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AGENCY: Environmental Protection Agency.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 191

Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes

[AH-FRL 2870-3]

50 FR 38066

September 19, 1985

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is promulgating generally applicable environmental standards for the management and disposal of spent nuclear fuel and high-level and transuranic radioactive wastes. The standards apply to management and disposal of such materials generated by activities regulated by the Nuclear Regulatory Commission (NRC) and to disposal of similar materials generated by atomic energy defense activities under the jurisdiction of the Department of Energy (DOE). These standards have been developed pursuant to the Agency's authorities and responsibilities under the Atomic Energy Act of 1954, as amended; Reorganization Plan No. 3 of 1970; and the Nuclear Waste Policy Act of 1982.

Subpart A of these standards limits the radiation exposure of members of the public from the management and storage of spent fuel or high-level or transuranic wastes prior to disposal at waste management and disposal facilities regulated by the NRC. Subpart A also limits the radiation exposures to members of the public from waste emplacement and storage operations at DOE disposal facilities that are not regulated by the NRC.

Subpart B establishes several different types of requirements for disposal of these materials. The primary standards for disposal are long-term containment requirements that limit projected releases of radioactivity to the accessible environment for 10,000 years after disposal. These release limits should insure that risks to future generations from disposal of these wastes will be no greater than the risks that would have existed if the uranium ore used to create the wastes had not been mined to begin with. A set of six qualitative assurance requirements is an equally important element of Subpart B designed to provide adequate confidence that the containment requirements will be met. The third set of requirements are limitations on exposures to individual members of the public for 1,000 years after disposal. Finally, a set of ground water protection requirements limits radionuclide concentrations for 1,000 years after disposal in water withdrawn from most Class I ground waters to the concentrations allowed by the Agency's interim drinking water standards (unless concentrations in the Class I ground waters already exceed the limits in 40 CFR Part 141, in which case this set of requirements would limit the increases in the radionuclide concentrations to those specified in 40 CFR Part 141). Subpart B also contains informational guidance for implementation of the disposal standards to clarify the Agency's intended application of these standards, which address a time frame without precedent in environmental regulations. Although disposal of these materials in mined geologic repositories has received the most attention, the disposal standards apply to disposal by any method, except disposal directly into the oceans or ocean sediments.

This notice describes the final rule that the Agency developed after considering the public comments received on the proposed rule published on December 29, 1982, and the recommendations of a technical review conducted by the Agency's Science Advisory Board (SAB). The major comments received on the proposed standards are summarized together with the Agency's responses to them. Detailed responses to all the comments received are discussed in the Response to Comments Document prepared for this final rule.

DATE: These standards shall be promulgated for purposes of judicial review at 1:00 p.m. eastern time on October 3, 1985. These standards shall become effective on November 18, 1985.

ADDRESSES: *Background Information* -- The technical information considered in developing this rule, including risk assessments of disposal of these wastes in mined geologic repositories, is summarized in the Background Information Document (BID) for 40 CFR Part 191, EPA 520/1-85-023. Single copies of both the BID and the Response to Comments Document, as available, may be obtained from the Program Management Office (ANR-458), Office of Radiation Programs, Environmental Protection Agency, Washington, DC 20460; telephone number (703) 557-9351.

Docket -- Docket Number R-82-3 contains the rulemaking record for 40 CFR Part 191. The docket is available for inspection between 8 a.m. and 4 p.m. on weekdays in the West Tower Lobby, Gallery 1, Central Docket Section, 401 M Street, SW., Washington, DC. A reasonable fee may be charged for copying.
FOR FURTHER INFORMATION CONTACT:Dan Egan or Ray Clark, Criteria and Standards Division (ANR-460), Office of Radiation Programs, Environmental Protection Agency, Washington, DC 20460; telephone number (703) 557-8610.

TEXT: SUPPLEMENTARY INFORMATION: Fissioning of nuclear fuel in nuclear reactors creates a small quantity of highly radioactive materials. Virtually all of these materials are retained in the "spent" fuel elements when they are removed from the reactor. If the fuel is then reprocessed to recover unfissioned uranium and plutonium, most of the radioactivity goes into acidic liquid wastes that will later be converted into various types of solid materials. These highly radioactive liquid or solid wastes from reprocessing spent nuclear fuel have traditionally been called "high-level wastes." If it is not to be reprocessed, the spent fuel itself becomes a waste. The nuclear reactors operated by the nation's electrical utilities currently generate about 2,000 metric tons of spent fuel per year. The relatively small physical quantity of these wastes is apparent when compared to the chemically hazardous wastes regulated under the Resource Conservation and Recovery Act, which are produced at a rate of about 150,000,000 metric tons per year.

Although they are produced in small quantities, proper management and disposal of high-level wastes and spent nuclear fuel are essential because of the inherent hazard of the large amounts of radioactivity they contain. Spent fuel from commercial nuclear power reactors contains about 1.6 billion curies of radionuclides with half-lives greater than 20 years. Over the next decade, this inventory is projected to grow at a rate of about 300 million curies per year from reactors currently licensed to operate. Most of this spent fuel is currently stored at reactor sites. Reprocessing reactor fuel used for national defense activities has produced about 700 million curies of radionuclides with half-lives greater than 20 years. Most of these wastes are stored in various liquid and solid forms on three Federal reservations in Idaho, Washington, and South Carolina.

In addition, a wide variety of wastes contaminated with man-made radionuclides heavier than uranium have been created by various processes, mostly from the atomic energy defense activities conducted by the DOE and its predecessor agencies (the Atomic Energy Commission and the Energy Research and Development Administration). These wastes are usually called "transuranic" wastes. Most of them are stored at Federal reservations in Idaho, Washington, New Mexico, and South Carolina.

National Programs for Disposal of These Wastes

Since the inception of the nuclear age in the 1940's, the Federal government has assumed ultimate responsibility for the care and disposal of these wastes regardless of whether they are produced by commercial or national defense activities. In October 1976, President Ford ordered a major expansion of the Federal program to demonstrate a permanent disposal method for high-level wastes. The Agency was directed to develop generally applicable environmental standards to govern the management and disposal of these wastes as part of this initiative. Among EPA's first activities in response to this directive were a series of public workshops conducted in 1977 and 1978 to better understand the various public concerns and technical issues associated with radioactive waste disposal.

In 1981, the DOE, after completing a comprehensive programmatic environmental impact statement, decided to focus the national program on disposal in mined geologic repositories (46 FR 26677). In 1982, Congress passed the Nuclear Waste Policy Act (henceforth designated "NWPA"), which President Reagan signed into law on January 7, 1983. The NWPA contains several provisions that are relevant to this rulemaking. First, it affirmed the DOE's 1981 decision

that mined repositories should receive primary emphasis in the national program, although research on some other technologies would be continued. Second, it established formal procedures regarding the evaluation and selection of sites for geologic repositories, including steps for the interaction of affected States and Indian tribes with the Federal Government regarding site selection decisions. Third, the NWPA levied a fee on utilities that generate electrical power with nuclear reactors in order to pay for Federal management and disposal of their spent fuel or high-level wastes. Fourth, the NWPA reiterated the existing responsibilities of the Federal agencies involved in the national program to develop mined geologic repositories, and it assigned some additional tasks regarding site evaluation. Finally, the Act provided a timetable for several key milestones that the Federal agencies were to meet in carrying out the program.

Section 121 of the NWPA reiterated the Agency's responsibility for developing the overall framework of requirements needed to assure protection of public health and the environment, in accordance with the Agency's authorities under the Atomic Energy Act of 1954 and Reorganization Plan Number 3 of 1970. Section 121 also called for the Agency to promulgate these standards by January 7, 1984. The Agency did not meet this deadline. On February 8, 1985, the Natural Resources Defense Council and four other environmental interest groups filed suit to bring about compliance with the NWPA mandate. This litigation was settled by the Agency and the plantiffs agreeing to a consent order requiring promulgation not later than August 15, 1985. The generally applicable environmental standards promulgated by this notice satisfy the terms of this consent order. However, they also represent the culmination of an effort that began almost nine years ago and that has included frequent interactions with the public to help formulate standards responsive to the concerns about disposal of these dangerous materials.

Objective and Implementation of the Standards

In developing the standards for disposal of spent nuclear fuel and high-level and transuranic radioactive wastes, the Agency has carefully evaluated the capabilities of mined geologic repositories to isolate the wastes from the environment. Because such repositories are capable of performing so well, it has been possible to choose containment requirements that will provide exceptionally good protection to current and future populations for at least 10,000 years after disposal. In fact, EPA's analyses indicate that the small residual risks allowed by the disposal standards would be comparable to the risks that future populations would have been exposed to if the uranium ore used to produce the high-level wastes had not been mined to begin with. 1 n The Agency believes that achieving this protection should not significantly increase the cost or difficulty of carrying out the national program for disposing of the wastes from commercial nuclear power plants. In addition, the containment requirements in the final rule are complemented by six qualitative assurance requirements designed to provide confidence that the containment requirements will be met, given the substantial uncertainties inherent in predictions of systems performance over 10,000 years. Because of this comprehensive framework, the Agency is confident that the national program to dispose of these wastes will be carried out with exceptional protection of public health and the environment.

n 1 Specifically, the Agency estimates that compliance with the disposal standards would allow no more than 1,000 premature deaths from cancer in the first 10,000 years after disposal of the high-level wastes from 100,000 metric tons of reactor fuel, an average of no more than one premature death every ten years. As this residual risk level is referred to in the following discussion, it should be remembered that it is a speculative calculation that is primarily intended as a tool for comparing risk levels; it should not be considered a reliable projection of the "real" number of health effects resulting from compliance with the disposal standards.

The Nuclear Regulatory Commission (NRC) and the DOE are responsible for implementing these standards. The NRC has already promulgated procedural and technical requirements in 10 CFR Part 60 for disposal of high-level wastes in mined geologic repositories (46 FR 13971, 48 FR 28194). The NRC will obtain compliance with 40 CFR Part 191 for disposal of all high-level wastes by issuing licenses to the DOE, in accordance with 10 CFR Part 60, at various steps in the construction and operation of a repository. The NWPA directs the DOE to select a number of potential sites for geologic repositories, successively reducing this set of alternatives from five to three to one, in consultation with affected States and Indian Tribes and with participation by the public in key steps in the selection process. The DOE will accomplish this through use of site selection guidelines (10 CFR Part 960) that it has developed in accordance with section 112 of the NWPA. Both NRC's 10 CFR Part 60 and DOE's 10 CFR Part 960 incorporate the standards the Agency is promulgating today as the overall performance requirements for a geologic repository. Both of these other rules were designed in concert with EPA"s ongoing development of 40 CFR Part 191. However, both the NRC and

DOE must now review these regulations to determine what specific changes will be needed to properly implement the final version of 40 CFR Part 191.

Review of the Proposed Standards

On December 29, 1982, shortly before the NWPA was enacted, the Agency published 40 CFR Part 191 for public review (47 FR 58196) and asked that comments be received by May 2, 1983. Eighty-three substantive replies were received from a broad spectrum of private citizens, public interest groups, members of the scientific community, representatives of industry, and State and Federal agencies. These responses contained information and recommendations regarding seven issues on which the Agency sought further public comment (48 FR 21666). Questions concerning these issues were directed to all of the witnesses at two public hearings held during May 1983 in Washington, D.C. and in Denver (48 FR 13444). Copies of these questions were also sent to all those who responded to the initial request for comment, and the availability of these questions was announced in the Federal Register (48 FR 21666). The comment period was then held open until June 20, 1983, to receive responses to these additional questions. Responses to major comments -- including all those specifically highlighted for public review -- are summarized below. Detailed responses to the full range of comments received is described in the Response to Comments Document prepared for the final rule.

Review of the Technical Basis of the Standards

In parallel with this public review and comment, the Agency conducted an independent scientific review of the technical basis for the proposed 40 CFR Part 191 through a special Subcommittee of the Agency's Science Advisory Board (SAB) (48 FR 509). This Subcommittee held nine public meetings from January 18, 1983, through September 21, 1983, and prepared a final report that was transmitted on February 17, 1984. While finding that the Agency had generally prepared comprehensive and scientifically competent technical analyses to support the proposed standards, the SAB review developed 46 findings and recommendations regarding specific improvements in the technical analyses and in the standards themselves. Since many of the SAB recommendations were to be considered in developing the final rule, the Agency sought public comment on the information and recommendations presented in the final SAB report (49 FR 19604).

Most of the SAB recommendations involve specific details of the technical assessments and judgments the Agency made in developing these standards. After evaluating the public comments received on the SAB report, the Agency agrees with almost all of the SAB's technical recommendations and has made corresponding changes in the technical basis of the final rule. A few of the Subcommittee's recommendations have implications that involve broader policy judgments. These recommendations have been treated as part of the public comment record and are described below as the major comments on the proposed 40 CFR Part 191 are discussed. A complete itemization of the Agency's responses to each of the findings and recommendations of the SAB is contained in the Response to Comments Document, together with a synopsis of the public comments on the SAB report.

Summary of the Final Rule

The rule being promulgated today establishes generally applicable environmental standards for the management and disposal of spent nuclear fuel, high-level radioactive wastes, and transuranic radioactive wastes. The final rule differs in a number of ways from the proposed rule because of changes the Agency has made in response to public comments and in response to the recommendations of the technical review by the Agency's Science Advisory Board. This section provides an overview of the major provisions of the final rule, and changes from the proposed rule are noted. More detail on many of these provisions is provided later as part of the discussion of the comments considered in development of 40 CFR Part 191. The final rule:

(1) Applies to management and disposal of spent nuclear fuel, high-level radioactive wastes as defined by the NWPA, and transuranic wastes containing more than 100 nanocuries per gram of alpha-emitting transuranic isotopes, except for wastes that either the NRC or the Administrator determines do not need the degree of isolation required by this rule. (The proposed rule applied to spent nuclear fuel, high-level wastes exceeding a specific set of concentration limits, and to transuranic wastes containing more than 100 nanocuries per gram.)

(2) Through Subpart A, "Standards for Management and Storage," establishes limits on annual doses to members of the public of 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ from exposures associated with management, storage, and preparation for disposal of any of these materials at facilities regu-

lated by the NRC. These limits apply to the combined exposures from all NRC-licensed facilities covered by this Part or 40 CFR Part 190, the Agency's standards for the commercial uranium fuel cycle. Subpart A also limits annual doses to members of the public from management and storage operations at DOE disposal facilities that are not regulated by the NRC to 25 millirems to the whole body and 75 millirems to any other organ. (The proposed rule applied to the combined exposures from operations regulated by 40 CFR Part 190, waste management and storage operations regulated by the NRC or Agreement States, *and* waste management and storage operations conducted at all DOE facilities.) Subpart A also contains a provision that allows the Administrator to issue alternative standards for waste management and storage operations at DOE disposal facilities that are not regulated by the NRC. (The proposed rule contained a provision to allow the implementing agency, either the NRC or the DOE, to grant variances for unusual operating conditions.)

