objective in EPA's proposed standards. NRC disagreed that this would necessarily be the case.

containers) intended to protect the repository from potential water incursion, as well as to meet EPA's proposed groundwater protection requirements in a rigorous NRC licensing process. Further design enhancements to achieve a cooler repository, which would keep temperatures in the repository below the boiling point of water, as favored by the Nuclear Waste Technical Review Board, could add about $2 billion more to costs. According to DOE and NRC officials, the latest design is essentially an attempt to achieve a virtually "no radioactive release" facility at Yucca Mountain. These officials maintain that such a design may not be needed to implement less restrictive standards such as 15-, 25- , or 100-millirem-a-year all-pathway exposure limits.

Costs of Implementing Nuclear Cleanup and Decommissioning Standards

Although comprehensive data on the costs of complying with nuclear site cleanup and decommissioning standards were unavailable, these costs could be immense in the long term. For example, complying with EPA Superfund cleanup and other environmental requirements may cost DOE several billion dollars annually, judging from the fact that the agency's fiscal year 1999 appropriation for the overall environmental management and cleanup of its nuclear facilities was about $5.8 billion. The agency's compliance activities could cost hundreds of billions of dollars and could extend for decades into the future, according to long-term funding estimates for environmental cleanup projects. The agency has projected funding for environmental cleanup at its nuclear sites from fiscal year 2000 through fiscal year 2070 to be anywhere from about $151 billion to $195 billion (in 1999 dollars). DOE spent about $52 billion for cleanup from fiscal year 1989 through fiscal year 1999. The overall bill for DOE's nuclear cleanup is uncertain and could go higher. According to DOE, the future costs of many of its cleanup programs are difficult to quantify because many projects are still in the planning stage. Moreover, as we noted in 1999, the data on some sites may not be reliable, in part because many field sites based their cost estimates on assumed cleanup levels that have not been finalized.[34] In addition, the operators of NRC-licensed nuclear facilities, including over 100 power plants, may spend over $38 billion for

[34]See *Nuclear Waste: DOE's Accelerated Cleanup Strategy Has Benefits but Faces Uncertainties* (GAO/RCED-99-129, Apr. 30, 1999). According to DOE, about 85-90 percent of its environmental management budget is directed toward ensuring compliance with the large number of legally enforceable cleanup and compliance agreements in place at major sites around the country. Such compliance involves not only EPA requirements, such as Superfund, but also any applicable state requirements, as well as DOE's own radiation protection orders.

decommissioning in coming decades, according to the Nuclear Energy Institute.

Even though EPA, NRC, and DOE generally did not have estimates for all U.S. nuclear sites of the costs of complying with different cleanup standards to achieve different protection levels,[35] officials from these agencies said that achieving more restrictive protection levels, especially the most restrictive levels—in the range below 100 millirem a year—can be considerably more expensive. To support their statements, they cited various generic and site-specific cost analyses conducted by DOE, NRC, and EPA. Our examination of these cost analyses generally confirmed higher estimated costs to comply with more restrictive cleanup levels for contaminated soil, as might be expected. Conversely, cost estimates were considerably less to comply with less restrictive soil cleanup levels. For example, analyses comparing the costs of achieving EPA's and NRC's conflicting all-pathway cleanup levels—15 millirem a year and 25 millirem a year, respectively—show cost differences in the millions of dollars for some sites—and even greater cost differences to achieve cleanup levels below 10 millirem a year. Analyses also show potential multimillion-dollar cost differences between the 15 to 25 millirem-a-year range and the less restrictive 100-millirem-a-year level.

Among the analyses we examined were a generic analysis by NRC to support its decommissioning standards and numerous site-specific cost analyses done by DOE in the course of analyzing cleanup options for its nuclear weapons complex. The estimated costs of meeting different soil cleanup levels for selected sites are summarized in table 1 and discussed in more detail in appendix V.

[35]An exception is a preliminary regulatory analysis done by EPA in 1996 to support its proposed cleanup standards. The analysis showed incremental cost differences in the low billions of dollars to meet various cleanup levels below 100 millirem a year. See app V.

Table 1: Estimated Costs to Achieve Different Soil Cleanup Levels at Selected DOE Sites and Generic NRC-Licensed Sites

Dollars in millions

Agency/site/ analysis date	Cost of 100 millirem a year	Cost of 25 millirem a year	Cost of 15 millirem a year	Cost of less than 10 millirem a year
DOE/Nevada Test Site and test ranges/1995	35	131	240	1,003[a]
DOE/Brookhaven Laboratory waste facility/1998	15.9	24.4	28.2	64.5[b]
NRC-licensed power plant[c] /1997	0.17	0.31	0.41	1.44[d]
NRC-licensed metal extraction facility[c]/1997	5.30	6.21	7.33	13.86[d]

Note: Totals do not represent overall estimates of cleanup costs, which may include costs for activities other than soil cleanup, including the decontamination and removal of equipment and structures, as well as liquid waste treatment.

[a]5 millirem a year.

[b]1 millirem a year. Totals are present values.

[c]Generic site.

[d]3 millirem a year.

Source: GAO's presentation of data from DOE and NRC.

As shown in table 1, for the listed sites, the estimated costs to achieve different soil cleanup levels vary, from hundreds of thousands of dollars in some cases to hundreds of million dollars in other cases. The cleanup costs also accelerate faster to achieve the most restrictive levels. For example, for the Nevada Test Site, from a 100-millirem-a-year baseline, the costs increase over three times and over six times to achieve the 25-millirem-a-year and 15-millirem-a-year levels, respectively, but over 28 times to achieve the 5-millirem-a-year level. Similarly, for the Brookhaven facility, from a 100-millirem-a-year baseline, the costs increase about 53 percent to achieve the 25-millirem-a-year level, about 77 percent to achieve the 15-millirem-a-year level, but over 300 percent to achieve the 1-millirem-a-year level. DOE and NRC officials said the large cost variations for different sites reflected site-specific factors, including the ratio of soil and building contamination, exposure and land-use scenarios, and waste disposal options. Officials said cost factors include not only the degree of on-site remediation, but also soil sampling and analysis to demonstrate compliance with standards, as well as procedural and other costs.[36]

Fewer analyses of the costs of complying with EPA's extra groundwater protection approach for nuclear cleanups were available. However, DOE's groundwater remediation analyses for aquifers at the Idaho National Engineering and Environmental Laboratory and at the Brookhaven National Laboratory showed that the additional costs of achieving drinking water standards at these sites could approach several hundred million dollars and a few million dollars, respectively, depending on the remediation option chosen. (See app. V.)

Conclusions

Although conclusive scientific evidence of the effects of low-level radiation is lacking and may not soon be found, U.S. regulators still have the challenge of developing radiation standards that represent their best estimates of acceptable radiation risks to the public. In this regard, as a national decision on high-level-waste disposal at Yucca Mountain approaches, and as EPA and NRC both continue to administer the cleanup and decommissioning of nuclear sites, it is important that the two agencies agree on protection approaches and policies for these regulatory applications. However, it does not appear that EPA and NRC will readily agree on appropriate groundwater protection approaches for Yucca Mountain. Also, EPA and NRC have been working on a memorandum of understanding since before August 1999, when the House Appropriations Committee encouraged them to clarify their conflicting regulatory roles related to nuclear facility cleanup and decommissioning, with little progress. Looking back, we note that they have not successfully addressed this matter since at least 1994, when we recommended that they pursue consensus on acceptable radiation risks to the public. Given the agencies' historical differences and lack of recent progress, without congressional intervention, they may not resolve their differences.

It is of note that EPA and NRC, while disagreeing over appropriate public protection levels, are both regulating at levels where the harm of radiation and the health benefits of radiation standards may not be clearly

[36]These analyses do not consider overall site cleanup costs, which may include many factors, such as the costs of decontaminating and removing structures and treating liquid waste. The analyses often estimated hypothetical cancer deaths averted from meeting various protection levels.

demonstrable. Regulating at these levels, well below the range where radiation effects have been conclusively verified, is essentially a policy judgment. Such an approach may arguably be prudent, in accordance with regulatory use of the linear model, which both agencies endorse. However, it will also be expensive, because compliance costs accelerate to achieve the lowest exposure levels, as our work confirms. The potential acceptable risks, health benefits, and costs of EPA's and NRC's differing regulatory approaches will be of interest to the Congress as it continues to focus on nuclear health and safety issues of national importance, such as the proposed Yucca Mountain repository and the cleanup and decommissioning of federal and commercial nuclear sites. These risks, benefits, and costs will also affect the public's belief in and acceptance of any resolution of their conflicting viewpoints that the two agencies may achieve.

Matters for Congressional Consideration

The congressional committees of jurisdiction may wish to reconcile EPA's and NRC's policy differences on groundwater protection for Yucca Mountain. Also, in connection with the two agencies' efforts to complete a memorandum of understanding relating to the cleanup and decommissioning of nuclear sites, these Committees may wish to clarify the agencies' regulatory responsibilities.

