2-11-92

WORKSHOP NOTES

MEMORANDUM FOR: The Commissioners

FROM: James M. Taylor
Executive Director
for Operations

SUBJECT: RECEIPT OF NEW DRAFT OF ENVIRONMENTAL PROTECTION AGENCY'S (EPA'S) HIGH-LEVEL WASTE STANDARDS

On February 4-6, 1992, the staff (including two Commissioners' assistants and representatives from the Advisory Committee on Nuclear Waste (ACNW) and its staff) attended a workshop sponsored by the Electric Power Research Institute (EPRI). The purpose of the workshop was to pursue a consensus within the technical community on the major issues associated with the high-level waste (HLW) standards being developed by EPA. At the workshop, EPA released a new, unnumbered draft of its standards and of the Supplementary Information describing the standards. Copies of those documents will be circulated to the Commission by S. Bilhorn of Commissioner Rogers' office.

Enclosed, for the Commission's information, is the staff's preliminary evaluation of the "Workshop Draft" of EPA's standards, including EPA's responses to NRC comments on Working Draft No. 3. The third page of the enclosure is a schedule, developed by EPRI, for providing comments to EPA consistent with EPA's intent to publish proposed standards in the Federal Register in May or June of this year. The fourth page is the staff's schedule for developing its comments, coordinating those comments with ACNW, and transmitting comments to EPA by the end of March.

James M. Taylor
Executive Director
for Operations

Enclosure: Workshop Notes

DISTRIBUTION:
Central Files
BJYoungblood, HLWM
MFederline, HLHP
SCoplan, HLHP
HThompson, EDO
HLGP r/f
JJLinehan, HLWM
JHolonich, HLPD
GArlotto, NMSS
JMTaylor, EDO
NMSS r/f
RBallard, HLGE
DFehringer, HLHP
RMBernero, NMSS

:D/NMSS	:EDO	:EDO
:RMBernero	:HThompson	:JMTaylor
:2/11/92	: / /92	: / /92

OFC : HLHP	:HLHP	:HLHP	:D/DHLWM	:D/HLEM	:D/DNMSS
NAME: DFehringerga	:SCoplan	:MFederline	:JLinehan	:BJYoungblood	:GArlotto
Date: 2/10/92	:2/11/92	:2/11/92	:2/11/92	:2/11/92	:2/11/92

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

MEMORANDUM FOR: The Commissioners

FROM: James M. Taylor
Executive Director
for Operations

SUBJECT: RECEIPT OF NEW DRAFT OF ENVIRONMENTAL PROTECTION AGENCY'S (EPA'S) HIGH-LEVEL WASTE STANDARDS

On February 4-6, 1992, the staff (including two Commissioners' assistants and representatives from the Advisory Committee on Nuclear Waste (ACNW) and its staff) attended a workshop sponsored by the Electric Power Research Institute (EPRI). The purpose of the workshop was to pursue a consensus within the technical community on the major issues associated with the high-level waste (HLW) standards being developed by EPA. At the workshop, EPA released a new, unnumbered draft of its standards and of the Supplementary Information describing the standards. Copies of those documents will be circulated to the Commission by S. Bilhorn of Commissioner Rogers' office.

Enclosed, for the Commission's information, is the staff's preliminary evaluation of the "Workshop Draft" of EPA's standards, including EPA's responses to NRC comments on Working Draft No. 3. The third page of the enclosure is a schedule, developed by EPRI, for providing comments to EPA consistent with EPA's intent to publish proposed standards in the Federal Register in May or June of this year. The fourth page is the staff's schedule for developing its comments, coordinating those comments with ACNW, and transmitting comments to EPA by the end of March.

James M. Taylor
Executive Director
for Operations

Enclosure: Workshop Notes

NOTES ON WORKSHOP DISCUSSING EPA HLW STANDARDS

- Attended EPRI-sponsored workshop on EPA/HLW Standard 2/4-6/92
- At the beginning of meeting, EPA distributed a revised draft Statement of Considerations and proposed rule

Significant Additions From EPA Working Draft 3

- A collective dose alternative has been added to containment requirements along with a requirement to project releases from undisturbed performance for up to 100,000 years. EPA proposes to prohibit all forms of truncation when projecting collective doses.

- Individual and groundwater protection requirements have been extended to 10,000 years. A requirement to project individual protection for 100,000 years has also been added.

- Groundwater classification schedule from 1985 standards was deleted in Draft 3 and exposure levels from Safe Drinking Water Act (SDWA) adopted in this draft.

- New sections have been added to Appendix C "Guidance for Implementation" dealing with defining a static biosphere and explaining what reasonable expectation is not.

EPA Attention to Draft 3 Comments

General:

- Several major NRC comments not addressed, especially the recommendation to base EPA's standards on comparisons with other standards and risks.*
- Some new features of the standards (e.g., prohibition of truncation for collective dose estimates) seem to deal with implementation of the standards.

Specific:

- Few changes to assurance requirements - more direction on implementation added in Standard and appendices.
- Uncertain of extent to which EPA will enhance analyses of hypothetical repositories.
- Added collective dose alternative.
- Incorporated 3-bucket, but with EPA's wording. EPA established quantitative rather than qualitative boundary definition.
- No addition of likelihood definition.
- 191.03 & 191.14 maximum exposure to individuals EPA adopted 25 mrem.
- Assurance requirement for qualitative evaluation over 100,000 years moved to containment and individual protection - NRC said to address site comparisons under NEPA.
- 10,000 year duration for individual and groundwater protection - NRC said no basis for either time period.
- 14C - No change - EPA says no one has proved a problem.

*EPA has informally provided the staff with draft contractor reports to be used as background for EPA's technical support for the standards. The staff will informally review these reports and notify EPA of any technical deficiencies identified.

General Schedule for Commenting on EPA Standards

- 2/28 Preliminary draft individual comments
- 3/3 Meet in Tucson*
- 3/31 Agency Comments
- 4/12 Workshop - Meet in Las Vegas*
- 6/15 ANPR or NPR**
- 9/15 End Comment Period

---

* NRC staff will not attend the Tucson meeting. Any participation at the Las Vegas meeting will be only as an observer.

** EPA indicated firm intention to publish proposed rule in May/June timeframe. DOE prefers another "Working Draft" to provide another opportunity for review and comment.

<u>Staff Schedule to Get Comments to EPA by 3/31</u>

- 2/14 Draft Comments on Standard (negative consent)
- 2/18 Division review - Transmit to ACNW
- 2/21 ACNW meeting
- 3/6 NMSS, OGC, RES concurrence
- 3/13 EDO forwards comments to the Commission
- 3/16 Commission Assistants' Briefing
- 3/31 Transmit comments to EPA (unless Commission objects)

THE "WORKSHOP DRAFT" OF EPA'S HIGH-LEVEL WASTE STANDARDS

February 13, 1992

Daniel J. Fehringer

Contact: Daniel J. Fehringer
Phone: 504-1426

PARTICIPANTS AT EPRI'S WORKSHOP

DOE & contractors
EPRI & contractors
EPA
NRC
States (NM & NV)
NAS/NRC
USGS
Others

EPA AND DOE STATUS

EPA plans to publish proposed standards in May or June. –

EPA's technical support is still under development.

DOE says EPA's standards are not needed right now and that EPA should slow down and take as much time as necessary to improve its technical support.

DOE is sponsoring technical work to provide support to EPA.

WORKING DRAFT NO. 3 COMMENTS

Comment: Base standards on risk comparisons.

EPA Resolution: No apparent change in the "Workshop Draft," but EPA staff says some comparisons have been done.

Significance: EPA needs to make comparisons available for review to gain acceptance within the technical community.

DRAFT NO. 3 COMMENTS (CONT'D)

Comment: Reevaluate guidance on frequency and severity of potential human intrusion.

EPA Resolution: No change in the "Workshop Draft."

Significance: NRC might need to formulate — a position on the long-term effectiveness of institutional controls. –

No discussion in the proposed rule in the early '80s

– DOE effort on WIPP - might be instructive.

– Swedes are also examining the issue

DRAFT NO. 3 COMMENTS (CONT'D)

<u>Comment</u>: Qualitative statement of "3-bucket" alternative.

<u>EPA Resolution</u>: None. The "Workshop Draft" retains a numerical formulation.

<u>Significance</u>: 1. Using a number partly defeats ✓ the purpose of the concept by requiring numerical probability estimates.
2. EPA's proposed number would be more stringent than the 1985 standards.

EPRI working group - Working to come up w/ an approach on 3-bucket.

DRAFT NO. 3 COMMENTS (CONT'D)

Comment: Suggested definition of "likelihood."

EPA Resolution: None. EPA staff indicated that our suggestion was being considered, but it was absent from the "Workshop Draft."

Significance: Definition is needed to foreclose bizarre interpretations of the standards or purely subjective demonstrations of compliance.

NRC position

Concept refers to likelihood

— not to level of confidence or uncertainties in probability estimates (see Ramsport at NAS)

DRAFT NO. 3 COMMENTS (CONT'D)

Comment: Adopt 25 mr/yr dose limit for operations and 10 mr/yr post-closure. Use "critical group" concept.

EPA Resolution: 25 mr/yr for both. Based on "max. exposed individual" rather than critical group. ✓

Significance: EPA thinks 25 mr/yr is more consistent with its drinking water stds. "Critical group" concept would allow some averaging of projected doses. ~ identify critical population - average of exposure to this group, rather than MEI

DRAFT NO. 3 COMMENTS (CONT'D)

Comment: 100,000 year comparisons of alternative sites is inappropriate. If protection is needed, use a standard.

EPA Resolution: "Workshop Draft" requires projections of releases for 100,000 years. ✓ No standards for acceptability are offered.

Significance: 100,000 year projections would be highly uncertain and possibly unworkable.

L if the standard during the first 10,000 years is used.

Bemoo - NRC may have shot itself in the foot in our comments.

DRAFT NO. 3 COMMENTS (CONT'D)

Comment: EPA has not justified either 1,000 or (10,000 year periods for ind.) and GW protection requirements.

EPA Resolution: None.

Significance: EPA is now proposing a 10,000 year period. At Yucca Mountain, the groundwater protection requirement may * now be more stringent than the cumulative release limits. (because there is no dilution component at Yucca Mtn.)

most significant change

DRAFT NO. 3 COMMENTS (CONT'D)

Comment: A "no degradation" requirement for special groundwaters is not appropriate.

EPA Resolution: This concept has been deleted from the "Workshop Draft."

Significance: A "no degradation" requirement would only have been significant if EPA had tried to apply it inside the controlled area.

DRAFT NO. 3 COMMENTS (CONT'D)

Comment: EPA has not justified any specific TRU waste unit for the standards.

EPA Resolution: The "Workshop Draft" retains EPA's 1985 formulation.

Significance: Only for WIPP unless commercial "greater than Class C" wastes go to a HLW repository. Even then, the small inventory of TRU would be overwhelmed by spent fuel.

Not a major issue

DRAFT NO. 3 COMMENTS (CONT'D)

Comment: C-14 release limit illustrates the vulnerability of technical achievability basis for EPA's standards.

EPA Resolution: Retain the 1985 limit since no one has proven it is impossible to meet.

Significance: C-14 should have been a wake-up call showing EPA's standards to be vulnerable to surprises. EPA doesn't seem to have recognized that.

Cost of compliance - will not be significant - (see DOE letter to EPA) Roberts Memo

DRAFT NO. 3 COMMENTS (CONT'D)

General Comment: Jurisdictional objection to assurance requirements, criteria for demonstrating compliance, and implementation guidance.

EPA Resolution: None.

Significance: NRC needs to develop agency policy on how strongly to pursue this issue.

NEW FEATURES OF "WORKSHOP DRAFT"

Feature: Implementing agency (NRC) may specify use of collective dose rather than cumulative release estimates.

Significance: 1. May eliminate excessive ✓ stringency for desolate sites. However, does nothing for C-14.

2. The applicant, rather than the regulator, should decide which alternative to use.

EPA- regulator would decide

NEW FEATURES OF "WORKSHOP DRAFT"

Feature: EPA prohibits all types of truncation when estimating collective doses.

Significance: 1. Involves implementation. Not within EPA's jurisdiction.

2. It is technically inappropriate to try to regulate on the basis of microdoses to megapeople.

NEW FEATURES OF "WORKSHOP DRAFT"

Feature: EPA recommends ~~an~~ assuming that the biosphere near a repository will be largely unchanged from today's.

Significance: 1. OK as far as it goes, but includes some vague wording.

2. EPA still asks for difficult projections of population sizes and climate changes, presumably including those caused by man.

NEW FEATURES OF "WORKSHOP DRAFT"

Feature: EPA has added an explanation of the meaning of "reasonable expectation."

Significance: EPA's explanation does not say what the term means - only that it is different from "reasonable assurance" as used by NRC.

SCHEDULE FOR COMMENTS

2/14 - New comments drafted (neg. consent)

2/18 - Transmit comments to ACNW

2/21 - ACNW meeting

3/6 - NMSS, OGC, RES concurrence

3/13 - Transmit comments to Commission

3/16 - Commission Assistants' briefing

3/31 - Transmit comments to EPA

NOTE - DOE is not planning to comment.

DRAFT *FEDERAL REGISTER* NOTICE FOR 40 CFR PART 191

NOTE: This document has been prepared for discussion purposes only. It has not been reviewed or approved by the Agency. Some provisions will likely be changed before it is published in the *Federal Register* for public review and comment. Its placement into EPA Docket Number R-89-01 is for the purpose of updating the public on the current thinking of the Agency.

This draft has several changes from the 1985 standards including the following, in order of appearance:

(1) The definitions from all subparts have been consolidated and alphabetized in Subpart A, several new definitions have been added and two deleted;

(2) All quantities are expressed in the International System of Units (SI) as well as the traditional system;

(3) Subpart A is now an operational standard in that the phrase "reasonable assurance" has been deleted;

(4) All individual dose requirements are now stated in the currently accepted health physics quantity "annual committed effective doses;

(5) An alternative method of showing compliance with the containment requirements that uses collective (population) dose has been added along with a requirement to project releases from undisturbed performance up to 100,000 years;

(6) The same 100,000-year requirement has been added to the individual protection requirements;

(7) The ground-water protection section of Subpart B has been removed, however, a new Subpart C, "Ground-water Protection Requirements," has been added. It will apply to activities subject to Subparts A and B. Related to this, the ground-water classification scheme from the 1985 standards has been deleted and the exposure levels from the Safe Drinking Water Act regulations have been adopted;

(8) [illegible] new sections have been added which state the timing on the compliance determination and the requirements necessary to conduct experiments with radioactive waste on-site prior to a final showing of compliance;

(9) A new Appendix B has been added which sets out the procedure for calculating committed effective doses;

(10) The 1985 Appendix B has been changed to Appendix C; new sections which have been added deal with iterative performance assessments and future states; and,

(11) The borehole sealing worst-case scenario from the 1985 standards has been supplemented with emphasis that the implementing agency may develop less severe assumptions.

Additions or modifications to the 1985 version of the standards are highlighted in this manner while deletions are ~~highlighted in this manner~~.

For further information, please contact either Ray Clark or Caroline Petti at FTS or (202) 260-9633.

A revised Part 191 is hereby incorporated into Title 40, Code of Federal Regulations, as follows:

SUBCHAPTER F - RADIATION PROTECTION PROGRAMS

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

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 Definitions.

As used in Part 191, the following terms have the meanings given in this section: ~~Unless otherwise indicated in this Subpart, all terms shall have the same meaning as in Subpart A of Part 190.~~

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

"Active institutional control" means any control dependent upon man's continuing presence and activity at the disposal site including any or all of the following: (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.

"Administrator" means the Administrator of the Environmental Protection Agency.

"Agency" means the Environmental Protection Agency.