(3) Establishes several sets of requirements for disposal of these wastes through Subpart B, "Standards for Disposal." The primary standards are *containment requirements* that limit projected releases of radioactivity to the accessible environment for 10,000 years after disposal. Equally important is a set of six *assurance requirements* chosen to provide adequate confidence that the containment requirements will be met. In addition, Subpart B of the final rule includes *individual protection requirements* that limit annual exposures from the disposal facility to members of the public in the accessible environment to 25 millirems to the whole body and 75 millirems to any organ for 1,000 years after disposal. The Subpart also contains *ground water protection requirements* that limit radioactivity concentrations in water withdrawn from most Class I ground waters near a disposal system (as defined in conjunction with the Agency's Ground Water Protection Strategy published in August 1984) for 1,000 years after disposal. Finally, Subpart B provides *guidance for implementation* that indicates how the Agency intends the various numerical standards to be applied. (The proposed rule contained only containment requirements, assurance requirements, and procedural requirements; this last category provided some of the basis for the "guidance for implementation" in the final rule.) Major provisions of each of these sets of requirements include the following:

(a) The containment requirements (Section 191.13) limit the total projected release of specific radionuclides over the entire 10,000-year period after disposal. Releases from all expected and accidental causes are included, except for releases from conceivable events that are judged to have an incredibly small likelihood of occurrence. Quantitative terms are used to identify the probabilities of the releases to which the containment requirements apply; however, the final rule acknowledges that determination of compliance will have to tolerate much larger uncertainties than would be appropriate for short-term estimates and that judgments may have to be substituted for quantitative predictions in certain situations. Disposal in compliance with the containment requirements is projected to cause no more than 1,000 premature cancer deaths over the entire 10,000-year period from disposal of all existing high-level wastes and most of the wastes yet to be produced by currently operating reactors -- an average of 0.1 fatality per year. This level of residual risk to future generations would be comparable to the risks that those generations would have faced from the uranium ore used to create the wastes if the ore had never been mined. Actual risks will probably be significantly less because of the conservative approach called for by the other parts of Subpart B. (The quantitative probabilities in the proposed rule were an order of magnitude smaller than those incorporated into the final rule. The release limits in the final rule are different than those in the proposed rule due to changes in EPA's technical analyses that were recommended by the SAB Subcommittee; however, the level of residual risk is the same as for the proposed rule.)

(b) The assurance requirements (Section 191.14) call for cautious steps to be taken in disposing of these wastes because of the inherent uncertainties in selecting and designing disposal systems that must be very effective for more than 10,000 years. The assurance requirements incorporate the following principles:

(i) Although active institutional controls, such as guarding and maintaining a disposal site, should be encouraged, they cannot be relied upon to isolate these wastes from the environment for more than 100 years after disposal. (The proposed rule limited reliance to "a few hundred years" after disposal.)

(ii) Disposal systems must be monitored to detect substantial changes from their expected performance until the implementing agency determines that there are no significant concerns to be addressed by further monitoring. (This requirement was not included in the proposed rule.)

(iii) The sites where disposal systems are located must be identified by permanent markers, widespread records, and other passive institutional controls to warn future generations of the dangers and location of the wastes.

(iv) Disposal systems must use several different types of barriers, including both engineered and natural ones, to isolate the wastes from the environment to help guard against unexpectedly poor performance from one type of barrier.

(v) Sites for disposal systems should be selected to avoid places where resources have previously been mined, where there is a reasonable expectation of exploration for scarce or easily accessible resources, or where there is a significant concentration of any material which is not otherwise available. (The wording in the proposed rule would have ruled out sites with a significant possibility of being considered for resource exploration in the future. The final rule revises this requirement to allow use of sites with some resource potential if they have other significant advantages compared to potential alternative sites.)

(vi) Recovery of most of the wastes must not be precluded for a reasonable period after disposal if unforeseen events require this in the future.

(c) The individual protection requirements (Section 191.15) limit annual exposures to members of the public in the accessible environment from the disposal system to 25 millirems to the whole body and 75 millirems to any organ. These requirements apply to undisturbed performance of the disposal system for 1,000 years after disposal. All potential pathways of radiation exposure from the disposal system to people must be considered, including the assumption that individuals consume all of their drinking water (2 liters per day) from any "significant source of ground water" located outside the "controlled area" established around a disposal system. A "significant source" is identified by several parameters intended to describe an aquifer sufficient to meet the needs of a "community water system" as defined in the Agency's National Interim Primary Drinking Water Regulations (40 CFR Part 141). (No explicit individual protection requirements were included in the proposed rule.)

(d) The ground water protection requirements (Section 191.16) limit the concentrations of radioactivity (or the *increases* in concentrations, if preexisting concentrations already exceed these limits) in waters withdrawn from most Class I sources of ground water near a disposal system to no more than 15 picocuries per liter of alpha-emitting radionuclides (including no more than 5 picocuries per liter of radium-226 and radium-228 but excluding radon) and to no more than the combined concentrations of radionuclides that emit either beta or gamma radiation that would produce an annual dose equivalent to the total body or any internal organ greater than 4 millirems if individuals consumed all of their drinking water from that source of ground water. These concentration limits are similar to those set in 40 CFR Part 141 for community water systems. Like the individual protection requirements, the ground water protection requirements apply to undisturbed behavior of the disposal system for a period of 1,000 years after disposal. (No explicit ground water protection requirements were included in the proposed rule.)

(e) Section 191.17 of the final rule establishes minimum procedural requirements that the Administrator must follow if additional information considered in the future indicates that it would be appropriate to modify any portion of the disposal standards through further rulemaking. (No similar provision was included in the proposed rule.)

(f) The "guidance for implementation" included as Appendix B to the final rule describes certain analytical approaches and assumptions through which the Agency intends the various long-term numerical standards of Subpart B to be applied. This guidance is particularly important because there are no precedents for the implementation of such long-term environmental standards, which will require consideration of extensive analytical projections of disposal system performance. (The proposed rule contained a corresponding, but less extensive, section entitled "procedural requirements.")

Overall Approach of the Final Rule

In general, the Agency developed the various elements of this rule by balancing several perspectives. One set of considerations was the expected capabilities of the waste management and disposal technologies to reduce both short- and long-term risks to public health and the environment. These capabilities were examined through a number of performance assessments of the waste management, storage, and disposal facilities planned for the wastes generated by commercial nuclear power plants. Since detailed plans have not yet been determined for disposition of the wastes generated by atomic energy defense activities, similar assessments were generally not performed for these materials. A second consideration, where applicable, was consistency with related environmental standards for radiation exposure. A third factor was evaluation of various benchmarks to assess the acceptability of the residual risks that might be allowed by the rule. This was particularly important for the disposal standards, where there were few precedents to guide the Agency's judgments. Finally, the Agency placed considerable emphasis on the public concerns expressed during the various phases of this rulemaking, particularly where these concerns involved addressing the substantial uncertainties inherent in the unprecedented time periods of interest.

The final rule reflects a combination of all these perspectives -- no single factor predominated. For instance, no portion of this rule is based solely on projections of the "best" protection that technology might provide. If this had been the case, the rule would have been significantly different. On the other hand, the rule cannot be interpreted as setting precedents for "acceptable risk" levels to future generations that should not be exceeded regardless of the circumstances. Instead, because of a number of unique circumstances, the Agency has been able to develop standards for the management and disposal of these wastes that are both reasonably achievable -- with little, if any, effort beyond that already planned for commercial wastes -- and that limit risks to levels that the Agency believes are clearly acceptably small. The following paragraphs describe how these various perspectives were used in developing the final rule.

Standards for Management and Storage (Subpart A)

Upon surveying the expected performance of the technologies planned for the management, storage, and preparation of these wastes for disposal, the Agency found that the likely exposures to members of the public would generally be very small. Therefore, compatibility with related radiation protection standards became a more important perspective for Subpart A.

For waste management and storage operations to be regulated by the NRC, the most relevant existing standards are those provisions of 40 CFR Part 190 that limit annual exposures of members of the public to 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ from uranium fuel cycle facilities. Accordingly, the Agency has decided to extend this coverage to include such waste management and storage operations so that the *combined* exposure from all of the NRC-licensed facilities covered under Part 190 and Subpart A of Part 191 shall not exceed these limits. This will include all operations prior to final closure at high-level waste disposal facilities, since these are to be regulated by the NRC.

For waste management and storage operations conducted at atomic energy defense facilities operated for the Department of Energy (which are not regulated by the NRC), the most relevant existing standards are the 40 CFR Part 61 limitations on air emissions of radionuclides that were recently promulgated under the Agency's Clean Air Act authorities (50 FR 5190). These standards limit annual exposures to members of the public to 25 millirems to the whole body and 75 millirems to any organ, with less stringent alternative standards available if it can be shown that no member of the public will receive a continuous exposure of more than 100 millirems per year or an infreqent exposure of more than 500 millirems per year from all sources (excluding natural background and medical exposures.) These Clean Air Act standards are applicable to those facilities *not* covered by 40 CFR Parts 190, 191 or 192. For DOE waste disposal facilities covered by this rule but not regulated by NRC (i.e., those for defense transuranic wastes), the Agency has included standards in Subpart A similar to those included in the Clean Air Act rule.

For other DOE waste management and storage operations, which are usually conducted on large facilities with many other potential sources of radionuclide emissions, the Agency believes that continued regulation under the broader scope of 40 CFR Part 61 is the most effective and practical approach. Otherwise, similar types of emissions from adjoining operations would have to be assessed and regulated through separate rules developed under different authorities; this would cause complex implementation practices without providing any additional protection.

Standards for Disposal (Subpart B)

Developing the standards for disposal of spent fuel and high-level and transuranic wastes involved much more unusual circumstances than those for waste management and storage. Because these materials are dangerous for so long, very long time frames are of interest. Standards must be implemented in the design phase for these disposal systems because active surveillance cannot be relied upon over such periods. At the same time, the standards must accommodate large uncertainties, including uncertainties in our current knowledge about disposal system behavior and the inherent uncertainties regarding the distant future. Subpart B addresses these issues by combining several different types of standards. The primary objective of these standards is to isolate most of the wastes from man's environment by limiting long-term releases and the associated risks to populations. In addition, Subpart B limits risks to individuals in ways compatible with this primary objective.

Although developed primarily through consideration of mined geologic repositories, these disposal standards apply to disposal of spent fuel and high-level and transuranic radioactive wastes by any method -- with one exception. The standards do not apply to ocean disposal or disposal in ocean sediments because such disposal of high-level waste is prohibited by the Marine Protection, Research, and Sanctuaries Act of 1972. If this law is ever changed to allow such

disposal (DOE continues to study the feasibility of this technology, consistent with the NWPA), the Agency will develop appropriate regulations in accordance with the different authorities that would apply.

Also, these disposal standards do not apply to wastes that have already been disposed of. The various provisions of Subpart B are intended to be met through a combination of steps involving disposal system site selection, design, and operational techniques (i.e., engineered barriers). Therefore, the Agency believes it appropriate that these disposal standards only apply to disposal occuring after the standards have been promulgated -- so that they can be taken into consideration in devising the proper selection of controls. Some transuranic wastes produced in support of national defense programs were disposed of before the current DOE procedures for transuranic waste management were adopted in 1970. The exclusion of wastes already disposed of applies to these transuranic wastes, for which selection of disposal system sites, designs, and operational techniques are no longer options.

Containment Requirements (Section 191.13)

To develop the containment requirements, the Agency assumed that some aspects of the future can be predicted well enough to guide the selection and development of disposal systems for these wastes. A period of 10,000 years was considered because that appears to be long enough to distinguish geologic repositories with relatively good capabilities to isolate wastes from those with relatively poor capabilities. On the other hand, this period is short enough so that major geologic changes are unlikely and repository performance might be reasonably projected.

The Agency assessed the performance of a number of model geologic repositories similar to those systems now being considered by DOE. Potential radionuclide releases over 10,000 years were evaluated, and very general models of environmental transport and a linear, non-threshold dose-effect relationship were used to relate these releases to the incidence of premature cancer deaths they might cause. For the various repository types, these assessments indicate that disposal of the wastes from 100,000 metric tons of reactor fuel would cause a population risk ranging from no more than about ten to a little more than one hundred premature deaths over the entire 10,000-year period, assuming that the existing provisions of 10 CFR Part 60 regarding engineered barriers are met.

The Agency also evaluated the health risks that future generations would be exposed to from the amount of uranium ore needed to produce 100,000 metric tons of reactor fuel, if this ore had not been mined to begin with. Population risks ranging between 10 and 100,000 premature cancer deaths over 10,000 years were associated with this much unmined uranium ore, depending upon the analytical assumptions made.

These analyses, which have been updated from those prepared for the proposed standards, reinforce the Agency's conclusion that limiting radionuclide releases to levels associated with no more than 1,000 premature cancer deaths over 10,000 years from disposal of the wastes from 100,000 metric tons of reactor fuel satisfies two important objectives. First, it provides a level of protection that appears reasonably achievable by the various options being considered within the national program for commercial wastes. Second, the Agency believes that such a limitation would clearly keep risks to future populations at acceptably small levels, particularly because it appears to limit risks to no more than the midpoint of the range of estimated risks that future generations would have been exposed to if the uranium ore used to create the wastes had never been mined. Thus, because mined geologic repositories appear capable of providing such good protection, the Agency has decided to establish containment requirements that meet these two objectives.

The specific release limits for different radionuclides in Table 1 of the final rule were developed by estimating how many curies of each radionuclide would cause 1,000 premature deaths over 10,000 years if released to the environment. The limits were then stated in terms of the allowable release from 1,000 metric tons of reactor fuel (so that the actual curie values in Table 1 correspond to a risk level of 10 premature deaths over 10,000 years). All of these limits have been rounded to the nearest order of magnitude because of the approximate nature of these calculations. For particular disposal systems, release limits based upon the amount of waste in the system will be developed and will be used in a formula that insures that the desired risk level will not be exceeded if releases of more than one type of radionuclide are predicted. For some of the wastes covered by this rule, 1,000 metric tons of reactor fuel is not an appropriate unit of waste. In these situations, the various Notes to Table 1 provide instructions on how to calculate the proper release limits. In particular, the final rule includes provisions for high-level wastes from reactor fuels that have received substantially different uses in national defense applications (and contain much different amounts of radioactivity) than is typical of most reactor fuel used to generate electricity. The proposed rule would have allowed releases for these different types of fuels to occur in much different proportions to their total radioactivity than the Agency intended.

The release limits apply to radionuclides that are projected to move into the "accessible environment" during the first 10,000 years after disposal. The accessible environment includes all of the atmosphere, land surface, surface waters, and oceans. However, it does not include the lithosphere (and the ground water within it) that is below the "controlled area" surrounding a disposal system. The standards are formulated this way because the properties of the geologic media around a mined repository are expected to provide much of the disposal system's capability to isolate these wastes over these long time periods. Thus, a certain area of the natural environment is envisioned to be dedicated to keeping these dangerous materials away from future generations and may not be suitable for certain other uses. In the final rule, this "controlled area" is not to exceed 100 square kilometers and is not to extend more than five kilometers in any direction from the original emplacement of the wastes in the disposal system. The implementing agencies may choose a smaller area whenever appropriate.

The containment requirements apply to accidental disruptions of a disposal system as well as to any expected releases. Accordingly, they are stated in terms of the probability of releases occurring. This is done in two steps.

First, the release limits calculated in accordance with Notes 1 through 5 to Table 1 apply to those release levels that are projected to occur with a cumulative probability greater than 0.1 for the entire 10,000-year period over which these disposal standards apply. This includes the total releases from those processes that are expected to occur as well as relatively likely disruptions (which the Agency assumes will primarily include predictions of inadvertent human intrusion).

Second, these release limits multiplied by ten apply to all of the releases projected to occur with a cumulative probability greater than 0.001 over the 10,000-year period. The Agency expects that this will include releases that might occur from the more likely natural disruptive events, such as fault movement and breccia pipe formation (near soluble media such as salt formations). This range of probabilities was selected to include the anticipated uncertainties in predicting the likelihood of these natural phenomena. Greater releases are allowed for these circumstances because they are so unlikely to occur.

