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Report to the Chairman, Committee on Governmental Affairs, U.S. Senate

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NUCLEAR HEALTH AND SAFETY

Consensus on Acceptable Radiation Risk to the Public Is Lacking



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GAO

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

Resources, Community, and Economic Development Division

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September 19, 1994

The Honorable John Glenn Chairman, Committee on Governmental Affairs United States Senate

Dear Mr. Chairman:

As you know, over several decades federal agencies have developed numerous radiation protection standards to help protect the public from radiation exposures resulting from nuclear operations, environmental contamination, and the disposal of nuclear waste. As new standards continue to be developed, potentially immense regulatory costs could be associated with decisions on acceptable levels of radiation risk at U.S. nuclear facilities and sites, and regulators may be faced with controversial trade-offs between radiation health effects and affordability. To help address these issues, you requested that we examine questions of consistency related to federal agencies' radiation standards.

As agreed with your office, we specifically examined the degree of consistency and compatibility in (1) the various limits on public exposure to radiation included in the federal radiation standards and (2) the various protective strategies associated with the standards. In addition, we focused on whether the standards as a whole provide a coherent, complete federal framework for public radiation protection.

Results in Brief

Differences exist in the limits on human exposure to radiation set by federal agencies,¹ raising questions about the precision, credibility, and overall effectiveness of federal radiation standards and guidelines in protecting public health. Taken together, the radiation standards that have been developed reflect a lack of overall interagency consensus on how much radiation risk to the public is acceptable. Because the standards have different regulatory applications and are based on different technical methodologies, the estimated risks to the public that are associated with these standards and guidelines vary considerably.

Over the years, agencies have not agreed on calculation methods and radiation protection strategies to support their regulations and guidelines. As a result, agencies may engage in time-consuming disagreements on

¹The limits often involve dose limits and estimates of risks to the public. Dose is a measure of radiation energy absorbed in tissue. Risk, as generally used in this report, refers to the chance of a premature human fatality from a radiation-caused cancer.

which protection levels are appropriate and at what costs, and regulators may have difficulty in assessing clearly the overall health impacts and cost-effectiveness of their radiation standards.

Differences in radiation limits and risks, calculation methods, and protective strategies reflect the historical lack of a unified federal framework for protecting the public from radiation exposure. Historically, interagency coordination of radiation protection policy, principally through the Environmental Protection Agency (EPA) and the presidential Committee on Interagency Radiation Research and Policy Coordination, has been ineffective. Time-consuming and potentially costly dual regulation of nuclear licensees has been an issue between EPA and the Nuclear Regulatory Commission (NRC), and standards for major sources of radiation have been lacking for years because interagency disagreements have delayed the completion of regulations. EPA and NRC have recently begun an effort to "harmonize" their respective calculation methodologies and protective strategies in order to avoid duplicative regulation. It remains to be seen whether this effort will be sustained and broadened to include effective participation by other agencies and the Committee on Interagency Radiation Research and Policy Coordination.

Background

Although low-level ionizing radiation surrounds us continually,² its dangers remain elusive. We are immersed in nuclear radiation, mostly from natural sources, including the cosmos and soil. Also, buildings and certain industrial and governmental activities in the United States regularly expose us to smaller amounts of radiation. On the average, according to the National Council on Radiation Protection and Measurements, the U.S. population receives a radiation dose of a little more than one-third of a rem a year,³ mostly from natural background radiation. Exposure to small amounts of radiation is believed to cause fatal cancer or hereditary defects in human beings, but verification of this causal relationship is difficult. While about 1 in 5 deaths that occur in the U.S. population (principally radon) in a lifetime has been estimated at 1 in 100. Exposures resulting from human-generated sources of radiation (excluding exposures resulting from medical sources, which

²Ionizing radiation is rays and atomic particles with enough energy to knock electrons free from (or ionize) atoms.

³Rem is an abbreviation for roentgen equivalent man and is a unit of measurement for radiation doses to human beings.

generally are not clearly limited) pose a still smaller estimated lifetime risk of cancer death.⁴

Various federal laws and regulations (or standards) and nonbinding guidelines on radiation protection are developed and administered by EPA, NRC, and other agencies. EPA has a mandate dating from a 1970 presidential reorganization plan not only to regulate environmental contamination, including radioactive contamination, but also to advise the President on radiation policy. NRC is generally responsible for regulating civilian uses of nuclear materials in the United States. In addition, under the Atomic Energy Act, the Department of Energy (DOE) issues and enforces standards for its nuclear facilities around the country. Other participants in the formulation of U.S. radiation protection policy include the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC), within the President's Office of Science and Technology Policy; the Office of Management and Budget (OMB); state governments; and numerous nongovernmental and international organizations. (See app. I.)

Federal radiation protection policy has been a matter of longtime congressional interest. In 1980, in response to congressional concerns about federal radiation protection policy coordination, the President created a federal radiation policy council. However, the council was soon thereafter abolished by the incoming presidential administration. In 1982, you introduced legislation to create a federal interagency council on radiation protection. This legislation was not enacted, but the administration established CIRRPC in 1984. More recently, Senate Governmental Affairs Committee oversight hearings in 1993 and GAO reviews have indicated continuing problems with various matters, such as the fragmented regulation of medical radiation and years of delay in developing EPA's radiation protection standards, because of low priority and a lack of coordination. For example, in June 1993 we recommended that for groundwater protection standards for inactive uranium-processing sites. EPA and OMB meet to resolve differences impeding the issuance of standards. In August 1994, we recommended that EPA complete work on developing cleanup standards for radionuclides by the end of 1995.5

⁴The estimated chance is about 1 in 3,000, based on a risk factor adopted by the International Commission on Radiological Protection.

⁵Radioactive Waste: EPA Standards Delayed by Low Priority and Coordination Problems (GAO/RCED-93-126, June 3, 1993) and Nuclear Cleanup: Completion of Standards and Effectiveness of Land Use Planning Are Uncertain (GAO/RCED-94-144, Aug. 26, 1994).

Differences in Federal Radiation Exposure Limits	The exposure limits and risks associated with the federal radiation standards and guidelines differ, in part because the standards rely on different calculation methods and protective strategies. The standards often contain different numerical limits on radiation exposure to the public and often reflect different estimated acceptable risks. As a result, taken together the limits present an imprecise picture of how much public health risk from exposure to low-level radiation is acceptable.
Different Limits and Associated Risks	At least 26 different draft or final federal radiation standards or guidelines contain numerical radiation limits, most administered by either EPA or NRC. Some of the radiation limits agree numerically, but others differ; still others are not expressed in comparable units, as shown by the selected public protection standards listed in table 1. ⁶ The estimated risks associated with these limits vary considerably. (Standards and guidelines for public, source-specific, and occupational exposure are listed in app. II.) The different risks shown in the table are indicative of the standards' different regulatory applications. In particular, the risks relate to various sources of exposure, such as the uranium fuel cycle, miscellaneous environmental sources, and occupational sources. The risks also reflect various modes of controlling exposure, such as setting requirements for nuclear site design and operations or setting limits on releases, emissions, environmental concentrations, and doses.
	For example, NRC's general public exposure limit of 0.1 rem per year applies to regulated radiation sources, such as those used in research laboratories and hospitals, and results in an implied lifetime estimated risk of about 1 in 300. The lower (0.025 rem per year) limit on public exposure from nuclear operations in EPA's uranium fuel cycle regulation is for a single operational activity; this limit is based primarily on the consideration of practicable technologies for controlling radioactive effluents, according to an EPA official. This limit results in an implied lifetime estimated risk of about 1 in 1,000. EPA's still lower (0.01 rem per year) air pollution limit is for a single environmental medium and is based on EPA's legally mandated estimates of the level of risk that will (1) be safe or acceptable considering only health-based factors and (2) protect public health "with an ample margin of safety," considering costs, feasibility, and

⁶For purposes of comparison, the risks in table 1 have been derived on the basis of commonly used assumptions, including a risk factor adopted by the International Commission on Radiological Protection. The use of different assumptions could result in considerably different risk estimates.

other relevant factors.⁷ EPA's air pollution limit has an implied lifetime estimated risk of about 1 in 3,000. These three examples demonstrate the lack of overall interagency consensus on how much radiation risk to the public is acceptable.