"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).

"Annual committed effective dose" means the committed effective dose resulting from a one-year intake of radionuclides released plus the annual effective dose caused by direct radiation from facilities or activities subject to this Part.

"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.

"Barrier" means any material or structure that prevents or substantially delays movement of ~~water or~~ radionuclides or their transport medium 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 radioactive waste, provided that the material or structure substantially delays movement of ~~water or~~ radionuclides or a transport medium for them, e.g., gases or water.

"Bequerel" is the SI unit for radioactivity and is represents one nuclear transformation (decay) per second; the abbreviation is "Bq."

"Commission" means the Nuclear Regulatory Commission.

"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.

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

"Department" means the Department of Energy.

"Disposal" means permanent isolation of ~~spent nuclear fuel or~~ radioactive waste from the accessible environment with no intent of recovery or retrieval whether or not such isolation permits the recovery or retrieval 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.~~

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

"Dose equivalent" means the product of absorbed dose and appropriate factors to account for differences in biological effectiveness due to the quality of radiation and its spatial distribution in the body; the unit of dose equivalent is the "rem" (sievert in SI units).

"Ecologically vital ground water" means ground water supplying an ecosystem which is located: (1) in a ground-water discharge area that supports a habitat for a listed or proposed endangered or threatened species, as designated pursuant to the Endangered Species Act, as amended; or (2) on Congressionally designated Federal lands managed for the purpose of ecological protection regardless of the presence of endangered or threatened species. Discharge area is an area of land beneath which there is a net transfer of water from the saturated zone to a surface water body, the land surface, or the root zone.

"Effective dose" means the sum over specified tissues of the products of the dose equivalent received following an exposure of, or an intake of radionuclides into, specified tissues of the body, multiplied by appropriate weighting factors. This allows the various tissue-specific health risks to be summed into an overall health risk. The method used to calculate effective dose is described in Appendix B of this Part.

"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.

"Ground water" means water which is present below the land surface ~~water below the land surface in a zone of saturation~~.

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

"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).

"Implementing agency" ~~as used in this Subpart~~, means the Commission for ~~spent nuclear fuel or high-level or transuranic~~ radioactive wastes to be managed, stored, or 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.

"International System of Units" is the modern version of the metric system which has been established by the International Bureau of Weights and Measures and is administered in the United States by the National Institute of Standards and Technology. The abbreviation for this system is "SI."

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

"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 into a disposal system.

"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.

"Passive institutional control" means controls not dependent upon man's continuing presence and activity at the disposal facility including the following: (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.

"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. In the case of disposal of radioactive waste in a mined geologic repository, for example, the time period over which the performance of the system shall be calculated shall begin when all of the shafts to the repository are backfilled and sealed.

"Public water system" means a system for the provision to the public of piped water for human consumption, if such system has at least fifteen service connections or regularly serves at least twenty-five individuals. Such term includes (A) any collection, treatment, storage, and distribution facilities under control of the operator of such system and used primarily in connection with such system, and (B) any collection or pretreatment storage facilities not under such control which are used primarily in connection with such system.

"Radioactive waste" ~~as used in this Part,~~ means ~~the~~ spent nuclear fuel, high-level ~~and~~ or transuranic radioactive waste ~~covered by this Part~~, and any other radioactive material managed or disposed of with these wastes.

"Radioactive material" means radionuclides subject to the Atomic Energy Act of 1954, as amended.

"Retrieval" means the removal of radioactive waste in the intact container(s) in which it has been retained.

"Recovery" means the removal of radioactive waste and any other material which has been contaminated by radioactive material from the waste.

"Sievert" is the SI unit of effective dose and is equal to 100 rem or one joule per kilogram. The abbreviation is "Sv."

"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 Subpart A.

"SI unit" means a unit of measure in the International System of Units.

"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.

"Storage" means retention of ~~spent nuclear fuel or~~ radioactive wastes in a manner which provides for ~~with the intent and capability to readily retrieve~~ ready retrieval of such ~~fuel or~~ waste ~~for subsequent use, processing, or disposal~~.

"Total dissolved solids" means the total dissolved solids as determined by use of the method specified in 40 CFR Part 136.

"Transuranic radioactive waste" means waste containing more than 100 nanocuries [37 bequerels (Bq)] of alpha-emitting transuranic isotopes, with half-lives greater than twenty years, per gram of waste, except for: (1) high-level radioactive waste; (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.

"Underground source of drinking water" means an aquifer or its portion which: (1) supplies any public water system; or (2) contains a sufficient quantity of ground water to supply a public water system; and (i) currently supplies drinking water for human consumption; or (ii) contains fewer than 10,000 milligrams of total dissolved solids per liter.

"Undisturbed performance" means the ~~predicted~~ projected behavior of a disposal system, including consideration of the uncertainties in ~~predicted~~ that behavior, if the disposal system is not disturbed by human intrusion or the occurrence of unlikely natural events.

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

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

§ 191.02. 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 an Agreement States, to the extent that such management and storage operations are not subject to the provisions of 40 CFR Part 190; 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~~ radioactive wastes at any disposal facility that is operated by the Department of Energy and that is not regulated by the Commission or by an Agreement States.

§ 191.03 Standards.

(a)(1) Management and storage of ~~spent nuclear fuel or high-level or transuranic~~ radioactive wastes at all facilities regulated by the Commission or by an Agreement States shall be conducted in such a manner ~~as to provide reasonable assurance~~ that the combined annual committed effective 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 40 CFR Part 190; shall not exceed 25 millirems (250 microsieverts). ~~to the whole body, 75 millirems to the thyroid, and 25 millirems to any other critical organ.~~ Doses currently calculated under 40 CFR Part 190 shall be converted to annual committed effective dose for purposes of this section.

(2) Management and storage of ~~spent nuclear fuel or high-level or transuranic~~ radioactive wastes at all facilities for the disposal of ~~such fuel or~~ radioactive waste that are operated by the Department and that are not regulated by the Commission or an Agreement States shall be conducted in such a manner ~~as to provide reasonable assurance~~ that the combined annual committed effective 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 (250 microsieverts). ~~to the whole body and 75 millirems to any critical organ.~~

(b) Annual committed effective doses shall be calculated in accordance with Appendix B.

§ 191.04 Compliance with other Federal regulations.

Compliance with the provisions in this Subpart does not abridge the necessity to comply with the requirements of Subpart C or other Federal regulations.

§ 191.05 Effective Date.

The modifications to ~~standards in~~ this Subpart shall be effective on [30 days after publication in the *FEDERAL REGISTER*] ~~November 18, 1985~~.

Subpart B - Environmental Standards for Disposal

§ 191.11 Applicability.

This Subpart applies to:

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

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

~~(c) radioactive contamination of certain sources of ground water in the vicinity of disposal systems for such fuel or wastes.~~

(c) 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~~ disposal that occurred before August 15, 1985.

§ 191.12 ~~13~~ Containment requirements.

The implementing agency may invoke either subsection (a) or (b) of this section.

(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 (including both natural and human-initiated 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)(1) Disposal systems for radioactive waste shall be designed to provide a reasonable expectation, based upon performance assessments, that the collective (population) effective dose, calculated using the weighting factors in Appendix B, caused by releases of radionuclides to the accessible environment for 10,000 years after disposal from all significant processes and events (including both natural and human-initiated processes and events) that may affect the disposal system shall:

(i) have a likelihood of less than one chance in 10 of exceeding 2.5 million person-rem (25,000 person-sieverts); and

(ii) have a likelihood of less than one chance in 1,000 of exceeding 25 million person-rem (250,000 person-sieverts).

(2) In calculating the collective effective dose, the implementing agency shall assume no truncation of any sort including dose, dose rate, distance, geography, or times less than 10,000 years.

(c) Potential releases or collective (population) effective doses resulting from the undisturbed performance of disposal systems shall be projected for 100,000 years after disposal.

(d) ~~(b)~~ Performance assessments need not provide complete assurance that the requirements of § 191.12 ~~13~~ (a) or (b) 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 finding of reasonable expectation by the implementing agency, on the basis of the record before it, ~~the implementing agency~~ that compliance with 191.12 ~~13~~ (a) or (b) will be achieved.

The Agency is considering a set of containment requirements which, if adopted, would be used as an option for the implementing agency. This option is presented here for the reader's convenience.

§ 191.12 Containment Requirements

The implementing agency may invoke either subsection (a) or (b) of this section.

(x) Disposal systems for radioactive waste shall be designed to provide a reasonable expectation that releases resulting from all significant processes and events (including both natural and human-initiated processes and events) that may affect the disposal system for 10,000 years after disposal shall:

(1) Have a likelihood of less than one chance in 10 that cumulative releases to the accessible environment will exceed the quantities calculated according to Table 1 (Appendix A), based upon performance assessments; and

(2) Not exceed ten times the quantities calculated according to Table 1 (Appendix A) based upon the projected release resulting from any process, event, or sequence of processes and events which has a likelihood of occurrence between one chance in 10 and one chance in 10,000.

(y)(1) Disposal systems for radioactive waste shall be designed to provide a reasonable expectation that the collective (population) effective doses resulting from releases of radionuclides to the accessible environment as a result of all significant processes and events (including both natural and human-initiated processes and events) that may affect the disposal system for 10,000 years after disposal shall:

(i) Have a likelihood of less than one chance in 10 of exceeding 2.5 million person-rem (25,000 person-sieverts), based upon performance assessments; and

(ii) Not exceed 25 million person-rem (250,000 person-sieverts), based upon the projected release resulting from any process, event, or sequence of processes and events which have a likelihood of occurrence between one chance in 10 and one chance in 10,000.

---

§ 191.13 ~~14~~ Assurance requirements.

To provide the confidence needed for long-term compliance with the requirements of § 191.12 ~~13~~, disposal of ~~spent nuclear fuel or high-level or transuranic~~ radioactive 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 systems ~~sites~~ should be maintained for as long a period of time as is practicable after disposal; however, performance assessments that assess isolation of the radioactive 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~~ projected performance. This monitoring shall be done with techniques that do not jeopardize the isolation of the radioactive wastes and shall be conducted until there are no significant concerns to be addressed by further monitoring.

(c) Disposal systems ~~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) In selecting disposal sites, 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 but not be limited to hydrocarbons, minerals, ~~petroleum or natural gas~~, geothermal energy, valuable geologic formations, ecologically vital ground water, and ground waters that are irreplaceable because either there is no reasonable alternative source of: (1) drinking water available for substantial populations or ~~that are vital to the preservation of unique and sensitive ecosystems.~~ (2) water for agricultural use. 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 recovery ~~removal~~ of most of the wastes is not precluded for a reasonable period of time after disposal.

§ 191.14 ~~15~~ Individual 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 10,000 ~~1,000~~ years after disposal, undisturbed performance of the disposal system shall not cause the annual committed effective dose, ~~equivalent~~ received through all potential pathways from the disposal system to any member of the public in the accessible environment, to exceed 25 millirems (250 microsieverts). ~~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 individual consume 2 liters per day of drinking water from any significant source of ground water outside of the controlled area.~~

(b) The annual committed effective doses, resulting from the undisturbed performance of disposal systems for radioactive waste, received through all potential pathways from the disposal system to any member of the public in the accessible environment shall be projected until they have reached their peak value or for 100,000 years after disposal, whichever is reached first.

(c) Annual committed effective doses shall be calculated in accordance with Appendix B.

~~**§ 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 or 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 191.15(a), the disposal system shall be designed to provide a reasonable assurance 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 that the limits established in 191.16(a).~~

§ 191.15 Determination of capability to comply.

The implementing agency shall determine that a disposal system is capable of complying with all of the requirements of this Part before any radioactive waste is emplaced into the system.

§ 191.16 Emplacement for experimental purposes.

The implementing agency may allow temporary emplacements of radioactive waste in a potential disposal system for experimental purposes before making the determination required in § 191.15. Such placements shall not occur until:

(a) There are written plans that describe:

(1) The purposes of the experiments;

(2) How the data will be used;

(3) The amount of radioactive waste required; and

(4) A time schedule for the experiments;

(b) There are preliminary compliance assessment calculations available to guide the experiments; and

(c) There are pre-established plans and tested procedures for the removal of the waste.

§ 191.17 Alternative provisions. ~~**for Disposal.**~~

The Administrator may, by rule, substitute alternative provisions for any of the provisions ~~of Subpart B~~ in this Part ~~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 with the alternative provisions and the reasons why compliance with the existing provisions of this Part ~~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 Compliance with other Federal regulations.

Compliance with the provisions in this Subpart does not abridge the necessity to comply with the requirements of Subpart C or other Federal regulations.

§ 191.19 ~~18~~ Effective date.

The standards in this Subpart shall be effective on [30 days after publication in the *FEDERAL REGISTER*] ~~November 18, 1985~~.

Subpart C - Environmental Standards for Ground-water Protection

§ 191.21 Applicability.

This Subpart applies to:

(a) radiation doses received by members of the public as a result of activities subject to Subparts A and B of this Part; and

(b) radioactive contamination of underground sources of drinking water in the vicinity of facilities as a result of such activities.

This Subpart does not apply to disposal that occurred before August 15, 1985.

§ 191.22 Management and storage standards.

Management and storage of radioactive waste shall not cause the levels of radioactivity in any underground source of drinking water outside the site to exceed the levels in § 191.24.

§ 191.23 Disposal standards.

Disposal systems for radioactive waste shall be designed to provide a reasonable expectation that 10,000 years of undisturbed performance after disposal shall not cause the levels of radioactivity in any underground source of drinking water outside the controlled area to exceed the limits in § 191.24.

§ 191.24 Maximum contaminant levels.

Determination of compliance with this section shall be based on underground sources of drinking water which have been identified at the time of the determination of compliance as required in § 191.15. The analytical methods in 40 CFR Part 141 shall be used for determining the amounts of these contaminants.

Contaminant	Level
Radon-222	300 pCi/L (11 Bq/L)
Radium-226	20 pCi/L (0.7 Bq/L)
Radium-228	20 pCi/L (0.7 Bq/L)
Uranium	20 µg/L[1] (0.7 Bq/L)
Adjusted gross alpha	15 pCi/L (0.6 Bq/L)
Beta particles and photon emitters	4 mrem (40 µSv) annual committed effective dose[2]

[1]NOTE: 20 micrograms per liter (µg/L) of uranium is approximately equal to 30 pCi/L (1 Bq/L), using an activity-to-mass conversion of 1.3 pCi/µg (0.05 Bq/µg). The activity-to-mass ratio can vary depending on the relative amounts of uranium-234, -235, and -238 that are present in a sample. This value applies to the total mass of uranium in the sample.

[2]NOTE: The unit "annual committed effective dose" refers to the dose committed over a period of 50 years from an annual intake at the rate of 2 liters (L) of drinking water per day.

§ 191.25 Compliance with other Federal regulations.

Compliance with the provisions in this Subpart does not abridge the necessity to comply with the requirements of other Federal regulations.

§ 191.26 Effective date.

The standards in this Subpart shall be effective on [30 days after publication in the *FEDERAL REGISTER*].

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 [curies (TBq*)] per 1,000 MTHM or other unit of waste (see Notes)
Americium-241 or -243	100 (3.7)
Carbon-14	100 (3.7)
Cesium-135 or -137	1,000 (37)
Iodine-129	100 (3.7)
Neptunium-237	100 (3.7)
Plutonium-238, -239, -240, or -242	100 (3.7)
Radium-226	100 (3.7)
Strontium-90	1,000 (37)
Technetium-99	10,000 (370)
Thorium-230 or -232	10 (0.37)
Tin-126	1,000 (37)
Uranium-233, -234,- 235, -235, -236, or -238	100 (3.7)
Any other alpha-emitting radionuclide with a half-life greater than 20 years	100 (3.7)
Any other radionuclide with a half-life greater than 20 years that does not emit alpha particles	1,000 (37)

* TBq in the International System of Units represents terabequerels or 10^{12} bequerels.