Finally, the containment requirements place no limits on releases projected to occur with a cumulative probability of less than 0.001 over 10,000 years. Probabilities this small would tend to be limited to phenomena such as the appearance of new volcanos outside of known areas of volcanic activity, and the Agency believes there is no benefit to public health or the environment from trying to regulate the consequences of such very unlikely events.

The containment requirements call for a "reasonable expectation" that their various quantitative tests be met. This phrase reflects the fact that unequivocal numerical proof of compliance is neither necessary nor likely to be obtained. A similar qualitative test, that of "reasonable assurance," has been used with NRC regulations for many years. Although the Agency's intent is similar, the NRC phrase has not been used in 40 CFR Part 191 because "reasonable assurance" has come to be associated with a level of confidence that may not be appropriate for the very long-term analytical projections that are called for by 191.13. The use of a different test of judgment is meant to acknowledge the unique considerations likely to be encountered upon implementation of these disposal standards.

Assurance Requirements (Section 191.14)

In contrast to the containment requirements, the assurance requirements were developed from that point of view that there may be major uncertainties and gaps in our knowledge of the expected behavior of disposal systems over many thousands of years. Therefore, no matter how promising the analytical projections of disposal system performance appear to be, these materials should be disposed in a cautious manner that reduces the likelihood of unanticipated types of releases. Because of the inherent uncertainties associated with these long time periods, the Agency believes that the principles embodied in the assurance requirements are important complements to the containment requirements that should insure that the level of protection desired is likely to be achieved.

Each of the assurance requirements was chosen to reduce the potential harm from some aspect of our uncertainty about the future. Designing disposal systems with limited reliance on active institutional controls reduces the risks if future generations do not maintain surveillance of disposal sites. On the other hand, planning for long-term monitoring helps reduce the chances that unexpectedly poor performance of a disposal system would go unnoticed. Using extensive markers and records and avoiding resources when selecting disposal sites both serve to reduce the chances that people may inadvertently disrupt a disposal system because of incomplete understanding of its location, design, or hazards. Designing disposal systems to include multiple types of barriers, both engineered and natural, reduces the risks if one type of barrier performs more poorly than current knowledge indicates. Finally, designing disposal systems so that it is feasible for the wastes to be located and recovered gives future generations an opportunity to rectify the situation if new

discoveries indicate compelling reasons (which would not be foreseeable now) to change the way these wastes are disposed of.

The proposed standards contained two other assurance requirements intended to reduce the risks of uncertainty. One of them called for these wastes to be disposed of promptly to reduce the uncertainties associated with storing these materials for indefinitely long times with methods that require active human involvement. However -- after this rule was published for public comment -- the NWPA was enacted, setting up mandates and procedures intended to insure development of the necessary disposal systems for spent fuel and high-level wastes. Furthermore, the Department has made substantial progress towards developing a repository for disposal of the transuranic wastes from atomic energy defense activities. Because of these steps, the Agency decided that the call for prompt disposal was no longer needed, and this assurance requirement has not been included in the final rule.

The other proposed assurance requirement deleted from the final rule is the provision that called for releases to be kept as small as reasonably achievable even when the numerical containment requirements have been complied with. This would have increased the confidence of achieving the desired level of protection even if there were major uncertainties in analytical projections of long-term isolation. However, the Agency does not believe that it is necessary to retain this assurance requirement in the final standards because of two aspects of the related rules subsequently promulgated by the NRC and DOE for disposal of spent fuel and high-level wastes.

First, NRC's 10 CFR Part 60 implemented the multiple barrier principle by requiring very good performance from two types of engineered components: A 300 to 1,000-year lifetime for waste packages during which there would be essentially no expected release of waste, and a subsequent long-term release rate from the waste form of no more than one part in 100,000 per year. The Agency fully endorses this approach and believes that it represents the best performance reasonably achievable for currently foreseeable engineered components. Second, the DOE has included a provision in its site selection guidelines (10 CFR Part 960) that calls for significant emphasis to be placed on selecting sites that demonstrate the lowest releases over 100,000 years compared to the other alternatives available. Particularly because of the longer time frame involved in this comparison, the Agency believes that this provides adequate encouragement to choose sites that provide the best isolation capabilities available. Therefore, the concept of keeping long-term releases as small as reasonably achievable has been embodied by other agencies' regulations for both the engineered and natural components of disposal systems.

The final rule incorporates the five remaining assurance requirements plus the requirement for long-term monitoring, but it makes them applicable only to disposal facilities that are not regulated by the NRC. In its comments on the proposed rule, the NRC objected to inclusion of the assurance requirements, asserting that they were not properly part of the Agency's authorities assigned by Reorganization Plan No. 3 of 1970. The Agency continues to believe that provisions such as the assurance requirements are an appropriate part of generally applicable standards where they are necessary to establish the regulatory context for numerical standards -- as they are in these circumstances because of the major uncertainties involved. However, the two agencies have agreed to resolve this issue by having the Commission modify 10 CFR Part 60 where necessary to incorporate the intent of the assurance requirements, rather than have them included in 40 CFR Part 191 for NRC-licensed disposal facilities. Thus, 10 CFR Part 60 will establish the context needed for appropriate implementation of 40 CFR Part 191.

The NRC staff is preparing the appropriate revisions to Part 60 and has told the Agency that they will be published in the Federal Register for public review and comment within approximately 120 days of today's promulgation of 40 CFR Part 191. EPA has provided NRC with all of the comments received on the assurance requirements during the 40 CFR Part 191 rulemaking, and the Agency will participate in the NRC rulemaking to facilitate our objective of having the intent of all of the assurance requirements embodied in Federal regulation. Finally, the Agency will review the record and outcome of the Part 60 rulemaking to determine if any subsequent modifications to 40 CFR Part 191 are needed.

Individual and Ground Water Protection Requirements (Sections 191.15 and 191.16)

While the primary objective of both the proposed and final disposal standards has been to limit potential long-term releases from disposal systems (and the population risks associated with such releases), these two sections have been added to the final rule to provide protection for those individuals in the vicinity of a disposal system. There are a number of difficult issues involved in formulating standards for individual protection in this situation, as discussed later in the "Release Limits vs. Individual Dose Limits" section. However, after evaluating the various comments received on this topic, the Agency believes that there are also important advantages in providing for individual protection in ways

compatible with the containment and assurance requirements. In discussing this issue, the SAB Subcommittee stated that: "We support the use of a population risk criteria. We believe it is impractical to provide absolute protection to every individual for all postulated events or for very long periods. On the other hand, in our view it is important that, for the first several hundred years, residents of the region immediately outside the accessible environment have very great assurance that they will suffer no, or negligible, ill effects from the repository."

The individual protection requirements in the final rule limit the annual exposure from the disposal system to a member of the public in the accessible environment, for the first 1,000 years after disposal, to no more than 25 millirems to the whole body or 75 millirems to any organs. These limitations apply to the predicted behavior of the disposal system, including consideration of the uncertainties in predicted behavior, assuming that the disposal system is not disrupted by human intrusion or the occurrence of unlikely natural events. The Agency chose the limits of 25 millirem/year to the whole body and 75 millirem/year to any organ because it believes that they represent a sufficiently stringent level of protection for situations where no more than a few individuals are likely to receive this exposure. If such an individual were exposed to this level over a lifetime (which seems particularly unlikely given the localized pathways through which waste might escape from a geologic repository), the Agency estimates this would cause a 5 X 10 -4 chance of incurring a premature fatal cancer.

In choosing a time period for these requirements to protect individuals nearby disposal systems, the Agency took into account concerns such as those expressed by the SAB by examining the effects of choosing different time frames. As 10,000 years was chosen for the containment requirements because it is long enough to encourage use of disposal sites with natural characteristics that enhance long-term isolation, 1,000 years was chosen for the individual protection provisions because the Agency's assessments indicate it is long enough to insure that particularly good engineered barriers would need to be used at potential sites where some ground water would be expected to flow through a mined geologic repository. Use of a time much shorter than 1,000 years would not call for substantial engineered barriers even at disposal sites with a lot of ground water flow.

On the other hand, demonstrating compliance with individual exposure limits for times much longer than 1,000 years appears to be quite difficult because of the analytical uncertainties involved. It would require predicting radionuclide concentrations -- even from releases of tiny portions of the waste -- in all the possible ground water pathways flowing in all directions from the disposal system, at all depths down to 2,500 feet, as a function of time over many thousands of years. At some of the sites being considered (and possibly all of them, depending upon what is discovered during site characterization) the only certain way to comply with such requirements for periods on the order of 10,000 years appears to be to use very expensive engineered barriers that would rule out any potential releases over most of this period. While such barriers could provide longer-term protection for individuals, they would not provide substantial benefits to populations because the containment and assurance requirements already reduce population risks to very small levels.

Based on all of these considerations, the Agency has decided that a 1,000-year duration is adequate for quantitative limits on individual exposures after disposal. For longer time periods, several of the qualitative assurance requirements should help to reduce the chances that individuals will receive serious radiation exposures. In addition, 40 CFR Part 191 in no way limits the future applicability of the Agency's drinking water standards (40 CFR Part 141) -- which protect community water supply systems through institutional controls -- or of similar standards that future generations may choose to adopt.

In assessing the performance of a disposal system with regard to individual exposures, all pathways of radioactive material or radiation from the disposal system to people shall be considered. In particular, the assessments must assume that individuals consume all of their drinking water (2 liters per day) from any portion of a "significant source of ground water" anywhere outside of the "controlled area" surrounding the disposal system. Significant sources of ground water are defined to include underground formations that are likely to be able to provide enough water for a community water system as defined in 40 CFR Part 141. (More information regarding this definition is provided later in the "Release Limits vs. Individual Dose Limits" discussion.) Formations that could only provide smaller amounts of potable water have not been included because the Agency wants to avoid discriminating against the use of low-productivity geologic formations that might provide very good long-term isolation as disposal sites. The Agency believes this is reasonable for these standards because of the very small number of such disposal facilities that are contemplated (no more than three or four over the next 100 years.) However, the Agency has no plans to use this classification for other ground water related standards, which usually affect a far greater number of situations.

The Agency has not required these individual protection provisions to assume ground water use within the controlled area because geologic media within the controlled area are an integral part of the disposal system's capability to provide long-term isolation. (But if the implementing agency plans to allow individuals to use ground water within the controlled area, such planned use would have to be considered within the pathways evaluated to determine compliance with § 191.15.) The potential loss of ground water resources is very small because of the small number of such disposal facilities contemplated. Nevertheless, the Agency has also added ground water protection requirements to the final rule (Section 191.16) that protect certain sources of ground water even within the controlled area. These ground water protection requirements are similar to the individual protection requirements because they apply to undisturbed performance for 1,000 years after disposal. However, the ground water protection requirements apply only to those Class I ground waters, as they are identified in accordance with the Agency's Ground-Water Protection Strategy published in August 1984, that meet the following three conditions: (1) They are within the controlled area or near (less than five kilometers beyond) the controlled area; (2) they are supplying drinking water for thousands of persons as of the date that the Department selects the site for extensive exploration as a potential location of a disposal system; and (3) they are irreplaceable in that no reasonable alternative source of drinking water is available to that population.

For such Class I ground waters, § 191.16 limits the radionuclide concentrations in water withdrawn from any portion of them to no more than concentration limits similar to those established for the output of community water systems in 40 CFR Part 141. However, if the preexisting concentrations of radioactivity in the Class I aquifer already exceed any of these limits at a particular site, § 191.16 then limits any *increases* in the preexisting concentrations to these same concentration limits. The Agency believes these provisions are necessary and adequate to avoid any significant degradation of the important drinking water resources provided by these Class I ground waters.

Alternative Provisions for Disposal (Section 191.17)

In developing the disposal standards, the Agency has had to make many assumptions about the characteristics of disposal systems that have not been built, about plans for disposal that are only now being formulated, and about the probable adequacy of technical information that will not be collected for many years. Thus, although the Agency believes that the disposal standards being promulgated today are appropriate based upon current knowledge, we cannot rule out the possibility that future information may indicate needs to modify the standards.

In recognition of this possibility, § 191.17 of the final rule sets forth procedures under which the Administrator may develop modifications to Subpart B, should the need arise. Any such changes would have to proceed through the usual notice-and-comment rulemaking process, and § 191.17 stipulates that such a rulemaking would require a public comment period of at least 90 days, to include public hearings in affected areas of the country. Although such procedures are common practice in rulemakings of this type, they are not required by the statutes relevant to this rule (Administrative Procedures Act mandates can be satisfied by a comment period as short as 14 days). Thus, § 191.17 insures an opportunity for significant public interaction regarding any proposed changes to the disposal standards.

There are several areas of uncertainty the Agency is aware of that might cause suggested modifications of the standards in the future. One of these concerns implementation of the containment requirements for mined geologic repositories. This will require collection of a great deal of data during site characterization, resolution of the inevitable uncertainties in such information, and adaptation of this information into probabilistic risk assessments. Although the Agency is currently confident that this will be successfully accomplished, such projections over thousands of years to determine compliance with an environmental regulation are unprecedented. If -- after substantial experience with these analyses is acquired -- disposal systems that clearly provide good isolation cannot reasonably be shown to comply with the containment requirements, the Agency would consider whether modifications to Subpart B were appropriate.

Another situation that might lead to suggested revisions would be if additional information were developed regarding the disposal of certain wastes that appeared to make it inappropriate to retain generally applicable standards addressing all of the wastes covered by this rule. For example, the DOE is considering disposal of some defense wastes by stabilizing them in their current storage tanks, rather than relocating them to a mined repository. The Agency has not assessed the ramifications of such disposal yet, and it is certainly possible that it could be carried out in compliance with all the provisions of Subpart B being promulgated today. However, it is also possible that there may be benefits associated with such disposal that would warrant changes in Subpart B for these types of waste. If so, § 191.17 would govern the consideration of any such revisions.

Other examples of developments that might offer reasons to consider alternative provisions in the future include: The use of reactor fuel cycles or utilizations substantially different than today's; new models of the environmental trans-

port and biological effects of radionuclides that indicate major changes (i.e., approaching an order of magnitude) in the relative risks associated with different radionuclides and the level of protection sought by the disposal standards; or information that indicates that particular assurance requirements might not be needed in certain situations to insure adequate confidence of long-term environmental protection.

Guidance for Implementation (Appendix B)

This supplement to the final rule is based upon some of the analytical assumptions that the Agency made in developing the technical basis used for formulating the numerical disposal standards. These analytical assumptions incorporate information assembled as part of the technical basis used to develop the proposed rule. In particular, Appendix B discusses: (1) The consideration of all barriers of a disposal system in performance assessments; (2) reasonable limitations on the scope of performance assessments; (3) the use of average or "mean" values in expressing the results of performance assessments; (4) the types of assumptions regarding the effectiveness of institutional controls; and (5) limiting assumptions regarding the frequency and severity of inadvertent human intrusion into geologic repositories.

The implementing agencies are responsible for selecting the specific information to be used in these and other aspects of performance assessments to determine compliance with 40 CFR Part 191. However, the Agency believes it is important that the assumptions used by the implementing agencies are compatible with those used by EPA in developing this rule. Otherwise, implementation of the disposal standards may have effects quite different than those anticipated by EPA. The final rule to be published in the Code of Federal Regulations will include this informational appendix as guidance to the implementing agencies. Although the other agencies are not bound to follow this guidance, EPA recommends that it be carefully considered in planning for the application of 40 CFR Part 191. The Agency will monitor implementation of the disposal standards as it develops over the next several years to determine whether any changes to the rule are called for to meet the Agency's objectives for these standards.