Table 1: Differing Federal Limits on Public Radiation Exposure

Standard or guideline/agency	Limit	Estimated lifetime risk of premature cancer death
General public limit/NRC	0.1 rem/yr.	1 in 300
Low-level waste/NRC	0.025 rem/yr.	1 in 1,000
Indoor radon/EPA	4 picocuries per liter concentration limit ^b	1 in 40
Uranium mill tailings/EPA		
Radium	5 picocuries per gram	1 in 50°
Radon	20 picocuries per square meter per second release rate	1 in 14,000 ^d
Uranium fuel cycle/EPA	0.025 rem/yr.	1 in 1,000
Spent fuel, transuranic waste	e disposal/EPA	
All pathway	0.015 rem/yr.	1 in 2,000
Groundwater	0.004 rem/yr.	1 in 7,000
Containment	1,000 deaths in 10,000 years	1 in 36,000°
Air pollution/EPA	0.01 rem/yr.	1 in 3,000
Drinking water/EPA (propose	ed)	
Radium	20 picocuries per liter concentration limit	1 in 14,000
Radon	300 picocuries per liter concentration limit	1 in 5,000
Beta/photon ¹	0.004 rem/yr.	1 in 7,000
Superfund cleanup/EPA	Risk range goals of 10 ⁻⁴ to 10 ^{-6 g}	1 in 15,000 to 1 in 1,500,00

^aFor purposes of comparison, the estimated risks in the table are derived from commonly used assumptions (e.g., a cancer death risk of 5x10⁻⁴ per rem to an individual continuously exposed over a 70-year lifetime). The estimated risks may differ from those derived by agencies, which used various assumptions in setting standards. Some estimated risks are to individuals, and others are to larger defined populations. Risks are rounded.

^bA picocurie is one-trillionth of a curie. A curie is a unit of radioactivity equal to 3.7x10¹⁰ radioactive disintegrations per second.

⁷According to EPA's draft guidance on general public exposure to radiation, limits on single sources of radiation should logically be a fraction of general public protection limits.

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	Based on exposure to an individual residing on-site after cleanup. The estimated risk to an individual off-site could be considerably less.
	^d Based on average population exposure. According to EPA and DOE, the estimated risk to a maximally exposed individual could be considerably greater.
	Based on an NRCs assumption of a population of 250,000.
	¹ Beta particle and photon radioactivity from man-made radionuclides in community water systems.
	$^{9}10^{-4}$ to $10^{-6} = 1$ in 10,000 to 1 in 1,000,000 risk of cancer incidence. In the risk column, risks have been converted to express the cancer mortality risk. The dose limit is determined on a site-specific basis, depending upon the exposure pathways, radionuclide, total inventory, and site's characteristics.
	Source: Derived by GAO in part from CIRRPC, NRC, EPA, and DOE data.
Different Calculation Methods Behind the Limits	Differences in the various radiation exposure limits point in part to the lack of interagency agreement on the technical assumptions underlying various standards. These assumptions are key elements of the dose and risk calculation methods used by agencies in deriving the limits. In practice, agencies' calculation methods often differ, giving different results. These methods can be theoretical, drawing upon scant actual data. They may incorporate different hypotheses, scenarios, assumptions, and mathematical simulations (models). ⁸ For example, EPA and NRC use different scenarios for depicting how human exposure may occur, including different assumptions about prospective human intrusion into a site and the period of human exposure. Assumptions that result in overestimations can lead to levels of regulatory dose and risk limitation that require large expenditures for compliance but do not necessarily significantly reduce the health risk to the public. Also, as a result of these methodological differences, standards may be difficult to compare to one another, and their overall technical credibility may be questioned. ⁹
	To date, agencies have taken limited steps to ensure that their calculation methods have sufficient consistency. For example, interagency guidance exists on preferable dose and risk coefficients to be used in calculations, but not on preferred environmental models ("pathway" and "exposure" models) to be used. According to EPA and NRC, a degree of consistency exists in the limits and in the technical methods supporting them, and bot

^oA major overall assumption is that even the smallest dose of radiation may be harmful—a generally accepted but unproven hypothesis.

⁹The details of uncertainties and inconsistencies in the technical methods supporting the standards are discussed in app. IV.

	agencies are working to further ensure such consistency. The two agencies recently identified both similarities and differences in their technical methods in a joint analysis, including differences in the risk levels they have considered acceptable. ¹⁰
Different Protective Strategies Behind the Limits	Different limits and calculation methods are indicative of the different protective strategies that agencies have used over the years in their radiation standards and guidelines. Often these strategies—or conceptual approaches—require that numerical dose and risk limits be supplemented with considerations of economic, social, technical, and other factors.
	Agencies have independently developed different approaches, according to different traditions and legal mandates. Some of their approaches may be categorized as either "top down" or "bottom up." The top-down protective strategy involves setting an "upper bound" or limit, but reducing dose and risk well below it, in site-specific compliance situations, to a reasonably achieved lower level; the limit is reduced on the basis of various factors, such as economic and social considerations and technical feasibility. ¹¹ NRC and DOE have consistently favored the top-down approach in their standards (for example, in NRC's general public protection standard).
	Conversely, the bottom-up strategy has been used to control certain specific environmental radiation sources. It involves setting a lower, relatively more stringent dose or risk goal (a desirable target, not a limit). The goal is to be pursued through use of the "best available technology" to control exposure or remove environmental contamination. Under this approach, if the goal is not achievable, on the basis of considerations of technical feasibility, cost, and other factors, the regulator may decide to accept a less stringent level of achieved protection. This strategy is reflected in some EPA regulations, such as the regulation on drinking water contamination. In addition, under the Atomic Energy Act and various environmental laws, EPA implements numerous other protective approaches. ¹²

¹⁰Generally, NRC has considered a lifetime risk of 1 in 1,000 to be acceptable, while EPA has strived for a lesser risk of 1 in 10,000.

¹¹This strategy is often called the "as low as reasonably achievable" approach.

¹²In general, the laws themselves do not prescribe either risk limits or protective strategies, although they may imply the use of a particular protective strategy.

Also, EPA uses different protective strategies drawn from the separate traditions of regulating chemical and radioactive contaminants. On the basis of 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 remediation¹³ and has considered a risk of greater than 1 in 10,000 to be potentially excessive. In some cases, EPA has also used these risk goals in connection with radiation protection.