Agency Comments

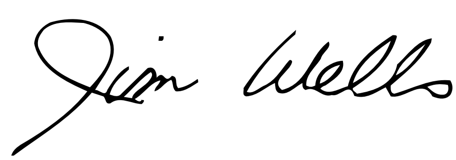
We provided NRC, DOE, and EPA with a draft of this report for their review and comment. NRC found the report to be fundamentally sound and said it should help the Congress understand the long-standing differences between EPA and NRC. NRC supported our conclusions that federal agencies should agree on decommissioning and high-level waste policies and approaches to ensure consistent standards and public protection. DOE found the report to be factual and balanced. EPA disagreed with the report, in separate letters from its Office of Radiation and Indoor Air and Office of Emergency and Remedial Response. The Director, Office of Radiation and Indoor Air, said EPA interprets the information presented in our report differently, and as a result, EPA disagrees with the report's conclusions. The Director, Office of Emergency and Remedial Response, said, among other comments, that the report inaccurately portrays EPA and NRC as making little progress in their negotiations on a memorandum of understanding to clarify the two agencies' regulatory roles and responsibilities related to the cleanup and decommissioning of nuclear facilities. EPA mentioned recent and continuing efforts by the two agencies to better clarify their respective regulatory roles through such a memorandum. While recognizing these recent initiatives, we note that since as long ago as 1992, the two agencies have been unsuccessful in addressing this matter, and on this basis we still question whether the two agencies' most recent initiatives will resolve their differences without congressional intervention.

NRC, DOE, and EPA provided technical clarifications to the draft report, which we incorporated into the final report where appropriate. EPA's, NRC's, and DOE's comments and our evaluation of them are included in appendixes VI, VII, and VIII.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 20 days after the date of this letter. At that time, we will send copies to the Honorable Carol Browner, Administrator, Environmental Protection Agency; the Honorable Richard Meserve, Chairman, Nuclear Regulatory Commission; and the Honorable Bill Richardson, Secretary of Energy. We will also make copies available to others upon request.

If you have any questions about this report, please contact me or (Ms.) Gary L. Jones on (202) 512-3841. Key contributors to this assignment were Duane G. Fitzgerald and Dave Brack.

Sincerely yours,



Jim Wells, Director, Energy, Resources,
and Science Issues

Scope and Methodology

To conduct our review of U.S. radiation standards, we obtained testimonial and written documentation from many dozen recognized scientists in the field of radiation research and radiation protection, including both active research scientists and representatives on national and international radiation protection committees; officials of federal agencies principally responsible for regulating public radiation protection and conducting scientific research into the health effects of low-level radiation, including EPA, NRC, DOE, the Department of Defense, and the Department of Health and Human Services; state radiation protection officials and the Conference of Radiation Control Program Directors; officials of radiation protection organizations, such as the National Council on Radiation Protection and Measurements, the National Academy of Sciences, and the International Commission on Radiological Protection; environmental and nuclear industry representatives; and individual radiation researchers in government, industry, and academia.

To examine the scientific basis of U.S. radiation standards, we obtained expert views representing various viewpoints in the controversy over low-level radiation and the linear model. In addition, we hired an expert consultant to help synthesize data and draw conclusions relating to the status of studies correlating worldwide natural background radiation levels to cancer rates, as well as their possible implications for setting radiation standards. The consultant, Dr. Thomas Gesell, Professor of Health Physics, Idaho State University, is a recognized expert in environmental radiation. (Results based on the consultant's work, representing GAO's views, are presented in detail in app. IV.) Furthermore, we asked several experts in the radiation protection field to informally review and comment on the accuracy of a draft version of our report, and we incorporated their suggested changes where appropriate.

To examine whether federal agencies have come closer to agreeing on radiation standards since we reported on this matter in 1994, we obtained views and documentation from agency officials, the Interagency Steering Committee on Radiation Standards, and the Conference of Radiation Control Program Directors. We examined various federal and state radiation standards, as well as the regulatory and compliance activities of various federal agencies. However, we mainly focused on prominent current instances of disagreement between EPA and NRC, over radiation protection standards for high-level waste disposal and for the cleanup and decommissioning of nuclear facilities.

To examine the costs of radiation standards, although comprehensive estimates of these costs were unavailable, we obtained indications of these costs through available agency radiation-related cost and funding data. To examine the costs of different standards and protection levels, although comprehensive estimates of these differences were unavailable, we obtained indications of these costs through examining generic and site-specific agency cost analyses. We especially looked for analyses that showed estimated costs to achieve different radiation exposure levels, and we took steps to reasonably ensure that the analyses represented the best available data. Specifically, we obtained (1) analyses agencies considered representative of the best available data, (2) information on internal and external peer review and other quality controls steps that agencies may have taken in connection with the analyses, and (3) agency officials' views on any data limitations in the analyses.

We performed our review between July 1999 and June 2000 in accordance with generally accepted auditing standards.

Major U.S. Radiation Standards

Standard/agency	Numerical limit
General standards	
General public/NRC (10 C.F.R. 20)	100 millirem/year
Source-specific standards	
Uranium mill tailings/EPA, NRC (40 C.F.R. 192; 10 C.F.R. 40, App. A)	Radium 226, 228: 5 picocuries/gram surface, 15 picocuries/gram subsurface Radon 222: 20 picocuries/square-meter-second[a]
High-level waste operations/NRC (10 C.F.R. 60)	100 millirem/year
Spent fuel, high-level waste, transuranic waste disposal/EPA (10 C.F.R. 191)	All pathway: 15 millirem/year Groundwater 4 millirem/year[b]
Yucca Mountain high-level waste (proposed)/EPA (64 Fed. Reg. 46976)	All pathway: 15 millirem/year Groundwater 4 millirem/year[b]
Yucca Mountain high-level waste (proposed)/NRC (64 Fed. Reg. 8640)	25 millirem/year all pathway
Low-level waste/NRC (10 C.F.R. 61)	25 millirem/year
Drinking water/EPA (40 C.F.R. 141)	Radium: 5 picocuries/liter Gross alpha: 5 picocuries/liter Beta/photon: 4 millirem/year[b]
Uranium fuel cycle/EPA (40 C.F.R. 190)	25 millirem/year
Superfund cleanup/EPA (40 C.F.R. 300)	Risk range goals: 1 in 10,000 to 1 in 1 million[c]
Decommissioning/NRC (10 C.F.R. 20)	25 millirem/year
Occupational standards	
Occupational Safety and Health Administration, NRC, DOE (29 C.F.R. 1910; 10 C.F.R. 20; 10 C.F.R. 835)	5,000 millirem/year

[a]A picocurie is a trillionth of a curie, which is a commonly used unit of measurement of the activity of radiation.

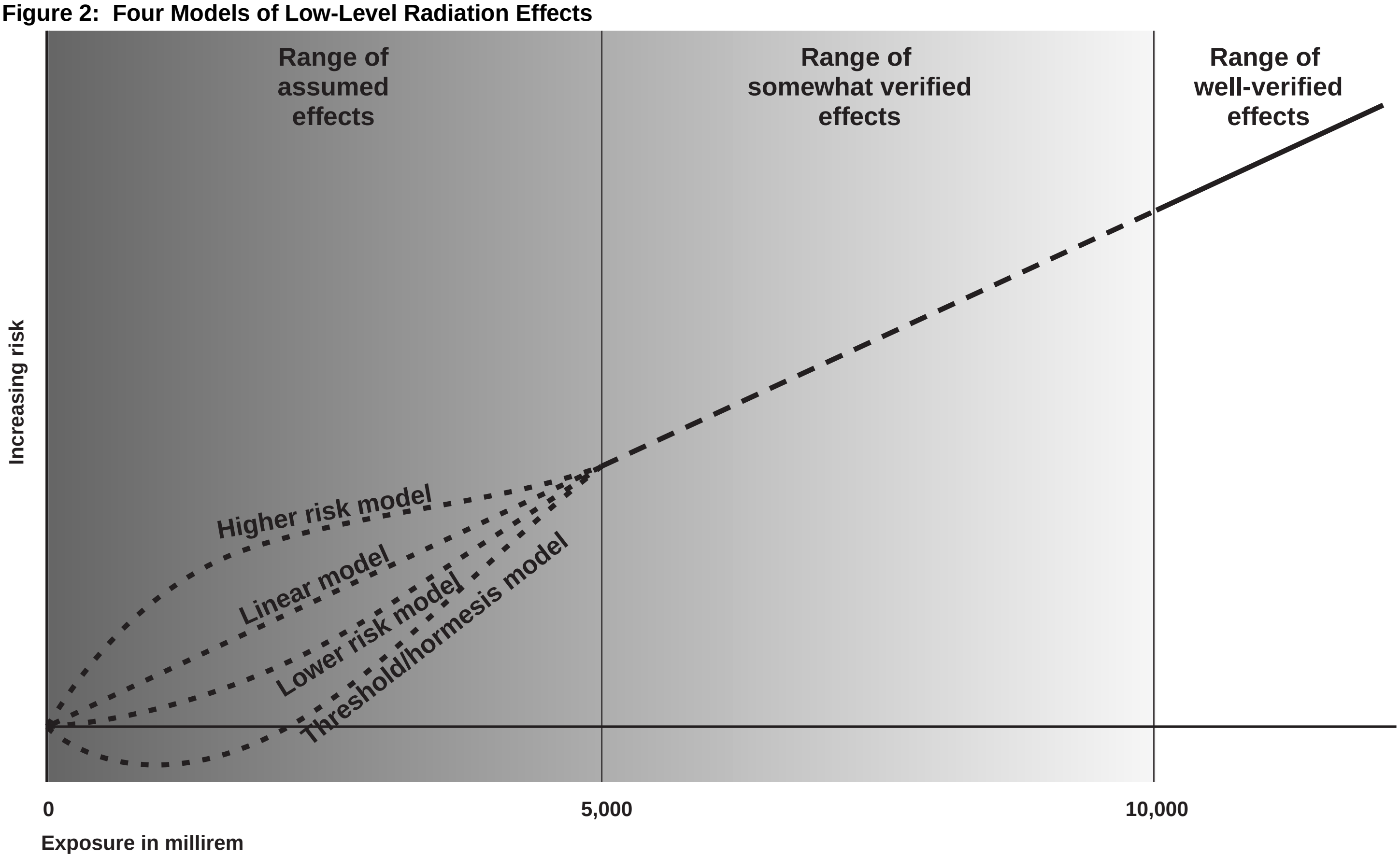
[b]Radioactivity from human-made radionuclides in community drinking water systems.