Comments on Issues Highlighted for Public Review

The Agency particularly requested public comment on six issues associated with the proposed rule (47 FR 58196). After these comments were received, additional comments and information were requested on seven issues raised by the initial comments (48 FR 21666). Two of these seven issues (the definition of high-level waste and the use of individual dose limitations in the disposal standards) had been included among the first six issues that were highlighted. Thus, a total of eleven questions received particular attention during the public review and comment process. The following paragraphs summarize the comments received on each of these issues and the Agency's responses to them, including descriptions of any resulting changes made in the final rule.

Definition of "High-Level Waste"

Traditionally, the term "high-level waste" has meant the highly radioactive liquid wastes remaining from the recovery or uranium and plutonium in a nuclear fuel reprocessing plant, and other liquid or solid forms into which such liquid wastes are converted to facilitate managing them. This traditional use of the term has not included radioactive materials from other sources, no matter how radioactive they are. However, somewhat different definitions of high-level waste have appeared in certain laws and regulations affecting specific aspects of radioactive waste management. Most notably, some of these definitions have included unreprocessed spent fuel as the prospects for a commercial fuel reprocessing industry became more uncertain.

In the proposed rule, high-level waste was defined in the traditional sense, including spent fuel if disposed of without reprocessing. But the proposed definition also included minimum radioactivity concentrations below which such materials would not be subject to the stringent isolation requirements of 40 CFR Part 191. To identify these minimum concentrations, the maximum concentrations that the NRC determined that it would generally accept in near-surface disposal facilities under 10 CFR Part 61 (47 FR 57446) were adapted. Since this represented a modification of the traditional meaning of high-level waste, the Agency particularly sought comment on this aspect of the proposed rule.

Shortly after 40 CFR Part 191 was published for public review, the NWPA was enacted. The NWPA distinguished between spent nuclear fuel and high-level waste, and it defined high-level waste to include both: "(A) The highly radioactive material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such liquid waste that contains fission products in sufficient concentrations; and (B) other highly radioactive material that the Commission, consistent with existing law, determines by rule requires

permanent isolation." This definition allow for inclusion of highly radioactive material not related to reprocessing of spent nuclear fuel, and it reflects the concept that some derivatives of nuclear fuel reprocessing may not contain sufficient radioactivity to warrant exceptional isolation.

Many of the comments regarding the proposed definition suggested that EPA adopt the definition in the NWPA, although in response to the specific questions distributed in conjunction with the Agency's public hearings, many responders thought that the Agency should define the phrase "sufficient concentrations" contained in part A of the NWPA definition. However, several commenters argued that the proposed lower limits for high-level waste concentrations had been improperly taken out of the context of 10 CFR Part 61 and could require expensive disposal of wastes with relatively small hazards.

After considering these comments and other information currently available, the Agency decided to incorporate the NWPA definition of high-level waste in the final 40 CFR Part 191 without further elaboration of the phrase "sufficient concentrations." The Agency recognizes that this introduces some uncertainty regarding the applicability of this rule. However, the Commission is now beginning a rulemaking that should assemble the technical information needed to develop a more specific definition of high-level wastes. Since the NRC definition would not necessarily apply to all the situations covered by 40 CFR Part 191 (e.g., management and storage of defense high-level wastes prior to disposal is not regulated by NRC), the Agency will follow the Commission's rulemaking to determine what appropriate elaborations of the NWPA definition should be incorporated into 40 CFR Part 191. Upon completion of the NRC rulemaking, the Agency will initiate steps to appropriately modify this rule. In addition, EPA will address disposal of any radioactive wastes that are not covered by 40 CFR Part 191 or 40 CFR Part 192 (the Agency's standards for disposal of uranium mill tailings) as it considers standards for disposal of low-level radioactive wastes (48 FR 39563).

Finally, incorporating the NWPA definition of high-level waste also includes the phrase "consistent with existing law" when describing the NRC's responsibilities to identify materials as high-level waste. Promulgation of 40 CFR Part 191 with this definition does not signify Agency acceptance or endorsement of any particular interpretation of the phrase "consistent with existing law." The Agency presumes that the Commission will specify the applicability of its existing authorities as it conducts the relevant rulemaking efforts.

The Level of Protection

In the proposed rule, the containment requirements for disposal systems limited the residual risks to no more than an estimated 1,000 premature cancer deaths over the first 10,000 years after disposal of the wastes from 100,000 metric tons of heavy metal (MTHM) used as fuel in a nuclear reactor. The Agency pointed out that a variety of mined repository designs using different combinations of geologic media and engineered controls were expected to meet these requirements. It was also estimated that the residual risks to future generations appeared to be no greater than if the uranium ore used to create the wastes had not been mined. EPA particularly asked for comment on whether it had taken an appropriate and reasonable approach in choosing this level of protection based upon these considerations.

Most of the public comments found this approach satisfactory. However, some commenters argued that the risks from unmined uranium ore did not necessarily define an acceptably low level of residual risks. They pointed out that such risks may vary from place to place (and a high-level waste repository could "redistribute" them) and that society sometimes does take measures to clean-up naturally-occurring radioactivity, implying that such natural risks are not always "acceptable."

On the other hand, some commenters felt that the level of protection sought in the proposed rule was far too stringent when compared to risks allowed and accepted by society from other activities. For example, the SAB Subcommittee recommended that the desired level of protection be relaxed by at least a factor of ten for this reason, coupled with the Subcommittee's concern that the uncertainties in analytical projections over thousands of years could make it difficult to demonstrate compliance with the proposed containment requirements.

After evaluating the public comments and updated performance assessments of geologic repositories, the Agency has retained the proposed level of protection as the basis for the long-term containment requirements in the final rule -- even though it is true that long-term assessments of repository performance will encounter substantial uncertainties, as the SAB Subcommittee pointed out. Three reasons support this decision.

First, revising the performance assessments in accordance with many of the technical recommendations of the SAB has reinforced the Agency's conclusion that the proposed level of protection can reasonably be achieved by a variety of

combinations of repository sites and designs -- and EPA's regulatory impact analyses indicate that this level of protection can be achieved without significant effects on the cost of disposing of these wastes.

Second, comparing this level of protection with the comparable risks from equivalent amounts of unmined uranium ore continues to reinforce the Agency's belief that this is an acceptably small residual risk for future generations. Therefore, the Agency believes that this level of protection represents a reasonable basis for these disposal standards.

Third, rather than relax the level of protection, the Agency has chosen to address the uncertainties that concerned the SAB Subcommittee by adding § 191.13(b) and by providing a more detailed "Guidance for Implementation" section to replace the proposed "Procedural Requirements." For example, this guidance points out that the entire range of possible projections of releases need not meet the containment requirements. Rather, compliance should be based upon the projections that the implementing agencies believe are more realistic. Furthermore, these revisions acknowledge that the quantitative calculations needed may have to be supplemented by reasonable qualitative judgments in order to appropriately determine compliance with the disposal standards.

In retaining the proposed level of protection, the Agency emphasizes that it is making a decision applicable only to the circumstances involving disposal of spent nuclear fuel and high-level and transuranic wastes. This rule cannot be used to establish precedents such as "no incremental risk to future generations" for extrapolation to other disposal problems. For other situations, evaluations of technological feasibility and cost-effectiveness must be considered for the particular set of circumstances. If mined geologic repositories were not capable of providing such good protection, the Agency might have chosen considerably different standards.

Time Period for Containment Requirements

Many commenters addressed the 10,000-year period used for the proposed containment requirements. A few argued that this period was too long and that EPA should only be concerned with a few hundred to a thousand years. A number of commenters supported the focus on 10,000 years. However, many commenters felt that it was inappropriate for the standards to ignore the period after 10,000 years. Some suggested that the containment requirements should address periods ranging from 50,000 to 500,000 years.

In the proposed rule, the Agency indicated that 10,000 years was chosen, in part, because compliance with quantitative standards for a substantially longer period would have entailed considerably more uncertain calculations. There was no intention to indicate that times beyond 10,000 years were unimportant, but the Agency felt that a disposal system capable of meeting the proposed containment requirements for 10,000 years would continue to protect people and the environment well beyond 10,000 years. The SAB Subcommittee reviewed and supported these technical arguments for limiting the containment requirements to a 10,000-year period. Those commenters who argued for longer periods did not suggest effective ways that might compensate for the substantially greater uncertainties inherent in longer projections of disposal system performance.

However, many of the commenters and the SAB Subcommittee suggested that more qualitative or comparative assessments beyond 10,000 years might be appropriate. The Agency agreed with these comments and worked with the DOE to formulate comparative assessment provisions that have been incorporated into the final version of the Department's site selection guidelines (10 CFR Part 960). These provisions call for comparisons of the projected releases from undisturbed performance of alternative repository sites over 100,000 years to be a significant consideration in site selection. Since natural barriers are expected to provide the primary protection for such long time frames, this provision should allow for appropriate consideration of longer time periods without requiring the absolute values of these very uncertain calculations to meet a specific quantitative test. With the inclusion of this comparative test in 10 CFR Part 960, the Agency believes that no modification is needed in 40 CFR Part 191.

Use of Quantitative Probabilities in the Containment Requirements

The containment requirements in the proposed rule applied to two categories of potential releases ("reasonably foreseeable" and "very unlikely") based upon their projected probabilities of occurrence over the first 10,000 years after disposal. In its comments on the proposed rule, the NRC objected to the proposed quantitative definitions of these probabilities on the basis that calculation of such probabilities could be so uncertain that it would be impractical to determine whether the standards had been complied with. Instead, the NRC suggested substitution of qualitative terms to identify the two categories of potential releases. The wording proposed by the NRC was formulated in terms of releases that might be caused by geologic processes and events.

In the second round of comment, the Agency sought information on whether to adopt the NRC's recommended wording or to retain definitions based on quantitative probabilities. Although a number of commenters agreed with the NRC position, the preponderance of comments supported retention of the quantitative probabilities. The SAB Subcommittee strongly supported retention of the probabilistic structure, but with substantially less restrictive probabilities and with the proviso that the Agency be sure that such conditions would be ". . . practical to meet and [would] not lead to serious impediments, legal or otherwise, to the licensing of high-level waste repositories." After considering all of this information, the Agency has revised the structure of the containment requirements in several ways that will retain quantitative objectives for long-term containment while allowing the implementing agencies enough flexibility to make qualitative judgments when necessary.

First, the final rule does not use the terms "reasonably foreseeable" and "very unlikely" releases. Instead, the permissible probabilities for two different levels of cumulative releases (over 10,000 years after disposal) are now incorporated directly into the containment requirements.

Second, the numerical probabilities associated with the two release categories have been increased by an order of magnitude to reflect further assessments of the uncertainties associated with projecting the probabilities of geologic events such as fault movement.

Third, the final rule clearly indicates that comprehensive performance assessments, including estimates of the probabilities of various potential releases whenever meaningful estimates are practicable, are needed to determine compliance with the containment requirements.

Fourth, a paragraph has been added to the final containment requirements (Section 191.13) to emphasize that unequivocal proof of compliance is neither expected nor required because of the substantial uncertainties inherent in such long-term projections. Instead, the appropriate test is a reasonable expectation of compliance based upon practically obtainable information and analysis. This paragraph was patterned after a paragraph that considered similar issues in NRC's 10 CFR Part 60.

Finally, the "Guidance for Implementation" section has been added (Appendix B). This part of the rule describes the Agency's assumptions regarding performance assessments and uncertainties and should discourage overly restrictive or inappropriate implementation of the containment requirements.

The Agency believes that these revisions to the proposed rule preserve an objective framework for application of the containment requirements that requires very stringent isolation while allowing the implementing agencies adequate flexibility to handle specific uncertainties that may be encountered.

Within this framework, the possibility of inadvertent human intrusion into or nearby a repository requires special attention. Such intrusion can significantly disrupt the containment afforded by a geologic repository (as well as being dangerous for the intruders), and repositories should be selected and designed to reduce the risks from such potential disruptions. However, assessing the ways and the reasons that people might explore underground in the future -- and evaluating the effectiveness of passive controls to deter such exploration near a repository -- will entail informed judgment and speculation. It will not be possible to develop a "correct" estimate of the probability of such intrusion. The Agency believes that performance assessments should consider the possibilities of such intrusion, but that limits should be placed on the severity of the assumptions used to make the assessments. Appendix B to the final rule describes a set of parameters about the likelihood and consequences of inadvertent intrusion that the Agency assumed were the most pessimistic that would be reasonable in making performance assessments. The implementing agencies may adopt these assumptions or develop similar ones of their own. However, as indicated under the discussion of institutional controls, the Agency does not believe that institutional controls can be relied upon to completely eliminate the possibility of inadvertent intrusion.

Definition of "Accessible Environment"

The containment requirements limit releases to the "accessible environment" for 10,000 years after disposal. In the proposed rule, ground water within 10 kilometers of a disposal system was excluded from the definition of accessible environment. This definition was intended to reflect the concept that the geologic media surrounding a mined repository are part of the long-term containment system, with disposal sites being selected so that the surrounding media prevent or retard transport of radionuclides through ground water. Such surrounding media would be dedicated for this purpose, with the intention to prohibit incompatible activities (either those that might disrupt the disposal system or those that could cause significant radiation exposures) in perpetuity. Applying standards to the ground water contained within

these geologic media surrounding a repository would ignore the role of this natural barrier, and it could reduce the incentive to search for sites with characteristics that would enhance long-term containment of these wastes. (At the same time, the Agency recognized that the institutional controls designed to reserve this area around a disposal system cannot be considered infallible, and other provisions of the rule are designed to reduce the consequences of potential failures.)

Many commenters objected to the definition of accessible environment incorporated in the proposed rule. Some recommended that all ground water, or all "potable" ground water, should be included. Others agreed that it was appropriate to exclude some ground water in the immediate vicinity of a repository, but argued that the proposed 10-kilometer distance was too long -- particularly for ground water sources that were likely to be used in the future. A few commenters thought that the proposed definition was too restrictive by including all ground water beyond 10 kilometers; they suggested that poor quality ground water sources unlikely to be used in the future should not be part of the accessible environment at all.

After considering these comments, the Agency has decided to make several changes in the definition of the "accessible environment." First, the concept of a "controlled area" has been adopted from NRC's 10 CFR Part 60. This establishes an area around a disposal system that is to be identified by markers, records, and other passive institutional controls intended to prohibit incompatible activities from the area. Consistent with the proposed 40 CFR Part 191, the current NRC definition of "controlled area" limits its distance from the edge of a repository to no more than 10 kilometers. The final 40 CFR Part 191 defines "accessible environment" to include: (1) The atmosphere, land surfaces, surface waters, and the oceans, wherever they are located; and (2) portions of the lithosphere -- and the ground water within it -- that are beyond the controlled area.

Second, the Agency has made the definition of the "controlled area" more restrictive than that currently incorporated in 10 CFR Part 60. This revised definition limits the controlled area to a distance no greater than five kilometers from the original emplacement of wastes in a disposal system, rather than 10 kilometers. Furthermore, the revised definition limits the area encompassed by the controlled area to no more than 100 square kilometers, which is approximately the area that would be encompassed by a controlled area at a distance of three kilometers from all sides of a typical repository configuration. (A distance of five kilometers from all sides of a typical repository would correspond to an area of about 200 square kilometers, whereas a distance of ten kilometers from all sides corresponds to an area of almost 500 square kilometers.) This revised definition substantially reduces the area of the lithosphere that would have been removed from the "accessible environment" defined in the proposed rule, and it somewhat reduces the distance used in the proposed rule. The five-kilometer distance was chosen to retain reasonable compatibility with the NRC's requirement for a preemplacement ground water travel time of 1,000 years to the accessible environment (one of the 10 CFR Part 60 requirements developed in concert with the proposed rule), while still providing for greater isolation than called for by the proposed rule. This definition of the accessible environment will allow a controlled area to be established asymmetrically around a repository based upon the particular characteristics of a site.