Using the top-down, bottom-up, and other strategies, agencies have set lower limits over the years. In so doing, they have increasingly supplemented numerical dose and risk limits with considerations of economic, social, technical and other factors in deciding on acceptable human exposure levels. Such decisions incorporate input from various interested parties, resulting in negotiated radiation exposure protection levels that represent overall social value judgments. In part because agencies use different calculation methods and protective strategies, these negotiations can involve time-consuming interagency disagreements on dose limits, risks, and cost considerations. For example, recent negotiations between EPA and DOE on cleaning up thorium contamination at a DOE Superfund site in New Jersey in part involved technical arguments about whether the cleanup level should be 5 or 15 picocuries per gram above natural background concentration levels. The decision on the remediation level included options involving multimillion-dollar differences in projected cleanup costs.

Interagency guidance has not been adopted to help structure the process of incorporating cost and benefit considerations into agencies' protective strategies. As a result, regulators and others are unable to assess clearly the overall health impacts and cost-effectiveness of their strategies and standards.¹⁴ While cost and benefit analyses are important to agencies' protective approaches, they can be complex and potentially controversial in use. For example, they may address not only the risk and cost of serious health effects, but also less quantifiable social factors. Such factors may include ethical concerns, equitable sharing of costs and benefits, perceived public aversion to radiation at any exposure level, and costs and benefits that could accrue to people who have been defined as not within the

¹³According to one estimate, this risk is in the range of the estimated chance that a given airline flight will result in a crash or that a person will be struck by lightning in his or her lifetime.

¹⁴The calculated dollar values associated with radiation risk reduction may vary widely from one regulation to another. For example, according to a 1992 OMB comparative analysis, in two EPA standards (for radionuclides in uranium mines and for covering/moving uranium mill tailings at active sites) such values ranged from about \$3.4 million to about \$45 million per premature death avoided, respectively.

at-risk population. The analyses supporting such considerations may be complex and quantitative, or they may be simpler, involving professional judgment and social and political considerations. In either instance, agencies may be subject to criticism if their cost-benefit analyses are perceived as being inequitable or unfairly placing monetary values on human lives.¹⁵

Because agencies have not agreed on dose and risk calculation methods and protective strategies (including cost-benefit analysis approaches to support these strategies), regulators may not have assurance that their standards have better protected the public health at an optimal cost. On the one hand, even though lower radiation limits may involve costly implementation, they still may represent prudent decision-making, because even the lowest human exposures to radiation may be assumed to be potentially harmful. On the other hand, because the relatively stringent protection levels in some federal radiation regulations have not been definitely shown to be associated with health effects in populations, it is not readily apparent that lower limits have necessarily resulted in significantly better protection of public health at an optimal cost. Thus, agencies' radiation standards and protective approaches ultimately reflect an overall lack of interagency consensus on how much radiation risk to the public is acceptable.

This lack of consensus has implications for the difficult regulatory decisions that EPA, NRC, DOE, and other agencies will face in upcoming years as they develop new standards to address nuclear cleanup and disposal at sites around the country. Such decisions may involve trade-offs between affordability and radiation protection, as well as potentially immense regulatory costs. Regulatory areas involved in such decisions may include low-level waste, cleanup of residual radioactive contamination, nuclear facility decommissioning, high-level waste storage, and potentially even indoor radiation in residences.

Lack of a Unified Framework for Federal Radiation Protection Differing federal radiation exposure limits have resulted from a historical lack of a unified interagency framework of radiation protection standards and protective strategies. Because of ineffective policy coordination over many years, agencies have to a degree gone their own ways in radiation protection. As a result, problems with overlapping regulation of nuclear

¹⁵For the most part, agencies have not established preferred regulatory cost-benefit ratios (for example, dollar values per avoided dose) that they consider applicable to compliance with their radiation standards. An exception is NRC's suggested benchmark of up to \$1,000 per person-rem, which is intended to guide licensees in designing protection into nuclear reactors. This amount converts to a estimated \$2 million expended per hypothetical death avoided.

licensees have developed, and agencies have engaged in lengthy disagreements on the merits of draft radiation regulations, leaving areas of public protection without clear coverage for years.

For example, EPA and NRC, the two principal agencies involved in issuing radiation standards, have engaged in ongoing disagreements on jurisdictional and philosophical issues, including protective strategies. Also, in recent years EPA and CIRRPC have coordinated federal radiation policy ineffectively. Although both EPA and CIRRPC have a coordinating role, EPA has a mandate to issue guidance and advise the President on radiation health matters. According to the Deputy Director of EPA's Criteria and Standards Division, Office of Radiation and Indoor Air, while EPA has had the authority to take the lead in formulating radiation policy, historically it did not do so. Coordination between EPA and CIRRPC on radiation policy matters has been and continues to be limited, and in general EPA deals directly with other agencies on radiation policy rather than through the forum of CIRRPC. Various federal and state officials whom we interviewed said that the lack of interaction between EPA and CIRRPC has impeded interagency coordination of radiation protection policy.

As a result of this historical situation, problems with overlapping regulation of nuclear licensees have developed and become more apparent. In some instances, radiation standards duplicate others or potentially conflict with other agencies' responsibilities in their coverage. In such cases, often involving EPA and NRC, time-consuming clarification of responsibilities may be necessary and costly dual regulation of licensees may occur.¹⁶ In other cases, standards have not been finalized for years, leaving areas of public protection without clear limits. For example, several EPA regulations on the handling and disposal of radioactive waste and cleanup of contamination have been in development or under review for up to 10 years or more—some have still not been issued—because of such issues as legal concerns, coordination, and the setting of priorities.¹⁷

Some EPA and NRC initiatives related to policy coordination have recently been undertaken. For example, EPA has recently led an interagency effort to develop federal cleanup standards for radiologically contaminated sites, including DOE sites. Other agencies involved in the effort include NRC, DOE, and the Department of Defense. In April 1993, EPA and DOE signed an agreement under which DOE would provide \$1.5 million in funding to EPA

¹⁶For example, as discussed in app. I, potentially costly conflicts have arisen between EPA's and NRC's regulations affecting the nuclear medical community.

¹⁷Details of regulatory overlap and delays in completing standards are discussed in app. I.

for greater resources to develop and complete the standards. Also, NRC, in coordination with EPA, has been developing standards for decommissioning NRC-licensed facilities. In addition, EPA has developed draft presidential guidance on radiation protection for the general public to replace existing guidance issued by the Federal Radiation Council in 1960. The new guidance updates the suggested limit on public exposure (from 0.5 rem to 0.1 rem annually), and it makes various recommendations that EPA expects will clarify basic considerations to be taken into account in the development of new radiation standards—thereby promoting consistency among federal agencies. According to an EPA official, the guidance will be published for public comment in the <u>Federal Register</u> in the fall of 1994.

Furthermore, EPA and NRC agreed in a March 1992 memorandum of understanding to, among other things, strive to avoid unnecessarily duplicative or piecemeal regulatory requirements for NRC licensees and to actively explore ways to harmonize risk goals and cooperate in developing a mutually agreeable approach to risk assessment methodologies for radionuclides. They intended to issue a joint report in January 1994 describing their specific goals and efforts, but the report is still in draft form. According to an EPA official, it is unclear when the report might be finally issued. The draft contains recommendations generally aimed at encouraging both agencies to (1) better agree on risk limits and (2) harmonize their approaches to radiation regulation.

These several efforts at policy coordination are important, but so far they represent limited steps toward a unified, ongoing, comprehensive framework for interagency radiation protection policy. In particular, the EPA-NRC harmonization effort has only begun to address and potentially resolve issues related to calculation methods, protective strategies, and acceptable risks. EPA and NRC officials said that the issues addressed in the harmonization effort are challenging, and they could not predict the long-run success of the effort. They agreed that the effort should at some point be broadened to include other federal agencies.