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 [3.7×10^{18} Bq or 3.7 exabequerels (EBq)] 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 [37×10^{15} Bq or 37 petabequerels (PBq)] 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 1,000,000 ~~one million~~ curies (37 PBq) 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 radioactive 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 3,000,000 ~~million~~ curies (111 PBq) of alpha-emitting transuranic wastes, the release limits for that system would be the quantities in Table 1 multiplied by three [3,000,000 ~~million~~ curies (111 PBq) divided by 1,000,000 ~~one-million~~ curies (37 PBq)].

(c) If a particular disposal system contained both the high-level radioactive wastes from 50,000 MTHM *and* 5,000,000 ~~million~~ curies (185 PBq) of alpha-emitting transuranic wastes, the release limits for that system would be the quantities in Table 1 multiplied by 55:

$$\frac{50{,}000 \text{ MTHM}}{1{,}000 \text{ MTHM}} + \frac{5{,}000{,}000 \text{ curies (185 PBq) TRU}}{1{,}000{,}000 \text{ curies (37 PBq) TRU}} = 55.$$

NOTE 3: *Adjustments for Reactor Fuels with Different Burnup.* For disposal systems containing spent nuclear ~~reactor~~ fuels (or the high-level radioactive wastes from spent nuclear ~~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 radioactive wastes with an average burnup of 3,000 MWd/MTHM, the unit of waste for that disposal system would be:

$$1{,}000 \text{ MTHM} \times \frac{(30{,}000 \text{ MWd/MTHM})}{(\ 5{,}000 \text{ MWd/MTHM})} = 6{,}000 \text{ MTHM}.$$

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 (10):

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

which is the same as:

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

NOTE 4: *Treatment of Fractionated High-Level Wastes.* In some cases, a high-level radioactive 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 radioactive 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 radioactive 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 to which ~~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 radioactive 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 radioactive 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: *Use of Release Limits to Determine Compliance with § 191.12(a)(1) ~~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 §§ 191.12(a)(1) ~~13~~ and (x) 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 § 191.12(a)(1)(i) ~~13(a)(1)~~ and may not exceed ten with regard to §§ 191.12(a)(1)(ii) ~~13(a)(2)~~ and (x).

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 relationships exists:

$$\frac{Q_a}{RL_a} + \frac{Q_b}{RL_b} + \frac{Q_c}{RL_c} \leq 1 \quad \text{for §§ 191.12(a)(1) and (x)}$$

[The following relationship is new since 1985 but due to technical reasons has not been shaded.]

$$\frac{Q_a}{RL_a} + \frac{Q_b}{RL_b} + \frac{Q_c}{RL_c} \leq 10 \quad \text{for § 191.12(a)(2).}$$

Appendix B -- Calculation of Annual Committed Effective Dose [NOTE: THE ENTIRETY OF THIS APPENDIX IS NEW SINCE 1985]

Equivalent dose. The calculation of the *committed effective dose* (CED) begins with the determination of the equivalent dose, H_T, to the tissues, T, listed in Table B.2 below by using the equation:

$$H_T = \sum_R D_{T,R} \cdot w_R$$

where $D_{T,R}$ is the absorbed dose in rads (one gray, an SI unit, equals 100 rads) averaged over the tissue or organ, T, due to radiation type, R, and w_R is the radiation weighting factor which is given in Table B.1 below. The unit of equivalent dose is the rem (sievert, in SI units).

Table B.1 Radiation weighting factors, w_R [1]

Radiation type and energy range [2]		w_R value
Photons, all energies		1
Electrons and muons, all energies		1
Neutrons, energy	< 10 keV	5
	10 keV to 100 keV	10
	> 100 keV to 2 MeV	20
	>2 MeV to 20 MeV	10
	> 20 MeV	5
Protons, other than recoil protons, > 2 MeV		5
Alpha particles, fission fragments, heavy nuclei		20

[1] All values relate to the radiation incident on the body or, for internal sources, emitted from the source.

[2] The choice of values for other radiation types and energies not in the table, see paragraph A14 in ICRP Publication 60.

Effective dose. The next step is the calculation of the *effective dose, E*. The probability of occurrence of a stochastic effect in an organ or tissue is assumed to be proportional to the equivalent dose in the organ or tissue. The constant of proportionality differs for the various tissues of the body, but in assessing health detriment the total risk is required. This is taken into account using the tissue weighting factors, w_T in Table B.2, which represent the proportion of the stochastic risk resulting from irradiation of tissue T to the total risk when the whole body is irradiated uniformly and H_T is the equivalent dose in tissue T, in the equation:

$$E = \sum_T w_T \bullet H_T.$$

Table A.2 Tissue weighting factors, w_T [1]

Organ or tissue	w_T value
Gonads	0.20
Red bone marrow	0.12
Colon	0.12
Lung	0.12
Stomach	0.12
Bladder	0.05
Breast	0.05
Liver	0.05
Oesophagus	0.05
Thyroid	0.05
Skin	0.01
Bone surfaces	0.01
Remainder	0.05 [2,3]

[1] The values have been developed from a reference population of equal numbers of both sexes and a wide range of ages. In the definition of effective dose, they apply to individuals and populations and to both sexes.

[2] For purposes of calculation, the remainder is comprised of the following additional tissues and organs: adrenals, brain, upper large intestine, small intestine, kidney, muscle, pancreas, spleen thymus, and uterus. The list includes organs which are likely to be selectively irradiated. Some organs in the list are known to be susceptible to dancer induction. If other tissues and organs subsequently become identified as having a significant risk of induced cancer, they will then be included either with a specific w_T or in this additional list constituting the remainder. The latter may also include other tissues or organs selectively irradiated.

[3] In those exceptional cases in which a single one of the remainder tissues or organs receives an equivalent dose in excess of the highest dose in any of the twelve organs for which a weighting factor is specified, a weighting factor of 0.025 should be applied to that tissue or organ and a weighting factor of 0.025 to the average dose in the rest of the remainder as defined above.

Annual committed tissue or organ equivalent dose. For internal irradiation from incorporated radionuclides, the total absorbed dose will be spread out in time, being gradually delivered as the radionuclide decays. The time distribution of the absorbed dose rate will vary with the radionuclide, its form, the mode of intake and the tissue within which it is incorporated. To take account of this distribution the quantity *committed equivalent dose*, $H_T(\tau)$ where τ is the integration time in years following an intake over any particular year, is used and is the integral over time of the equivalent dose rate in a particular tissue or organ that will be received by an individual following an intake of radioactive material into the body. The time period, τ, is taken as 50 years as an average time of exposure following intake:

$$H_T(\tau) = \int_{t_0}^{t_0 + 50} H_T(t)\, dt$$

for a single intake of activity at time t_0 where $H(t)$ is the relevant equivalent-dose rate in an organ or tissue at time t. For the purposes of this rule, the previously mentioned single intake may be considered to be an annual intake.

Annual committed effective dose. If the committed equivalent doses to the individual tissues or organs resulting from an annual intake are multiplied by the appropriate weighting factors, w_T, and then summed, the result will be the *annual committed effective dose*, $E(\tau)$:

$$E(\tau) = \Sigma\, w_T \bullet H_T(\tau)\, dt.$$

Appendix B C - Guidance for Implementation of Subparts B and C

> [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 Subparts B and C. This appendix will appear in the Code of Federal Regulations.]

The Agency believes that The implementing agencies must should determine compliance with §§ 191.12 13, 191.14 15, and Subpart C 191.16 of Subpart B by evaluating long-term predictions of disposal system performance. Determining compliance with § 191.12 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 Subparts B and C have yet to be not been fully formulated and fully 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 Subparts B and C. 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 should 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.

Iterative Compliance Assessments and Timing of Compliance. The Agency believes that the calculations needed for long-term predictions of disposal system performance should be done in many iterations, with frequent opportunities for public and external peer review. The Agency believes that such frequent reviews will improve confidence in the completeness and appropriateness of the analyses.

Initial versions of the calculations to evaluate compliance with Subparts B and C should be available for review well before any waste is placed into the disposal system, even for experimental purposes.

The implementing agency should demonstrate that the disposal system complies with Subparts B and C before any waste is placed into the system for disposal. This evaluation should represent the primary decision point as to whether the system is appropriate for use as a disposal facility.

The implementing agency should continue to collect data through the operational period and periodically reexamine its long-term predictions of performance to validate its finding that the disposal system complies with Subparts B and C.

Finally, a demonstration of compliance should occur before the system is backfilled and sealed.

Future States. Uncertainties involving things that are unknowable about the future can only be dealt with by making assumptions and recognizing that these may, or may not, correspond to a future reality. The Agency believes that speculation concerning certain factors should not be the focus of the compliance determination process. Therefore, it would be appropriate for assessments made under Part 191 to contain the assumption that many factors are essentially the same as today's. Factors which could be included in this category include demographic patterns, e.g., emergence of large populations where there are currently none, level of knowledge and technical capability, human physiology and nutritional needs, the state of medical knowledge, societal structure and behavior, and pathways through the accessible environment. The Agency would not find it appropriate to extend this to geologic, hydrologic, climatic conditions, or total national or world populations evaluated under § 191.12.

Scope of Performance Assessments. Section 191.12 ~~13~~ requires the implementing agencies to evaluate compliance through performance assessments as defined in § 191.01 ~~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 191.12 ~~13~~. ~~The Agency assumes that,~~ Whenever practicable, the implementing agency will assemble all of the results of the performance assessments to determine compliance with § 191.12 ~~13~~ into a "complementary cumulative distribution function" that indicates the cumulative probability of exceeding various levels of ~~cumulative~~ release. When the uncertainties in parameters values 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 may ~~can~~ be considered to be in compliance with § 191.12 ~~13~~ if this single distribution function meets the requirements of § 191.12 ~~13~~ (a).

When there are multiple models applicable to the performance assessment, the implementing agency should consult with a spectrum of experts, including experts independent of the licensing and implementing agencies, to assist it in determining which model(s) is most appropriate.

Reasonable Expectation. The Agency's concept of "reasonable expectation of compliance" involves examination of all evidence which bears upon the assessment including any expert judgment used to determine input parameter values and appropriate models. Further, the use of the term "reasonable expectation" reflects the fact that unequivocal proof of compliance is neither necessary nor likely to be obtained. A similar qualitative test, termed "reasonable assurance," has been used with Commission rules applicable to operating facilities for many years and has become associated with relatively high levels of confidence. Although the intent is similar, the NRC phrase has not been used in Part 191. The Agency believes that the uncertainty involved in projecting the performance of operating facilities is not as great as in projecting the performance of disposal systems over much longer times and, therefore, believes that the same stringency in the level of confidence is inappropriate.

Institutional Controls. To comply with § 191.13 ~~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 § 191.13 ~~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 The implementing agency may develop less severe assumptions than these, including justification, for a particular disposal system based upon the characteristics of the system including its judgment of the effectiveness of the disposal system's design and passive institutional controls.

Compliance with Sections 191.14 ~~15~~ and Subpart C ~~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 § 191.14 ~~15~~ and Subpart C ~~191.16~~, respectively. ~~The Agency assumes that~~ Compliance may ~~can~~ be determined based upon "best estimate" predictions (e.g., the mean or the median of the appropriate distribution, whichever is higher).

DRAFT DATED: FEBRUARY 3, 1992

ENVIRONMENTAL PROTECTION AGENCY

40 CFR 191

ENVIRONMENTAL STANDARDS FOR THE MANAGEMENT AND DISPOSAL OF SPENT NUCLEAR FUEL, HIGH-LEVEL AND TRANSURANIC RADIOACTIVE WASTES

AGENCY: Environmental Protection Agency

ACTION: Proposed Rule

SUMMARY: The U.S. Environmental Protection Agency (EPA) is developing generally applicable environmental standards for the management and disposal of spent nuclear fuel, high-level and transuranic radioactive wastes. These wastes are produced as a result of defense activities under the jurisdiction of the U.S. Department of Energy (DOE) and civilian activities regulated by the U.S. Nuclear Regulatory Commission (NRC).

Standards were promulgated in 1985 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. Following a legal challenge, the U.S. Court of Appeals for the First Circuit (hereinafter referred to as the "court"), in 1987, remanded Subpart B of the 1985 standards to the Agency for further consideration. The proposed standards being issued today represent the Agency's response to the issues raised by the court remand and to relevant new programmatic changes and information.

Today's proposal consists of three Subparts. Subpart A applies to radiation exposures of members of the public from the management and storage of radioactive wastes prior to disposal.

Subpart B applies to the disposal of radioactive waste and establishes several different types of requirements. The primary standards for disposal are long-term containment requirements that are designed to limit projected releases of radioactivity to the accessible environment for 10,000 years after disposal. A set of qualitative assurance requirements is an equally important element of Subpart B designed to provide adequate confidence that the containment requirements will be met. Finally, a set of individual protection requirements limits radiation exposures to individual members of the public after disposal. Accompanying the Subpart B disposal standards in Appendix C is a set of

informational guidance for implementation of the disposal standards to clarify the Agency's intended application of these standards.

Finally, today's proposal contains a new Subpart C--Environmental Standards for Ground Water Protection--which limits contamination of drinking water in the vicinity of waste management, storage, and disposal systems.

After the Agency considers comments received on this proposal, it will develop a final version of these standards and promulgate them as Part 191 of Title 40 of the Code of Federal Regulations (40 CFR Part 191).

DATE: Public hearings on this proposed rule will be held ________________. Comments on the proposed rule should be received on or before ________________________.

ADDRESS: Comments should be submitted, in duplicate, to: Docket No. R-89-01, Air Docket, Room M-1500 (LE-131), Waterside Mall, 401 M Street, S.W., Washington, D.C. 20460. Materials relevant to this rulemaking are contained in Docket No. r-89-01, located in Room 1500 (first floor in Waterside Mall near the Washington Information Center), Waterside Mall, 401 M Street, S.W., Washington, D.C. 20460. The docket may be inspected between 8:30 a.m. and 12:00 noon and between 1:30 p.m. and 3:30 p.m. on weekdays. As provided in 40 CFR Part 2, a reasonable fee may be charged for photocopying docket materials.

Single copies of the Draft Background Information Document and the Economic Impact Analysis for this action may be obtained by writing to: William Russo, Criteria and Standards Division (ANR-460), Office of Radiation Programs, Environmental Protection Agency, Washington, D.C. 20460 or calling (202)260-9633.

FOR FURTHER INFORMATION CONTACT:

Ray Clark or Caroline Petti; telephone number (202)260-9633.

SUPPLEMENTARY INFORMATION

Nature and Hazards of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes

Radioactive wastes are the result of governmental and commercial uses of nuclear fuel and material. There are five main categories of radioactive wastes: spent nuclear fuel, high-level waste, transuranic wastes, uranium mill tailings and low-level wastes. This proposed rule covers management and disposal of spent nuclear fuel, high-level wastes, transuranic wastes and any other Atomic Energy Act radioactive wastes or material managed or disposed of with these wastes. The Agency has issued under separate authorities, standards to cover uranium mill tailings (40 CFR Part 192 and 40 CFR Part 61) and plans to issue standards to cover low-level wastes (40 CFR Part 193).

Fissioning of nuclear fuel in nuclear reactors creates what is known as "spent" or irradiated nuclear fuel. Sources of spent nuclear fuel include 1) fuel discharged from commercial nuclear power plants; 2) fuel elements generated by government-sponsored R&D programs, universities and industry; 3) fuels from experimental reactors [e.g., liquid metal fast breeder reactors and high-temperature gas-cooled reactors]; 4) U.S. Government-controlled nuclear weapons production reactors; and 5) naval reactor fuels and other U.S. Department of Defense (DOD) reactor fuels. Most spent fuel is currently being stored in water pools at reactor sites where it is produced.