[c]Lifetime risk of an individual's getting cancer.

Examples of Different Models of Low-Level Radiation Effects

Figure 2 shows different models of low-level radiation effects that could fit the available research data. The linear model is used and endorsed by regulators and radiation protection organizations. The threshold model is preferred by those who interpret the data as showing that there are no effects below a certain exposure level. The higher-risk model is preferred by those who interpret the data as showing higher risks than the linear model. The lower-risk model is preferred by those who interpret the data as showing lower risks than the linear model.

Figure 2: Four Models of Low-Level Radiation Effects



Overview of Epidemiological Research on Low-Level Radiation Effects

Epidemiological research has been part of the scientific basis for the linear model and radiation standards. However, epidemiology may not soon fully verify or disprove low-level radiation effects. Specific epidemiological research correlating natural background levels in the United States and around the world with cancer rates has been generally inconclusive, showing mixed results. Much of this research has used methodologies that have been widely considered too limited for the research to be influential in setting radiation standards.

Several U.S. agencies are involved in epidemiological research on low-level radiation effects, including the Department of Energy (DOE), the Department of Health and Human Services (HHS), and the Department of Defense (DOD). In fiscal year 1999, about $41 million in DOE funding went for epidemiological research, including about $24 million provided to HHS for epidemiological and environmental research at DOE’s nuclear sites, under a 1994 memorandum of understanding that established independent management of such research. (In comparison, in fiscal year 1999, about $12 million for radiobiological research was funded within DOE’s Office of Biological and Environmental Research, and DOD provided an estimated $11 million for radiobiological research at its Armed Forces Radiobiology Research Institute.)

Japanese and Worker Studies

Epidemiological results have been a key basis for the linear model, including the study of over 85,000 Japanese survivors of the Hiroshima and Nagasaki bomb blasts. The United States has for many years participated in this study, conducted by the international Radiation Effects Research Foundation, with funding by DOE—$14 million in fiscal year 1999—through the National Academy of Sciences. The still-continuing study has helped to establish the effects of radiation at levels above 10,000 millirem, for which the data show a relationship between exposures and health effects that is generally consistent with a linear model. With a considerable degree of inherent uncertainty, scientists have extrapolated this relationship to the low-level radiation range as well. Based in large part on the Japanese data, major radiation protection organizations have endorsed the assumption of a linear dose-response relationship at far lower public exposure levels, down to those commonly regulated—100 millirem a year and below.

Some scientists have questioned the foundation’s work, asserting that the study understates radiation risk because it necessarily focuses on bomb survivors, who likely were the healthiest of the blast victims. Others assert that the important neutron component of the estimated Hiroshima dose is questionable, calling into doubt the overall Hiroshima-Nagasaki dose estimates dating from 1986. Recognizing that the Japanese data have historically been central to radiation risk estimation and that credible Hiroshima and Nagasaki dose estimates are needed, DOE and the National Academy of Sciences are conducting a reassessment of the Hiroshima neutron doses. Results are expected in late 2000. According to DOE, it is likely that new Radiation Effects Research Foundation dose estimates for Hiroshima and Nagasaki will be derived and that they will be issued in 2001.

In addition, there have been many epidemiological studies of U.S. and foreign nuclear workers, medical patients, miners, and others exposed to various levels of low-level radiation. For example, historically DOE has funded over 40 epidemiological studies of radiation effects on workers at sites in the U.S. nuclear weapons complex. According to DOE, the results have shown elevated cancer levels from chronic exposure at some sites, among the most highly exposed workers, although the results have been inconsistent and, looking complex-wide, DOE has not found a clear pattern of excess risk for any specific cancer type. In general, epidemiological studies of workers and other groups have the limitation of attempting to follow research populations that may be too small to give statistically powerful or conclusive results about very low radiation doses, and sometimes the studies do not follow populations over a long enough period of time, according to researchers and agency officials.

Studies Correlating Natural Background Radiation With Cancer Rates

Epidemiological studies have been involved in the controversy over low-level radiation effects because many such studies have attempted to statistically correlate natural background radiation levels (principally radon) in the United States and around the world with local cancer rates. A premise in the controversy is that in places with higher background radiation levels, the studies should show elevated cancer rates if there is a linear relationship between low-level exposures and health risks. Some of the studies have focused specifically on areas with the highest natural background radiation levels. In some places, these levels are four or five times as high as average U.S. levels. Two types of studies have been conducted. One type relates regional rates of disease, often obtained from published vital statistics, to measures of regional radiation levels. These are called ecologic studies. The other type obtains disease data by direct interviews of individuals or their representatives and by direct measurement of radiation exposures. These are called analytic studies.

Analytic studies can be prospective, following populations and current exposures for future outcomes, or retrospective, comparing current outcomes to past exposures.

For this review, we hired a consultant, Dr. Thomas Gesell, Professor of Health Physics, Idaho State University, a recognized expert in the field of environmental radiation, to identify and summarize worldwide ecologic and analytic studies of natural background radiation or radon. Through his work, we found that many ecologic and analytic studies have been done in the United States, Europe, Asia, and South America. Some focused mainly on radon effects, and others focused more broadly on overall natural background radiation effects. The results of such studies differ and are inconclusive overall. Most showed no evidence of elevated cancer risk, but a minority did show slightly elevated cancer risks. Taken together, the studies may suggest that low-level radiation effects are either very small, or nonexistent. Scientists have disputed the importance of such studies in determining low-level radiation effects. A factor in the dispute is the methodological difficulty of performing meaningful epidemiological studies of cancer rates in populations exposed to chronic low-level radiation doses. In many cases the population being studied is limited in size, and the cancer effects being pursued are small, making them difficult to detect among all cancers in the population.

In most places on earth, natural background radiation (excluding radon) varies within about a factor of four, and cosmic radiation varies by about a factor of two in the elevations where most of the world's population lives. Average world natural background radiation levels are about 240 millirem a year (including radon), and about 300 millirem a year in the United States. Particularly high concentrations of natural background radiation have been reported in Brazil, India, China, and Iran. For example, there are areas of elevated levels in Brazil, one along the coast (Guarapari) and another in the interior (state of Minas Gerias); in the Kerala area, India; in Yangjiang County, southwest Guangdong Province, China; and in Ramsar, Caspian coast, Iran. In some of these areas, mean annual doses can be more than double average U.S. levels, and hot spots into several thousand millirem a year have been reported. In the United States, natural background levels are over three times higher in the Rocky Mountains than along the Gulf Coast.

With the help of our expert consultant, we examined 82 ecologic and analytic studies of natural background radiation or radon, in the United States and around the world. Of these studies, 45 were directly radon related. The studies examined a variety of different types of cancer, and some examined cancer effects on children, while others examined genetic effects. Results of the studies varied, and we did not independently assess their quality. Some reported statistically significant results—elevated cancer rates, no elevation in rates, or a negative correlation—and others reported inconclusive results. (Some lacked basic information for assessing their quality.) Of 67 radon-related cancer studies, 22 reported results indicating a statistically significant correlation between natural background radiation or radon and cancer rates, while 45 found no such correlation (including 8 that found a negative correlation), and 4 were inconclusive. Others reported statistically significant chromosomal aberrations in subjects, but not cancer correlations.

In 1999, the National Academy of Sciences issued a report on the health effects of radon exposure, called BEIR VI. Of 39 studies examined in the report, including 19 ecologic studies, 17 studies reported a positive correlation between radon and lung cancer, and 15 reported no correlation. Three reported a negative correlation, including a 1995 ecologic study by Bernard Cohen, University of Pittsburgh, of radiation-cancer correlations in 1,601 U.S. counties. The study found a strong tendency for lung cancer rates to decrease with increasing radon exposures, in sharp contrast to the increase expected from the linear model. The study and follow-up analysis took steps to test for over 500 potential confounding factors, including smoking and other lifestyle factors. The author found no potential explanation for the discrepancy other than failure of the linear model. Some critics of the study consider it to be carefully and thoroughly done but believe that it lacks adequate data to control for smoking or other factors. Many epidemiologists consider all ecologic studies to be methodologically inferior to analytic case control studies because the former compile average statistics, not individual statistics. Some analytic case control studies have contradicted the Cohen study, including a 1997 meta-analysis (study of studies) involving eight individual analytic studies of radon and lung cancer. The meta-analysis found a small positive correlation between indoor radon levels and lung cancer. However, the meta-analysis also found considerable variance in the eight studies' results, and specific lifestyle or socioeconomic confounding factors that would directly negate the Cohen study's results have not been isolated, although various theories have been put forward.

Costs of Different Radiation Standards

We examined numerous EPA, NRC, and DOE analyses of different nuclear cleanup options and costs. The analyses generally confirmed that, as might be expected, compliance costs varied to achieve different radiation protection levels and accelerated to achieve more restrictive levels. The analyses were done between 1991 and 1999, and they estimated costs under varying scenarios to achieve different dose, risk, and contamination levels.[1] In particular, we examined several site-specific DOE nuclear cleanup studies; an NRC environmental impact study of four types of generic NRC-regulated facilities, performed to support NRC's decommissioning standard; and a draft EPA regulatory impact analysis of the potential nationwide costs (at 16 generic types of sites) of EPA's proposed comprehensive cleanup standards. Selected analyses that showed cost variations in relation to achieving different millirem levels are discussed below.