Conclusions

The public's health and safety, potentially costly regulatory decisions, and the general credibility of nuclear regulation depend in part on the ability of EPA and NRC, along with other agencies, to work toward achieving a more unified federal framework for radiation protection standards. As radiation standards have become more stringent over the years, regulators have been faced in an era of budgetary constraints with decisions involving

	difficult, judgmental trade-offs between limiting expenditures and reducing radiation risk to the public. In such circumstances, agencies need to reach better agreement on radiation dose and risk calculation methods as well as the overall strategies they use in federal standards and guidance to protect public health. In addition, they need ongoing radiation protection policy guidance from EPA, in cooperation with other agencies and CIRRPC. At present, it is apparent that agencies' radiation standards and protective approaches ultimately reflect a general lack of interagency consensus on acceptable radiation risk to the public.
	To date, agencies have taken limited steps to agree on dose and risk estimation methods and protective strategies. EPA's and NRC's efforts to better harmonize their standards and protective strategies could bring important results if those efforts can be sustained. However, the issue of differing protective strategies is complex, and for many years EPA, NRC, and other federal agencies have not effectively coordinated their radiation policies. Therefore, unless the harmonization effort is given ongoing attention and broadened to include the effective participation of other agencies and CIRRPC, it may not go very far toward achieving interagency consensus on federal radiation protection policy. In such an instance, congressional reconsideration of the merits of the present federal interagency framework for formulating and coordinating radiation protection policy may be warranted.
Recommendation	To better unify federal radiation protection policy, we recommend that the Administrator, EPA, in cooperation with the Chairman, NRC, take the lead in sustaining and broadening the ongoing EPA-NRC harmonization effort to include the effective participation of other agencies and CIRRPC in pursuing interagency consensus on preferred radiation dose and risk calculation methods and radiation protection strategies, as well as an overall consensus on how much radiation risk to the public is acceptable.
Scope and Methodology	To develop this report, we interviewed knowledgeable EPA, NRC, DOE, and CIRRPC officials and examined documents provided by them related to radiation protection standards and radiation dose and risk calculation. We also interviewed nongovernment officials with knowledge in the area of radiation effects and examined technical literature related to radiation dose and risk calculation methods and protective strategies. For purposes of risk comparison, we compiled a list of federal radiation standards and

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	guidelines and calculated the radiation risks associated with them, in part on the basis of data from NRC, EPA, and CIRRPC.
Agency Comments	We distributed a draft fact sheet reflecting the contents of this report to the mentioned above officials and numerous other knowledgeable government and nongovernment officials in the area of radiation protection for their informal review. Those providing informal comments included EPA's Deputy Director, Criteria and Standards Division, Office of Radiation and Indoor Air; branch chiefs within NRC's Regulatory Applications and Low-Level Waste Management and Decommissioning divisions; DOE's Director, Air, Water, and Radiation Division, Office of Environmental Guidance; a senior science-policy adviser at the Committee on Interagency Radiation Research and Policy Coordination; state radiation control directors; an official of the Natural Resources Defense Council; and members of the National Council on Radiation Protection and Measurements and the Health Physics Society. As requested, we did not obtain written agency comments on the report.
	On the basis of these officials' comments, which were generally technical in nature, changes were made to improve the accuracy of the report. Numerous commenters, including EPA, NRC, and DOE officials, generally agreed that better coordination of federal agencies' radiation dose and risl calculation methods and protective strategies would be helpful. In addition, EPA and NRC officials concurred that their ongoing harmonization effort should eventually include the participation of other federal agencies
	As arranged with your office, unless you publicly release its contents earlier, we plan no further distribution of this report until 30 days after the date of this letter. At that time, we will send copies of this report to the Administrator, EPA, the Chairman, NRC, and other interested parties. We

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will make copies available to others on request. Please contact me at (202) 512-3841 if you have any questions. Major contributors to this report are listed in appendix V.

Sincerely yours,

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Victor S. Rezendes Director, Energy and Science Issues

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Abbreviations

CIRRPC	Committee on Interagency Radiation Research and Policy
	Coordination
DOE	Department of Energy
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
GAO	General Accounting Office
ICRP	International Commission on Radiological Protection
NCRP	National Council on Radiation Protection and Measurements
NRC	Nuclear Regulatory Commission
OMB	Office of Management and Budget
WLM	working level month

Appendix I Framework for Controlling Radiation Exposure

Sources of public exposure to radiation that are controlled under federal regulations include emissions from the nuclear power industry and federal production operations, miscellaneous environmental sources, and commercial applications. In addition, occupational exposures are subject to separate standards. The standards include those that provide for general radiation protection under the Atomic Energy Act of 1954 and those relating to subsequent laws passed to control human exposure from specific practices not covered under that act. Under Reorganization Plan No. 3 of 1970, the Environmental Protection Agency (EPA) succeeded the Federal Radiation Council (established in 1959 under section 274 of the Atomic Energy Act) and assumed its duties of providing a federal policy on human radiation exposure, advising the President with respect to radiation health matters, and issuing environmental protection standards and guidance for federal agencies. The Nuclear Regulatory Commission (NRC), as the principal regulator of the U.S. commercial nuclear industry since the dissolution of the Atomic Energy Commission in 1974, is responsible for regulation of most civilian uses of nuclear materials in the United States. In this role, it issues radiation standards for public and occupational protection.

In addition, other agencies, including the Department of Energy (DOE), the Department of Health and Human Service's Food and Drug Administration (FDA), the Department of Labor's Occupational Safety and Health Administration, and the Department of the Interior's Mine Safety and Health Administration, regulate certain radiation sources and practices. Federal agencies participate in health and research related coordination initiatives through the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC), made up of 18 participating agencies and chartered in 1984 within the President's Office of Science and Technology Policy. CIRRPC serves as a forum in which the agencies' radiation policy officials can discuss and resolve radiation policy issues. In addition, the Office of Management and Budget (OMB) reviews agencies' proposed regulations, including those related to radiation protection, prior to their issuance.

In addition to the federal protection framework, states have a regulatory role, and non-government and international organizations have an advisory role. Some state responsibilities for regulating radiation are related to materials that are not federally regulated, and others have been assumed by the the states under agreement with NRC. States coordinate their protection efforts with the federal government through the Conference of Radiation Control Program Directors. Other national and international

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	organizations involved in radiation protection matters include the congressionally chartered National Council on Radiation Protection and Measurements (NCRP), the National Research Council's Committees on the Biological Effects of Ionizing Radiation, the International Commission on Radiological Protection (ICRP), the United Nations Scientific Committee on the Effects of Atomic Radiation, the International Atomic Energy Agency, and the Nuclear Energy Agency of the Organization for Economic Cooperation and Development.
Examples of Overlapping or Incomplete Coverage	Without a unified radiation protection policy framework, agencies issue duplicative, potentially conflicting regulations. For example, EPA, NRC, and DOE have issued potentially duplicative (and in some respects potentially contradictory) regulations and guidelines according to different laws and their individual agency jurisdictions. All three have also issued limits on public exposure to radiation. Also, EPA's limits on public exposure to uranium mill tailings are virtually identical to those of NRC (both of which implement the Uranium Mill Tailings Radiation Control Act), and both of these regulations potentially duplicate mill-tailings-related provisions of EPA regulations implementing the Clean Air Act. (All three regulations set "design guide" limits on radon releases from tailings piles at 20 picocuries per square meter per second.) Overlapping standards reflect individual legal mandates and independent development by agencies to fulfill their different responsibilities.
	Potentially duplicative regulations, administered by different agencies, require clarification and may be costly for those conducting nuclear operations to implement. For example, EPA and NRC have been administratively engaged for years in addressing issues related to their dual regulation of uranium mill tailings under the regulations outlined above. Likewise, in regulating mixed hazardous and radioactive wastes under both NRC's regulation for land disposal of radioactive waste and the Resource Conservation and Recovery Act, they are attempting to resolve issues pertaining to radioactive materials that were not considered when that act was developed.
	As another example, conflicts have arisen between provisions of EPA and NRC regulations as applied to radioactive emissions generated by operations of the nuclear medical community. ¹ These regulations may require the use of dual, potentially conflicting compliance strategies by medical institutions. On the one hand, under NRC's regulation, annual

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¹40 C.F.R. 61 and 10 C.F.R. 20.