Spent nuclear fuel from defense reactors is routinely reprocessed to recover unfissioned uranium and plutonium for use in weapons programs. 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. Only one commercial spent fuel reprocessing facility--the Nuclear Fuel Services Plant in West Valley, New York--ever operated in the United States and it was closed in 1972. No commercial spent fuel is being reprocessed in the United States at this time. High-level wastes derived from reprocessing activities are presently stored on Federal reservations in South Carolina, Idaho, and Washington and at the Nuclear Fuel Services Plant in New York.

Transuranic wastes, as defined in this rule, are materials containing elements having atomic numbers greater than 92 in concentrations greater than 100 nanocuries of alpha-emitting transuranic isotopes, with half-lives greater than twenty years, per gram of waste. Most transuranic wastes are items that have become contaminated as a result of activities associated with the production of nuclear weapons (e.g. rags, equipment, tools, and contaminated organic and inorganic sludges). These wastes are currently being stored on Federal reservations in Washington, Idaho, New Mexico, Tennessee, South Carolina, Nevada and Colorado.

The Federal government is responsible for disposing of spent fuel, high-level and transuranic radioactive wastes. The DOE is the Federal agency with lead responsibility for carrying out radioactive waste management programs. The principal activities of DOE and its predecessor agencies (the Atomic Energy Commission and the Energy Research and Development Administration) have been directed toward the siting and construction of geologic repositories for waste disposal and surface facilities for waste storage.

The NRC is responsible for licensing spent fuel storage and disposal facilities for waste from commercial activities. NRC has developed requirements and procedures for licensing such facilities in 10 CFR Parts 72 and 60.

Under authority derived from the Atomic Energy Act, Reorganization Plan No. 3 of 1970, and the Nuclear Waste Policy Act of 1982, the EPA is responsible for developing generally applicable environmental standards to govern the management, storage and disposal of radioactive wastes. Once promulgated, these standards will apply to both DOE and NRC-licensed facilities. NRC will ultimately incorporate these standards into their licensing regulations.

Proper management and disposal of spent nuclear fuel, high-level and transuranic radioactive wastes are essential because of the inherent hazard of the radioactivity they contain and the length of time they remain hazardous. The objective of these proposed standards is to provide a regulatory framework for limiting the risks caused by these waste materials to both present and future generations.

National Programs for Disposal of Radioactive Waste

In 1981, the DOE, after completing a comprehensive programmatic environmental impact statement, adopted a national strategy to develop mined geologic repositories for disposal of commercially generated radioactive waste (46 FR 26677). Repositories would be constructed in suitable host media at depths greater than 300 meters by conventional mining techniques. Wastes in canisters would be placed into holes in the mine floor or walls. When the repository is full, the holes and shafts would be backfilled and sealed. Radionuclide releases would be mitigated by a stable and insoluble waste form, a durable canister, a stable host medium, and low migration potential for radionuclides through the environment around the host media.

In 1982, Congress passed the Nuclear Waste Policy Act (the "Act") which affirmed the DOE's 1981 decision that mined repositories should receive primary emphasis in the national program, while allowing research on other technologies to continue. Among other things, the Act: 1) established formal procedures regarding the evaluation and selection of sites for geologic repositories; 2) established procedures for interacting with affected States and Indian tribes regarding site selection decisions; 3) provided a source of funds for the program by establishing a Nuclear Waste Fund financed by a fee on nuclear-generated electricity; 4) reiterated the existing responsibilities of the Federal agencies involved in the National program to develop mined geologic repositories, and assigned some additional tasks regarding site evaluation; 5) provided a target timetable for achieving several key programmatic milestones, and; 6) required the President to evaluate the feasibility of disposing of defense high-level waste in commercial waste repositories. Section 121 of the Act reiterated the EPA's responsibility for developing the overall framework of requirements and standards needed to assure protection of public health and the environment from nuclear waste disposal, in accordance with its authorities under the Atomic Energy Act of 1954 and Reorganization Plan No.3 of 1970. In February 1983, the DOE formally identified nine potentially acceptable sites for the first repository in the states of Washington, Nevada, Texas, Utah, Louisiana, and Mississippi. In December 1984, three of these (Yucca Mountain, Nevada; Deaf Smith, Texas; and Hanford, Washington) were recommended as tentative choices for further site investigations or "characterization". In April 1985, President Reagan directed DOE to dispose of defense high-level waste together with commercial power plant spent fuel and high-level waste, in civilian repositories.

In January 1986, DOE identified twelve potentially acceptable sites for a second repository in the states of Georgia, Maine, Minnesota, New Hampshire, North Carolina, Virginia, and Wisconsin. Four months later, the Department announced it was going to focus its efforts instead on investigating repository sites in Washington, Nevada, and Texas and defer any further investigation of second repository sites.

In 1987, Congress passed the Nuclear Waste Policy Amendments Act of 1987 (the "Amendments Act"). The Amendments Act significantly changed the scope of the high-level waste disposal program by directing DOE to investigate only the site at Yucca Mountain, Nevada for its suitability as a repository and to terminate investigations at all other potential first and second repository sites. It also authorized the development of a Monitored Retrievable Storage facility for interim storage of spent nuclear fuel. The 1987 Amendments Act did not change EPA's responsibility for developing standards.

Defense Transuranic Radioactive Waste

The DOE is developing the Waste Isolation Pilot Plant (WIPP) near Carlsbad in southeastern New Mexico as a deep geologic repository for disposal of retrievably stored and newly generated transuranic (TRU) radioactive waste from various DOE defense programs. Congress authorized DOE to build the WIPP in 1979 (Public Law 96-164). The repository has been excavated from a bedded salt formation 2150 feet underground.

Although DOE has conducted extensive studies of the WIPP site and the repository's expected performance, uncertainties remain. For example, concerns have been raised over the possibility that gas generated underground at the WIPP will, over the long term, build up to unacceptable pressures, leading to possible releases of radioactivity from the repository. To address this and other questions, DOE plans to initiate a Test Phase at the WIPP. This period will involve in-situ tests with TRU wastes, as well as other investigations. Under DOE's current plans, the in-situ tests will initially involve wastes amounting to a small percentage of the total repository capacity. DOE expects to gather information from these tests that will be used to assess compliance with 40 CFR 191 and other applicable regulatory requirements as well as identify any engineering modifications that may be necessary to comply with these standards. If the WIPP site is eventually determined to be suitable for disposal of TRU wastes, the underground disposal area of the WIPP will cover 100 acres, with a total design capacity of 6.45 million cubic feet (or approximately 850,000 barrels of waste). To date, 15 acres of underground disposal rooms have been mined.

DOE is also investigating the near surface disposal of classified TRU waste from nuclear weapons programs. In 1981, a greater confinement disposal (GCD) test program was initiated at the Nevada Test Site (NTS) to demonstrate the disposal of high-specific-activity low-level radioactive waste. The GCD technique involves emplacement of waste packages in deep boreholes at the NTS. The boreholes are 10 feet in diameter and 120 feet deep. After waste emplacement, the boreholes are backfilled with about 70 feet of earth overburden. Approximately 5,600 cubic feet of transuranic waste has been emplaced at the site.

History of Proposed Action

In December 1976, the Agency announced its intent to develop Federal guidance for the management and disposal of radioactive waste to assure protection of the public health and the general environment. Among EPA's first activities in developing guidance was a series of public workshops conducted in 1977 and 1978 in order to gain a better understanding of public concerns and issues associated with radioactive waste disposal.

In November 1978, the EPA proposed "Criteria for Radioactive Wastes." In March 1981, however, EPA withdrew the proposed criteria because the many different types of radioactive wastes made the issuance of generic disposal guidance impractical.

Regulatory development efforts continued, and on December 29, 1982, EPA published a proposed rule titled "40 CFR Part 191, Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes" (47 FR 58196).

In parallel with the public review and comment on the proposed rule, the Agency conducted an independent review of the technical basis of the proposed 40 CFR 191 standards through an ad hoc committee of the Agency's Science Advisory Board (SAB). The SAB transmitted its final report to the Administrator in February 1984. Although the SAB review found that the Agency's analyses in support of the proposed standards were comprehensive and scientifically competent, the report contained several findings and recommendations for improvement. The public was notified of the availability of this report and encouraged to comment on its findings and recommendations (49 FR 19604). On September 19, 1985, the final 40 CFR 191 was published in the **Federal Register** (50 FR 38066).

In March 1986, several petitions for review were filed by a number of States and environmental groups. They were consolidated in the U.S. Court of Appeals for the First Circuit in Boston. The court issued its ruling on July 17, 1987 (NRDC v. EPA, 824 F. 2nd 1258; 1st Cir. July 1987). In general, the court:

1. remanded the Individual and Ground Water Protection Requirements (Sections 191.15 and 16) for further consideration of their inter-relationship with Part C of the Safe Drinking Water Act and for further explanation of the 1,000-year time frame for the requirements;

2. remanded the Ground-Water Protection Requirements (Section 191.16) for further notice and comment; and

3. remanded the entirety of 40 CFR 191 even though all but two sections were either unchallenged or upheld.

The ruling was appealed by the Department of Justice which asked for reinstatement of all sections except 191.15 and 191.16. In September 1987, the court reinstated Subpart A but left the entirety of Subpart B in remand.

The next step in the evolution of 40 CFR 191 is occurring today: the proposal of revised standards and guidance for implementation.

Objective and Implementation of the Standards

This regulation limits exposures of members of the public to radiation and radionuclide releases from the management, storage and disposal of spent nuclear fuel, high-level and transuranic radioactive wastes and any other radioactive material managed or disposed with these wastes.

The Agency developed the various elements of this proposed rule and selected the level of acceptable risk which underlies it by balancing several considerations. First, the Agency considered the expected capabilities of waste management and disposal technologies. Expected risks to public health and the environment were examined through a number of generic performance assessments of the potential waste facilities. A second consideration, where applicable, was consistency with other related Agency 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 public comments and concerns expressed throughout the various phases of this rulemaking. Today's proposed rule reflects a combination of all these considerations.

The NRC and the DOE are responsible for implementing these standards. The NRC has promulgated procedural and technical requirements in 10 CFR Part 72 for storage and in 10 CFR Part 60 for disposal of high-level wastes in mined geologic repositories (46 FR 13971, 48 FR 28194). The NRC will ascertain compliance with 40 CFR 191 before issuing licenses to the DOE, in accordance with 10 CFR Parts 72 and 60, at various phases in the construction and operation of such facilities. Under current law, DOE is solely responsible for determining compliance with the standards at defense waste management and disposal facilities not licensed by the NRC. Both the NRC and the DOE will review their regulations to determine what specific changes are needed to properly implement the final version of 40 CFR 191.

Description of Proposed Action

This proposed rule differs in a number of respects from the final rule published in the **Federal Register** on September 19, 1985. This section describes major provisions and changes being proposed in this rulemaking.

Definitions (Section 191.01)

Definitions from Subparts A, B and C are consolidated in alphabetical order into one section appearing at the beginning of the proposed rule. The only significant change to this section from the 1985 standard is in the definition of "radioactive waste."

The Agency proposes to define the term "radioactive waste" to include any radioactive materials, regulated under Atomic Energy Act authorities, that might be managed and/or disposed with spent fuel, high-level or transuranic radioactive wastes. There may arise circumstances where the implementing agency determines it is appropriate that materials not presently classified as spent nuclear fuel, high-level, or transuranic wastes, as considered by this rule, be managed or disposed with these wastes. For instance, the NRC recently issued a final rule requiring disposal of "greater-than-Class C" low-level radioactive wastes in a deep geologic repository unless disposal elsewhere has been approved by the Commission (54 FR 22578). "Greater-than-Class C" wastes are wastes which exceed certain radionuclide concentrations specified by the NRC (10 CFR 61). The Agency's proposed change would ensure that radiation exposures to members of the public from "greater-than Class C" or any other radioactive materials commingled with spent nuclear fuel, high-level and/or transuranic radioactive wastes would be covered by this Part.

Standards for Management and Storage (Subpart A)

Subpart A applies to management of radioactive waste and includes storage, preparation of the wastes for disposal and emplacement in a disposal system. Subpart A does not cover the transportation of these materials. Waste management and storage facilities regulated by the NRC (for example, monitored retrievable storage facilities) would be covered by this Subpart. Waste management and storage facilities operated by the DOE at disposal sites are also covered by this Subpart.

In 1985, EPA evaluated the expected performance of the technologies planned for the management, storage, and preparation of these wastes for disposal. The Agency found that likely exposures and associated risks to members of the public would be small.

Subpart A of the 1985 standard limited annual doses to members of the public to 25 millirems to the whole body, 75 millirems to the thyroid, or 25 millirems to any other organ from exposures associated with management, storage and preparation for disposal of any of these materials at facilities regulated by the NRC. These limits applied to the combined exposures from all NRC-licensed facilities covered by this Part and 40 CFR Part 190, the Agency's standards for the commercial uranium fuel cycle. The combined exposures to an individual from all of the NRC-licensed facilities covered under Part 190 and Subpart A of Part 191 could not exceed these limits. Subpart A of the 1985 standards also limited annual doses to members of the public from management and storage operations at DOE disposal facilities not regulated by the NRC to an annual 25 millirems to the whole body or an annual 75 millirems to any other organ.

Although Subpart A was reinstated by the Court, today's proposal:

Changes Subpart A from a predictive standard to an operational standard

Subpart A of the 1985 standard was written as a design standard. It required the implementing agency to conduct waste management and storage operations in such a manner "as to provide reasonable assurance" that specified doses will not be exceeded. The Agency's proposed revision converts Subpart A to an operational standard. That is, in any given year of waste management operations, doses to members of the public cannot exceed 25 millirems committed effective dose. An operational standard of this sort is appropriate in the case of waste management and storage activities which are only expected to occur over short time frames--not the thousands of years associated with disposal. Monitoring and remedial actions are clearly possible over these short time frames.

Adopts the effective dose methodology

Since 1985, when EPA first issued dose standards for radioactive waste disposal systems, a different methodology for calculating dose has come into widespread use, the committed effective dose (CED). In 1987, EPA, in recommending to the President new standards for all workers exposed to radiation, accepted this methodology for the regulation of doses from radiation. The methodology was originally developed by the International Commission on Radiological Protection (ICRP). In the past, EPA dose standards were specified in terms of limits on specific organ doses and the "whole body dose," a methodology which is no longer in keeping with current practices of radiation protection.

The CED is simple, is more closely related to risk, and is recommended by the leading national and international advisory bodies. By changing to this new methodology, EPA will be converting to the internationally accepted method for calculating dose and estimating risk.

The CED is the risk weighted sum of the doses to the individual organs of the body. The dose to each organ is weighted according to the risk that that dose represents. These weighted organ doses are then added together and that total is the committed effective dose. In this manner, the risk of radiation exposure to various parts of the body can be controlled by a single numerical standard. The weighting factors for the individual organs are listed in Appendix A. EPA risk assessment models used for standards development and impact assessment differ from those underlying the ICRP recommendations. This is primarily due to advances in the field of radiation risk estimation since the ICRP recommendations were published. As a result, the estimates of risks calculated by EPA are not strictly proportional to the CED derived using ICRP quality factors and organ weighting factors. A discussion of the basis for the EPA factors is included in the Background Information Document prepared in support of this standard.

For purposes of demonstrating compliance with Subpart A, doses currently calculated under 40 CFR 190 shall be converted to committed effective dose so that exposures can be added. (In making CED calculations, implementing agencies should consult Appendix B.)