Release Limits vs. Individual Dose Limits

The Agency believes that the containment requirements in § 191.13 will insure that the overall population risks to future generations from disposal of these wastes will be acceptably small. However, the situation with regard to potential individual doses is more complicated. Even with good engineering controls, some waste may eventually (i.e., several hundreds or thousands of years after disposal) be released into any ground water that might be in the immediate vicinity of a geologic repository. Since ground water generally provides relatively little dilution, anyone using such contaminated ground water in the future may receive a substantial radiation exposure (e.g., several rems per year or more). This possibility is inherent in collecting a very large amount of radioactivity in a small area.

The proposed rule did not contain any numerical restrictions on such potential individual doses after disposal. Rather, the proposal relied on several of the qualitative assurance requirements to greatly reduce the likelihood of such exposures. In particular, the assurance requirement calling for extensive permanent markers and records was intended to perpetuate information to future generations about the dangers of intruding into the vicinity of a repository. The assurance requirement to avoid sites with significant resources was intended to reduce the incentive to explore around a repository even if the information passed on was ignored or misunderstood. And the assurance requirements to use multiple barriers, both engineered and natural, and to keep releases as small as reasonably achievable were intended to encourage reduction of releases to ground water beyond that needed to meet the containment requirements -- further reducing the potential for harmful individual exposures.

This approach to potential individual exposures was highlighted for comment when 40 CFR Part 191 was proposed. After receiving many recommendations to incorporate a limitation on individual doses after disposal, the Agency sought comment on further details of such a limitation in the second round of comments. For example, EPA asked whether such a limitation should apply to ground water use, whether it should apply only for ground water at some distance from a geologic repository or for any ground water source, and whether reliance on existing individual dose limitations (such as 40 CFR Part 141 or 10 CFR Part 20) for protection regarding ground water would be adequate.

The responses resulting from these questions offered a wide range of suggestions. A number of commenters opposed inclusion of an individual dose limitation for disposal on the grounds that calculations to judge compliance with such a standard would be highly speculative and not an appropriate basis upon which to judge the adequacy of a disposal system. In contrast, some other commenters argued that an individual dose standard in the 5 to 25 millirems per year range should apply to use of ground water in the accessible environment for an indefinitely long period into the future. Another group of commenters supported inclusion of some limitation on individual exposure, but only to the extent that it would not compromise the primary intent of long-term isolation and containment of the wastes.

These comments did not offer information that changed the Agency's perception of some of the problems associated with individual dose limitations for disposal. First, relying *only* upon an individual dose standard for disposal could encourage disposal methods that would enhance dilution of any wastes released. Thus, disposal sites near bodies of surface water or large sources of ground water might be preferred -- which the Agency believes is an inappropriate policy that would usually increase overall population exposures.

This concern could be met by *adding* an individual dose limitation to the proposed containment requirements, rather than replacing them. However, the Agency's performance assessments of geologic repositories indicate that doses from using ground water close to a repository can become substantial (e.g., several rems per year) after a few hundred or thousand years, because the geological and geochemical characteristics of appropriate sites tend to concentrate eventual releases of wastes in any ground water that is close to the site. A study published by the National Academy of Sciences in April 1983 confirms this potential for large individual doses if flowing ground water can contact the wastes after the waste canisters are presumed to start leaking. Although it might be possible to find certain geologic settings that avoid this problem, such restrictive siting prerequisites could substantially delay development of disposal systems without providing significantly more protection to populations. Furthermore, even if reasonable limitations on individual exposure might be met at certain sites for very long times, demonstrating compliance with such limitations could be very difficult because of the additional complexities involved in estimating individual exposures rather than amounts of radioactivity released. The SAB Subcommittee report generally agreed with the technical aspects of these conclusions.

On the other hand, analyses of repository systems with good engineering controls show that they should be able to prevent significant doses from ground water use for at least a thousand years after disposal. Such protection would be compatible with both the proposed containment and assurance requirements. Accordingly, the SAB Subcommittee recommended that the Agency include a requirement limiting individual doses for the first 500 years after disposal, and one of the States that commented on the proposed rule suggested an individual dose limit for 1,000 years after disposal.

After considering all of this information, the Agency has decided to include two new sections in the final rule. The first (Section 191.15) limits exposures to members of the public after disposal, while the second (Section 191.16) limits concentrations in water withdrawn from certain important sources of ground water after disposal.

The individual protection requirements in § 191.15 limit exposures from a disposal system to individuals in the accessible environment to 25 millirems per year to the whole body and 75 millirems per year to any organ. These limits apply only to undisturbed performance of the disposal system (i.e., without any consideration of human intrusion or disruption by unlikely natural events), and they apply for the first 1,000 years after disposal. All potential pathways of radiation or radioactive material from the disposal system to people (associated with undisturbed performance) shall be considered, including the assumption that an individual drinks two liters per day of water from any "significant source of ground water" outside of the "controlled area" surrounding a disposal system. If the implementing agency plans to allow individuals to use ground water within the controlled area, such planned use would also have to be considered within the pathways evaluated to determine compliance with § 191.15.

"Significant sources of ground water" are defined to include any aquifer currently providing the primary source of water for a community water system or any aquifer that satisfies all of the following five conditions: (1) It is saturated with water containing less than 10,000 milligrams per liter of total dissolved solids; (2) it is within 2,500 feet of the land surface; (3) it has a transmissivity of a least 200 gallons per day per foot, provided that (4) each of the underground formations or parts of underground formations included within the aquifer must have an individual hydraulic conductiv-

ity greater than 2 gallons per day per square foot; and (5) it must be capable of providing a sustained yield of 10,000 gallons per day of water to a pumped or flowing well.

Although such quantitative distinctions are inevitably somewhat arbitrary, the Agency believes that they provide reasonable demarcations to identify underground formations that could meet the needs of community water systems in the future. The selected transmissivity of 200 gallons per day per foot and the sustained yield of 10,000 gallons per day roughly correspond to the size of a ground water source required to support the needs of about 20 households; this is similar to the size of the community water system considered in 40 CFR Part 141. The water quality criterion of 10,000 milligrams per liter of total dissolved solids has been used in several previous Agency regulations and is based upon congressional guidance in the legislative history of the Safe Drinking Water Act. The maximum depth criterion of 2,500 feet was chosen because almost all of the wells used to provide water to significant numbers of people do not extend below this depth. The minimum hydraulic conductivity criterion of 2 gallons per day per square foot was chosen to insure that only reasonably permeable formations are considered, rather than including unproductive formations that might be in the vicinity of a "significant source of ground water."

The ground water protection requirements in § 191.16(a) limit the concentrations in water withdrawn from any "special source of ground water" in the vicinity of a disposal system to concentrations similar to those established for the output of community water systems by 40 CFR Part 141: (1) 5 picocuries per liter of radium-226 and radium-228; (2) 15 picocuries per liter of alpha-emitting radionuclides (including radium-226 and radium-228 but excluding radon); or (3) the combined concentrations of radionuclides that emit either beta or gamma radiation that would produce an annual dose equivalent to the total body or any internal organ greater than 4 millirems per year if an individual continuously consumed 2 liters per day of drinking water from that source of water. However, if the preexisting radionuclide concentrations in the special source of ground water already exceed any of these limits, then § 191.16(b) limits any *increases* in the preexisting concentrations to the concentration limits set in § 191.16(a). Like the individual protection requirements, the ground water protection requirements apply only for undisturbed performance of the disposal system and apply for the first 1,000 years after disposal. Unlike the individual protection requirements, the ground water requirements would apply to a "special source" if it was within the controlled area.

"Special sources" are defined to include only those Class I ground waters -- to be identified in accordance with the Agency's Ground-Water Protection Strategy published in August 1984 -- that meet the following three conditions: (1) They are within the controlled area or near (less than five kilometers beyond) the controlled area; (2) they are supplying drinking water for thousands of persons as of the date that the Department selects the site for extensive exploration as a potential location of a disposal system; and (3) they are irreplaceable in that no reasonable alternative source of drinking water is available to that population.

Need for the Assurance Requirements

The preceding issues dealt with the quantitative requirements of the disposal standards. While numerical standards are important to bring about appropriate selection and design of disposal systems, the Agency has long recognized that the numerical standards chosen for Subpart B, by themselves, do not provide either an adequate context for environmental protection or a sufficient basis to foster public confidence in the national program. There are too many uncertainties in projecting the behavior of natural and engineered components for many thousands of years -- and too many opportunities for mistakes or poor judgments in such calculations -- for the numerical requirements on overall system performance in Subpart B to be the sole basis to determine the acceptability of disposal systems for these very hazardous wastes. These uncertainties and potential errors in quantitative analysis could ultimately prevent the degree of protection sought by the Agency from being achieved. (Theoretically, it might be possible to develop adequate confidence in achieving this level of protection by choosing much more stringent numerical standards, but this could lead to substantial difficulties in implementation.) Therefore, the proposed standards also included qualitative assurance requirements chosen to ensure that cautious steps are taken to reduce the problems caused by these uncertainties. The proposed rule emphasized that the assurance requirements were an essential complement to the quantitative containment requirements that were selected.

In its comments on the proposed rule, the NRC argued that the assurance requirements were not properly part of the Agency's generally applicable standards. The Commission agreed that the overall numerical performance standards were not sufficient, but suggested that its regulations and procedures were the appropriate vehicle to provide the necessary confidence that the inherent uncertainties would not compromise environmental protection. The Agency believes that it does have the authority to give regulatory expression to the context within which it has chosen to establish one set

of numerical standards rather than another. However, because it might not be appropriate to exercise this authority, the Agency sought public comment on the need for the assurance requirements in the second round of comments.

The preponderance of comments received on this question strongly supported retention of the assurance requirements in 40 CFR Part 191. In particular, virtually all of the various State governments that commented on the rule described the assurance requirements as an essential part of the regulations governing disposal of these wastes. Subsequently, two of these States, Nevada and Minnesota, petitioned the Commission to incorporate the assurance requirements proposed as part of 40 CFR Part 191 into its own rules (50 FR 18267).

Based upon these comments, the Agency and the NRC have reached an agreement that should accomplish the desired regulatory goals while avoiding the jurisdictional issue. EPA has included the assurance requirements in the final rule, modified as appropriate in response to other comments. However, these requirements will not be applicable to disposal facilities to be licensed by the Commission. Instead, as discussed previously, the NRC staff plans to propose modifications to 10 CFR Part 60, developed in consultation with EPA, for public review and comment within approximately 120 days to insure that the objectives of all of the assurance requirements in 40 CFR Part 191 will be accomplished through compliance with 10 CFR Part 60. The Agency has provided the Commission with all of the comments received by EPA regarding the assurance requirements, so that the NRC can use them in its rulemaking. In addition, the Agency will participate in the NRC rulemaking to facilitate incorporation of the principles of all of the assurance requirements in Federal regulation. Finally, the Agency will review the record and outcome of the Part 60 rulemaking to determine if any subsequent modifications to 40 CFR Part 191 are needed.

Approach Toward Institutional Controls

The Agency particularly sought comment on its proposed approach to reliance on institutional controls. The proposed rule limited reliance on "active institutional controls" (such as controlling access to a disposal site, performing maintenance operations, or cleaning up releases) to a reasonable period of time after disposal, described as on the order of a "few hundred years." On the other hand, "passive institutional controls" (such as permanent markers, records, archives, and other methods of preserving knowledge) were considered to be at least partially effective for a longer period of time.

Few commenters argued with the distinction between active and passive institutional controls, or with the amount of reliance the proposed rule envisioned for passive controls. However, many commenters felt that "a few hundred years" was too long a period to count on active controls. Accordingly, the final rule limits reliance on active institutional controls to no more than 100 years after disposal. This was the time period the Agency considered in criteria for radioactive waste disposal that were proposed for public comment in 1978 (43 FR 53262), a period that was generally supported by the commenters on that proposal. After this time, no contribution from any of the active institutional controls can be projected to prevent or limit potential releases of waste from a disposal system.

The concept of passive institutional controls has now been incorporated into the definition of "controlled area" that is used to establish one of the boundaries for applicability of the containment requirements and the individual protection requirements in the final rule. Because the assumptions made about the effectiveness of passive institutional controls can strongly affect implementation of the containment requirements, the Agency's intent has been elaborated in the "guidance for implementation" section. The Federal Government is committed to retaining control over disposal sites for these wastes as long as possible. Accordingly (and in compliance with one of the assurance requirements), an extensive system of explanatory markers and records will be instituted to warn future generations about the location and dangers of these wastes. These passive controls have not been assumed to prevent all possibilities of inadvertent human intrusion, because there will always be a realistic chance that some individuals will overlook or misunderstand the markers and records. (For example, exploratory drilling operations occasionally intrude into areas that clearly would have been avoided if existing information had been obtained and properly evaluated.) However, the Agency assumed that society in general will retain knowledge about these wastes and that future societies should be able to deter systematic or persistent exploitation of a disposal site.

The Agency also assumed that passive institutional controls should reduce the chance of inadvertent intrusion compared to the likelihood if no markers and records were in place. Specific judgments about the chances and consequences of intrusion should be made by the implementing agencies when more information about particular disposal sites and passive control systems is available. The parameters described in the "guidance for implementation" represent the most severe assumptions that the Agency believed were reasonable to use in its analyses to evaluate the feasibility of compli-

ance with this rule (analyses that are summarized in the BID). The implementing agencies are free to use other assumption if they develop information considered adequate to support those judgments.

The role envisioned for institutional controls in this rulemaking has been adapted from the general approach the Agency has followed in its activities involving disposal of radioactive wastes since the initial public workshops conducted in 1977 and 1978. The Agency's overall objective has been to protect public health and the environment from disposal of radioactive wastes without relying upon institutional controls for extended periods of time -- because such controls do not appear to be reliable enough over the very long periods that these wastes remain dangerous. Instead, the Agency has pursued standards that call for isolation of the wastes through the physical characteristics of disposal system siting and design, rather than through continuing maintenance and surveillance. This principle was enunciated in the general criteria published for public comment in 1978 (43 FR 53262), and it has been incorporated into the Agency's standards for disposal of uranium mill tailings (48 FR 590, 48 FR 45926).

This approach has been tailored to fit two circumstances associated with mined geologic repositories. First, 40 CFR Part 191 places containment requirements on a broad range of potential unplanned releases as well as the expected behavior of the disposal system. Therefore, determining compliance with the standards involves performance assessments that consider the probabilities and consequences of a variety of disruptive events, including potential human intrusion. Not allowing passive institutional controls to be taken into account to some degree when estimating the consequences of inadvertent human intrusion could lead to less protective geologic media being selected for repository sites. The Agency's analyses indicate that repositories in salt formations have particularly good capabilities to isolate the wastes from flowing ground water and, hence, the accessible environment. However, salt formations are also relatively easy to mine and are often associated with other types of resources. If performance assessments had to assume that future societies will have no way to ever recognize and limit the consequences of inadvertent intrusion (from solution mining of salt, for example), the scenarios that would have to be studied would be more likely to eliminate salt media from consideration than other rock types. Yet, this could rule out repositories that may provide the best isolation, compared to other alternatives, if less pessimistic assumptions about survival of knowledge were made.