Appendix I Framework for Controlling Radiation Exposure

permissible releases of numerous radionuclides are subject to specific quantitative regulatory limits. On the other hand, under EPA's regulation, the licensee must supply data on annual possession quantities or concentration levels, or use computer models, to demonstrate compliance with a general annual atmospheric exposure limit of 0.01 rem. Industry representatives estimated in 1990 that it would cost about \$100 million annually to comply with both NRC's and EPA's regulations.

Also, federal radiation standards are incomplete in their coverage, in part because some major radiation sources are not clearly subject to federal exposure limits. Such sources principally include natural radiation and radiation used in the diagnostic and therapeutic practice of nuclear medicine. These sources account for about 98 percent (83 percent and 15 percent, respectively) of all annual radiation doses to the U.S. population. Among the principal natural sources are radon (which accounts for about two-thirds of natural background radiation), cosmic rays, other terrestrial radiation, and in-body radiation. The principal medical sources are diagnostic x-rays and accelerator-related radioisotopes used in nuclear medicine.

In general, although natural sources are estimated to be a much higher risk to the average individual compared to nuclear industry related sources of radiation, they are not systematically controlled. It is not considered practical to regulate natural background radiation, although in some instances exposure to radon is regulated because its natural presence in the environment has been altered by human intervention. Also, EPA and the Mine Safety and Health Administration have in place nonbinding guidelines and regulations, respectively, on acceptable radon levels in mining operations, and EPA has issued guidelines on indoor radon limits (4 picocuries per liter) beyond which corrective actions are suggested.

Of the two principal medical sources, x-rays account for about three-fourths of the average annual exposures to humans. To the extent that medical practices release radioactive materials into the environment, they come under applicable regulations administered by the NRC and EPA. However, most medicine-related radiation exposure is received by patients in quantities that are intentional (as with diagnostic x-rays) and discretionary—not specifically limited in dose. For example, under FDA guidance on diagnostic x-ray exposures, the use of x-rays should maintain exposures at levels "as low as is reasonably achievable without loss of requisite diagnostic information."

	Appendix I Framework for Controlling Radiation Exposure
	Also, the disposal of wastes from certain radioactive materials used in medical, industrial, military, and commercial applications is not federally regulated. Such materials, including radium and certain other naturally occurring or accelerator-produced materials, do not come under NRC control under the Atomic Energy Act. The regulation of these materials generally has been left to the individual states, which in some cases have inconsistent requirements or do not regulate them. Many states have expressed a need for federal standards for the disposal of these materials. In the 1980s, EPA drafted such standards under the authority of the Toxic Substances Control Act, but it has not yet issued them, as discussed below.
Incomplete Coverage Because of Incomplete Regulations	The lack of a unified radiation protection policy may also lead to gaps in regulatory coverage because regulations have not been completed in a timely manner. For example, as we reported in 1993, several EPA regulations relating to handling and disposing of radioactive waste have been envisioned for years but not completed because of problems with legal concerns, coordination, and the setting of priorities among agencies, including principally EPA, NRC, DOE, and OMB. ² The unfinalized regulations are as follows:
	 In 1985, EPA issued high-level waste standards. They were legally challenged and partially remanded by a federal court in 1987, in part for further consideration of their interrelationships with the Safe Drinking Water Act. The regulations were finally reissued, as applicable to DOE's Waste Isolation Pilot Plant, in December 1993. EPA has a mandate under the Energy Policy Act of 1992, in consultation with the National Academy of Sciences, to develop and issue separate high-level waste disposal standards for a future site (possibly DOE's Yucca Mountain site) by the end of 1994. In 1983, EPA published notice of its intent to issue low-level waste disposal standards, sent a draft to OMB for its review in 1988, and hoped to resubmit the standards to OMB by the end of 1993. According to an EPA official, these standards are still in draft form, and EPA expects to submit them again to OMB in the fall of 1994. In 1984, EPA proposed to federally regulate the disposal of naturally occurring and accelerator-produced nuclear wastes under the Toxic Substances Control Act and submitted a draft rule to OMB in 1988. However, DOE raised concerns that the rule did not adequately address
	² Radioactive Waste: EPA Standards Delayed by Low Priority and Coordination Problems (GAO/RCED-93-126, June 3, 1993).

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Appendix I Framework for Controlling Radiation Exposure

how such wastes would be disposed of or who would be responsible for doing so. According to an EPA official, there are no plans at present to resubmit a proposed rule to OMB.

- In 1983, EPA issued standards for active and inactive uranium processing sites, but the groundwater provisions for inactive sites were remanded in 1985, and EPA resubmitted them to OMB in 1987 and again in 1991. According to an EPA official, OMB returned them to EPA in 1993, and EPA revised and resubmitted them in May 1994.
- In 1986, EPA published notice of its intent to develop standards for cleanup of land and facilities contaminated with residual radiation. As stated in our recent report, <u>Nuclear Cleanup</u>: Completion of Standards and <u>Effectiveness of Land Use Planning Are Uncertain (GAO/RCED 94-144)</u>, EPA now plans to issue draft standards for comment in the spring of 1995.

Technical and cost issues raised in the interagency review process have also been a factor in the failure to complete these regulations. For example, in 1988 NRC questioned EPA's draft low-level waste standards because in its view the estimated health benefit from the standards did not justify the costs. In 1991, DOE commented that the proposed standards could be implemented only at very large costs, with very little benefit. According to an NRC official, depending in part on the regulatory protection approach adopted, low-level-waste disposal costs at sites with larger waste quantities could be as high as about \$50 million per site.

Both technical issues and questions of regulatory consistency have affected the development of EPA's high-level waste standards. EPA developed "probabilistic" containment requirements for the standards that required the implementing agency to predict the probability of the radioactive releases occurring and the consequences of such releases over 10,000 years. NRC and DOE raised various issues concerning this requirement, including doubts about the feasibility of attempting to make statistically valid predictions far into the future. DOE and NRC eventually agreed that the standards probably could be implemented after EPA added language to the standards that did not require absolute proof of compliance.

In addition, on the basis of a legal challenge by environmental groups and several states, the First Circuit Court of Appeals ruled in 1987 that EPA, among other things, had not adequately considered its own safe drinking water regulations in setting individual protection limits in the high-level waste standards. The court vacated and remanded the standards to EPA in part because of deficiencies in their promulgation. Before EPA could Appendix I Framework for Controlling Radiation Exposure

complete its revision of these provisions, in October 1992 the Congress enacted legislation reinstating all but two parts of the original disposal regulations and directing EPA to issue final high-level disposal regulations that will be applicable to noncommercial high-level nuclear waste. These final regulations were issued on December 20, 1993.