Proposes an annual 25 millirem CED exposure limit

Today's proposal would limit the annual committed effective dose from the intake of all radionuclides in a given year plus the effective dose from any external exposure to 25 millirems. This represents a maximum lifetime risk of premature fatal cancer to a member of the public in the general environment of about 7×10^{-4} (seven in ten thousand)--a slightly higher risk level than the 1985 standard. This is in part due to slightly higher risk estimates associated with 25 millirem exposures. (In 1985, a 25 millirem exposure was believed to represent a 5×10^{-4} chance of incurring a fatal cancer.) However, the actual maximum individual risk is the same as would have been possible under the 1985 standards. Because of the use of the committed effective dose methodology, exposures to some individual organs could be higher than what the 1985 standard allowed. Also, the Agency has chosen this exposure level because it is consistent with what is possible under the Agency's newly-proposed drinking water standards for radionuclides. (See Federal Register Vol. 56, No.138 July 18, 1991.) This is due to the possible CED if there is a co-occurrence of nuclides in drinking water for which separate maximum contaminant levels are listed.

Specifies the need to comply with the requirements of other applicable Federal regulations

The Agency proposes to add a new subsection which would clarify that exposures from management and storage of radioactive waste shall be in keeping with any other applicable Federal regulations and not just the requirements of 40 CFR 190. For instance, exposures resulting from air emissions shall not exceed any of the applicable limits found in 40 CFR 61--EPA's National Emission Standards for Hazardous Air Pollutants (NESHAPs) for Radionuclides.

Standards for Disposal (Subparts B and C)

Environmental protection standards for the disposal of radioactive waste require far different considerations than those for management and storage. For example:

1. The intent of disposal is to isolate the wastes from the environment for a longer time than any period over which active controls, such as monitoring the disposal site to detect releases of radionuclides, can be relied upon for protection.

2. Disposal systems will be designed so that, if the system performs as intended, radionuclide releases to the environment will be minimized. Thus, the principal concern is the possibility of accidental releases, either due to unintended events or due to failure of parts of the disposal system to perform as expected.

These considerations have several ramifications for developing environmental protection standards. First, the requirements we establish can only be implemented by NRC and DOE in the design phase--by setting design principles or by analytically projecting disposal system performance. The more familiar concepts of implementation involving monitoring of emissions or ambient levels of pollutants are not sufficient because such surveillance cannot be relied upon for the long periods involved.

Second, the standards must address releases caused by disruptive events such as those resulting from human intrusion or geologic faulting.

Third, the standards must accommodate large uncertainties. These include uncertainties in our current knowledge about disposal system performance and the uncertainties inherent in trying to predict the distant future.

Our proposed disposal standards address these issues by combining several different types of requirements. The primary standards are containment requirements that limit expected and accidental releases of radioactivity to the accessible environment and the associated risks to populations. Equally important is a set of assurance requirements chosen to provide additional confidence that the containment requirements will be met. In addition, annual exposures to individuals and radioactive contamination of ground water in the vicinity of the disposal facility are limited.

Although developed primarily through consideration of mined geologic repositories, these disposal standards apply to disposal of radioactive waste by any method--with one exception. The standards do not apply to ocean disposal or disposal in ocean sediments. Such disposal of high-level waste is prohibited by the Marine Protection, Research and Sanctuaries Act of 1972. If the law is ever changed to allow such disposal, the Agency will develop appropriate regulations for it.

Also these disposal standards do not apply to wastes that have already been disposed of. The various provisions of Subparts B and C are intended to be met through a combination of steps involving disposal system site selection, design, and operational techniques (i.e., engineered barriers). As a result, a vital part of implementation will be the use of adequate models, including the probabilities of disruptive events, to relate appropriate site and engineering data to projected performance. Therefore, the Agency believes it is appropriate that these disposal standards only apply to disposal occurring since the standards were originally promulgated--i.e., August 15, 1985--so that they can be taken into consideration in devising the proper selection of controls.

The major provisions of proposed Subparts B and C are as follows:

Containment Requirements (Section 191.12)

The containment requirements in today's proposal are designed to limit the total projected release of specific radionuclides over a 10,000-year period after disposal. 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. This overall level of residual risk to future generations is 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 lower because of the complementary protections afforded by the other provisions of Subparts B and C and because carefully selected and designed disposal systems may perform better than the generic repositories upon which this risk level is based.

The proposed containment requirements in Section 191.12 were derived with the assistance of performance assessments of long-term repository performance. We based our performance assessments on relatively simple models of generic repositories and the data that was available for such models. Where information was uncertain, we made conservative assumptions that should tend to overestimate the long-term risks of disposal. We do not intend that the implementing agencies should use all of the same models, data, and assumptions that we did in making performance assessments. Instead, the implementing agencies generally should use the best information available for each particular site.

To develop the long-term containment requirements, we assumed that we can predict some aspects of the future well enough to use the predictions for comparing and selecting disposal methods. Thus, we evaluated ways that radionuclides might be released from a generic mined geologic repository, developed analytical models to predict potential releases and their distribution throughout the ecosystem over 10,000 years, and estimated the possible risks that could result from these releases if they occurred in an environment similar to today's.

In our assessments of geologic disposal, we identified expected and accidental scenarios which could result in releases of radioactivity from a generic model of a repository. Our model repository contained 100,000 metric tons of heavy metal (MTHM) of spent reactor fuel, about as much as would be generated during the operating lifetimes of 100 nuclear reactors.

In developing the proposed containment requirements, we considered the overall protection which should be achievable by the combination of barriers in a geologic repository. We examined the capabilities of waste canisters, waste chemical forms, repository designs, and geologic media to prevent or delay the release of radionuclides. We selected reasonably achievable characteristics for each portion of the disposal system. Analyses used by the implementing agencies to evaluate compliance with our requirements should consider realistic assessments of the protection provided by all of the engineered and natural barriers of a disposal system. For example, performance assessments of a geologic repository system should include the protection afforded by geochemical retardation of radionuclides in ground water, provided that reasonable evidence is developed to support such mechanisms for that particular site.

For accidental releases, we estimated the probabilities of events leading to releases including inadvertent and intermittent intrusion events by exploratory drilling for resources. Intentional disruption or sabotage of the disposal system was not considered.

Radionuclides were considered to be released from the disposal system if they reached the "accessible environment," which includes surface waters, land surfaces, the atmosphere, the oceans and all of the lithosphere beyond the controlled area including any ground water contained within it. It does not include the lithosphere (and the ground water within it) that is below the "controlled area" surrounding a disposal system. 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 other uses. Applying standards to ground water in the immediate vicinity of the site would ignore the role of this natural barrier and could remove the incentive to search for sites with properties that would enhance long-term containment of these wastes.

The "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 if appropriate.

Our regulations and the assessments on which we base them cover releases of radionuclides to the accessible environment for a period of 10,000 years after disposal. We believe that a disposal system capable of meeting these requirements for 10,000 years will continue to protect people and the environment beyond 10,000 years. We selected 10,000 years as the assessment period for three primary reasons:

1. It is long enough for releases through ground water from poorly selected and designed facilities to reach the accessible environment. If we had selected a shorter time, such as 1,000 years, our estimates of long-term risks in the accessible environment could be deceptively low, because radionuclide releases may not occur at any sites within 1,000 years. Choosing 10,000 years for assessment encourages selection of sites where the geochemical properties of the geologic formations can significantly impede and reduce releases of radioactivity.

2. Major geologic changes, such as development of a faulting system or a volcanic region, take much longer than 10,000 years. Thus, the likelihood and characteristics of geologic events which might disrupt the disposal system are reasonably predictable over this period.

3. Compliance with quantitative standards for a substantially longer period would entail considerably more uncertain calculations. This is not to say that times beyond 10,000 years are not important, but the Agency feels 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.

We estimated radionuclide releases that could reach the accessible environment over this period under various circumstances. We used our estimates of releases and their likelihoods to select limits on total releases of radionuclides over 10,000 years. Limits were set for two categories of releases in terms of their probabilities--releases caused by likely disruptions of a disposal system and releases by more unlikely disruptions.

Our assessments of repository performance gave estimates of the possible health effects expected from releases after disposal. These estimates can vary considerably depending upon the assumptions used and the geologic media considered. For the various generic repository types, these assessments indicate that disposal of radioactive 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.

According to our models, at well-chosen repository sites more of the projected risk from releases is due to possible human intrusions than from releases by geologic processes--if we make the assumption that passive institutional controls have no effect in deterring or limiting inadvertent human intrusion for more than 100 years after disposal. Predicting human actions (such as drilling for resources) is much more uncertain than predicting natural events.

The Agency also evaluated other sources of radiation risks to present and future generations. We looked at the radiation risks from natural background radiation, from commercial nuclear power generation and from fallout from previous atmospheric testing of nuclear weapons. The Agency also evaluated the health risks that future generations may face 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 natural variability of the formations and the analytical assumptions made. This is not to suggest that manmade sources present acceptable risks simply by posing less of a risk than natural sources but to provide a basis for comparison.

Implementation

Compliance with the containment requirements will be achieved if the projected releases from a disposal system do not exceed the release limits found in Table 1.

The release limits were 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 ensures that the desired risk level will not be exceeded if releases of more than one 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. For example, this is the case for transuranic waste and for high-level wastes from reactor fuels which have received substantially different uses in national defense applications (and contain a much different inventory of radioactivity) than is typical of most reactor fuel used to generate electricity.

For a particular disposal system, the release limits and corresponding health impact of the containment requirements depend upon the amount of waste in that disposal system measured in terms of the units of waste defined in Note 1 to Table 1. For example, the unit of waste for spent nuclear fuel is 1,000 metric tons of heavy metal (MTHM). If, for instance, a disposal system is ultimately used to dispose of 70,000 MTHM, the release limits for the facility would be the limits of Table 1 times seventy (70,000 MTHM divided by 1,000 MTHM).

Compliance with the containment requirements found in this proposed rule is established in two steps.

First, the release limits are calculated in accordance with Notes 1 through 6 to Table 1 and compared to those releases that are projected to occur with a cumulative probability greater than 0.1 (1 chance in 10) during the 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 acute disruptions.

Second, these release limits are multiplied by ten and applied to all of the releases projected to occur with a cumulative probability greater than 0.001 (1 chance in 1000) over the 10,000-year period. This probability level was selected because of the anticipated uncertainties in predicting the likelihood of these natural phenomena. Greater releases are allowed for events of this likelihood because they are so unlikely to occur. The Agency expects that this will include releases that might occur from natural disruptive events, such as fault movement.

The proposed 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 volcanoes outside of known areas of volcanic activity or the impact of a large meteorite occurring when the disposal system still contained a significant inventory of undecayed radionuclides. The Agency believes there is no benefit to public health or the environment from trying to regulate the consequences of such very unlikely events.

Finally, the Agency has added new language to the 1985 standards that requires an evaluation of potential releases from disposal systems to be projected over a 100,000-year time span after disposal. The Agency believes it is important, in selecting and designing disposal systems, to do a longer-term assessment of the systems' potential strengths and weaknesses.

The containment requirements call for a "reasonable expectation" that their various quantitative tests will be met. This phrase reflects the fact that unequivocal numerical proof of compliance is neither necessary nor likely to be obtained. Because they address such a long time period and because they include unplanned releases, the containment requirements can be implemented only through analytical projections of disposal system performance. There will be many uncertainties in making such long-term performance projections. Accordingly, our proposed standards require a "reasonable expectation" that these containment requirements will be met. 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 §191.12. The long-term performance of a given disposal system cannot be determined to the degree of precision possible for the man-made components of a nuclear power plant. 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.

Proposed Alternative Configurations of the Containment Requirements

The containment requirements found in this proposal and in the 1985 40 CFR 191 standards apply to two categories of potential cumulative releases based upon their projected probabilities of occurrence over the first 10,000 years after disposal. Some commenters have suggested that this configuration does not allow adequate flexibility to handle specific uncertainties that may be encountered in the development of disposal systems. In an attempt to respond to this concern, the Agency is proposing two alternative configurations of the containment requirements for comment.

Alternative 1: NRC Staff Proposal

The 1985 standards required implementing agencies to estimate both the probabilities and the sizes of all potential releases with likelihoods greater than one chance in ten over 10,000 years and with likelihoods greater than one chance in one thousand over 10,000 years. NRC staff have expressed concerns about the workability of this approach because it requires precise numerical probability estimates for unlikely processes and events. They have suggested alternative wording for the containment requirements which they claim would ease potential implementation problems without sacrificing the overall level of safety that the containment requirements represent.

The alternative formulation of the containment requirements found in today's proposal retains the 1985 formulation for relatively likely releases, i.e., those events with probabilities of one chance in ten or greater over 10,000 years. For such releases, a comprehensive analysis of both the probabilities and the consequences of all scenarios (viz., both natural and human-initiated processes, events or sequences of processes and events) contributing to releases would be required. However, for less likely releases, probability estimates for scenarios leading to such releases would only need to demonstrate that the scenarios have a likelihood between one chance in ten and one chance in 10,000 over 10,000 years. Precise numerical probability estimates for individual scenarios would not be required.

not NRC proposal

The Agency believes this alternative formulation of the containment requirements, while more flexible in its implementation, still maintains the protectiveness of the 1985 formulation. Likely releases would be limited to the same table of release limits as in the 1985 standards, and unlikely releases would be limited to ten times the table values. The proposed reformulation of the containment requirements refers to "releases resulting from any process, event or sequence of processes and events." The phrase "sequence of processes and events" include any combination of processes and/or events that would constitute a release scenario (e.g., climate change followed by fault movement). The release caused by any scenario with a probability of greater than one chance in ten thousand but less than one chance in ten would be limited to ten times the Table 1 values. Precise probability estimates for individual scenarios would no longer by required.

not NRC's version!

Commenters on this NRC staff proposal are particularly requested to discuss their views on the impacts of this approach upon the stringency of the standard.

Alternative 2: Use of Collective Effective Dose Limits vs. Release Limits

In developing the 1985 Containment Requirements, the Agency considered a number of possible formats for limiting risks to population groups. Standards expressed in terms of total integrated radionuclide releases (curies) to the accessible environment over 10,000 years after disposal was the format we ultimately selected. Release limits are a surrogate for limits on health effects or population doses. We selected this format because we believed standards expressed in these terms would be easiest to implement since they only require estimation of the quantities of radionclides entering the "accessible environment." We rejected the idea of standards expressed in terms of limits on health effects or doses to populations (person-rems) because we felt they would likely be more difficult to implement in that they require assumptions on such things as the exact relationship between dose and health effects, knowledge of future populations and demography at a site, and details of environmental pathways and related transport factors.

The 1985 release limits, which were stated in terms of the allowable release from 1,000 metric tons of reactor fuel, were developed by estimating how many curies of each radionuclide would cause 10 premature deaths over 10,000 years if released to the environment. For these calculations, we used very general models of environmental transport and a linear, non-threshold, dose-effect relationship between exposure and premature deaths from cancer. This relationship assumes that the number of cancers induced in a population is proportional to the total dose received by the population, even at very low individual doses. At the low levels of exposure that might be associated with releases from a mined geologic repository, actual health effects may be lower than those calculated by this relationship, and certainly would not be detectable since they would be indistinguishable from the much larger number of cancers occurring in the population due to other causes (including natural background radiation). However, the Agency believes that health impact estimates using a linear, non-threshold relationship is a prudent approach to developing radiation protection requirements.

Since the Agency's analyses showed that releases to surface water through ground water are usually the most important release mode for mined repositories, and since the health effects per curie released are usually the highest for this release mode, the Table 1 limits were based on the surface water release mode and route of exposure to individuals.

Some commenters argue that the surface water pathway is not in all cases, the appropriate pathway. They argue that at some potential disposal sites there is no surface water and point to the Yucca Mountain site in Nevada as a case in point.