Costs of Cleaning Up to Different Protection Levels

Our examination of DOE's and NRC's analyses showed potential site-specific cost differences of millions of dollars, in some cases, between cleaning up radioactively contaminated soil to 15 millirem a year and cleaning it up to 25 millirem a year, under various scenarios. (These analyses do not represent estimates of overall site cleanup costs, which may include factors in addition to soil cleanup, including remediation activities such as the decontamination and removal of contaminated equipment and structures and liquid waste treatment.) EPA's analysis showed potential nationwide incremental costs in the low billion dollars to achieve more restrictive cleanup levels.[2] Major analyses that showed cost variations in the range of 100 millirem a year and below are shown in table 2.

[1]Often, in addition to costs, the analyses estimated doses and cancer deaths averted from meeting various protection levels, using the linear model.

[2]EPA quantified soil cleanup costs in the draft analysis. According to DOE's comments on the analysis, EPA may have greatly underestimated the potential costs of implementing EPA's drinking water standards for groundwater at DOE sites.

Table 2: Potential Costs to Achieve Different Soil Cleanup Levels—DOE's, NRC's, and EPA's Analyses

Dollars in millions

Agency/site/analysis date	Estimated soil cleanup cost			
	100-millirem-a-year level	25-millirem-a-year level	15-millirem-a-year level	Less than 10-millirem-a-year level
DOE				
Hanford process waste areas, 1994[a]	b	14	19	59[c]
Nevada Test Site and test ranges, 1995[d]	35	131	240	1,003[e]
Weldon Spring, 1991[f]	b	0.58	1.4[g]	2.0[h]
Brookhaven waste facility, 1998[i]	15.9	24.4	28.2	64.5[j]
NRC[k]				
Generic nuclear power plant, 1997	0.17	0.31	0.41	1.44[c]
Generic fuel fabrication facility, 1997	2.89	6.35	7.83	13.56 [c]
Generic metal extraction facility, 1997	5.30	6.21	7.33	13.86 [c]
Generic sealed source facility, 1997	0.08	0.26	0.35	0.64 [c]
EPA				
Generic nationwide sites, 1996[l]	m	1,000	1,500	3,200[c]

[a]The analysis was part of a feasibility study for a Superfund cleanup of ponds, trenches, and burial grounds in Area 300, where uranium and other wastes from processing nuclear fuel for Hanford's production reactors were disposed of over decades. Under an industrial scenario, the analysis considered five cleanup options. The totals shown are for the selected cleanup and disposal option and are present values.

[b]Cost not calculated for this level.

[c]3 millirem a year.

[d]At the site and test ranges (Nellis and Tonapah), plutonium contaminates surface soils over an estimated 90,000 hectares (at levels above 10 picocuries per gram). The contamination resulted from atmospheric nuclear tests, as well as safety tests that subjected nuclear devices to conventional explosives. The analysis was conducted separately from the Superfund process, as a cost-risk-benefit case study to evaluate a range of cleanup alternatives, using an active institutional controls scenario to limit costs. An integration model was used to estimate individual risks, population risks, costs (cleanup costs, costs of worker fatalities), and benefits (including reduced future on-site cancer fatalities). The totals assume on-site disposal for the Tonapah range waste.

[e]5 millirem a year.

[f]The analysis supported the Superfund process for the site, in Missouri, where uranium and thorium ore were processed from 1957 until 1966, contaminating buildings and soil. Under an on-site farmer scenario, alternative uranium soil cleanup levels were calculated. A 25-millirem-a-year cleanup target was selected, with an as low as reasonably achievable (ALARA) goal equivalent to 6.7 millirem a year.

[g]12 millirem a year.

[h]6.7 millirem a year.

[i]The facility historically processed, treated, and stored radioactive and hazardous waste. The analysis was conducted apart from the Superfund process, as an ALARA case study. Using an open space scenario, the analysis undertook risk optimization to determine the cost savings from the remedial action, the life-cycle costs for the remedial action, the value of the net dose avoided, and the value of

other avoided risks and damages. In the net benefit-cost analysis, net costs resulted at all millirem-per-year levels. The totals shown represent present values.

[j]1 millirem a year.

[k]The four generic types of NRC-liensed facilities were included in a generic environmental impact statement supporting the issuance of the agency's decommissioning standard. The generic environmental impact statement included analyses of human health impacts, costs, and the cost-benefit of the regulatory action, under an unrestricted-use scenario. The totals shown reflect soil removal and survey costs, based on "real world" soil characterization estimates.

[l]The analysis was part of a regulatory impact analysis supporting EPA's prospective nuclear site cleanup standard. The analysis addressed incremental soil cleanup cost and health impact differences nationwide, between a base case (100 millirem a year, absent the proposed EPA standard) and the regulatory case (assuming promulgation of the EPA standard) for 16 types of reference sites, based on actual DOE, DOD, and NRC-licensed sites. Results were calculated for three scenarios—upper- and lower-bound scenarios and an intermediate scenario representing EPA's best estimate. The totals shown reflect the intermediate case, representing incremental soil cleanup costs below a 100-millirem-a-year baseline. The totals represent present values.

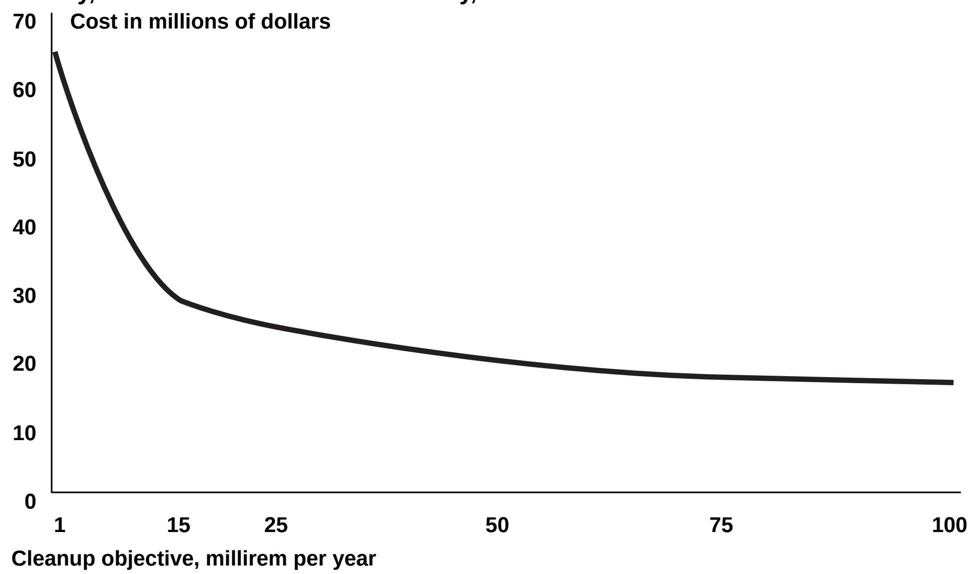
[m]The 100-millirem-a-year baseline.

As shown in table 2, for individual DOE and NRC-licensed sites, the estimated differences in compliance costs between the 15-millirem-a-year and the 25-millirem-a-year levels—reflecting EPA's and NRC's all-pathway standards, respectively—varied widely, from thousands of dollars to over $100 million. Similarly, the table shows widely varying cost differences between the 100-millirem-a-year level and lower levels. EPA's analysis estimated incremental compliance costs for multiple sites nationwide. As shown in the table, the analysis found cost differences of over a billion dollars between the 100-millirem-a-year level and lower levels.

The varied costs in table 2 reflect not only different protection levels but also different land-use scenarios and site characteristics, among other factors. For example, the 1995 analysis for the Hanford process waste areas used an industrial scenario, at a location with a variety of soil and structure components; the 1995 analysis for the Nevada test ranges used an active institutional controls scenario, at a large, soil dominated location; and NRC's 1997 analysis used unrestricted access scenarios, at generic industrial sites with substantial on-site structures. According to DOE analysts, scenarios involving on-site unrestricted, residential, or industrial use can result in much lower cleanup levels and higher cleanup costs than scenarios involving restricted or open-space use.[3]

The analyses also generally showed that cleanup costs accelerated to achieve the most restrictive protection levels. These accelerating costs can be shown graphically in the form of a cost-benefit curve, as depicted in figure 3, for the Brookhaven hazardous waste facility:

Figure 3: Cleanup Costs as a Function of Cleanup Levels—Hazardous Waste Facility, Brookhaven National Laboratory, 1998



As shown in figure 3, in the Brookhaven analysis, costs were a function of cleanup levels, increasing gradually, from right to left, from 100 millirem a year to 15 millirem a year, and accelerating from 15 millirem a year to 1 millirem a year. Conversely, rates of dose reduction (and potential

[3]For example, the choice of an open space scenario for the Rocky Flats facility in Colorado was a factor in the decision to apply a less restrictive plutonium cleanup level there than was required at the Nevada Test Site. See *DOE: Accelerated Cleanup of Rocky Flats—Status and Obstacles* (GAO/RCED-99-100, Apr. 30, 1999). The Rocky Flats plutonium cleanup level is being reconsidered in response to stakeholders' concerns, and a preliminary DOE cost estimate for a many times more restrictive cleanup level showed potential cleanup cost increases for Rocky Flats in the tens of millions of dollars.

associated increased health benefits) decelerated at costs above $30 million. This relationship generally held for many DOE analyses we examined, including some that expressed cleanup levels in terms of risk and others that expressed cleanup levels in terms of concentration levels achieved.[4] According to DOE analysts, under the principle of reducing doses to levels as low as reasonably achievable (ALARA), there is a point or “elbow” on the cost-curve where an optimal balance between costs and cleanup level is chosen.