Appendix II Federal Radiation Exposure Limits

Standard or guideline/ agency Type/effective date Limit premature can General standards/guidelines				Estimated lifetime risk of
1. General public/NRC Regulation (10 C.F.R 20), 1993 0.1 rem/yr. 1 in 300 2. General public/EPA Guidance, 1960 0.5 rem/yr. 1 in 60 3. General public/EPA (draft) Proposed regulation (10 C.F.R. 0.1 rem/yr. 1 in 300 4. General public/DOE (draft) Proposed regulation (10 C.F.R. 0.1 rem/yr. 1 in 300 834) Source-specific standards/guidelines 5. 1 in 300 5. Uranium mill tailings/ NRC Regulation (10 C.F.R. 40), 1985 Radium 226: 5 pCi/g 1 in 50° 6. Reactor effluent design/NRC Regulation (10 C.F.R. 50, App. 1 1 in 0,000 9. Air pollution/EPA Regulation (10 C.F.R. 60), 1983 0.1 rem/yr. total 1 in 6,000 9. Air pollution/EPA Regulation (10 C.F.R. 60), 1983 0.025 rem/yr. total 1 in 0,000 9. Air pollution/EPA Regulation (10 C.F.R. 61), 1983 0.025 rem/yr. 1 in 1,000 9. Air pollution/EPA Regulation (40 C.F.R. 61), 1983 0.025 rem/yr. 1 in 7,000 10. Drinking water (interim)/ Regulation (40 C.F.R. 141), 1977 Beta/photon ⁴ : 0.004 rem/yr. 1 in 7,000 11. Uranium fuel cycle/EPA	Standard or guideline/ agency	Type/effective date	Limit	premature cancer death*
2. General public/EPA Guidance, 1960 0.5 rem/yr. 1 in 60 3. General public/EPA (draft) Proposed guidance 0.1 rem/yr. 1 in 300 4. General public/DE (draft) Proposed regulation (10 C.F.R. 8). 0.1 rem/yr. 1 in 300 8. General public/DE (draft) Proposed regulation (10 C.F.R. 40), 1985 0.1 rem/yr. 1 in 300 Source-specific standards/guidelines Regulation (10 C.F.R. 40), 1985 Radium 226: 5 pCi/g 1 in 14,000* Readon: 20 pCi/m ² s 1 in 14,000* Redon: 20 pCi/m ² s 1 in 14,000* 6. Reactor effluent design/NRC Regulation (10 C.F.R. 50, App. 1), 1975 Liquid: 0.003 rem/yr. total body 1 in 6,000 .0 pertations/ NRC Regulation (10 C.F.R. 60), 1983 0.1 rem/yr. 1 in 300 7. High-level waste repository pertations/ Regulation (10 C.F.R. 61), 1983 0.025 rem/yr. 1 in 1,000 8. Low-level waste/NRC Regulation (40 C.F.R. 141), 1977 Beta/photon ⁴ : 0.004 rem/yr. 1 in 7,000 9. Air pollution/EPA Regulation (40 C.F.R. 141), 1977 Beta/photon ⁴ : 0.004 rem/yr. 1 in 7,000 10. Drinking water (interim)/ Proposed regulation (40 C.F.R. 190), 197-93	General standards/guidelines			······································
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4. General public/DOE (draft) Proposed regulation (10 C.F.R. 0.1 rem/yr. 1 in 300 Source-specific standards/guidelines Regulation (10 C.F.R. 40), 1985 1 in 50° S. Uranium mill tailings/ NRC Regulation (10 C.F.R. 40), 1985 1 in 14,000° Readom: 20 pCi/m ² s 1 in 14,000° 6. Reactor effluent design/NRC Regulation (10 C.F.R. 50, App. 1), 1975 Liquid: 0.003 rem/yr. total body 1 in 10,000 Gaseous: 0.005 rem/yr. total 1 in 6,000 1 in 300 1 in 300 7. High-level waste repository operations/ Regulation (10 C.F.R. 60), 1963 0.1 rem/yr. 1 in 300 8. Low-level waste/NRC Regulation (10 C.F.R. 61), 1983 0.025 rem/yr. 1 in 1,000 9. Air pollution/EPA Regulation (40 C.F.R. 61), 1983 0.025 rem/yr. 1 in 7,000 10. Drinking water (interim)/ EPA Regulation (40 C.F.R. 141), 1977 Beta/photon ⁴ : 0.004 rem/yr. 1 in 7,000 11. Uranium fuel cycle/EPA Regulation (40 C.F.R. 190), 1973-83 0.25 rem/yr. 1 in 14,000 12. Spent fuel, high-level, ransuranic waste disposal/ EPA Regulation (40 C.F.R. 191), 1994 1 in 7,000 12. Spent fuel, high-level, ransuruaric waste disposal/ EPA All path	2. General public/EPA	Guidance, 1960	0.5 rem/yr.	1 in 60
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EPA Proposed regulation (40 C.F.R. 141) I0a. Drinking water (draft)/EPA Proposed regulation (40 C.F.R. 141) Radium: 20 pCi/l 1 in 14,000 Radon: 300 pCi/l 1 in 5,000 Beta/photon ^d : 0.004 rem/yr. 1 in 7,000 11. Uranium fuel cycle/EPA Regulation (40 C.F.R. 190), 1979-83 0.025 rem/yr. 1 in 1,000 12. Spent fuel, high-level, ransuranic waste disposal/ Regulation (40 C.F.R. 191), 1994 All pathway: 0.015 rem/yr. 1 in 2,000 Ground water: 0.004 rem/yr.d 1 in 7,000 Containment: 1,000 deaths in 1,000 1 in 36,000° 13. Uranium mill tailings/ EPA Regulation (40 C.F.R. 192), 1983 1983 1 in 36,000°	. Air pollution/EPA		0.01 rem/yr.	1 in 3,000
141) Radium: 20 pCi/l 1 in 14,000 Radon: 300 pCi/l 1 in 5,000 Beta/photond: 0.004 rem/yr. 1 in 7,000 11. Uranium fuel cycle/EPA Regulation (40 C.F.R. 190), 1979-83 0.025 rem/yr. 1 in 1,000 12. Spent fuel, high-level, ransuranic waste disposal/ EPA Regulation (40 C.F.R. 191), 1994 1 in 2,000 Ground water: 0.004 rem/yr. 1 in 7,000 0.025 rem/yr. 1 in 2,000 I3. Uranium mill tailings/ EPA Regulation (40 C.F.R. 192), 1983 1983		Regulation (40 C.F.R. 141), 1977	Beta/photon ^d : 0.004 rem/yr.	1 in 7,000
Radon: 300 pCi/l 1 in 5,000 Beta/photon ^d : 0.004 rem/yr. 1 in 7,000 11. Uranium fuel cycle/EPA Regulation (40 C.F.R. 190), 1979-83 0.025 rem/yr. 1 in 1,000 12. Spent fuel, high-level, ransuranic waste disposal/ EPA Regulation (40 C.F.R. 191), 1994 All pathway: 0.015 rem/yr. 1 in 2,000 Ground water: 0.004 rem/yr. All pathway: 0.015 rem/yr. I in 7,000 Containment: 1,000 deaths in 10,000 yrs. I in 36,000° I in 36,000° I in 36,000°	0a. Drinking water (draft)/EPA			
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11. Uranium fuel cycle/EPA Regulation (40 C.F.R. 190), 1979-83 0.025 rem/yr. 1 in 1,000 12. Spent fuel, high-level, ransuranic waste disposal/ EPA Regulation (40 C.F.R. 191), 1994 All pathway: 0.015 rem/yr. 1 in 2,000 Ground water: 0.004 rem/yr. ^d 1 in 7,000 Containment: 1,000 deaths in 10,000 yrs. 1 in 36,000° 13. Uranium mill tailings/ EPA Regulation (40 C.F.R. 192), 1983			Radon: 300 pCi/l	1 in 5,000
1979-83 12. Spent fuel, high-level, ransuranic waste disposal/ PA All pathway: 0.015 rem/yr. 1 in 2,000 Ground water: 0.004 rem/yr. ^d 1 in 7,000 Containment: 1,000 deaths in 1 in 36,000° 13. Uranium mill tailings/ EPA			Beta/photond: 0.004 rem/yr.	1 in 7,000
All pathway: 0.015 rem/yr. 1 in 2,000 Ground water: 0.004 rem/yr. ^a 1 in 7,000 Containment: 1,000 deaths in 1 in 36,000° 10,000 yrs. 13. Uranium mill tailings/ EPA Regulation (40 C.F.R. 192), 1983	1. Uranium fuel cycle/EPA		0.025 rem/yr.	1 in 1,000
Ground water: 0.004 rem/yr.d 1 in 7,000 Containment: 1,000 deaths in 1 in 36,000e 10,000 yrs. 10,000 yrs.	12. Spent fuel, high-level, transuranic waste disposal/ EPA	Regulation (40 C.F.R. 191), 1994		
Containment: 1,000 deaths in 1 in 36,000° 10,000 yrs. 13. Uranium mill tailings/ EPA Regulation (40 C.F.R. 192), 1983			All pathway: 0.015 rem/yr.	1 in 2,000
10,000 yrs. 13. Uranium mill tailings/ EPA Regulation (40 C.F.R. 192), 1983			Ground water: 0.004 rem/yr.d	1 in 7,000
				1 in 36,000°
Radium 226: 5 pCi/g 1 in 50 ^b	3. Uranium mill tailings/ EPA	Regulation (40 C.F.R. 192), 1983		
			Radium 226: 5 pCi/g	1 in 50°
Radon: 20 pCi/m ² s 1 in 14,000 ^c			Radon: 20 pCi/m ² s	1 in 14,000°