The second circumstance that the Agency considered in evaluating the approach towards institutional controls taken in this rule is the fact that the mined geologic repositories planned for disposal of the materials covered by 40 CFR Part 191 are different from the disposal systems evisioned for any other types of waste. The types of inadvertent human activities that could lead to significant radiation exposures or releases of material from geologic repositories appear to call for much more intensive and organized effort than those which could cause problems at, for example, an unattended surface disposal site. It appears reasonable to assume that information regarding the disposal system is more likely to reach (and presumably deter) people undertaking such organized efforts than it is to inform individuals involved in mundane activities.

These considerations led the Agency to conclude that a limited role for passive institutional controls would be appropriate when projecting the long-term performance of mined geologic repositories to judge compliance with these standards. However, such assumptions would not necessarily be applicable to other Agency actions where different issues are involved.

Avoiding Sites With Natural Resources

The proposed rule contained an assurance requirement that would have prohibited use of sites where there is a reasonable expectation that future exploration for scarce or easily accessible resources might occur. The comments received on this issue generally agreed that sites with resources should be avoided. However, some commenters suggested that the requirement should be more restrictive, to include "potentially accessible" resources. Other commenters argued that the Agency should be less restrictive regarding sites with possible resource potential -- discouraging but not prohibiting their use -- because other attributes of the site might overcome the relative disadvantages presented by resource potential.

After considering these comments, the Agency agreed with the latter viewpoint. This judgment was reinforced by the belief that disposal sites should be chosen after comparative evaluation of a variety of alternatives, and the proposed assurance requirement could have inhibited this process. Therefore, this assurance requirement has been revised in the final rule to identify resource potential as a disincentive but not as an outright prohibition for site selection. Instead, the revised assurance requirement states that places with resource potential shall not be used "unless the favorable characteristics of such places compensate for their greater likelihood of being disturbed in the future."

This wording implies a qualitative comparison, because the Agency is not aware of quantitative formulas comprehensive enough to provide adequate comparisons to govern site selection. However, the Agency does not intend that sites with resource potential can be used merely upon identification of a few features that might be more favorable than at a site without significant resources. Rather, sites with resources should only be used if it is reasonably certain that they would provide better *overall* protection than the practical alternatives that are available.

The following example illustrates the effect of the change in this assurance requirement. When discussing the proposed assurance requirement, the Agency implied that disposal in salt domes might not be acceptable because such formations seemed more likely than others to attract exploration in the future. The modification of this assurance requirement in the final rule means that salt domes should not be peremptorily removed from consideration, but should be compared against all of the characteristics of alternative sites in terms of the overall environmental protection expected.

Long-Term Monitoring

The proposed rule addressed active institutional controls over a disposal site only in a negative sense -- to prohibit reliance upon them for more than a few hundred years after disposal. The Agency's intent was to be sure that long-term protection of the environment did not depend upon positive actions by future generations. Almost all commenters agreed with this intent, although many suggested a shorter period of reliance was appropriate (see the preceding discussion under "Approach Towards Institutional Controls").

However, several commenters (including most of the States) also urged addition of a requirement for long-term monitoring of a repository after disposal. This view did not deny the need to select and design disposal systems without depending upon active controls in the future. However, it broadened this perspective by arguing that a disposal system so designed should still be monitored for a long time after disposal to guard against unexpected failures.

The Agency had not considered this viewpoint in developing the proposed rule. Accordingly, further information on this idea was sought during the "second round" of public comment, and the Agency surveyed the capabilities and expectations of long-term monitoring approaches. Evaluating this information led the Agency to several conclusions:

(1) Perhaps most importantly, the techniques used for monitoring after disposal must not jeopardize the long-term isolation capabilities of the disposal system. Furthermore, plans to conduct monitoring after disposal should never become an excuse to relax the care with which systems to isolate these wastes must be selected, designed, constructed, and operated.

(2) Monitoring for radionuclide releases to the accessible environment is not likely to be productive. Even a poorly performing geologic repository is very unlikely to allow measurable releases to the accessible environment for several hundreds of years of more, particularly in view of the engineered controls needed to comply with 10 CFR Part 60. A monitoring system based only on detecting radionuclide releases -- a system which would almost certainly not be detecting anything for several times the history of the United States -- is not likely to be maintained for long enough to be of much use.

(3) Within the above constraints, however, there are likely to be monitoring approaches which may, in a relatively short time, significantly improve confidence that a repository is performing as intended. Two examples are of particular interest. One involves the concept of monitoring ground water sources at a variety of distances for benign tracers intentionally released to the ground water in the repository; this approach can evaluate the delay involved in ground water movement from the repository to the environment and can serve to validate expectations of the performance expected from the system's natural barriers. Another concept involves monitoring the small uplift of the land surface over the repository in order to validate predictions of the system's thermal behavior. Both of these approaches can be carried out without enhancing pathways for the wastes to escape from the repository.

Based on these conclusions and the public comments on this question, the Agency has included a provision for long-term monitoring after disposal in the assurance requirements of the final rule: "Disposal systems shall be monitored after disposal to detect substantial and detrimental deviations from expected performance. This monitoring shall be done with techniques that do not jeopardize the isolation of the wastes and shall be conducted until there are no significant concerns to be addressed by further monitoring." This new provision is consistent with the overall intent of the assurance requirements: To take prudent and cautious steps necessary to minimize the risks posed by the inherent uncertainties in expectations of the future. Beyond this broad mandate, however, the Agency has not specified the details of a monitoring program. That is properly left to the implementing agencies. Furthermore, the precise objectives of an ap-

propriate monitoring program probably should not be spelled out until much more information is gathered about the characteristics and expected behavior of specific sites and designs.

Ability To Recover Wastes After Disposal

The proposed rule included an assurance requirement that recovery of these wastes be feasible for "a reasonable period of time" after disposal. The Agency specifically sought comment on whether this was a desirable provision, since it would rule out certain disposal concepts, such as deep-well injection of liquid wastes. The comments received were split about evenly between those who thought the provision should be retained and those who thought it was detrimental to the overall rule. Many of those who opposed the requirement argued that it would encourage designing a geologic repository to make retrieving waste relatively easy -- which might compromise the isolation capabilities of the repository or which might encourage recovery of the waste to make use of some intrinsic value it might retain (the potential energy content of spent nuclear fuel, for example).

The intent of this provision was not to make recovery of waste easy or cheap, but merely possible in case some future discovery or insight made it clear that the wastes needed to be relocated. EPA reiterates the statement in the preamble to the proposal that *any* current concept for a mined geologic repository meets this requirement *without* any additional procedures or design features. For example, there is no intent to require that a repository shaft be kept open to allow future recovery. To meet this assurance requirement, it only need be technologically feasible (assuming current technology levels) to be able to mine the sealed repository and recover the waste -- albeit at substantial cost and occupational risk. The Commission's requirements for multiple engineered barriers within a repository (10 CFR Part 60) adequately address any concerns about the feasibility of recovering wastes from a repository.

Therefore, this provision should not have any effect upon plans for mined geologic repositories. Rather, it is intended to call into question any other disposal concept that might not be so reversible -- because the Agency believes that future generations should have options to correct any mistakes that this generation might unintentionally make. Almost all of the commenters agreed with the validity of this objective. Accordingly, the Agency has decided to retain this assurance requirement in the final rule as proposed.

Health Impacts of 40 CFR Part 191

Waste Management and Storage. Waste management and storage activities conducted in accordance with Subpart A would limit the maximum risk to a member of the public in the general environment to a 5 X 10 -4 chance of incurring a premature fatal cancer over a lifetime. Of course, a risk this large would exist only for an individual continuously exposed to the full amount of the dose limits over his or her lifetime. Because the Agency believes that such continuous exposure is very unlikely, the actual risks to individuals are expected to be much lower. It is theoretically possible under the final rule that an individual could be exposed to 25 millirems per year (to the whole body) from *both* an NRC-licensed facility and a DOE facility not licensed by NRC, for a total of 50 millirem/year. However, the Agency believes that this is particularly improbable and does not foresee a significant public health impact from this possibility.

Waste Disposal. A disposal system complying with Subpart B would confine almost all of the radioactive wastes to the immediate vicinity of the repository for a very long time. Because the wastes would be so well isolated from the environment, the Agency is confident that any risks to future populations would be very small. Similarly, risks to most future individuals would also be very small (and effectively zero in almost all cases) -- except for the possibility that an individual in the distant future might use ground water from the vicinity of a repository. In this case, there is a chance that such an individual might receive a substantial exposure. The following paragraphs describe the possible health impacts of the residual risks from a disposal system that would be in compliance with 40 CFR Part 191.

Population Risks: With regard to exposure of populations, the Agency has estimated the potential long-term health risks to future generations from various types of mined geologic repositories using very general models of environmental transport and a linear, nonthreshold dose-effect relationship between radiation exposures and premature deaths from cancer. Food chains, ways of life, and the size and geographical distributions of populations will undoubtedly change over a 10,000-year period. Unlike geological processes, factors such as these cannot be usefully predicted over such long periods of time. Thus, in making these health effects projections, the Agency found it necessary to depend upon very general models of environmental pathways and to assume current population distributions and death rates. The SAB Subcommittee evaluated these models carefully, and, although a number of specific changes were recommended for particular parameters, the Subcommittee endorsed the general approach. As a consequence of using these

generalized models, EPA's projections are intended to be used primarily as a tool for comparing the performance of one waste disposal system to another and for comparison of the risks of waste disposal with those of undisturbed ore bodies. The results of these analyses should not be considered a reliable projection of the "real" or absolute number of health effects resulting from compliance with the disposal standards.

These health risk models were used to assess the long-term health risks from several different model repositories containing the wastes from 100,000 MTHM -- which could include all existing wastes and the future wastes from all currently operating reactors. The Agency estimates that this quantity of waste, when disposed of in accordance with the proposed standards, would cause no more than 1,000 premature deaths from cancer in the first 10,000 years after disposal: an average of no more than one premature death every 10 years. Most of the model repositories considered had projected population risks at least a factor of ten below this, or about 100 deaths over 10,000 years. The projections for the actual repositories that are constructed are expected to be closer to this lower figure. Any such increase in the number of cancer deaths would be very small compared to today's incidence of cancer, which kills about 350,000 people per year in the United States. Similarly, any such increase would be much less than the approximately 6,000 premature cancer deaths per year that the same linear, non-threshold dose-effect relationship predicts for the nation due to natural background radiation.

Individual Risks: With regard to exposures of individuals, the Agency examined the potential doses to persons who might use ground water from the immediate vicinity of a repository at various times in the future. For these analyses, only the expected undisturbed performance of a repository was considered (e.g, there was no evaluation of exposures that might occur if a repository was disrupted by movement of a fault). In most of the cases studied, no exposures occurred for more than one thousand years after disposal. After that, these analyses predict that significant exposures (on the order of a few rems per year in the vicinity of the repository over the next several thousands of years) may appear for some of the geologic media considered. These projections are similar to those contained in the April 1983 report published by the National Academy of Sciences. The BID contains more detailed descriptions of the Agency's individual dose calculations.

Intergenerational Risk: As described earlier, the Agency has chosen to rely on provisions that limit risks to populations as the primary standards for the long-term performance of disposal systems. Although the projections of the residual population risk are clearly very small, the discontinuity between when the wastes are generated and when the projected health effects manifest themselves made it difficult to determine what level of residual risk should be allowed by these disposal standards. The difficulty arose because most of the benefits derived in the process of waste production fall upon the current generation, while most of the risks fall upon future generations. Thus, a potential problem of intergenerational equity with respect to the distribution of risks and benefits became apparent. This problem is sometimes referred to as the intergenerational risk issue, and it is not unique to the disposal of high-level radioactive wastes. If the Agency tried to insure that these standards fully satisfied a criterion of intergenerational equity with respect to the distribution of risks and benefits, it might appear that no risk should be passed on to future generations. This is a condition which the Agency believes cannot be met by disposal technologies foreseeable within this century. However, there is one particular factor which has reinforced EPA's decision about the reasonableness of the risks permitted under the disposal standards. This is the following evaluation of the risks associated with undisturbed uranium ore bodies. Additionally, for the purpose of comparing the risks permitted under the standards to other radiation risks which people are currently exposed to, a brief discussion of the risks from other natural sources of radiation is also included.

Uranium Ore: Most uranium ore in the United States occurs in permeable geologic strata containing flowing ground water. Radionuclides in the ore, particularly uranium and radium, continuously enter this ground water. EPA estimated the potential risks from these undisturbed ore bodies using the same generalized environmental models that were used for releases from a waste repository. The effects associated with the amount of ore needed to produce the high-level wastes that would fill the model geologic repository can vary considerably. Part of this variation corresponds to actual differences from one ore body to another; part can be attributed to uncertainties in the assessment. After revising the population risk models in accordance with the recommendations of the SAB Subcommittee, these estimates of the risks from unmined ore bodies ranged from about 10 to more than 100,000 excess cancer deaths over 10,000 years. Thus, leaving the ore unmined appears to present a risk to future generations comparable to the risks from disposal of wastes covered by these standards.

Variations in Natural Background: Radionuclides occur naturally in the earth in very large amounts, and are produced in the atmosphere by cosmic radiation. Everyone is exposed to natural background radiation from these natural radionuclides and from direct exposure to cosmic radiation. Individual exposures average about 100 millirems per year, with a range of about 60 to 200 millirem/year. These natural background radiation levels have remained relatively con-

stant for a very long time. According to the same linear, nonthreshold dose effect relationship used in EPA's other analyses, an increase of one millirem per year (about one percent) in natural background in the United States would result in about 60 additional deaths per year, or 600,000 over a 10,000-year period.

Natural Radionuclide Concentrations in Ground Water: One source of this exposure to natural background radiation comes from naturally occurring radionuclides found in ground water. Radium is the most important of the naturally occurring radioactive materials likely to occur in public water supply systems, but uranium is also found in ground waters due to its natural occurrence. Surveys of radionuclides in ground water systems indicate: a United States range of 0.1 to 50 picocuries (pCi) per liter for radium-226 (with isolated sources exceeding 100 pCi/liter); up to 74 pCi/liter for all alpha-emitting radionuclides other than uranium (although most of the alpha-emitting concentrations are below 3 pCi/liter); and up to 650 pCi/liter for total uranium concentrations. Elevated radium-226 concentrations are found along the Atlantic coastal region and the Midwest; low levels are usually found in the treated water supplies in the western States. Elevated uranium and alpha-emitting radionuclide concentrations are generally limited to the Rocky Mountain region and Maine and Pennsylvania in the east.

The Agency's primary drinking water regulations (40 CFR Part 141) limit the contamination levels for radium-226 and radium-228 to 5 pCi/liter and the levels for total alpha-emitting contamination (excluding radon and uranium) to 15 pCi/liter. Elevated concentrations of radium in drinking water are generally a problem associated with smaller community water systems, with an estimated 500 systems exceeding 5 pCi/liter. The Agency's risk assessments indicate that continuous consumption of water containing the maximum amount of radium allowed may cause between 0.7 and 3 cancers per year per million exposed persons.

Environmental Impacts

A Draft Environmental Impact Statement (EIS) was prepared for the proposed rule, in accordance with the Agency's procedures for the voluntary preparation of EIS's (30 FR 37419). However, section 121(c) of the NWPA subsequently exempted this action from preparation of an EIS under section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA) and from any environmental review under subparagraph (E) or (F) of section 102(2) of the NEPA. Accordingly, a Final EIS has not been prepared for promulgation of this rule. The potential health impacts of this action are summarized above, and much of the information that would have been contained in a Final EIS is documented in the Background Information Document that accompanies this final version of 40 CFR Part 191.