Costs of Groundwater Cleanup

Agencies generally did not have overall estimates of the cost differences between achieving NRC’s all-pathway 25-millirem-a-year limit for nuclear cleanups and achieving EPA’s proposed extra groundwater protection requirements, based on the agency’s more restrictive drinking water standards. However, available DOE and NRC analyses showed potential multibillion dollar cost differences per site to achieve EPA’s standards. Both NRC and DOE expressed concern that the extra groundwater protection favored by EPA for nuclear sites could impose multimillion dollar additional costs annually at sites with groundwater contamination. NRC, in part, based its concern on an analysis done to support its decommissioning standard. This analysis showed that at a generic nuclear site with strontium 90 groundwater contamination, from a baseline of 25 millirem a year, incremental costs using “pump and treat” methods could be as high as $7 million to achieve a 3-millirem-a-year level (below the original 4 millirem-a-year drinking water standard, but above the level for strontium 90 using up-to-date dose estimation methods—0.07 millirem a year) and an additional $32 million to achieve natural background levels. (“Pump and treat” means that the water is pumped out of the ground, treated by various means, and discharged back into the ground.)

Site-specific DOE analyses also indicated incremental costs of many millions of dollars per site to meet drinking water standards through long-term pump and treat techniques. For example, a 1998 DOE analysis, issued in concert with EPA and the Idaho Department of Health and Welfare, showed options for cleaning up the Snake River Plain Aquifer underneath

[4]Other analyses included a draft 1999 analysis at two Nevada Test Site locations in the Tonapah test range; a 1999 analysis at the Energy Technology and Environmental Center, Santa Susana, California; a 1995 analysis at the Elza Gate, Tennessee, former waste storage site; and a 1994 analysis at the Ventron, Massachusetts, former uranium compounds processing facility.

the spent fuel processing facility at the Idaho National Engineering and Environmental Laboratory. According to the analysis, the costs of using a pump and treat approach, if necessary to achieve the drinking water standard for a key radionuclide, Iodine 129, by 2095, could be anywhere from about $40 million to about $788 million depending on the aggressiveness of the approach taken.[5]

Also, a 1998 Brookhaven National Laboratory analysis of pump and treat options to clean up tritium and strontium 90 in the on-site groundwater showed that natural attenuation of the strontium 90 for 60 years or more might meet the drinking water standard for strontium 90 and cost less than a million dollars for monitoring activities. Alternatively, pump and treat methods might achieve the drinking water standards in 30 or more years, at costs of from $5.8 million to $6 million.

[5]According to a DOE-Idaho official, a December 1999 record of decision based on the analysis chose a less expensive aquifer dilution and monitoring approach.

Comments From the Environmental Protection Agency

Note: GAO comments supplementing those in the report text appear at the end of this letter.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 13 2000

OFFICE OF
AIR AND RADIATION

Jim Wells, Director
Energy, Resources, and Sciences Issues
Resources, Community, and Economic Development Division
U. S. General Accounting Office
Washington, DC 20548

Dear Mr. Wells:

Thank you for the opportunity to provide comments on the General Accounting Office (GAO) Report, "Low-level Radiation Standards - Scientific Basis Inconclusive, and EPA and NRC Disagreement Continues." Our principal comments on the report can be divided into three areas - the use of the linear non-threshold (LNT) model for estimating the risk of radiogenic cancers; the Environmental Protection Agency's (EPA) groundwater protection strategy and its application in the proposed Yucca Mountain regulations; and, our efforts to develop a Memorandum of Understanding (MOU) with the Nuclear Regulatory Commission (NRC) on the clean-up of NRC-licensed sites. In all these areas, we interpret the information differently and as a result, we disagree with the report's conclusions.

Linear No-Threshold Dose Response Model

The first issue, that of whether the U.S. government should continue to use the LNT model, is a question that has received considerable attention in recent years. While there is some uncertainty associated with the risk estimates at low radiation exposures, the LNT is supported by all major consensus scientific organizations and is used by every national and international regulatory body as the basis for its radiation protection strategies. Until the evidence suggests otherwise, EPA is simply following the consensus of scientific organizations in continuing to use the LNT model to estimate risks.

See comment 1.

Several national and international workshops have been held to re-examine the validity of the LNT. Always the answers are the same. Although some individual scientists have supported the existence of a threshold, there is currently no conclusive evidence that health risks don't exist at low levels of radiation exposure. In fact, the majority of radiobiologists can offer no biological mechanism to explain why there should be a threshold, irrespective of whether there are off-setting beneficial effects. The report indicates that this lack of conclusive scientific evidence has led the EPA and NRC to establish differing exposure limits. However, it is not the scientific evidence the has led to these differences. Both EPA and NRC use the LNT model. Rather, the different exposure limits are due to the risk management decisions that the agencies have made based on differing statutory mandates. Regardless, EPA is following with interest the current research in this area, in particular the research that the Department of Energy is currently funding to examine the sub-cellular processes that lead to radiogenic cancer. As noted in the report, EPA is also co-sponsoring a new National Academy of Sciences study to examine new evidence of radiation risk at low doses (the BEIR VII study).

See comment 2.

Your report also cites low-level radiation as a weak carcinogen and footnotes that low-level radiation accounts for far less than one percent of the cell-altering events that occur daily in cells. This assertion completely ignores the evidence that the type of damage done by ionizing radiation has a much higher probability of resulting in DNA misrepair than other normally occurring cell-altering events.

Ground Water Protection at Yucca Mountain

Next, I would like to comment on the difference in the radiation standards proposed for Yucca Mountain by EPA and NRC. Your report correctly reflects that EPA strongly supports separate ground water protection in its Yucca Mountain standards, as well as for other radiation protection standards for waste disposal sites, while NRC endorses the all pathways approach. The Agency, as well as the current and previous Administrations, has maintained the position to protect ground water for several reasons. The first and most obvious reasons are consistent and equitable public health protection. For example, the recently-licensed Waste Isolation Pilot Plant in New Mexico was afforded a ground water protection standard for disposal of transuranic radioactive waste. Virtually every state has taken steps toward comprehensive ground water protection. Forty-nine states have developed programs to protect current ground water sources of drinking water through the Wellhead Protection Program. Forty-one states have numeric or narrative ground water standards to help differentially protect their ground water supplies. EPA believes Yucca Mountain and the citizens of Nevada should be extended the same protection for the disposal of spent nuclear fuel and high level radioactive waste. Second, EPA believes that ground water in a region growing as rapidly as the Las Vegas metropolitan area should be protected from pollution "up front," rather than becoming polluted, and then forcing the residents to bare the cost of the environmental clean-up afterwards.

See comment 3.

Finally, EPA has not seen any documentation in DOE's own technical analyses that has shown that, even with separate ground water protection, Yucca Mountain cannot meet EPA's standards. We understand that these are preliminary analyses, and DOE still has to undergo the NRC licensing process; however, to date, DOE's most rigorous studies show compliance with the ground water standard by at least an order of magnitude. As our economic impact analysis for our final standards will illustrate, DOE's costs for the facility are driven by many external influences all striving to enhance repository safety. Some more notable influences include the Nuclear Waste Technical Review Board and the rigorous NRC licensing process. EPA's ground water standard alone is not responsible for driving the cost of Yucca Mountain; it is one of many

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safety factors DOE has considered as it has developed the repository. In fact, relative to the 20-year history of Yucca Mountain, EPA's standards have had little time to influence the overall cost of the program in any significant way.

MOU with NRC on Clean-up of NRC-Licensed Sites

See comment 4.

Our third area of disagreement with the report's conclusions is that the efforts towards developing a Memorandum of Understanding (MOU) with the NRC on the clean-up of NRC-licensed sites have had little progress. While this has not been an easy process, our two agencies have made substantial progress recently towards clarifying our respective roles in the cleanup and decommissioning of NRC- licensed facilities. It is premature to conclude that an MOU is unlikely.

See comment 5.

As a final comment, we note that the report, in Table 1, accentuates the large differences in costs between cleaning up a site to a 100 millirem per year standard or to a less than 10 millirem per year standard (including 1 millirem). We believe these comparisons are misleading. The relevant difference should be between the middle two columns, 25 millirem and 15 millirem, which represent the difference that NRC and EPA have often argued about. The cost difference between these two levels is actually very small and, if the Nevada Test Site example is ignored, one might be tempted to say negligible. We believe that NRC's application of the "as low as reasonably achievable" or ALARA approach will likely eliminate even these small cost differences. A more relevant cost difference would be the additional cost of meeting EPA's ground water standard. The rationale for this standard has been discussed above, but it is worth noting that by NRC's own estimation, ground water contamination would only be a concern at a very few nuclear power plant sites.

If you have any questions regarding these comments, please contact Frank Marcinowski at (202) 564-9290.

Sincerely,

Stephen D. Page, Director
Office of Radiation and Indoor Air

The following are GAO's comments on the letter dated June 13, 2000, from the Director, Office of Radiation and Indoor Air, Environmental Protection Agency.

1. EPA said the draft report raised the issue of whether the U.S. government should continue to use the linear model, and EPA said it is following the consensus of scientific organizations in doing so. EPA also said the lack of scientific evidence has not led to the agency's regulatory disagreement with NRC. Rather, according to EPA, the two agencies have made different risk-management decisions, based on differing statutory mandates. One of our report's objectives was to describe the scientific basis for U.S. radiation standards, which we found to be inconclusive. The report raises no expectation that the linear model will or should be soon superseded, pending the existence of better evidence of low-level radiation effects. We agree that risk management decisions made by EPA and NRC, based on differing statutory mandates and protective strategies, largely account for the disagreement between the two agencies. Our report says this.