(continued)

1

Appendix II Federal Radiation Exposure Limits

Standard or guideline/ agency	Type/effective date	Lìmit	Estimated lifetime risk of premature cancer death ^a
14. Ocean dumping/EPA	Regulation (40 C.F.R. 220), 1977	Alpha emitters: 1.35x10 ⁻³ Ci/kg, 10 ⁸ kg/yr. rate	Not available
15. Superfund cleanup/EPA	Regulation (40 C.F.R. 300)	10 ⁻⁴ to 10 ⁻⁶ risk range goals ^f	1 in 15,000 to 1 in 1,500,000
16. Mining effluents/ EPA	Regulation (40 C.F.R. 440), 1983		
		Radium 226 (dissolved): 10 pCi/l/day	Not available
		Uranium: 0.004 g/l/day	Not available
17. Indoor radon/EPA	Guidance	4 pCi/l action level	1 in 40
18. Low-level waste/EPA (draft)	Proposed regulation (40 C.F.R. 193)	All pathway: 0.025 rem/yr.	1 in 1,000
19. Decommissioning/NRC (draft)	Proposed regulation	0.015 rem/yr.	1 in 2,000
20. Cleanup/EPA(draft)	Proposed regulation	0.015 rem/yr.	1 in 2,000
Occupational standards/guideline	S		
21. Occupational/NRC	Regulation (10 C.F.R. 20)	5 rem/yr.	1 in 89
22. Occupational/EPA	Guidance, 1987	5 rem/yr.	1 in 89
23. Radon in uranium mines/EPA	Guidance, 1971	4 WLM/yr. ^h	1 in 16
24. Occupational/DOE	Regulation (10 C.F.R. 835), 1993	5 rem/yr.	1 in 89
25. Under-ground mines/MSHA	Regulation (30 C.F.R. 57), 1977	Radon: 4 WLM/yr.	1 in 16
26. Occupational/OSHA	Regulation (29 C.F.R. 1910.96), 1971	5 rem/yr.	1 in 8º

(Table notes on next page)

Appendix II Federal Radiation Exposure Limits

^{aF}or purposes of comparison, the estimated risks in the table are derived from commonly used assumptions (e.g., a cancer death risk of 5x10⁴ per rem to an individual continuously exposed over a 70-year lifetime; for workers, 50-year exposure). The estimated risks may differ from those derived by agencies, which used various assumptions in setting standards and guidelines. Some estimated risks are to individuals, and others are to larger defined populations. Risks are rounded.

^bBased on exposure to an individual residing on site after cleanup. The estimated risk to an individual off-site could be considerably less.

^eBased on average population exposure. According to EPA and DOE, the estimated risk to a maximally exposed individual could be considerably greater.

^dBeta particle and photon radioactivity from man-made radionuclides in community water systems.

Based on an NRC assumption of a population of 250,000.

 $^{1}10^{-4}$ to $10^{-6} = 1$ in 10,000 to 1 in 1,000,000 risk of cancer incidence. The goals in the risk column have been converted to express cancer mortality risk. The dose limit is determined on a site-specific basis, depending upon exposure pathways, radionuclide, total inventory, and site characteristics.

⁹Based on a 50-year working lifetime.

^hWLM \neq working level month, equivalent to about 100 picocuries per liter of radon in equilibrium with its progeny for 170 hours of worker exposure.

Source: Derived by GAO in part from CIRRPC, NRC, EPA, and DOE data. A principal source is "A Compendium of Major U.S. Radiation Protection Standards and Guides: Legal and Technical Facts," prepared for CIRRPC by W. A. Mills, D. S. Flack, F. J. Arsenault, and E. F. Conti (Oak Ridge Associated Universities, ORAU 88/F-111, July 1988).

Appendix III Comparative Radiation Risks

Table III.1 compares various estimated risks associated with selected radiation standards and guidelines for public protection. It expresses these risks as a fraction or multiple of the estimated risk from natural background radiation (which has been assigned a value of 1 for comparison purposes). The table shows that some radiation standards or guidelines are set considerably higher—and some considerably lower, approaching zero—in comparison to the estimated risks from natural background radiation.

Table III.1: Comparative Risks Associated With Radiation Standards, Guidelines, and Exposures

Fraction or multiple of natural background	Standard, guideline, or exposure	
3.3	Uranium mill tailings standard	
2.5	Federal residential radon guidance	
1.7	EPA general public guidance of 0.5 rem/yr.	
1.0	Natural background (including radon)	
0.7	Average indoor radon exposure	
0.3	General public standard of 0.1 rem/yr.	
0.08	Environmental standard of 0.025 rem/yr.	
0.02	Radium standard in drinking water	
0.01	Drinking water standard of 0.004 rem/yr	
0.003	Negligible risk level per NCRP ^a	
0.000005	High-level waste containment standard ^b	

*NCRP Report No. 91, 1987.

^bBased on average risk in the U.S. population.

Source: Adapted by GAO from D. C. Kocher, "Perspective on the Historical Development of Radiation Standards," Health Physics, vol. 61, no. 4, 1991.