Regulatory Impacts

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. The final rule has not been classified as a "major rule" in accordance with the guidelines provided by the Executive Order. Any comments received from OMB and EPA's responses to those comments are available for public inspection in the docket cited above under the heading "ADDRESSES."

The Agency has had to take an unusual approach in considering the regulatory impacts of this proposed action -- as required by Executive Order 12291. In most cases, a regulation concerns an ongoing activity and may be considered a burden whose costs should be judged against the regulatory benefits. Here, it was not possible to quantify the costs and benefits of this action compared to the consequences of no regulation because there is no specific "baseline" program to consider. The appropriate regulations must be established before the regulated activity can even begin. Thus, the typical perspectives on costs and benefits are altered. Instead, the Agency evaluated how the costs of commercial waste management and disposal might change in response to different levels of protection from the containment requirements. Similar evaluations were not performed for the wastes from atomic energy defense activities because sufficient information was not available.

To evaluate the effects of different levels of protection, EPA considered the performance of different repository designs in several different geologic media. The costs of the various engineering controls that might be needed to meet different levels of protection were estimated. In addition, allowances were made for the increased research and development costs that might be needed to demonstrate compliance with the standards if projected performance for a particular disposal system indicated releases less than an order of magnitude below the long-term radionuclide release limits in § 191.13.

Since the regulatory impact analyses that supported the proposed rule were performed, the NRC has promulgated minimum requirements for the engineered barriers of a disposal system (in 10 CFR Part 60), more data concerning dis-

posal sites being considered by the Department have become available, and the Agency has reviewed its performance assessments to reduce overestimates of long-term risks in accordance with the SAB review. After evaluating all of this new information, the Agency believes that there need not be any significant additional costs to the national program for disposal of commercial wastes caused by retaining the proposed level of protection in the final rule, compared to the costs of choosing levels considerably less stringent. In other words, all of the disposal sites being evaluated by the Department, assuming compliance with the existing requirements of 10 CFR Part 60, are expected to be able to meet these disposal standards without additional precautions beyond those already planned.

List of Subjects in 40 CFR Part 191

Environmental protection, Nuclear energy, Radiation protection, Uranium, Waste treatment and disposal.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Administrator hereby certifies that this rule will not have any significant impact on small businesses or other entitites, and that a Regulatory Flexibility Analysis is not required. This rule will affect only a small number of facilities, most of which are or will be operated by the United States Government.

Dated: August 15, 1985.

Lee M. Thomas,

Administrator.

A new Part 191 is hereby added to Title 40, Code of Federal Regulations, as follows:

SUBCHAPTER F -- RADIATION PROTECTION PROGRAMS

PART 191 -- ENVIRONMENTAL RADIATION PROTECTION STANDARDS FOR MANAGEMENT AND DISPOSAL OF SPENT NUCLEAR FUEL, HIGH-LEVEL AND TRANSURANIC RADIOACTIVE WASTES

Subpart A -- Environmental Standards for Management and Storage

Sec.

Subpart B -- Environmental Standards for Disposal

Authority: The Atomic Energy Act of 1954, as amended; Reorganization Plan No. 3 of 1970; and the Nuclear Waste Policy Act of 1982.

Subpart A -- Environmental Standards for Management and Storage

§ 191.01 Applicability.

This Subpart applies to:

(a) Radiation doses received by members of the public as a result of the management (except for transportation) and storage of spent nuclear fuel or high-level or transuranic radioactive wastes at any facility regulated by the Nuclear Regulatory Commission or by Agreement States, to the extent that such management and storage operations are not subject to the provisions of Part 190 of title 40; and

(b) Radiation doses received by members of the public as a result of the management and storage of spent nuclear fuel or high-level or transuranic wastes at any disposal facility that is operated by the Department of Energy and that is not regulated by the Commission or by Agreement States.

§ 191.02 Definitions.

Unless otherwise indicated in this Subpart, all terms shall have the same meaning as in Subpart A of Part 190.

(a) "Agency" means the Environmental Protection Agency.

(b) "Administrator" means the Administrator of the Environmental Protection Agency.

(c) "Commission" means the Nuclear Regulatory Commission.

(d) "Department" means the Department of Energy.

(e) "NWPA" means the Nuclear Waste Policy Act of 1982 (Pub. L. 97-425).

(f) "Agreement State" means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended (68 Stat. 919).

(g) "Spent nuclear fuel" means fuel that has been withdrawn from a nuclear reactor following irradiation, the constituent elements of which have not been separated by reprocessing.

(h) "High-level radioactive waste," as used in this Part, means high-level radioactive waste as defined in the Nuclear Waste Policy Act of 1982 (Pub. L. 97-425).

(i) "Transuranic radioactive waste," as used in this Part, means waste containing more than 100 nanocuries of alpha-emitting transuranic isotopes, with half-lives greater than twenty years, per gram of waste, except for: (1) High-level radioactive wastes; (2) wastes that the Department has determined, with the concurrence of the Administrator, do not need the degree of isolation required by this Part; or (3) wastes that the Commission has approved for disposal on a case-by-case basis in accordance with 10 CFR Part 61.

(j) "Radioactive waste," as used in this Part, means the high-level and transuranic radioactive waste covered by this Part.

(k) "Storage" means retention of spent nuclear fuel or radioactive wastes with the intent and capability to readily retrieve such fuel or waste for subsequent use, processing, or disposal.

(l) "Disposal" means permanent isolation of spent nuclear fuel or radioactive waste from the accessible environment with no intent of recovery, whether or not such isolation permits the recovery of such fuel or waste. For example, disposal of waste in a mined geologic repository occurs when all of the shafts to the repository are backfilled and sealed.

(m) "Management" means any activity, operation, or process (except for transportation) conducted to prepare spent nuclear fuel or radioactive waste for storage or disposal, or the activities associated with placing such fuel or waste in a disposal system.

(n) "Site" means an area contained within the boundary of a location under the effective control of persons possessing or using spent nuclear fuel or radioactive waste that are involved in any activity, operation, or process covered by this Subpart.

(o) "General environment" means the total terrestrial, atmospheric, and aquatic environments outside sites within which any activity, operation, or process associated with the management and storage of spent nuclear fuel or radioactive waste is conducted.

(p) "Member of the public" means any individual except during the time when that individual is a worker engaged in any activity, operation, or process that is covered by the Atomic Energy Act of 1954, as amended.

(q) "Critical organ" means the most exposed human organ or tissue exclusive of the integumentary system (skin) and the cornea.

§ 191.03 Standards.

(a) Management and storage of spent nuclear fuel or high-level or transuranic radioactive wastes at all facilities regulated by the Commission or by Agreement States shall be conducted in such a manner as to provide reasonable assurance that the combined annual dose equivalent to any member of the public in the general environment resulting from: (1) Discharges of radioactive material and direct radiation from such management and storage and (2) all operations covered by Part 190; shall not exceed 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other critical organ.

(b) Management and storage of spent nuclear fuel or high-level or transuranic radioactive wastes at all facilities for the disposal of such fuel or waste that are operated by the Department and that are not regulated by the Commission or Agreement States shall be conducted in such a manner as to provide reasonable assurance that the combined annual dose equivalent to any member of the public in the general environment resulting from discharges of radioactive material and direct radiation from such management and storage shall not exceed 25 millirems to the whole body and 75 millirems to any critical organ.

§ 191.04 Alternative standards.

(a) The Administrator may issue alternative standards from those standards established in 191.03(b) for waste management and storage activities at facilities that are not regulated by the Commission or Agreement States if, upon review of an application for such alternative standards:

(1) The Administrator determines that such alternative standards will prevent any member of the public from receiving a continuous exposure of more than 100 millirems per year dose equivalent and an infrequent exposure of more than 500 millirems dose equivalent in a year from all sources, excluding natural background and medical procedures; and

(2) The Administrator promptly makes a matter of public record the degree to which continued operation of the facility is expected to result in levels in excess of the standards specified in 191.03(b).

(b) An application for alternative standards shall be submitted as soon as possible after the Department determines that continued operation of a facility will exceed the levels specified in 191.03(b) and shall include all information necessary for the Administrator to make the determinations called for in 191.04(a).

(c) Requests for alternative standards shall be submitted to the Administrator, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

§ 191.05 Effective date.

The standards in this Subpart shall be effective on November 18, 1985.

Subpart B -- Environmental Standards for Disposal

§ 191.11 Applicability.

(a) This Subpart applies to:

(1) Radioactive materials released into the accessible environment as a result of the disposal of spent nuclear fuel or high-level or transuranic radioactive wastes;

(2) Radiation doses received by members of the public as a result of such disposal; and

(3) Radioactive contamination of certain sources of ground water in the vicinity of disposal systems for such fuel or wastes.

(b) However, this Subpart does not apply to disposal directly into the oceans or ocean sediments. This Subpart also does not apply to wastes disposed of before the effective date of this rule.

§ 191.12 Definitions.

Unless otherwise indicated in this Subpart, all terms shall have the same meaning as in Subpart A of this Part.

(a) "Disposal system" means any combination of engineered and natural barriers that isolate spent nuclear fuel or radioactive waste after disposal.

(b) "Waste," as used in this Subpart, means any spent nuclear fuel or radioactive waste isolated in a disposal system.

(c) "Waste form" means the materials comprising the radioactive components of waste and any encapsulating or stabilizing matrix.

(d) "Barrier" means any material or structure that prevents or substantially delays movement of water or radionuclides toward the accessible environment. For example, a barrier may be a geologic structure, a canister, a waste form with physical and chemical characteristics that significantly decrease the mobility of radionuclides, or a material placed over and around waste, provided that the material or structure substantially delays movement of water or radionuclides.

(e) "Passive institutional control" means: (1) Permanent markers placed at a disposal site, (2) public records and archives, (3) government ownership and regulations regarding land or resource use, and (4) other methods of preserving knowledge about the location, design, and contents of a disposal system.

(f) "Active institutional control" means: (1) Controlling access to a disposal site by any means other than passive institutional controls; (2) performing maintenance operations or remedial actions at a site, (3) controlling or cleaning up releases from a site, or (4) monitoring parameters related to disposal system performance.

(g) "Controlled area" means: (1) A surface location, to be identified by passive institutional controls, that encompasses no more than 100 square kilometers and extends horizontally no more than five kilometers in any direction from the outer boundary of the original location of the radioactive wastes in a disposal system; and (2) the subsurface underlying such a surface location.

(h) "Ground water" means water below the land surface in a zone of saturation.

(i) "Aquifer" means an underground geological formation, group of formations, or part of a formation that is capable of yielding a significant amount of water to a well or spring.

(j) "Lithosphere" means the solid part of the Earth below the surface, including any ground water contained within it.

(k) "Accessible environment" means: (1) The atmosphere; (2) land surfaces; (3) surface waters; (4) oceans; and (5) all of the lithosphere that is beyond the controlled area.

(l) "Transmissivity" means the hydraulic conductivity integrated over the saturated thickness of an underground formation. The transmissivity of a series of formations is the sum of the individual transmissivities of each formation comprising the series.

(m) "Community water system" means a system for the provision to the public of piped water for human consumption, if such system has at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents.

(n) "Significant source of ground water," as used in this Part, means: (1) An aquifer that: (i) Is saturated with water having less than 10,000 milligrams per liter of total dissolved solids; (ii) is within 2,500 feet of the land surface; (iii) has a transmissivity greater than 200 gallons per day per foot, provided that any formation or part of a formation included within the source of ground water has a hydraulic conductivity greater than 2 gallons per day per square foot; and (iv) is capable of continuously yielding at least 10,000 gallons per day to a pumped or flowing well for a period of at least a year; or (2) an aquifer that provides the primary source of water for a community water system as of the effective date of this Subpart.

(o) "Special source of ground water," as used in this Part, means those Class I ground waters identified in accordance with the Agency's Ground-Water Protection Strategy published in August 1984 that: (1) Are within the controlled area encompassing a disposal system or are less than five kilometers beyond the controlled area; (2) are supplying drinking water for thousands of persons as of the date that the Department chooses a location within that area for detailed characterization as a potential site for a disposal system (e.g., in accordance with Section 112(b)(1)(B) of the NWPA); and (3) are irreplaceable in that no reasonable alternative source of drinking water is available to that population.

(p) "Undisturbed performance" means the predicted behavior of a disposal system, including consideration of the uncertainties in predicted behavior, if the disposal system is not disrupted by human intrusion or the occurrence of unlikely natural events.

(q) "Performance assessment" means an analysis that: (1) Identifies the processes and events that might affect the disposal system; (2) examines the effects of these processes and events on the performance of the disposal system; and (3) estimates the cumulative releases of radionuclides, considering the associated uncertainties, caused by all significant processes and events. These estimates shall be incorporated into an overall probability distribution of cumulative release to the extent practicable.

(r) "Heavy metal" means all uranium, plutonium, or thorium placed into a nuclear reactor.

(s) "Implementing agency," as used in this Subpart, means the Commission for spent nuclear fuel or high-level or transuranic wastes to be disposed of in facilities licensed by the Commission in accordance with the Energy Reorganization Act of 1974 and the Nuclear Waste Policy Act of 1982, and it means the Department for all other radioactive wastes covered by this Part.

§ 191.13 Containment requirements.

(a) Disposal systems for spent nuclear fuel or high-level or transuranic radioactive wastes shall be designed to provide a reasonable expectation, based upon performance assessments, that the cumulative releases of radionuclides to the accessible environment for 10,000 years after disposal from all significant processes and events that may affect the disposal system shall:

(1) Have a likelihood of less than one chance in 10 of exceeding the quantities calculated according to Table 1 (Appendix A); and

(2) Have a likelihood of less than one chance in 1,000 of exceeding ten times the quantities calculated according to Table 1 (Appendix A).

(b) Performance assessments need not provide complete assurance that the requirements of 191.13(a) will be met. Because of the long time period involved and the nature of the events and processes of interest, there will inevitably be substantial uncertainties in projecting disposal system performance. Proof of the future performance of a disposal system is not to be had in the ordinary sense of the word in situations that deal with much shorter time frames. Instead, what is required is a reasonable expectation, on the basis of the record before the implementing agency, that compliance with 191.13 (a) will be achieved.

§ 191.14 Assurance requirements.

To provide the confidence needed for long-term compliance with the requirements of 191.13, disposal of spent nuclear fuel or high-level or transuranic wastes shall be conducted in accordance with the following provisions, except that these provisions do not apply to facilities regulated by the Commission (see 10 CFR Part 60 for comparable provisions applicable to facilities regulated by the Commission):

(a) Active institutional controls over disposal sites should be maintained for as long a period of time as is practicable after disposal; however, performance assessments that assess isolation of the wastes from the accessible environment shall not consider any contributions from active institutional controls for more than 100 years after disposal.

(b) Disposal systems shall be monitored after disposal to detect substantial and detrimental deviations from expected performance. This monitoring shall be done with techniques that do not jeopardize the isolation of the wastes and shall be conducted until there are no significant concerns to be addressed by further monitoring.

(c) Disposal sites shall be designated by the most permanent markers, records, and other passive institutional controls practicable to indicate the dangers of the wastes and their location.

(d) Disposal systems shall use different types of barriers to isolate the wastes from the accessible environment. Both engineered and natural barriers shall be included.