To accommodate site-specific circumstances which differ from the assumed circumstances underlying 40 CFR 191's Table 1 limits, today's proposal gives implementing agencies the choice of either determining compliance with the release limits of Table 1 or with limits expressed in terms of population dose equivalents. New language has been added which states that disposal systems shall be designed to provide a reasonable expectation that the collective effective dose shall have a likelihood of less than one chance in ten of exceeding 2.5 million person-rem (25,000 person-sieverts) over 10,000 years and a likelihood of less than one chance in one thousand of exceeding 25 million person-rem (250,000 person-sieverts) over 10,000 years. These limits represent 1000 and 10,000 premature fatal cancers, respectively--the level of protection represented by the Table 1 release limits.

Associated with the collective dose limits found in today's proposal are specific prohibitions against the truncation of doses in adding up the collective dose or the size of the populations to be considered.

Commenters should focus their comments on the advantages and/or disadvantages of this collective dose alternative in terms of implementation and protectiveness. Any suggestions for additional methodological or calculational guidance would also be appreciated.

Level of Protection

The containment requirements and release limits found in the 1985 standards and this proposal are based on desired risk goal of no more than 1,000 fatal cancers over 10,000 years from disposal of 100,000 MTHM.

In arriving at the appropriate level of protection, the Agency first assessed the performance of a number of model geologic repositories. 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 a hundred premature deaths over the entire 10,000-year period.

Then, in order to gain a perspective on how the risks associated with unmined uranium ore compare to the risks associated with a high-level radioactive waste repository, the Agency evaluated the health risks that future generations would be exposed to from the amount of unmined uranium ore needed to produce 100,000 metric tons of reactor fuel.

Using the same generalized environmental pathway models that were used to assess the risks from geologic repositories, we found that the risks from the amount of unmined uranium ore needed to produce 100,000 metric tons of spent fuel range from a few hundred to more than one million health effects over 10,000 years. (The wide range is due, in part, to the wide variety of settings in which uranium ore is found.) These assessments, like the geologic repository assessments, were subsequently updated in response to recommendations from the SAB Subcommittee and the revised assessments showed risks ranging from a minimum of 10 and a maximum of 100,000 excess fatal cancers over 10,000 years.

Risks at the lower end of both the original and updated assessments are roughly comparable to the residual risk associated with the 40 CFR 191 release limits. The upper limit of the risk that these proposed standards allow appears to pose a risk very similar to the risk posed by nature had the uranium ore never been mined and the high-level wastes never been generated. Thus, these analyses reinforced the Agency's conclusion that limiting radionuclide releases to a level associated with no more than 1,000 premature cancer deaths over 10,000 years from disposal of 100,000 metric tons of reactor fuel was appropriate. Had we chosen to develop a strictly technology-based standard, the risk objective underlying it would likely have been close to an order of magnitude more protective.

Although the Agency believes it struck an appropriate balance in choosing the level of protection for the containment requirements, some still argue that the standards are unduly stringent. We believe this view may be based, to a certain extent, on inappropriate comparisions to standards which are aimed at limiting risks to individuals over the short-term.

Some assessments of the stringency of the containment requirements have assumed that the radionuclide releases permitted by the 40 CFR 191 would be evenly distributed over the 10,000 years. Under these circumstances, doses to individuals would likely be small--much smaller than what most radiation standards allow.

Although evenly distributed releases from radioactive waste disposal systems are not outside the realm of possibility, one should not ignore the fact that at some sites releases will occur as a result of disruptive events. Doses to individuals, under these circumstances, will likely be high--well in excess of what most radiation standards allow.

Most of today's radiation protection programs and standards are designed to mitigate the hazards associated with nuclear operations where releases to the environment or radiation doses can be controlled in order to limit the risks to individuals in the present generation. In general, radionuclide releases from these operations can be measured as they occur and, if necessary, action can be taken to prevent, control and remediate such releases. These operations are very different from the nuclear activity at issue in this rulemaking--that is, long-term disposal of radioactive waste.

The containment requirements in this proposal are intended to serve two basic purposes: 1) provide a measure of disposal system integrity to help guide the siting and design of such systems; and 2) assure that the collective exposure to future populations is limited. Collective exposure is the summed product of all the expected individual exposures.

Human Intrusion

Compliance with the containment requirements found in today's proposal is determined by evaluating the degree to which various processes and events affecting the performance of a disposal system are likely to lead to radionuclide releases. Such evaluations are to include analyses of the effects of both natural processes and events (e.g., faulting, ground-water flow) as well as the effects of human-initiated events (e.g., inadvertent human intrusion.

The Agency's generic repository analyses indicate that one of the most important causes of radionuclide releases appears to be human intrusion resulting from the exploration for resources. Our analyses show a single intrusion could cause about 50 to 100 excess cancer deaths over 10,000 years.

The possibility of inadvertent human intrusion into or near a repository requires special attention. Such intrusion can significantly disrupt the containment afforded by a geologic repository 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 on a site-by-site basis. It will not be possible to develop a generic or "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 C describes the considerations 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 and justify ones of their own. However, the Agency does not believe that institutional controls can be relied upon to completely eliminate the possibility of inadvertent intrusion because there is always a chance the controls will be overlooked or misunderstood.

We considered setting separate containment requirements that would limit the radioactivity that could be released by any one likely human intrusion, in order to avoid having to estimate such frequencies. However, we did not do this because: (1) setting separate requirements for natural and human events would not place an upper limit on risk; and (2) setting separate requirements for individual intrusions in addition to the total combined requirements would not appreciably increase confidence that the overall requirements would be met unless we made limits on individual intrusions unreasonably low.

Assurance Requirements (Section 191.13)

Closely associated with our numerical containment requirements are a set of qualitative requirements we believe are essential for developing the needed confidence that our long-term release limits will be met. These assurance requirements address and compensate for the uncertainties that necessarily accompany plans to isolate these dangerous wastes from the environment for a very long time. No matter how promising the analytical projections of disposal system performance appear to be, radioactive wastes should be disposed of 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 following proposed assurance requirements are important complements to the containment requirements and should help ensure that the level of protection desired is likely to be achieved:

(i) Disposal systems shall not rely upon active institutional controls to isolate the wastes beyond a hundred years after disposal of the wastes. Although active institutional controls, such as guarding and maintaining a disposal site, should be encouraged, in calculating potential disposal site releases implementing agencies shall not assume they will exist as controls beyond 100 years after disposal. (Credit for active institutional controls should be taken only for the period of control that is committed to.)

This requirement does not mean we think society will lose all knowledge of radioactivity, nuclear energy, radioactive wastes, or even specific disposal sites after a hundred years. On the contrary, we believe that such information is likely to survive, even without the extensive markers and records called for by another of our assurance requirements. However, merely having this knowledge does not guarantee that it will be widely disseminated or effectively acted upon. We believe it is prudent to assume that society may not retain active controls over disposal systems for very long, and that unrelated activities may resume at a disposal site even though the presence of radioactive waste is documented.

In today's society there are numerous examples of the failure to maintain waste facilities over the decades. It is expected that repositories for nuclear waste will receive special attention but there is no basis to expect that active human controls will be reliable beyond 100 years.

(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. The proposed requirement stipulates against using monitoring techniques which could create escape pathways for the radionuclides.

(iii) 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 shall reduce the consequences of possible mistakes in selection, design, or construction by using several different types of engineered and natural barriers against release of the wastes, and by taking full advantage of the protection each has to offer. With this redundancy, the unexpected failure of one or more barriers will be compensated for by other barriers. Different kinds of engineered barriers may be appropriate, depending upon the type of waste involved. They could include canisters, the physical and chemical forms of the waste itself, waste package overpacks, or other structures within the disposal system that will prevent or substantially delay release of the waste to the environment.

(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 more readily available from other sources.

(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. The various isolation requirements of these standards would make recovery after disposal very difficult, expensive and probably dangerous. Nevertheless, because some of our scientific understanding may prove to be wrong in a way that would produce much greater risks than we expect, future generations should be able to recover the wastes if they deem it necessary. An important implication of this requirement is that the physical location of most of the wastes must be reasonably predictable after disposal. Current plans for mined geologic disposal would likely meet this requirement. However, some possible disposal methods, such as deep well injection of liquid wastes or rock melting concepts, may not.

Each of the proposed 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 suveillance of disposal sites. On the other hand, 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 valuable and potentially valuable 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 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 rule makes the assurance requirements applicable only to disposal facilities that are not regulated by the NRC. EPA and NRC have agreed that NRC will modify 10 CFR 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. EPA will provide NRC with all of the comments received on the assurance requirements during this rulemaking, and will participate in the NRC rulemaking. The Agency will review the record and outcome of the 10 CFR 60 rulemaking to determine if any subsequent modifications to 40 CFR Part 191 are needed.

Individual Protection Requirements (Section 191.14)

The containment requirements in Section 191.12 are designed to help ensure that the overall population risks to future generations from disposal of these wastes will be acceptably small. The situation with regard to potential individual risks is more complicated. Even with good engineering controls, some wastes 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, a person using such contaminated ground water in the future could receive a substantial radiation exposure on the order of several rems per year or more. (The risk associated with exposure to one rem/year of low-LET radiation is approximately 4 x 10^{-4}/year or 3 x 10^{-2}/lifetime.) This possibility is inherent in collecting a very large amount of radioactive material in a small area.

The proposed rule issued for comment in 1982 did not contain any numerical restrictions on such potential individual doses after disposal. Rather, it relied on the qualitative assurance requirements to reduce the likelihood of such exposures. In particular, the assurance requirement calling for extensive permanent markers and records was intended to transmit 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 possibility of human intrusion even if the information transmitted about the existence of a disposal system was ignored or misunderstood. And the assurance requirement to use multiple barriers, both engineered and natural, was 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 limiting potential individual exposures was highlighted for comment when 40 CFR 191 was issued as a proposal in 1982. Comments received, however, 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 could lead to overall increases in population exposures.

Second, disposal systems have to isolate radioactive waste for much longer time spans than institutional controls can be guaranteed to be effective. Any individual exposure limit could only be applied at some distance from a repository, or it would have to ignore the risks from unplanned events such as inadvertent intrusion. This is because individuals who fail to understand passive warnings and penetrate directly into or close to a disposal system (through exploratory drilling for water or mineral resources, for example) could receive very large exposures.

Lastly, the disposal standards have to be applied through analytical performance projections--implementing such standards through environmental monitoring and potential remedial actions over thousands of years is not a credible approach. When we compared the analyses needed for compliance with release limits, we found that release limits are likely to be easier to implement than individual exposure limits. Predicting radionuclide releases avoids the need to make uncertain predictions of pathways and living patterns that are associated with predicting individual doses.

After receiving many recommendations in favor of incorporating individual dose limits, the Agency decided the best approach would be to add individual dose criteria rather than replace the proposed containment requirements.

The individual protection requirements in this proposed rule limit the annual exposure to radiation from the disposal system to a member of the public. These limits apply to the expected performance of the disposal system, including consideration of the uncertainties in expected performance, assuming that the disposal system is not disturbed by human intrusion or the occurrence of unlikely disruptive external events. In general, processes and events occurring within the repository system, such as waste package corrosion, would be included in models of repository performance.

In assessing the performance of a disposal system with regard to individual exposures, all pathways of radioactive material or radiation and routes of exposure from the disposal system to people must be considered.

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 § 191.14.) The potential loss of ground water resources is very small because of the small number of such disposal facilities contemplated.

Devising individual protection requirements gives rise to two primary considerations. The first is the length of time over which the requirements would apply. The second is the appropriate dose level.

1. Time frame of Individual Protection Requirements

The individual protection requirements in the final rule issued in 1985 limited annual exposures to individuals from a disposal system over the first 1,000 years after disposal. To assist in selecting an appropriate time period for these requirements, the Agency examined the effects of choosing different time periods. 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 indicated it was long enough to ensure 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 frame much shorter than 1,000 years would not call for substantial engineered barriers even at disposal sites with a large ground-water flow.

On the other hand, demonstrating compliance with individual exposure limits over time frames much longer than 1,000 years appeared to be difficult because of the analytical uncertainties involved. There was a concern that at some disposal sites, the only certain way to comply might involve very expensive engineered barriers.

Based on these considerations, the Agency decided that a 1,000-year duration was adequate for quantitative limits on individual exposures after disposal. In 1986, the Natural Resources Defense Council and others challenged EPA's decision to limit the duration of the individual protection requirements to 1,000 years as arbitrary and capricious.

Petitioners argued that the Agency erred in: 1) setting a 1000-year period that ensures that the numerical standards will not apply at the precise moment in time when significant contamination of the accessible environment is expected to occur (i.e. as engineered barriers begin to degrade); 2) impermissibly considering population risk in setting the time limit; and 3) considering the likelihood of delay in the construction of a disposal system and in concluding, without record support, that a duration longer than 1,000 years would lead to prohibitive costs and difficulties in demonstrating compliance with the standards.

The First Circuit Court of Appeals ruled on this matter and others on July 17. The Court held that the Agency's choice of a 1,000-year design criterion was arbitrary and capricious and remanded that portion of the regulations to the Agency for reconsideration or, "at the very least" a more thorough explanation of the reasons underlying the choice of 1,000 years.

In light of this court ruling and additional assessments of generic repositories, the Agency is proposing a 10,000-year time frame for the individual protection requirements. Our own generic analyses show that, under conditions of ground-water flow, time frames much longer than 10,000 years are achievable for geologic repositories in a variety of geologic media if the repository is carefully sited and designed. These assessments also indicated that aquifer flow is not as difficult to estimate as was previously believed. Incorporating a 10,000-year time frame in the individual protection requirements would make them consistent with the containment requirements of this Part and other EPA regulations (for example, underground injection and hazardous waste requirements).

The Agency examined potential doses to individuals from radioactive waste disposal systems. In most of the cases studied, no exposures occurred for more than one thousand years after disposal because of the general robustness of the engineered and geologic barriers. However, beyond one thousand years significant exposures on the order of a few rems per year may appear in some of the geologic media studied. The Agency, therefore, believes individual risks from the disposal of radioactive waste might be significantly reduced if the duration of the protections are extended to 10,000 years.

Consistent with new language proposed in the containment requirements (191.12), today's proposal also requires assessment of the doses to individuals beyond 10,000 years. The new language requires projections of doses until they reach their peak or until 100,000 years after disposal, whichever is reached first.

2. Dose Limits in the Individual Protection Requirements

The individual protection requirements in the final rule issued in 1985 limited annual doses to members of the public in the accessible environment to 25 millirems to the whole body or 75 millirems to any organ. The Agency chose these limits because it believed they represented 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), in 1985 the Agency estimated this would cause about a five in ten thousand (5×10^{-4}) chance of incurring a premature fatal cancer.

Based on the same general rationale as was found in Subpart A in today's proposal, the Agency is proposing to limit the annual committed effective dose from the intake of all radionuclides plus the effective dose from any external exposure to 25 millirems per year. The Agency estimates, based on updated assessments of the relationship between exposures and health effects, that this would cause about a seven in ten thousand (7×10^{-4}) chance of incurring a premature fatal cancer.

Also, similar to our approach in proposed Subpart A, we have added language to clarify that the provisions of this section are not intended in any way to abridge or supersede other applicable Federal regulations.

Determination of Capability to Comply (Section 191.15)

Since 1985, there has been considerable confusion over the timing of determinations of compliance with 40 CFR 191. The 1985 standards did not specifically identify a point in time (i.e., in the disposal system development process) when the implementing agency was obliged to determine compliance. In an attempt to clarify this matter, two new sections patterned after requirements in Section 113(c) of the Nuclear Waste Policy Act of 1982 are proposed.