2. EPA said that in citing low-level radiation as a weak carcinogen, GAO ignored evidence that ionizing radiation has a much higher probability of resulting in DNA misrepair than other, more commonplace cell-altering events. We are aware of such evidence, and in agreement with EPA's qualifying point, we modified the final report accordingly.

3. EPA said that its groundwater standard is not alone responsible for driving the cost of the Yucca Mountain project, and EPA's standards have had little time to influence the overall cost of the program. Our report mentions several factors, significantly but not exclusively including EPA's proposed groundwater standard, that have influenced the project's costs to date and could do so in the future.

4. EPA said it is premature to conclude that a memorandum of understanding clarifying EPA's and NRC's regulatory roles is unlikely. We believe that, given the lack of progress by the two agencies since as long ago as 1992, it is questionable whether they will finalize such a memorandum. Even if they do, we question whether such a finalized memorandum will fundamentally resolve the problem between them.

5. EPA said the draft report should have focused more on the relatively small differences in cleanup costs between the 25-millirem-a-year and 15-millirem-a-year levels, which EPA and NRC have often argued about. The scope of our review did not exclude consideration of levels both higher and

lower than 25 millirem a year and 15 millirem a year. The report shows that cost differences to achieve these levels vary, depending on the site involved, and may be small in some cases. However, in relation to the hundreds of potential cleanup sites that exist nationwide, overall cost differences between the 25-millirem-a-year and 15-millirem-a-year levels could be substantial.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 12 2000

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

Mr. Jim Wells, Director
Energy, Resources, and Science Issues
United States General Accounting Office
441 G Street NW
Room 2T23
Washington, D.C. 20548

Dear Mr. Wells:

I would like to express my appreciation for the opportunity to provide comments on the draft report "Low-Level Radiation Standards: Scientific Basis Inconclusive, and EPA and NRC Disagreement Continues." The comments contained in this letter will be limited to those issues directly impacting Superfund. Comments related to Yucca Mountain standards and scientific basis for radiation risk assessments will be addressed in a separate letter from EPA's Office of Radiation and Indoor Air.

See comment 1.

Risk harmonized radiation and chemical site cleanups. The draft report appears to evaluate the issues related to cleanup of radiological contamination at sites without acknowledging that at almost all sites with significant radiological contamination there also exists non-radiological (chemical) contamination. It is EPA's policy under CERCLA to address radioactively contaminated sites in a manner that is consistent with our guidance for addressing chemically contaminated sites, except to account for the technical differences between radio nuclides and chemicals. We would like to make it clear that radioactive contamination is not singled out in CERCLA as amended or EPA regulations as a privileged pollutant for which EPA should allow exceedances above the carcinogenic risk range (10^{-4} to 10^{-6}) that was determined generally to be protective for other carcinogenic contaminants. Further, ground waters should be returned to beneficial reuse which includes meeting MCLs established under the Safe Drinking Water Act for all contaminants including radio nuclides within the ground water plume, where MCLs are relevant and appropriate. EPA is committed to using the full range of alternatives available to achieve cleanup of ground waters and in selecting cleanup goals that reflect reasonably anticipated land uses to attain cleanups that are protective of human health and the environment. EPA's experience with remediating Superfund sites has shown that these objectives are achievable with limitations on land use, and the use of institutional and engineering controls. EPA's regulatory philosophy continues to be that the public deserves the same level of protection for radiation as they expect and get for chemical contaminants. This seems particularly appropriate for CERCLA sites since much, if not most, of the radiological contaminants are co-mingled with chemical contaminants.

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See comment 1.

Consistent risk management approach within the Administration. The draft paper should clarify further that in regards to the risk management approach for cleaning up sites, the agencies within the Administration (which includes EPA, DOE and DOD, but excludes NRC) are generally consistent, both under the current CERCLA statute and pertaining to proposals for reauthorizing the CERCLA statute. When cleaning up their sites, including those sites not on the NPL, DOE and DOD have generally conducted response actions using CERCLA authority. On May 22, 1995, EPA and DOE jointly issued a "Policy on Decommissioning Department of Energy Facilities Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)." The purposes of that Policy includes to "ensure that decommissioning activities are protective of worker and public health and the environment, [and are] consistent with CERCLA . . ." The Policy establishes that DOE generally will treat decommissioning activities as CERCLA removal actions, and that decommissioning response actions "should comply with the requirements of CERCLA, the NCP, and other applicable authorities." As explained in the policy, DOE's response actions will be consistent with CERCLA "regardless of whether or not the release or threatened release is from a site listed on the NPL." In addition, Section 120(a)(2) of CERCLA prohibits Federal Facilities (e.g., DOE, DOD) from adopting or utilizing any rule, guidance or criteria applicable to CERCLA remedial actions that are inconsistent with EPA CERCLA remedial action requirements. Also, the Administration's Superfund Legislative Reform Principles state that ". . . Maximum Contaminant Levels under the Safe Drinking Water Act or more stringent applicable State standards should be established as the cleanup standards for ground water whose beneficial use is or is anticipated to be as a drinking water source, unless technically impracticable."

See comment 2.

Potential dual regulation at Sites. The draft report seems to allege that there is confusion over possible dual regulation by EPA and NRC at several sites. Unfortunately, the report fails to discuss EPA's recent memorandum entitled "Interim Final Evaluation of Facilities Currently or Previously Licensed NRC Sites under CERCLA" (OSWER Directive 9272.0-15P) that was issued on February 17, 2000. This memo provides interim guidance to clarify EPA's role under CERCLA at facilities previously or currently licensed by NRC. If EPA finalizes an MOU with NRC in the future, EPA will revise this memorandum as necessary to reflect the coordination procedures agreed upon by NRC and EPA. In this interim guidance EPA states that "since September 8, 1983, EPA has generally deferred listing on the National Priorities List (NPL) sites that are subject to NRC's licensing authority because NRC's actions are generally believed to be consistent with the CERCLA requirement to protect human health and the environment."

See comment 2.

EPA MOU negotiations. We believe that the draft report inaccurately portrays EPA and NRC as making little progress in our MOU negotiations. The two agencies are in the process of working on a draft MOU and are continuing to make progress on finalizing a document. EPA's letter to the Appropriation Committee's direction to report on the status of MOU negotiations, which was established by the signing of the EPA's appropriation bill on October 20, indicated that the two Agencies were beginning to discuss possible language for an MOU. On May 23, 2000, NRC presented a draft MOU to EPA that incorporated much of earlier

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language that EPA had drafted and the two agencies discussed during a meeting on April 24. While meeting on May 23, EPA and NRC agreed to several changes to the NRC drafted MOU. On June 8, EPA transmitted to NRC several additional suggested changes for discussion with NRC during our next scheduled meeting of June 23. EPA believes that we are making progress in developing an MOU with NRC.

See comment 2.

Potential congressional intervention on site cleanup issue. The draft report several times raises the possibility of congressional intervention regarding EPA's and NRC's disagreement over acceptable cleanup levels for radioactively contaminated sites. The draft report fails to mention that the Administration has already opposed legislative provisions that would amend CERCLA to limit the role of the Superfund program at facilities currently or previously licensed by NRC. On September 3, 1997, former NRC Chairman Shirley Ann Jackson sent a letter to Senator John H. Chafee which proposed such legislative provisions to limit EPA's authority at NRC sites (see attached letter). In a March 25, 1998 letter to Senator Joseph Lieberman, EPA stated the Administration's opposition to NRC's draft legislative language, and reiterated EPA's position that development of an MOU by EPA and NRC, as opposed to legislative amendments to CERCLA, are the most appropriate process for addressing this issue (see attached letter). On July 21, 1999, EPA testified before the House Energy and Power Subcommittee opposing similar legislative provisions that were included in Section 207 of H.R. 2531 (see attached testimony). This testimony was followed with a letter on September 22, 1999 from EPA to Chairman Joe Barton answering several questions pertaining to EPA's opposition to NRC's legislative proposals (see attached letter).

See comment 3.

Cost Analyses of site cleanup. Although we have not had time to review the numerous studies cited in the draft report and are therefore unable to comment in detail, we find it difficult to believe that costs would begin to dramatically rise at the same cleanup level for different sites, particularly the level of soil to be addressed would be dependent upon such a variety of site-specific factors (e.g., land use selected, contaminants of concern at the site, how diffuse or discrete is the contamination, potential treatment technologies). In addition, it appears that most of these studies may not have been conducted to look at remedial alternatives in a manner consistent with CERCLA policy. Under CERCLA, a remedial alternative must meet the threshold requirements (protectiveness, compliance with ARARs). Cleanup levels that are not protective and ARAR compliant are screened out of the CERCLA process and not considered further, while the studies cited in the draft report contained primarily remedial alternatives that are not either protective or ARAR compliant. Therefore most of the studies cited in the draft report are not adequate for this type of analysis because they do not reflect the decision making process or choices that occur at CERCLA sites. In addition, **under CERCLA all remedies must be cost-effective**. Its overall effectiveness is then evaluated based on the following three balancing criteria: (1) long-term effectiveness and permanence, (2) reduction of toxicity, mobility, or volume through treatment, (3) short-term effectiveness. "Overall effectiveness is then compared to cost to ensure that the remedy is cost-effective. A remedy shall be cost-effective if its costs are proportional to its overall effectiveness" (see 55 FR 8850). Under current CERCLA policy, if a site cannot be cleaned up to a protective level (i.e., within the 10^{-4}

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to 10^{-6} risk range) for the "reasonably anticipated future land use" because it is **not cost-effective or practicable** based, among other things, on an analysis of adverse effects on the environment or workers), then a **more restricted land use should be chosen that will meet a protective level**. (This may include use as a waste management area (OSWER Directive No. 9355.7-04 "Land Use in the CERCLA Remedy Selection Process," May 25, 1995, pp. 8-9).) This policy reflects the Administrator's CERCLA reauthorization position on land use. A number of the studies cited by the draft Report appear not to take this land use policy into account, and some of the studies actually predate the 1995 guidance on land use. Also, when not based on ARARs, remedies under CERCLA should be based on risk, rather than millirem. Most of the remedial alternatives cited in the draft report are expressed in millirem levels.