Appendix IV Uncertain Science and Methods Behind the Standards

	Federal radiation limits are based in part on estimates of dose and risk ¹ as well as on economic and social policy considerations. The estimation methods behind the limits can be theoretical, drawing upon limited actual data on radiation sources and their effects on humans. These methods incorporate various assumptions and mathematical simulations (models), and agencies have taken only limited steps to ensure that the many assumptions and models they use to conduct the assessments are reasonably consistent.
Uncertain Science	The science that supports the limits is complex, difficult, and multidisciplinary. It involves conceptual modeling of the interactions of low-level radiation with the surrounding environment and the human body. ² The limits often rely less on actual measurement of such interactions than on judgments or assumptions. For example, two basic parameters underlying the limits—radiation dose and radiation risk—are often estimated rather than directly measured, and they involve mathematical estimation methods that incorporate unknowns and large uncertainties. ³
	The estimation of a dose to a person living near a radiation source includes examining the type and quantity of radioactive material that might be released from the source, how it might move through the environment and into contact with the person, and how radioactive materials might be absorbed into body organs or tissue. To a large extent, direct measurement or validation of these phenomena (especially exposure) is not possible or practical. Instead, detailed scenarios and conceptual models are developed—based on best judgment and evidence—to explain these phenomena. Then, consistent with the conceptual models, mathematical models (and the numerical factors or parameters they require) are developed for determining deposition into the aquatic or terrestrial environment by means of various routes or "pathways," either directly to human beings or indirectly through reconcentration in the food chain. Many details of these conceptual and
	¹ Dose is a measure of radiation energy absorbed in tissue. Risk, as generally used in this report, is the chance that a person will die prematurely from a radiation-caused cancer. ² A low-level dose has been estimated to be somewhere below 10 rem. It is not known for certain

A low-level dose has been estimated to be somewhere below 10 rem. It is not known for certain whether doses below this level are detrimental to human health. The carcinogenic effects of low-level radiation have not been directly proved. They have been predicted statistically on the basis of higher doses to populations, such as the Japanese survivors of World War II bombings. It is assumed that even the smallest dose of radiation may be harmful, an assumption commonly known as the linear no-threshold hypothesis.

³Even less direct knowledge exists about the impact of nonradioactive pollutants in the environment.

Appendix IV Uncertain Science and Methods Behind the Standards

mathematical models must be inferred or assumed in order to get a numerical result—a dose estimation.

The use of different assumptions can lead to large variations in results. The use of "reasonable" versus "worst case" scenarios can result in dose estimates that vary by up to 100 times or much more. If an agency uses "realistic" assumptions, it may invite criticism that its dose estimates do not adequately protect public health; the use of conservative assumptions, on the other hand, can lead to large expenditures on dose and risk limitation without necessarily bringing compensating benefits in reduced health risk to the public. In the past, OMB has argued that agencies have applied assumptions too conservatively, thereby overstating risks by 1,000 or even a million times. EPA policy in implementing Superfund has been that when in doubt, the risk should be overstated rather than understated.

The estimated dose is used in estimating risk. Essentially, risk estimation converts the dose into a numerical projection of the chance that a given dose will cause premature cancer death. Because the process of radiation carcinogenesis is understood mainly in theoretical terms and has not been directly verified, risk calculations rely on predetermined multipliers (estimates of risk per unit dose called "risk factors") derived from research into the incidence of radiation-caused cancers. Principally, such research involves observations of the numbers of cancers of different kinds that arise in irradiated groups. Through the use of statistical estimation techniques, the cancer incidence detected in these groups may be projected to the other populations. However, studies of irradiated groups typically involve extrapolations-from larger to lower doses, or from one population to another-whose validity may be questioned, and they lack sensitivity-they are inherently unable to detect small health effects, such as those associated with low-level radiation. To some, a single numerical risk estimate gives a misleading impression of precision because any such estimate is likely to be based on highly uncertain data.⁴

To illustrate the lack of sensitivity in such studies of irradiated groups, using an International Commission on Radiological Protection (ICRP) risk factor and an assumed 70-year lifetime, a continuous low exposure level of 0.1 rem (the general federal public protection limit) might result in 350 radiation-caused cancer deaths in a population of 100,000 over a lifetime. As a practical matter, 350 additional radiation-caused cancer deaths in a U.S. population of 100,000 would probably not be detectable, given that

⁴According to the National Council on Radiation Protection and Measurements (Report No. 96, 1989), if the dose is accurately known, best estimates of risk can be made within a statistical uncertainty factor of about 2 for all cancers combined for whole-body external radiation.

······	Appendix IV Uncertain Science and Methods Behind the Standards
	about 20,000 deaths from all types of cancers could be expected to occur in that population.
	As a result, federal radiation limits (however precise they may appear to be numerically) reflect a series of theories and assumptions about radiation effects. They are inherently imprecise, confronting fundamental scientific questions that may be answered only incrementally in coming years. According to a CIRRPC official, validation of low dose radiation effects may advance through experimental studies of cancer at the cellular and molecular levels.
Differences in Estimation Methods	Various theories, scenarios, and techniques have been developed among agencies to help in estimating doses and risks. The estimation methods and assumptions used by agencies in setting radiation limits and assessing compliance with them have similarities and differences. Methodological similarities include, for example, the fact that EPA and NRC usually consider the same general pathways of exposure, and both agencies translate exposure and intakes into dose and risk using internationally accepted techniques. In addition, EPA has issued federal guidance on parameters for agencies to use in calculating external and internal exposure and dose. Likewise, CIRRPC has issued guidance on risk factors that agencies may use in risk estimation. Methodological differences include EPA's and NRC's use of different exposure scenarios, including different assumptions about inadvertent intrusion, reliance on institutional controls, and period of exposure. Also, EPA, NRC, and DOE have different models for estimating the dose to an individual living on a radiologically contaminated site. The models incorporate differing assumptions and give results that may differ considerably, by up to 100 times or much more. ⁵ EPA and NRC use some different risk coefficients, and in some cases they use considerably different dose and risk conversion factors.
	EPA, NRC, and DOE have issued separate guidance on estimating doses and risks for the use of those implementing their regulations. For example, NRC and DOE have developed generic models that are suggested for use in environmental dose assessments. EPA has issued Superfund risk assessment guidance and exposure assessment guidance. Also, NRC has issued (1) a technical methodology for translating contamination into dose and (2) Regulatory Guide 1.109, which prescribes models and assumptions to be used in license applications for constructing nuclear power reactors

 $^{^5}$ For example, differences related to external dose, inhalation, and ingestion pathways were found in a 1993 DOE-sponsored analysis.

Appendix IV Uncertain Science and Methods Behind the Standards

and in checking releases during operations against design specifications. Also, under its air pollution regulation, EPA requires the use of certain computer codes in demonstrating compliance with regulatory requirements for airborne radioactive emissions.

However, the use of particular exposure scenarios, exposure routes, and assumptions for dose estimation is generally not prescribed in regulations. In part, this reflects the idea that there is no simple formula or "cookbook" for dose and risk estimation. On the other hand, differences in agencies' methods may reflect on the technical credibility of their dose and risk estimates and standards. In their harmonization initiative, EPA and NRC are beginning to explore the idea of ensuring the use of more consistent assumptions and mathematical simulations in setting exposure limits and regulating compliance with them. For example, they are considering the use of the same dose and risk factors and the use of consistent exposure scenarios.

Appendix V Major Contributors to This Report

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