Compliance with 40 CFR 191 Subparts B and C is demonstrated through long-term modelling projections of disposal system performance. Proposed Section 191.15 would require implementing agencies to perform these analyses and determine compliance with the standards before any radioactive waste is emplaced in the system. The Agency recognizes, however, that there may be some instances where temporary emplacements of waste are necessary for gathering information relative to the compliance analysis required by this Part. Proposed Section 191.16 would permit such temporary experimental emplacements under the following conditions:

(i) The implementing agency has prepared written plans that describe the purposes of experiments, the ways in which the results of the experiments will be used in assessing compliance with this Part, the amount of radioactive waste required and a time schedule for experiments. Written plans provide a means for assessing whether or not planned experiments will yield information that will be useful for assessing long-term disposal system performance.

(ii) The implementing agency has prepared preliminary performance assessments. The assessments should highlight the uncertain aspects of the analyses and indicate their potential impact on long-term performance. Taking this step will help guide the experiments and provide a basis for determining the relative importance of various performance-related issues.

(iii) The implementing agency has prepared plans and tested procedures for the retrieval of radioactive wastes from the disposal system in the event of a determination of non-compliance with the standards.

Alternative Provisions (Section 191.17)

In developing the proposed standards, the Agency has had to make many assumptions about the characteristics of waste management and disposal systems that have not been built, about plans for waste management and 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 standards being proposed 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, Section 191.17 sets forth procedures under which the Administrator may develop modifications to 40 CFR 191, should the need arise. Any such changes would have to proceed through the usual notice-and-comment rulemaking process, and Section 191.17 stipulates that such a rulemaking would require a public comment period of at least 90 days. 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 successfuly 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 will consider whether modifications to Subparts B or C are 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 and C being proposed today. However, it is also possible that there may be issues associated with such disposal that would warrant changes in Subparts B or C for these situations or types of waste. If so, Section 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 transport 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.

Environmental Standards for Ground-Water Protection (Subpart C)

In response to comments received on the proposed radioactive waste standard issued in 1982, the Agency decided to include ground water protection requirements in the final standard issued in 1985. These requirements limited radionuclide 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 in 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 four millirems per year if an individual continuously consumed two liters per day of drinking water from that source of water. If the preexisting concentrations of radioactivity in the special source of ground water already exceeded any of these limits at a particular site, then §191.16 limited any increases in the preexisting concentrations to the above concentration limits.

"Special sources" was defined to include those Class I ground waters--identified in accordance with the Agency's Ground-Water Protection Strategy published in 1984--that (1) were within the controlled area or near (less than five kilometers beyond) the controlled area; (2) were 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) were irreplaceable in that no reasonable alternative source of drinking water was available to that population.

Like the individual protection requirements of the 1985 standard, the ground-water protection requirements applied to undisturbed performance of the disposal system for the first 1,000 years after disposal. Unlike the individual protection requirements, the ground water requirements applied to "special sources" of ground water both inside and outside the controlled area. The intent was to deter the siting of disposal facilities in locations containing these valuable ground-water resources.

Shortly after the final standard was issued in 1985, the Natural Resources Defense Council (NRDC), several states and others filed a petition for review in the First Circuit Court of Appeals in Boston, Massachusetts. The central thrust of their challenge was that the individual and ground-water protection requirements found in §191.15 and 16 violated the requirements of the Safe Drinking Water Act (SDWA). Petitioners argued that since emplacement of radioactive waste in a geologic repository constitutes underground injection and since underground injection is regulated under the SDWA, any standard promulgated by the Agency to cover radioactive waste emplacement in a geologic repository must be no less stringent than the requirements of the SDWA.

In July 1987, the Court ruled that EPA had, indeed, been "arbitrary and capricious" in its promulgation of the radioactive waste standard because the Agency had failed to reconcile its requirements with the more stringent requirements of the Safe Drinking Water Act and had not adequately explained the reason for the discrepancy. In addition, based on a challenge brought by the State of Texas, the Court ruled that the ground-water protection requirements were invalid because the Agency had failed to provide proper notice and opportunity for comment as required by the Administrative Procedure Act, 5 U.S.C. § 553(c). The standard was remanded to the Agency for reconsideration.

Summary of 1987 Court Ruling

In order to fully understand the Court's ruling, it is necessary to have an understanding of the Safe Drinking Water Act and its requirements. The SDWA was enacted in 1974 to assure safe drinking water supplies, protect valuable aquifers, and protect potential sources of drinking water from contamination by the underground injection of waste materials. The law requires EPA to promulgate standards for protecting public health by specifying either (1) maximum contaminant levels for pollutants in a public water supply, or (2) a treatment technique to reduce the pollutants to an acceptable level if the maximum contaminant level is not economically or technologically attainable. Maximum contaminant levels are to be set at a level having no known or adverse effect on human health, with an adequate margin for safety. In 1976, EPA established maximum contaminant levels for radionuclides at 40 C.F.R. §141.15 and 16.

The SDWA's only provision for directly regulating pollution-causing activities is found in Part C, 42 U.S.C. § 300h. Part C prohibits the "endangerment" of actual and potential underground sources of drinking water by underground injections. It requires EPA to promulgate regulations governing State underground injection control programs which ensure that those State programs prevent underground injections which endanger drinking water sources.

The SDWA defines underground injection broadly as "the subsurface emplacement of <u>fluids</u> by <u>well injection</u>. The SDWA defines underground injection broadly as "the subsurface emplacement of <u>fluids</u> by <u>well injection</u>." (Emphasis added.) EPA, in its regulations enacted pursuant to the SDWA, defined the terms "fluids" and "well injection." Well injection is the "subsurface emplacement of fluids through a bored, drilled or driven well; or through a dug well, where the depth of the dug well is greater than the largest surface dimension." EPA defined the term "fluids" as: "[any] material or substance which flows or moves whether in a semisolid, liquid, sludge, gas <u>or any other form or state.</u>" (Emphasis added.) The Agency took these definitions almost directly from the legislative history accompanying the SDWA which made it clear that "[t]he definition of 'underground injection' is intended to be broad enough to cover any contaminant which may be put below ground level and which flows or moves, whether the contaminant is in semi-solid, liquid, sludge, or any other form or state." H.R. Rep. No. 1185, 93d Cong., 2d Sess., reprinted in 1974 U.S. Code of Cong. & Admin. News at 6483.

Thus, a disposal system constitutes underground injection if: (1) the waste disposed of is a material or substance in a semisolid, liquid, sludge, gas or any other form or state; (2) the waste is emplaced underground in a bored, drilled or driven shaft, or a dug hole whose depth is greater than the largest surface dimension; and (3) the waste flows or moves. Petitioners, NRDC, et al., argued that since disposal of radioactive waste in a repository meets each one of these criteria, it should therefore be construed as underground injection.

Intervenors on behalf of EPA, the Arizona Nuclear Power Project, et al., disagreed. They argued that disposal of high-level radioactive waste in a repository is fundamentally different from the type of underground disposal that Congress was concerned with when it enacted Part C of the SDWA. Wastes disposed of by well injection are injected into the natural subsurface and allowed to disperse freely into the environment. In contrast, geologic repositories developed pursuant to 40 CFR 191 are mined containment areas and waste will be packaged in containers and will be surrounded by both engineered and natural barriers designed to isolate it from the environment. Part C of the SDWA, they argued, does not apply to this type of disposal system.

The Court was not persuaded:

> "While Congress may have been especially concerned with a different type of underground disposal when it passed Part C of the SDWA, this does not negate its overall intent to protect future supplies of drinking water against contamination. Unusable ground water is unusable ground water no matter whether the original source of the pollution arrived in a loose, free form manner, or in containers injected into the ground. We find no language in the SDWA showing that Congress meant to regulate only certain forms of underground pollution, while overlooking other forms of contamination of ground water via injection."

As further confirmation, the Court pointed to the legislative history of the SDWA indicating that Congress intended the phrase "underground injection which endangers drinking water sources" to have the broadest applicability:

> "It is the Committee's intent that the definition be liberally construed so as to effectuate the preventative and public health protective purposes of the bill. The Committee seeks to protect not only currently-used sources of drinking water, but also potential drinking water sources for the future. . . .
>
> The Committee was concerned that its definition of "endangering drinking water sources" also be construed liberally. Injection which causes or increases contamination of such sources may fall within this definition even if the water source would not by itself cause the maximum allowable levels to be exceeded. The definition would be met if injected material were not completely contained in the well, and if it may enter either a present or potential drinking water source, and if it (or some form into which it might be converted) may pose a threat to human health or render the water source unfit for human consumption."

H.R. Rep. No. 1185, 93d Cong., 2d Sess., <u>reprinted in</u> 1974 U.S. Code Cong. & Admin. News at 6484.

The Court's conclusion on the question of whether or not disposal of radioactive waste in a repository constitutes underground injection was as follows: The Court's conclusion on the question of whether or not disposal of radioactive waste in a repository constitutes underground injection was as follows:

> "We believe that the narrow and constrained reading of Part C of the SDWA advocated by intervenors would do violence to the intent of Congress. We decline that reading.
>
> We conclude that the primary disposal method being considered, underground repositories, would likely constitute an "underground injection" under the SDWA."

Once the Court had concluded that deep geologic disposal of radioactive waste in repositories could constitute underground injection, then the issue became whether or not disposal of radioactive waste carried out pursuant to EPA's radioactive waste standard could "endanger" underground sources of drinking water.

The SDWA defines the term "endanger" to include any injection which may result in the presence "in underground water which supplies or can reasonably be expected to supply any public water system of any contaminant. . . if the presence of such contaminant may result in such system's not complying with any national primary drinking water regulation." Petitioners NRDC, et al., argued that EPA, in promulgating the radioactive waste standard, had violated the "no endangerment" mandate of the SDWA because the standard allowed underground injections that could cause the levels of contaminants in underground sources of drinking water to exceed drinking water regulations.

First, while the ground-water protection provisions included in the standard imposed the same concentration limits as those required by the SDWA, they applied only to "special sources" of ground water. Special sources of ground water represent a far narrower class of ground waters than the actual and potential sources of drinking water protected under the SDWA.

Second, the individual protection requirements included in the standard tolerated levels of contamination to underground sources of drinking water beyond that permitted under the SDWA's "no endangerment" provision. EPA's National Primary Drinking Water regulations specify that drinking water shall not produce an annual dose equivalent to the total body or any internal organ greater than 4 millirems/year. In contrast, the individual protection requirements found in the 1985 standards limited annual exposures to 25 millirems/year to the whole body, and 75 millirems/year to any organ.

The Court's conclusion on the question of whether or not the radioactive waste standard violated the "no endangerment" mandate of the SDWA was as follows:

> "While the individual protection requirements thus provide a level of protection, they also tolerate levels of contamination of drinking water sources well in excess of primary drinking water standards established by EPA under the SDWA, thus permitting "endangerment" of such sources as defined in the SDWA."

The Court speculated on whether or not there might be explanation for EPA's failure to reconcile the inconsistency between the radioactive waste standard and the SDWA:

> "Perhaps if it were scientifically impossible to meet the goals of the NWPA except by reducing the standards for sources of drinking water near a repository, this would justify a deviation from the SDWA. Or perhaps there are good reasons reconciling the apparent inconsistency between the two standards. But the Administrator nowhere states that compliance with the SDWA is impossible or inconsistent with the goals of the NWPA, nor does he offer any explanation of why he deems the lesser standard in the HLW rules to be adequate to protect the public although he does not find it adequate under the SDWA."

Accordingly, the Court declared the 1985 rule "arbitrary and capricious" and remanded it back to the Agency for either a new rule or for explanation of the grounds for a less stringent standard than is required under the SDWA.

Is Geologic Disposal of Radioactive Waste Underground Injection?

In light of the 1987 Court ruling, the Agency has given the subject of whether geologic disposal of radioactive waste constitutes underground injection considerable thought. It is the Agency's conclusion that disposal of radioactive waste in geologic repositories operated in the manner envisioned by the DOE does not constitute underground injection.

EPA believes that the time to assess whether the material flows or moves is the time of emplacement and the term "injection" itself connotes delivery by flow. Congress focused on injection practices when directing EPA to control underground injection (H.R.Rep. No. 1185, 93d Cong. 2d Sess. 32 (1974) reprinted in <u>Legislative History of the Safe Drinking Water Act</u> at 563). EPA's regulatory program has also focused on the identification and control of injection practices. Focusing on the practice of injection ties the concept of a fluid directly to the emplacement. This connection is expressed practically by examining the material at the time of injection and, if the injected material flows into the well, then the well is subject to the requirements of Part C of the SDWA. The process of lowering solid materials down a shaft on an elevator or some human-controlled conveyance and, upon reaching the disposal horizon, either emplacing or transporting them via some form of mechanical transport to their emplacement locations is not considered to be well injection because the waste is not fluid at the time of injection, i.e., it does not flow into the disposal location. It follows that such a disposal method is not subject to Part C of the SDWA. EPA is, nevertheless, proposing to make the ground-water protection requirements consistent with the SDWA. The Agency stands by the environmental and risk objectives reflected in the ground-water protection requirements of the SDWA. These issues are discussed further below.

EPA Approach to Ground-Water Protection

Ground-water contamination is of particular concern to the Agency because of its potential impact on sources of drinking water. Over 50 percent of the U.S. population draws upon ground water for its potable water supply. Approximately 117 million people in the U.S. get their drinking water from ground water supplied by 48,000 community public water systems and approximately 12 million individual wells. The remaining people get their drinking water from 11,000 public water systems drawing from surface water sources. About 95 percent of rural households depend on ground water, as does a still larger proportion (97 percent) of the 165,000 non-community public water supplies (such as camps or restaurants serving a transient population).

Finally, 34 of the 100 largest U.S. cities rely completely or partially on ground water.

Once contaminated, ground water presents particularly difficult problems for monitoring and clean-up. In many ways ground water is far more difficult to manage than air or surface water because it is not directly accessible. Ground water is slow-moving, with velocities generally in the range of 5 to 50 feet per year. Large amounts of a contaminant can enter an aquifer and remain undetected until a water well or surface water body is affected. Moreover, contaminants in ground water--unlike those in surface water--generally move in a plume with relatively little mixing or dispersion, so concentrations remain high. These plumes of relatively concentrated contaminants move slowly through aquifers and are typically present for many years--sometimes for decades or longer--potentially making the resource unusable for those periods of time. Although opportunity exists for chemical or biological transformation, changes in the concentrations of contaminants occur slowly so that they may not be readily discernible in the short-term. Because an individual plume may underlie only a very small part of the land surface, it is difficult to detect by aquifer-wide or regional monitoring. In most circumstances, it is prudent to protect the resource from contamination in the first place, rather than rely on clean-up after the fact.

In January 1990, EPA completed development of a strategy to guide future EPA and State activities in ground-water protection and cleanup. Two papers were developed by an Agency-wide Ground Water Task Force and were issued for public review: an EPA Statement of Ground-Water Principles and an options paper covering the issues involved in defining the Federal/State relationship in ground-water protection. These papers and other Task Force documents have been combined into an EPA Ground-Water Task Force Report: Protecting The Nation's Ground Water: EPA's Strategy for the 1990's (EPA 21Z-1020 July 1991.)

This report is intended to set forth an aggressive approach to protecting the nation's ground-water resources and directing the course of the Agency's efforts over the coming years. It will be reflected in EPA policies, programs, and resource allocations and is intended to guide EPA, States and local governments, and other parties in carrying out ground-water protection programs.

A key element of EPA's strategy for ground-water protection and cleanup is a statement of "EPA Ground-Water Protection Principles" that has as its overall goals the prevention of adverse effects on human health and the environment and protection of the environmental integrity of the nation's ground-water resources. Ground water should be protected to ensure that the nation's currently used and potential sources of drinking water, both public and private, are preserved for present and future generations.