Risk Assessment at CERCLA sites. The draft report raises questions regarding the certainty of risk posed by radiation. The report discusses the possibility that both EPA and NRC are cleaning up sites under their regulatory authority to limit exposure to radiation to levels that science may eventually conclude is below a threshold level that poses a potential risk of cancer. Although this issue will be more fully explored in a letter from ORIA, we would like to point out that in the absence of ARARs that are sufficiently protective, cleanup levels at CERCLA sites are generally expressed in terms of risk levels, rather than millirem, as a unit of measure. CERCLA guidance recommends the use of slope factors in the EPA Health Effects Assessment Summary (HEAST) tables when estimating cancer risk from radioactive contaminants. Were the slope factors in HEAST to change, the actual site-specific concentrations that correspond to the risk range would change to reflect this change in science. Although EPA acknowledges uncertainty on the risks of radioactivity, there is more certainty for radiation risk then for almost any other pollutant. If in the future the current estimates of radiation risk were to change, the Superfund risk range would allow flexibility in reflecting those changes in actual cleanup decisions. In contrast, NRC would have to do a new rulemaking to reflect updated risk estimates.

If you have any questions regarding our comments, please contact Stuart Walker of my staff at (703) 603-8748.

Sincerely,

Stephen D. Luftig, Director
Office of Emergency and Remedial Response

Enclosure:

cc:
Steve Page

The following are GAO's comments on the letter dated June 12, 2000, from the Director, Office of Emergency and Remedial Response, Environmental Protection Agency.

1. EPA said the draft report appears to evaluate radiological site contamination and cleanup issues without sufficient acknowledgement that chemical contamination also exists at almost all of these sites. Although the subject of our report is radiation protection, the report states that EPA's policy is to coregulate chemicals and radionuclides, within the same risk range, rather than to treat them differently. EPA also said its risk management approach for cleaning up sites is generally consistent with that of other agencies, including DOE (but not NRC). Although our report focused mainly on regulatory differences between the two principal standard-setting agencies, EPA and NRC, the report points out that NRC and DOE (in its worker protection standards and proposed public protection standards) generally favor a “top down” approach of setting a relatively less restrictive dose limit, and then reducing doses well below the limit in site-specific situations. On the other hand, EPA's Superfund approach has been “bottom up,” setting a relatively restrictive risk goal but allowing less restrictive limits in site-specific situations.

2. EPA said the draft report does not adequately discuss recent EPA-NRC initiatives to avoid potential dual regulation at cleanup sites and inaccurately portrays the two agencies as making little progress in negotiating a memorandum of understanding. Our draft report refers to these recent initiatives, but we modified the final report to make more specific mention of them. Overall, in relation to the EPA-NRC disagreement and these initiatives, our report essentially takes the longer view, noting that since as long ago as 1992, the two agencies have been unsuccessful in addressing their potentially conflicting roles in site cleanups. On this basis, it is unclear that the latest initiatives will succeed without congressional intervention. EPA also said the draft report fails to mention the administration's opposition to proposed legislative changes, such as amending Superfund legislation, in lieu of the memorandum of understanding approach. While we are aware of past legislative proposals, our report does not delineate what form congressional clarification of the two agencies' regulatory responsibilities might take.

3. EPA doubted that nuclear site cleanup costs would begin to dramatically rise at the same cleanup level for different sites. Our report makes no such assertion. In general, the agency analyses we examined showed faster rising costs at lower cleanup levels.

Comments From the Nuclear Regulatory Commission

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 9, 2000

CHAIRMAN

Mr. James Wells, Director
Energy, Resources and Science Issues
Resources, Community,
and Economic Development Division
United States General Accounting Office
Washington, D. C. 20548

Dear Mr. Wells:

I am responding to your June 2, 2000, letter and the enclosed draft report to Senator Domenici (GAO/RCED-00-152), addressing the scientific basis and costs of U. S. radiation standards at low levels, and differences between the standards of the U.S. Environmental Protection Agency (EPA) and the U.S. Nuclear Regulatory Commission (NRC). We believe that this is a fundamentally sound report, which should help Congress understand the long-standing differences between the agencies, differences which we have thus far been unable to bridge. We support your conclusions that the Federal agencies should agree on decommissioning and high-level waste policies and approaches to ensure consistent standards and public protection.

As you note in the report, the regulatory standards that the NRC promulgated for decommissioning arrived at dose criteria with ample safety margins, protective of all pathways, including groundwater, with a cost-benefit analysis that allows for site-specific evaluation. EPA takes a different approach. The NRC is continuing to discuss the differences in decommissioning policies with the EPA in an attempt to eliminate the potential for dual regulation at sites undergoing decommissioning. We agree that Congressional resolution of lead Federal agency regulatory authority may be necessary if the NRC and the EPA are unsuccessful at resolving their differences.

Your report also notes that the NRC-proposed high-level waste standards for Yucca Mountain apply the all-pathways approach, which has been supported by the National Academies of Sciences and other commenters. EPA's addition of a separate groundwater standard lacks technical support and applies drinking water concentration limits to groundwater at the repository that are outdated and that present non-uniform risks. Here, too, reconciliation of the differences in approach may require Congressional action.

As page 3 of your report correctly points out, ground water protection is a central issue between NRC and EPA both at Yucca Mountain and the cleanup and decommissioning of licensed sites. EPA chooses to apply certain standards to groundwater that were developed to apply "at the tap" to public drinking water supplies pursuant to the Safe Drinking Water Act (SDWA). This application of SDWA's standards to groundwater is questionable. Moreover, NRC believes that EPA may be fundamentally misinterpreting Congressional intent with regard to the "anti-backsliding" provision of the SDWA (42 U.S.C. 300g-1(b)(9)). NRC believes that Congress never intended this provision to preclude the use of up-to-date scientific information to translate the 4 millirem/yr regulatory limit in EPA's drinking-water regulations (40 CFR

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141.16), into radionuclide-specific concentration limits. Instead, as your report also correctly points out, EPA uses an outdated 1959 dose methodology (by reference to National Bureau of Standards Handbook 69), which results in doses for individual radionuclides that vary by orders of magnitude, with many of crucial importance well below 4 millirem/yr (e.g., 0.07 millirem/yr for Strontium-90 and 0.2 millirem/yr for Iodine-129). The NRC believes that a reasonable interpretation of the statute might require EPA to maintain the 4 millirem/yr standard, but would allow EPA discretion to determine the appropriate approach for calculating compliance consistent with current scientific understanding. The normalization of all radionuclide concentration limits to 4 millirem/yr total effective dose equivalent, using current scientific methodologies, would go part way to resolving the differences between the two agencies. As a result, we strongly suggest a recommendation be added to your report that Congress may wish to clarify its intent in enacting the SDWA's "anti-backsliding" provision.

The final resolution to these issues should also ensure that Federal standards for radiation protection provide protection of public health consistent with state-of-the-art scientific methodologies. There is general consensus that health effects from radiation exposures at the current 100 mrem/yr public dose limit, or below, are indistinguishable from health effects from other everyday risks encountered by the general public. In addition, the current NRC occupational exposure limit, at a level 50 times higher than the national non-occupational dose limit, is deemed to be protective of workers' health. Studies have not demonstrated deleterious health effects from occupational radiation exposures at the current limit.

Specific recommended changes to the text of the report are enclosed for your consideration. These changes should clarify the findings in your report.

Again, we believe the report is fundamentally sound and should prove helpful. I look forward to receiving the final version.

Sincerely,

Richard A. Meserve

Enclosure:
Mark-up of Recommended Changes
to GAO Draft Report

Comments From the Department of Energy

Note: GAO comments supplementing those in the report text appear at the end of this letter.

Department of Energy
Washington, DC 20585
June 13, 2000

Mr. Jim Wells, Director
Energy, Resources and Science Issues
United States General Accounting Office
Washington, DC 20548

Dear Mr. Wells:

This is in response to your letter of June 2, 2000, to Secretary Richardson regarding the review of your draft report on low level radiation standards for Senator Domenici. In general, we found the report factual and balanced. We have no major disagreements with the report and the attached comments are intended to clarify discussions in the report or to emphasize issues that were not fully discussed.

Thank you for the opportunity to review the report. If you have any questions regarding these comments please contact Andrew Wallo at 202-586-4996.

Sincerely,

David Michaels, PhD, MPH
Assistant Secretary for
Environment, Safety and Health

DOE Comments on Draft GAO Report
"Low -Level Radiation Standards"

In general, the Department found the subject report factual and balanced in its presentation. We look forward to completion of the final report. We provide the following general and specific comments for the purposes of clarification.