(e) Places where there has been mining for resources, or where there is a reasonable expectation of exploration for scarce or easily accessible resources, or where there is a significant concentration of any material that is not widely available from other sources, should be avoided in selecting disposal sites. Resources to be considered shall include minerals, petroleum or natural gas, valuable geologic formations, and ground waters that are either irreplaceable because there is no reasonable alternative source of drinking water available for substantial populations or that are vital to the preservation of unique and sensitive ecosystems. Such places shall not be used for disposal of the wastes covered by this Part unless the favorable characteristics of such places compensate for their greater likelihood of being disturbed in the future.

(f) Disposal systems shall be selected so that removal of most of the wastes is not precluded for a reasonable period of time after disposal.

§ 191.15 Individual protection requirements.

Disposal systems for spent nuclear fuel or high-level or transuranic radioactive wastes shall be designed to provide a reasonable expectation that, for 1,000 years after disposal, undisturbed performance of the disposal system shall not cause the annual dose equivalent from the disposal system to any member of the public in the accessible environment to exceed 25 millirems to the whole body or 75 millirems to any critical organ. All potential pathways (associated with undisturbed performance) from the disposal system to people shall be considered, including the assumption that individuals consume 2 liters per day of drinking water from any significant source of ground water outside of the controlled area.

§ 191.16 Ground water protection requirements.

(a) Disposal systems for spent nuclear fuel or high-level or transuranic radioactive wastes shall be designed to provide a reasonable expectation that, for 1,000 years after disposal, undisturbed performance of the disposal system shall not cause the radionuclide concentrations averaged over any year in water withdrawn from any portion of a special source of ground water to exceed:

(1) 5 picocuries per liter of radium-226 and radium-228;

(2) 15 picocuries per liter of alpha-emitting radionuclides (including radium-226 and radium-228 but excluding radon); or

(3) The combined concentrations of radionuclides that emit either beta or gamma radiation that would produce an annual dose equivalent to the total body or any internal organ greater than 4 millirems per year if an individual consumed 2 liters per day of drinking water from such a source of ground water.

(b) If any of the average annual radionuclide concentrations existing in a special source of ground water before construction of the disposal system already exceed the limits in 191.16(a), the disposal system shall be designed to provide a reasonable expectation that, for 1,000 years after disposal, undisturbed performance of the disposal system shall

not increase the existing average annual radionuclide concentrations in water withdrawn from that special source of ground water by more than the limits established in 191.16(a).

§ 191.17 Alternative provisions for disposal.

The Administrator may, by rule, substitute for any of the provisions of Subpart B alternative provisions chosen after:

(a) The alternative provisions have been proposed for public comment in the Federal Register together with information describing the costs, risks, and benefits of disposal in accordance with the alternative provisions and the reasons why compliance with the existing provisions of Subpart B appears inappropriate;

(b) A public comment period of at least 90 days has been completed, during which an opportunity for public hearings in affected areas of the country has been provided; and

(c) The public comments received have been fully considered in developing the final version of such alternative provisions.

§ 191.18 Effective date.

The standards in this Subpart shall be effective on September 19, 1985.

Appendix A -- Table for Subpart B

Table 1. -- Release Limits for Containment Requirements
[Cumulative releases to the accessible environment for 10,000 years after disposal]

Radionuclide	Release limit per 1,000 MTHM or other unit of waste (see notes) (curies)
Americium-241 or -243	100
Carbon-14	100
Cesium-135 or -137	1,000
Iodine-129	100
Neptunium-237	100
Plutonium-238, -239, -240, or -242	100
Radium-226	100
Strontium-90	1,000
Technetium-99	10,000
Thorium-230 or -232	10
Tin-126	1,000
Uranium-233, -234, -235, -236, or -238	100
Any other alpha-emitting radionuclide with a half-life greater than 20 years	100
Any other radionuclide with a half-life greater than 20 years that does not emit alpha particles	1,000

Application of Table 1

Note 1: *Units of Waste.* The Release Limits in Table 1 apply to the amount of wastes in any one of the following:

(a) An amount of spent nuclear fuel containing 1,000 metric tons of heavy metal (MTHM) exposed to a burnup between 25,000 megawatt-days per metric ton of heavy metal (MWd/MTHM) and 40,000 MWd/MTHM;

(b) The high-level radioactive wastes generated from reprocessing each 1,000 MTHM exposed to a burnup between 25,000 MWd/MTHM and 40,000 MWd/MTHM;

(c) Each 100,000,000 curies of gamma or beta-emitting radionuclides with half-lives greater than 20 years but less than 100 years (for use as discussed in Note 5 or with materials that are identified by the Commission as high-level radioactive waste in accordance with part B of the definition of high-level waste in the NWPA);

(d) Each 1,000,000 curies of other radionuclides (i.e., gamma or beta-emitters with half-lives greater than 100 years or any alpha-emitters with half-lives greater than 20 years) (for use as discussed in Note 5 or with materials that are identified by the Commission as high-level radioactive waste in accordance with part B of the definition of high-level waste in the NWPA); or

(e) An amount of transuranic (TRU) wastes containing one million curies of alpha-emitting transuranic radionuclides with half-lives greater than 20 years.

Note 2: *Release Limits for Specific Disposal Systems.* To develop Release Limits for a particular disposal system, the quantities in Table 1 shall be adjusted for the amount of waste included in the disposal system compared to the various units of waste defined in Note 1. For example:

(a) If a particular disposal system contained the high-level wastes from 50,000 MTHM, the Release Limits for that system would be the quantities in Table 1 multiplied by 50 (50,000 MTHM divided by 1,000 MTHM).

(b) If a particular disposal system contained three million curies of alpha-emitting transuranic wastes, the Release Limits for that system would be the quantities in Table 1 multiplied by three (three million curies divided by one million curies).

(c) If a particular disposal system contained both the high-level wastes from 50,000 MTHM *and* 5 million curies of alpha-emitting transuranic wastes, the Release Limits for that system would be the quantities in Table 1 multiplied by 55:

50,000 MTHM	+	5,000,000 curies TRU	=55
1,000 MTHM		1,000,000 curies TRU	

Note 3: *Adjustments for Reactor Fuels with Different Burnup.* For disposal systems containing reactor fuels (or the high-level wastes from reactor fuels) exposed to an average burnup of less than 25,000 MWd/MTHM or greater than 40,000 MWd/MTHM, the units of waste defined in (a) and (b) of Note 1 shall be adjusted. The unit shall be multiplied by the ratio of 30,000 MWd/MTHM divided by the fuel's actual average burnup, except that a value of 5,000 MWd/MTHM may be used when the average fuel burnup is below 5,000 MWd/MTHM and a value of 100,000 MWd/MTHM shall be used when the average fuel burnup is above 100,000 MWd/MTHM. This adjusted unit of waste shall then be used in determining the Release Limits for the disposal system.

For example, if a particular disposal system contained only high-level wastes with an average burnup of 3,000 MWd/MTHM, the unit of waste for that disposal system would be:

1,000 MTHM X	(30,000) (5,000)	=6,000 MTHM

If that disposal system contained the high-level wastes from 60,000 MTHM (with an average burnup of 3,000 MWd/MTHM), then the Release Limits for that system would be the quantities in Table 1 multiplied by ten:

$$\frac{\text{60,000 MTHM}}{\text{6,000 MTHM}} = 10$$

which is the same as:

$$\frac{\text{60,000 MTHM}}{\text{1,000 MTHM}} \times \frac{\text{(5,000 MWd/MTHM)}}{\text{(30,000 MWd/MTHM)}} = 10$$

Note 4: *Treatment of Fractionated High-Level Wastes.* In some cases, a high-level waste stream from reprocessing spent nuclear fuel may have been (or will be) separated into two or more high-level waste components destined for different disposal systems. In such cases, the implementing agency may allocate the Release Limit multiplier (based upon the original MTHM and the average fuel burnup of the high-level waste stream) among the various disposal systems as it chooses, provided that the total Release Limit multiplier used for that waste stream at all of its disposal systems may not exceed the Release Limit multiplier that would be used if the entire waste stream were disposed of in one disposal system.

Note 5: *Treatment of Wastes with Poorly Known Burnups or Original MTHM.* In some cases, the records associated with particular high-level waste streams may not be adequate to accurately determine the original metric tons of heavy metal in the reactor fuel that created the waste, or to determine the average burnup that the fuel was exposed to. If the uncertainties are such that the original amount of heavy metal or the average fuel burnup for particular high-level waste streams cannot be quantified, the units of waste derived from (a) and (b) of Note 1 shall no longer be used. Instead, the units of waste defined in (c) and (d) of Note 1 shall be used for such high-level waste streams. If the uncertainties in such information allow a range of values to be associated with the original amount of heavy metal or the average fuel burnup, then the calculations described in previous Notes will be conducted using the values that result in the smallest Release Limits, except that the Release Limits need not be smaller than those that would be calculated using the units of waste defined in (c) and (d) of Note 1.

Note 6: *Uses of Release Limits to Determine Compliance with 191.13* Once release limits for a particular disposal system have been determined in accordance with Notes 1 through 5, these release limits shall be used to determine compliance with the requirements of 191.13 as follows. In cases where a mixture of radionuclides is projected to be released to the accessible environment, the limiting values shall be determined as follows: For each radionuclide in the mixture, determine the ratio between the cumulative release quantity projected over 10,000 years and the limit for that radionuclide as determined from Table 1 and Notes 1 through 5. The sum of such ratios for all the radionuclides in the mixture may not exceed one with regard to 191.13(a)(1) and may not exceed ten with regard to 191.13(a)(2).

For example, if radionuclides A, B, and C are projected to be released in amounts Q_A, Q_B, and Q_C, and if the applicable Release Limits are RL_A, RL_B, and RL_C, then the cumulative releases over 10,000 years shall be limited so that the following relationship exists:

$$\frac{Q_A}{RL_A} + \frac{Q_B}{RL_B} + \frac{Q_C}{RL_C} \leq 1$$

Appendix B -- Guidance for Implementation of Subpart B

[Note: The supplemental information in this appendix is not an integral part of 40 CFR Part 191. Therefore, the implementing agencies are not bound to follow this guidance. However, it is included because it describes the Agency's assumptions regarding the implementation of Subpart B. This appendix will appear in the Code of Federal Regulations.]

The Agency believes that the implementing agencies must determine compliance with § § 191.13, 191.15, and 191.16 of Subpart B by evaluating long-term predictions of disposal system performance. Determining compliance with § 191.13 will also involve predicting the likelihood of events and processes that may disturb the disposal system. In making these various predictions, it will be appropriate for the implementing agencies to make use of rather complex computational models, analytical theories, and prevalent expert judgment relevant to the numerical predictions. Substantial uncertainties are likely to be encountered in making these predictions. In fact, sole reliance on these numerical predictions to determine compliance may not be appropriate; the implementing agencies may choose to supplement such predictions with qualitative judgments as well. Because the procedures for determining compliance with Subpart B have not been formulated and tested yet, this appendix to the rule indicates the Agency's assumptions regarding certain issues that may arise when implementing § § 191.13, 191.15, and 191.16. Most of this guidance applies to any type of disposal system for the wastes covered by this rule. However, several sections apply only to disposal in mined geologic repositories and would be inappropriate for other types of disposal systems.

Consideration of Total Disposal System. When predicting disposal system performance, the Agency assumes that reasonable projections of the protection expected from all of the engineered and natural barriers of a disposal system will be considered. Portions of the disposal system should not be disregarded, even if projected performance is uncertain, except for portions of the system that make negligible contributions to the overall isolation provided by the disposal system.

Scope of Performance Assessments. Section 191.13 requires the implementing agencies to evaluate compliance through performance assessments as defined in § 191.12(q). The Agency assumes that such performance assessments need not consider categories of events or processes that are estimated to have less than one chance in 10,000 of occurring over 10,000 years. Furthermore, the performance assessments need not evaluate in detail the releases from all events and processes estimated to have a greater likelihood of occurrence. Some of these events and processes may be omitted from the performance assessments if there is a reasonable expectation that the remaining probability distribution of cumulative releases would not be significantly changed by such omissions.

Compliance with Section 191.13. The Agency assumes that, whenever practicable, the implementing agency will assemble all of the results of the performance assessments to determine compliance with § 191.13 into a "complementary cumulative distribution function" that indicates the probability of exceeding various levels of cumulative release. When the uncertainties in parameters are considered in a performance assessment, the effects of the uncertainties considered can be incorporated into a single such distribution function for each disposal system considered. The Agency assumes that a disposal system can be considered to be in compliance with § 191.13 if this single distribution function meets the requirements of § 191.13(a).

Compliance with Sections 191.15 and 191.16. When the uncertainties in undisturbed performance of a disposal system are considered, the implementing agencies need not require that a very large percentage of the range of estimated radiation exposures or radionuclide concentrations fall below limits established in § § 191.15 and 191.16, respectively. The Agency assumes that compliance can be determined based upon "best estimate" predictions (e.g., the mean or the median of the appropriate distribution, whichever is higher).

Institutional Controls. To comply with § 191.14(a), the implementing agency will assume that none of the active institutional controls prevent or reduce radionuclide releases for more than 100 years after disposal. However, the Federal Government is committed to retaining ownership of all disposal sites for spent nuclear fuel and high-level and transuranic radioactive wastes and will establish appropriate markers and records, consistent with § 191.14(c). The Agency assumes that, as long as such passive institutional controls endure and are understood, they: (1) can be effective in deterring systematic or persistent exploitation of these disposal sites; and (2) can reduce the likelihood of inadvertent, intermittent human intrusion to a degree to be determined by the implementing agency. However, the Agency believes that passive institutional controls can never be assumed to eliminate the chance of inadvertent and intermittent human intrusion into these disposal sites.

Consideration of Inadvertent Human Intrusion into Geologic Repositories. The most speculative potential disruptions of a mined geologic repository are those associated with inadvertent human intrusion. Some types of intrusion would have virtually no effect on a repository's containment of waste. On the other hand, it is possible to conceive of intrusions (involving widespread societal loss of knowledge regarding radioactive wastes) that could result in major

disruptions that no reasonable repository selection or design precautions could alleviate. The Agency believes that the most productive consideration of inadvertent intrusion concerns those realistic possibilities that may be usefully mitigated by repository design, site selection, or use of passive controls (although passive institutional controls should not be assumed to completely rule out the possibility of intrusion). Therefore, inadvertent and intermittent intrusion by exploratory drilling for resources (other than any provided by the disposal system itself) can be the most severe intrusion scenario assumed by the implementing agencies. Furthermore, the implementing agencies can assume that passive institutional controls or the intruders' own exploratory procedures are adequate for the intruders to soon detect, or be warned of, the incompatibility of the area with their activities.

Frequency and Severity of Inadvertent Human Intrusion into Geologic Repositories. The implementing agencies should consider the effects of each particular disposal system's site, design, and passive institutional controls in judging the likelihood and consequences of such inadvertent exploratory drilling. However, the Agency assumes that the likelihood of such inadvertent and intermittent drilling need not be taken to be greater than 30 boreholes per square kilometer of repository area per 10,000 years for geologic repositories in proximity to sedimentary rock formations, or more than 3 boreholes per square kilometer per 10,000 years for repositories in other geologic formations. Furthermore, the Agency assumes that the consequences of such inadvertent drilling need not be assumed to be more severe than: (1) Direct release to the land surface of all the ground water in the repository horizon that would promptly flow through the newly created borehole to the surface due to natural lithostatic pressure -- or (if pumping would be required to raise water to the surface) release of 200 cubic meters of ground water pumped to the surface if that much water is readily available to be pumped; and (2) creation of a ground water flow path with a permeability typical of a borehole filled by the soil or gravel that would normally settle into an open hole over time -- not the permeability of a carefully sealed borehole.

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