In carrying out its programs, the Agency will use Maximum Contaminant Levels (MCLs) under the SDWA as "reference points" for water-resource protection efforts when the ground water in question is a potential source of drinking water. Best technologies and management practices should be relied upon to protect ground water to the maximum extent practicable. Detection of a percentage of the reference point at an appropriate monitoring location will be used to trigger consideration of additional action (e.g., additional monitoring; restricting, limiting use or banning the use of the potential contaminant). **Reaching the MCL would be considered a failure of prevention.**

Description of Proposed Ground-Water Protection Requirements

EPA proposes to add a new Subpart to the 40 CFR 191 standards--Subpart C, "Ground Water Protection Requirements." These requirements will apply to radioactive waste management, storage and disposal facilities and are designed to parallel the dose-limit requirements under Part C of the Safe Drinking Water Act.

A number of factors went into deciding upon this approach. First, it is consistent with the Agency's overall approach to ground-water protection; that is, to prevent the contamination of current and potential sources of drinking water. Second, we think there is merit in the environmental and risk objectives of the ground-water protections developed by the Agency under the SDWA. Therefore, divergence from the dose-level requirements in the SDWA regulations is not appropriate.

A basic premise of the ground-water protection requirements presented in today's proposal is that a release from a radioactive waste management, storage or disposal facility should not cause a present or future community water supplier to have to implement a treatment that was not otherwise necessary. Failure to prevent the contamination of ground water may end up costing hundreds of millions of dollars to clean up. If radioactive waste activities cause, or are expected to cause, migration of radionuclides in excess of the levels established by EPA under the SDWA, the implementing agency must take appropriate action to prevent the migration. Unless this approach is taken, the management, storage or disposal system is likely to find itself subject to the clean-up requirements under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (Superfund). Radioactive waste facilities should be operated in an environmentally sound manner from the start rather than rely on costly cleanup in the future.

The SDWA requires that EPA promulgate regulations for protecting drinking water sources, i.e., "underground water which supplies or can reasonably be expected to supply any public water system." Accordingly, proposed Subpart C limits radioactive contamination in both public and private "underground sources of drinking water" to the Maximum Contaminant Levels (MCLs) found in the Agency's National Primary Drinking Water standards (40 CFR 141). Consistent with the 1987 Court ruling, the proposed standard pertains to drinking water sources located outside the controlled area surrounding these facilities.

Proposed Subpart C protects what is known as an "underground source of drinking water." The definition of "underground source of drinking water", and indeed all of the definitions pertinent to proposed Subpart C, are taken directly from the Agency's underground injection control regulations found in 40 CFR Parts 144-146. These definitions are designed to be consistent with the SDWA requirements.

The definition of "underground source of drinking water" received extensive discussion in the legislative history of the SDWA. The Committee Report to the Act instructed EPA to construe the term liberally: both currently used and potential drinking water sources warrant inclusion in the definition.

As a guide to the Agency, the Report suggested that aquifers with fewer than 10,000 parts per million (or milligrams per liter) of total dissolved solids (TDS) be included [H.R. No.93-1185, p.32]. The Agency has reviewed the current information on the drinking water use of aquifers containing high levels of total dissolved solids. This review found that the use of water containing up to 3,000 milligrams per liter TDS is fairly widespread. The Agency has also found that gound water containing as much as 9,000 mg/l TDS is currently supplying public water systems. EPA also believes that technology for treating water containing high levels of TDS is advancing. Therefore, based on this review and the legislative history of the SDWA, the Agency believes that it is reasonable to protect aquifers containing water with fewer than 10,000 milligrams per liter TDS as potential sources of drinking water.

The ground-water protections found in today's proposal apply to all aquifers or their portions which currently or potentially provide drinking water and all aquifers or their portions with fewer than 10,000 milligrams per liter TDS.

Proposed Subpart C prevents any degradation of public or private underground sources of drinking water, in the vicinity of radioactive waste management and disposal facilites, beyond the concentrations established by the Agency for public water systems under 40 CFR 141--National Primary Drinking Water Regulations. We propose to adopt the Agency's recently proposed Maximum

Contaminant Levels (MCLs) for radionuclides which are as follows: (1) 300 picocuries per liter of radon-222; (2) 20 picocuries per liter of radium-226 and radium-228; (3) 20 micrograms per liter of uranium; (4) 15 picocuries per liter of adjusted gross alpha emitters; and (5) 4 millirem committed effective dose/year for beta particle and photon emitters. (See Federal Register Vol. 56, No. 138 July 18,1991.) The unit millirem ced/year refers to the dose committed over a period of 50 years to reference man (ICRP 1975) from an annual intake at the rate of 2 liters of drinking water per day. Each of these MCLs individually represents a lifetime risk level of approximately 1 x 10^{-4} (one in ten thousand). A co-occurrence of two or more of these regulated nuclides in drinking water could place an individual at total risk higher than EPA's target of 10^{-4} lifetime risk. EPA is soliciting additional data on co-occurrence to enable a more complete assessment of the potential for co-occurrence of radionuclides near the proposed MCLs.

These proposed MCL's would apply to underground sources of drinking water found in the vicinity of radioactive waste management and disposal facilities. In the case of radioactive waste management and storage facilities, the implementing agency must not exceed the MCLs even if it means upgrading the facility. In the case of waste disposal facilities, making after-the-fact changes to the facility may not be possible. Hence, the proposed standard requires the implementing agency to demonstrate a reasonable expectation that the radionuclide MCLs will not be exceeded.

The Agency's intent is to conform the radionuclide MCL's found in this Part to those found in 40 CFR 141--EPA's National Primary Drinking Water Regulations. The radionuclide MCLs found in today's proposal represent levels which are part of a proposed rule which has yet to be finalized. Commenters should anticipate that the Agency will adopt whatever levels are in effect under 40 CFR Part 141 when the Agency finalizes this Part.

As with the individual protection requirements contained in this proposal, the Agency is proposing a 10,000-year time frame for the duration of ground-water protection requirements pertaining to disposal facilities. Implementing agencies will determine compliance by making 10,000-year projections of the disposal system performance. As such, the disposal standards in this Subpart, and indeed in this Part, are design standards. The implementing agency must have a reasonable expectation that the natural and engineered features of a disposal facility will prevent degradation beyond the radionuclide MCLs to any underground source of drinking water outside the controlled area.

It is not the Agency's intent in this proposal to solicit comment on the UIC program requirements. Most of these requirements were promulgated in the 1970's and 1980's and were subject to extensive notice and comment procedures at that time. The Agency is not revisiting these requirements as part of this rulemaking. Instead, the Agency solicits comment on the broader issues of the appropriateness and desireability of making the ground-water protection provisions found in 40 CFR 191 consistent with the UIC program requirements and on the specific question raised by the Court: Is there justification, in this case, for promulgating a less protective standard than what the SDWA prescribes?

Guidance for Implementation (Appendix C)

This supplement to the proposed 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 C discusses: (1) the consideration of all barriers of a disposal system in performance assessments; (2) reasonable limitations on the scope of performance assessments; (3) timing of compliance assessment; (4) the use of average or "mean" values in expressing the results of individual dose projections; (5) the types of assumptions regarding the effectiveness of institutional controls; and (6) limiting, worst-case, assumptions regarding the frequency and severity of inadvertent human intrusion into geologic repositories. EPA has estimated drilling rates that are intended to be upper bounds on the future likelihood of drilling at a repository site. It is emphasized that these "upper bounds" are not being recommended but are, rather, the worst case conditions that need to be considered by the implementing agency. It is expected that site-specific circumstances and evaluations will provide a basis for supporting whatever assumptions the implementing agency may choose.

The final rule, to be published in the Code of Federal Regulations, will include this informational appendix as guidance to the implementing agencies. Although those agencies are not bound to follow this guidance, EPA recommends that it be carefully considered in planning for the application of 40 CFR 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.

Health Impacts of 40 CFR 191

Waste Management and Storage. Waste management and storage activities conducted in accordance with the 25 millirems ced found in proposed Subpart A will result in a maximum lifetime risk of premature fatal cancer to a member of the public in the general environment of about seven in ten thousand (7×10^{-4}).

Of course, risks 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 unlikely, actual risks to individuals are expected to be lower. It is theoretically possible under the proposed rule that an individual could be exposed to *both* an NRC-licensed and a DOE facility not licensed by NRC, for a total exposure equal to the limits from each. However, the Agency believes that this is highly improbable and does not foresee a significant public health impact from this possibility.

Population Risks. 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. 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, non-threshold 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, 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 developing appropriate regulations and for comparing the risks of waste disposal with those of undisturbed ore bodies. The results of these analyses are uncertain and are not intended to reflect an 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, each 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. 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. Such an 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 (excluding the effects of indoor radon).

Individual Risks: With regard to exposures to 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 the repository was considered (e.g. there was no evaluation of exposures that might occur if a repository was disrupted by movement of a fault or human intrusion). In most of the cases studied, no exposures occurred tens of thousands of 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) could appear for some of the geologic media considered. (The risk associated with exposure to one rem/year of low-LET radiation is approximately 4×10^{-4}/year or 3×10^{-2}/lifetime.) These projections are similar to those contained in a 1983 report published by the National Academy of Sciences (National Academy of Sciences--National Research Council, A Study of the Isolation System for Geologic Disposal of Radioactive Wastes, Report of the Waste Isolation System Panel, Board of Radioactive Waste Management, Washington, D.C., 1983.) The Background Information Document accompanying this proposal contains more detailed descriptions of the Agency's individual dose calculations.

Intergenerational Risk: As described earlier, the Agency has chosen 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 makes it difficult to determine what level of residual risk should be allowed by these disposal standards. The difficulty arises 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 becomes 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. Some may feel that no risk should be passed on to future generations. This is a condition which the Agency believes cannot be met by any foreseeable disposal technologies. There is one additional 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 to which people are currently exposed, a brief discussion of the risks from other natural sources of radiation is included.

Uranium Ore: Most of the uranium ore bodies in the contiguous portion of the United States are secondary deposits of waterborne uranium in permeable geologic formations. If water moves through these formations, it is possible for both the uranium and its daughters to dissolve into water moving through the deposit. 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 naturally occurring radionuclides and from direct exposure to cosmic radiation. Individual exposures average about 100 millirems per year, with a range of about 60 to 200 millirems per year or as high as 1000 millirems or more per year if exposures from radon gas are included. These background radiation levels have remained relatively constant for a very long time. According to the same linear, non-threshold dose effect relationship used in EPA's other analyses, an increase of one millirem per year in natural background in the United States would result in about 100 additional deaths per year, or 1 million over a 10,000-year period.

Natural Radionuclide Concentrations in Ground Water: One source of exposure to natural background radiation comes from naturally occurring radionuclides found in ground water. The most significant natural radionuclides (as determined by their levels of occurrence in drinking water and their potential to cause adverse health effects by this exposure route) are radon-222, radium-226, radium-228, and uranium. Some other alpha emitting radionuclides have occasionally been found in drinking water. 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 per liter); up to 74 pCi per liter for all alpha-emitting radionuclides other than uranium (although most of the alpha-emitting concentrations are below 3 pCi per liter); and up to 650 pCi per liter for total uranium concentrations. Elevated radium-226 concentrations are found along the Atlantic coastal region and in the Midwest; low levels are usually found 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 current primary drinking water regulations (40 CFR 141) limit the contamination levels for radium-226 and radium-228 to 5 pCi per liter and the levels for total alpha-emitting contamination (excluding radon and uranium) to 15 pCi per liter. Elevated concentrations of radium in drinking water are generally a problem associated with smaller community water systems, with an estimated 500 systems exceeding the 5 pCi per 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.

List of Subjects in 40 CFR Part 191

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

SECOND EPRI WORKSHOP -- TECHNICAL BASIS FOR THE EPA HLW DISPOSAL CRITERIA

Stouffer Concourse Hotel
Arlington, Virginia

PRELIMINARY AGENDA

Tuesday, February 4, 1992

8:30 am	I.	**Plenary and Opening**	
		Welcome and Introduction	R. Shaw / R. Williams
		Overview of EPA Discussion Paper and Schedule	M. Oge
		Overview of Workshop	R. Williams
9:45 am	**Break**		
10:00 am	II.	**Gas Pathway**	
		Session Chairman Overview	L. Ramspott
		Issue: Proposed Basis for Gas Pathway Limits	
		Technical Comments on the Issue:	Panelists
		Panel: R. Van Konynenburg, U. Park, T. Cochrane, B. Ross	
11:00 pm	III.	**Individual and Groundwater Protection**	
		Session Chairman Overview	V. Rogers
		Issue: Nuclide Concentration Limits in Groundwater	
		Technical Comments on the Issue:	Panelists
		Panel: R. Wilems, S. Osten, E. Regnier, D. Reicher	
12:15 pm	**Lunch - Stouffer Concourse Hotel**		
1:30 pm	IV.	**Human Intrusion**	
		Session Chairmen Overview	R. Neill / S. Hora
		Issue: Prescriptive Guidance for Human Intrusion Analyses	
		Technical Comments on the Issue:	Panelists
		Panel: M. Bauser, D. Reicher, F. Bingham, J. Channell	
3:15 pm	**Break**		
3:30 pm	**Begin Working Group Discussions**		
6:00 pm	**Adjourn**		
6:30 pm	**Hosted Cocktails**		
7:15 pm	**Dinner - Stouffer Concourse Hotel**		

SECOND EPRI WORKSHOP -- TECHNICAL BASIS FOR THE EPA HLW DISPOSAL CRITERIA

Stouffer Concourse Hotel
Arlington, Virginia

PRELIMINARY AGENDA (continued)

Wednesday, February 5, 1992

8:30 am	**Overview of Day 2**		R. Williams
8:35 am	**V.**	**Population Protection**	
		Session Chairmen Overview	C. Whipple / R. Budnitz
		Issue: Alternatives for Deriving and Demonstrating Compliance with Table 1 Population Protection Limits	
		Technical Comments on the Issue:	Panelists
		Panel: R. Klett, S. Osten, R. Wilems	
10:15 am	**Break**		
10:30 am	**VI.**	**Performance Assessment and Assurance Requirements**	
		Session Chairmen Overview	R. Neill / S. Pahwah
		Issues: Guidance on Probabilistic Analysis Implementation and Assurance Requirements	
		Technical Comments on the Issues:	Panelists
		Panel: F. Bingham, L. Rickertsen, E. Regnier	
12:00 pm	**Lunch - Open**		
1:00 pm	**VII.**	**TRU Conversion Factor**	
		Session Chairmen Overview	R. Williams / J. Channell
		Issue: TRU Conversion Factor	
		Technical Comments on the Issue:	Panelists
		Panel: R. Klett, J. Channell, S. Osten	
1:45 pm	**VIII.**	**Open Discussion**	
		Audience Questions and Comments on Unresolved Issues	Panel of Session Chairs
2:30 pm	**Begin Working Group Discussions**		
5:00 pm	**Adjourn**		

SECOND EPRI WORKSHOP -- TECHNICAL BASIS FOR THE EPA HLW DISPOSAL CRITERIA

Stouffer Concourse Hotel
Arlington, Virginia

PRELIMINARY AGENDA (continued)

Thursday, February 6, 1992

8:30 am	IX.	Report of the Working Groups	Working Group Chairmen
10:00 am	Break		
10:15 am	X.	Status of Issues as Seen By Interested Parties	R. Williams
		DOE-EH	E. Regnier
		DOE-WIPP	J. Rhoderick
		DOE-YM	G. Parker
		NRDC	D. Reicher / T. Cochrane
		Industry	C. Henkel / M. Bauser
		NARUC	R. Callen
		New Mexico - EEG	R. Neill
		Clark County, Nevada	E. Von Tiesenhausen
		UCLA, Self	D. Okrent
		Others	
12:00 pm	Closing Remarks		R. Williams
12:15 pm	Adjourn		