The Department of Energy, unlike most other organizations, operates facilities that are subject to radiation protection standards issued by several agencies including its own. The Department is responsible for cleanups and waste management operations that must comply with DOE requirements, with CERCLA and RCRA requirements and, in some cases, requirements issued by NRC. Most DOE requirements are similar to those of the NRC. Cleanups under DOE requirements and guidance must meet the 25 mrem/year plus ALARA requirements similar to NRC's 10 CFR Part 20 requirements. At the same time, we have sites (actually most of our cleanups) that are remediated under CERCLA requirements where the 10^{-6} to 10^{-4} risk range must be met. At many of these facilities the 15 mrem/y limit has been used as the cap for the risk range. For the most part both systems (the NRC/DOE approach and the EPA approach) work and produce protective actions with reasonably similar results. The disagreement over these two approaches is continuously discussed in terms of 25 mrem vs 15 mrem or 100 mrem/y all sources vs 10^{-6} to 10^{-4} lifetime risk range for specific activities. For the most part this does not truly define the problem or the real issue. The real issue is whether the standard, in addition to being protective, is flexible enough to ensure it does not bring about in actions that cause more harm than good or that have costs that are not commensurate with the benefit they may provide.

As the GAO report noted, it is in the area of groundwater protection where large differences arise. The report characterizes the issue reasonably well by indicating EPA's preference to use tap water standards as groundwater protection standards on the basis of policy without supporting cost/benefit analyses or without assessing alternatives for their application to ground water. NRC and DOE have not been able to justify the use of this policy and instead protect ground water as one element of the "all pathways" assessment. The draft GAO report notes (1) that the specific numerical limits are obsolete because of newer dosimetric models (pages 16-17) and that (2) the "no backsliding" provisions of the 1996 Safe Drinking Water Act Amendments may rule out raising the limits for radionuclides (page 18 also see specific comment). What is not mentioned in the draft report is that these differences are at least in part due to enabling legislation. Under their AEA authority NRC and DOE are charged to protect the public and environment and can do it through an all pathways approach. However, under some EPA implemented legislation Congress has specifically endorsed the use of the tap water standard approach for ground water (i.e., RCRA and CERCLA) by specify that the drinking water standards should be used for non-degradation of groundwater. EPA has expanded this approach into areas outside of RCRA and CERCLA.

See comment 1.

Throughout the report, there are statements that report the conclusions of interviews with various individuals and organizations and others that report specific facts or technical conclusions (including dose and cost estimates). We understand that this is a draft report and assume the references will be in the final report. We recognize most of the information but feel clear references will improve the report's credibility and assist readers not as familiar with the topic.

Specific Comments:

Report Title: As written the title could be misunderstood to imply the report applies to low-level radioactive waste. GAO may wish to consider a title along the lines "Standards Regulating Exposures to Low Levels of Radiation."

Page 6, line 16: Suggest changing "nuclear waste storage" to "nuclear waste disposal."

Page 8, footnote 12: The footnote on page 8 incompletely cites the degree of confidence of the cancer estimates of the 1990 BEIR study. The footnote states that, for 100 millirem per year over a lifetime at the 90 percent confidence interval, the number of additional deaths per 100,000 people is 410 to 980 for men and 500 to 930 for women. Pages 180 and 181 of the BEIR V report make clear that these confidence intervals assume the validity of the linear model and only reflect the uncertainty of the inputs to that model. As the BEIR report states on page 181: "Moreover, epidemiological 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, it must be acknowledged that the lower limit of the range of uncertainty in the risk estimates extends to zero."

Page 9: Figure 1 is presented as an illustration of the linear no threshold concept and to clarify the remark below the table "that as exposure doubles, risk doubles..." Inclusion of units or divisions on the table or redrawing the line at a 45 degree angle showing a 1:1 slope would help the illustration for readers not familiar with the topic.

Page 11, " Research Efforts to Verify Low-Level Radiation Effects are On-going", paragraph 3: This paragraph explains the conduct of epidemiologic studies and refers to case-control and ecologic studies but omits any reference to cohort studies (such as the study of atomic bomb survivors). The following changes in the second and third sentences that will also make the wording consistent with that in Appendix IV are recommended:

"In this regard, epidemiologists consider two types of epidemiologic studies **1) analytic or 2) ecologic. Analytic studies either compare individuals who have received an exposure to an agent such as radiation to those individuals who were not exposed and determine if there are subsequent differences in their health status (cohort studies) or** compare individual cases of disease to a **comparison set of individuals who do not have the disease to determine if there were differences in the past exposures of these two groups** (case control studies). Ecologic studies rely on regional data on disease and radiation levels instead of individual data**, and are considered** to be less reliable **than analytic studies**."

Also the last sentence of the second paragraph of Appendix IV needs editing. The word "funded" should be deleted where it appears for the second time in that sentence.

Page 14, lines 13 and 14: Suggest changing "national decision will be made in coming months" to "national decision will be made in 2001."

See comment 2.

Page 18, paragraph 1: This paragraph correctly notes EPA's interpretation of the "no backsliding" provision of the 1996 Safe Drinking Water Act Amendments; however, it may also be important to note that based on a review of the Congressional record and the legislation, others have a somewhat different interpretation of these provisions. One interpretation is that Congress was directing EPA to use the best possible science in developing and updating standards and that the provision should be applied to the dose or risk goals not the concentration limits that are a product of the dose/risk goal and the science. The way the provision is interpreted could have significant impact in many areas.

See comment 3.

Pages 18-21 (and Appendix V): The discussions here and the appendix discuss the relationship between costs and dose but do not address the integrated health risk or detriment associated with or averted by the standards and associated cleanup levels. Using the LTN model, at most sites the integrated cancer risk (individual risk x number of individuals at risk) is typically less then one at all dose limit levels; suggesting zero expected cancers for most site-specific cleanup alternatives. Therefore, reducing "risk" below the 25/15 mrem levels provides little if any health benefit. Even when the hypothetical risks averted are added for all sites to produce numbers in excess of one, there are generally small differences between 25 mrem vs.15 mrem dose limits. As noted in our general comment the important issue is the flexibility of the regulatory system.

Page 23, line 9: Change "would" to "may." The sentence would read "...such a design may not be needed..." This would indicate that the decision is not absolute, at this time.

Page 23, line10: Suggest changing "less restrictive standards such as" to a "more flexible all-pathway standard." This would clarify the NRC and DOE preference not to have a separate groundwater standard.

Page 31: The draft report states that the cleanup criterion for radium-226 is 5 picoCuries per gram. In reality, the criteria for both radium-226 and radium-228 is 5 picoCuries per gram in the surface soil and 15 picoCuries per gram in the subsurface soil. Also, we presume that because DOE requirements (excepting 10 CFR Part 835) are published in DOE Orders and this table only lists requirements published in the Code of Federal Regulations, DOE requirements are not included. For the record, we do note that DOE radiation control requirements for public protection are in DOE 5400.5 and for waste management in DOE O 435.1.

Page 34, 2nd paragraph, 2nd to last sentence: Change sentence "Results are expected in mid to late summer 2000." to: "Results are expected in late 2000."

Appendix IV: GAO may also want to summarize the Navy shipyards study in the report because it is one of the largest low dose epidemiological studies completed in the United States. In 1991, researchers from the Johns Hopkins University, Baltimore, Maryland, completed a comprehensive epidemiological study of the health of workers at the six Navy shipyards and two private shipyards that serviced Navy nuclear-powered ships. This independent study evaluated a population of 70,730 civilian workers over a period from 1957, beginning with the first overhaul of the first nuclear-powered submarine (USS NAUTILUS) through 1981, to determine whether there was an excess risk of leukemia or other cancers associated with exposure to low levels of gamma radiation.

This study did not show any cancer risks linked to radiation exposure. Furthermore, the overall death rate among radiation-exposed shipyard workers was less than the death rate for the general U.S. population. It is well recognized that many worker populations have lower mortality rates than the general population, because the workers must be healthy to perform their work. This study shows that the radiation-exposed shipyard population falls in this category. In conclusion, the Johns Hopkins study found no evidence to conclude that the health of people involved in work on U.S. nuclear-powered ships has been adversely affected by exposure to low levels of radiation incidental to this work.

Appendix V (and the discussion on pages 21-26): As this data shows the difference in costs in the 25 to 15 mrem/y cleanup limit ranges is marginal and is many times within the uncertainty of these estimates. It is usually only as one moves to significantly higher or lower doses that differences in cost become very significant. Although there are a few situations (sites) where the differences between 25 mrem and 15 mrem are significant, the fact is that given the nature of cleanup activities, a cleanup to 25 mrem or 15 mrem all-pathways limit normally achieves protection from actual use well below either level. (Also see previous comment on risk relating to the discussion on pages 18 through 21).

The following are GAO's comments on the Department of Energy's letter dated June 13, 2000.

1. DOE raised the question of references to information sources in our draft report. Our report, for the most part, does not cite technical sources, in keeping with GAO's policy and the role of our reports as other than technical treatises, as well as in the interest of report brevity.

2.DOE said there may be different interpretations of the “no backsliding” provision of the 1996 Safe Drinking Water Act Amendments. We believe that groundwater protection policy and legal matters, including the specific “no backsliding” provision, will be of interest to the congressional committees of jurisdiction in any efforts they may wish to undertake to reconcile EPA's and NRC's regulatory approaches.

3. DOE said the draft report did not address the integrated health risk or detriment associated with or averted by the standards and associated cleanup levels, and it pointed out that risk reductions associated with cleanup efforts may provide little if any health benefit. Our report recognizes that agencies routinely calculate hypothetical cancer deaths averted in achieving cleanup levels. However, we regard such calculations with caution because they are based on the linear model, and therefore we did not highlight such calculations in our report.

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