

Dated: December 28, 1992

The Environmental Protection Agency is hereby proposing to amend Part 191 of Title 40, Code of Federal Regulations, as follows:

1. The Table of Contents is amended to read 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**

**Subpart A - Environmental Standards for Management and Storage**

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- 191.01 Applicability.
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- 191.03 Standards.
- 191.04 Alternative standards.
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**Subpart B - Environmental Standards for Disposal**

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- 191.13 Containment requirements.
- 191.14 Assurance requirements.
- 191.15 Individual protection requirements.
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**Subpart C - Environmental Standards for Ground-water Protection**

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- 191.25 Compliance with other Federal regulations.
- 191.26 Effective date.

Appendix A Table for Subpart B

Appendix B Calculation of Annual Committed Effective Dose

Appendix C Guidance for Implementation of Subpart B

2. A new citation is added to the authority citation to read as follows:

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

3. Section 191.11(b) is revised to read as follows:

**§ 191.11 Applicability.**

\* \* \* \* \*

(b) This Subpart does not apply to:

- (1) Disposal directly into the oceans or ocean sediments;
- (2) Wastes disposed of before November 18, 1985; and
- (3) The characterization, licensing, construction, operation, or closure of any site required to be characterized under section 113(a) of Public Law 97-425.

4. Section 191.12 is amended by removing the paragraph designation for each term, alphabetizing all terms therein, removing the terms community water system, significant source of ground water, special source of ground water, and transmissivity and their definitions, revising the definition of the term implementing agency, and adding the following terms, in alphabetical order, and their definitions to read as follows:

**§ 191.12 Definitions.**

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 Subparts B and C.

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).

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.

Implementing agency means, as used for operations covered by this Part, the Commission for facilities licensed by the Commission, the Agency for those implementation responsibilities given to the Agency by the WIPP Land Withdrawal Act, and the Department of Energy for any other disposal facility.

International System of Units is the 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."

Radioactive material means matter composed of or containing radionuclides, with radiological half-lives greater than 20 years, subject to the Atomic Energy Act of 1954, as amended.

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

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

5. Section 191.15 is revised to read as follows:

**§ 191.15 Individual protection requirements.**

(a) Disposal systems for waste and any associated radioactive material shall be designed so that, for 10,000 years after disposal, undisturbed performance of the disposal system shall not cause the annual committed effective dose, received through all potential pathways from the disposal system, to any member of the public in the accessible environment, to exceed 15 millirems (150 microsieverts).

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

(c) Compliance assessments need not provide complete assurance that the requirements of § 191.15 (a) of this Subpart will be met. Because of the long time period involved and the nature of the processes and events 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.

(d) Compliance with the provisions in this section does not negate the necessity to comply with any other applicable Federal regulations or requirements.

(e) The standards in this section shall be effective on the date of promulgation of this rule.

6. Section 191.16 is removed.

7. Section 191.17 is redesignated Section 191.16.

8. Subpart C is added to read as follows:

**Subpart C - Environmental Standards for Ground-Water Protection**

**§ 191.21 Applicability.**

(a) This Subpart applies to:

(1) Radiation doses received by members of the public as a result of activities subject to Subpart B of this Part; and

(2) Radioactive contamination of underground sources of drinking water in the accessible environment as a result of such activities.

(b) This Subpart does not apply to:

(1) Disposal directly into the oceans or ocean sediments;

(2) Wastes disposed of before November 18, 1985; and

(3) The characterization, licensing, construction, operation, or closure of any site required to be characterized under § 113(a) of Public Law 97-425.

**§ 191.22 Definitions.**

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

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.

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

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.

§ 191.23 General provisions.

(a) Determination of compliance with this Subpart shall be based upon underground sources of drinking water which have been identified on the date the implementing agency determines compliance with Subpart C of this Part.

(b) The analytical methods in 40 CFR 141 shall be used to determine the levels for comparison with the limits in 40 CFR 141.

§ 191.24 Disposal standards.

(a) Disposal systems for waste and any associated radioactive material shall be designed so that 10,000 years of undisturbed performance after disposal shall not cause the levels of radioactivity in any underground source of drinking water, in the accessible environment, to exceed the limits specified in 40 CFR 141 as they exist on the date the implementing agency determines compliance with Subpart C of this Part.

(b) Compliance assessments need not provide complete assurance that the requirements of § 191.25(a) of this Subpart will be met. Because of the long time period involved and the nature of the processes and events 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.

**§ 191.25 Compliance with other Federal regulations.**

Compliance with the provisions in this Subpart does not negate the necessity to comply with any other applicable Federal regulations or requirements.

**§ 191.26 Effective date.**

The standards in this Subpart shall be effective on the date of promulgation of this rule.

9. Appendix B is redesignated Appendix C.

10. A new Appendix B is added to read as follows:

Appendix B -- Calculation of Annual Committed Effective Dose

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:

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

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,  $w_R$ <sup>1</sup>

Radiation type and energy range <sup>2</sup>	$w_R$ 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

<sup>1</sup> All values relate to the radiation incident on the body or, for internal sources, emitted from the source.

<sup>2</sup> See paragraph A14 in ICRP Publication 60 for the choice of values for other radiation types and energies not in the table.

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:

$$E = \sum w_T \cdot H_T.$$

**Table B.2 Tissue weighting factors,  $w_T$  <sup>1</sup>**

<b>Organ or tissue</b>	<b><math>w_T</math> value</b>
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 <sup>2,3</sup>

<sup>1</sup> 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.

<sup>2</sup> 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 cancer 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.

<sup>3</sup> 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  $\tau$  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,  $\tau$ , 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  $H_T(t)$  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*,  $E(\tau)$ :

$$E(\tau) = \sum w_T \cdot H_T(\tau).$$

11. The authority citation for Part 144 will be amended to read as follows:

Authority: Safe Drinking Water Act, 42 U.S.C. 300f et seq.; Resource Conservation and Recovery Act, 42 U.S.C. 6901 et seq.; Atomic Energy Act of 1954, as amended, 42 U.S.C. 2021(h) and 2201; Waste Isolation Pilot Plant Land Withdrawal Act, Pub. L. 102-579.

12. 40 CFR 144.31(a) is amended by adding the following sentence at the end of the paragraph to read as follows:

**§ 144.31 Application for a permit; authorization by permit**

(a) \* \* \* A license, a permit, a certification, or an approval otherwise of a waste disposal system, as defined in 40 CFR 191, Subpart B, which complies with 40 CFR Part 191, Subpart C, shall constitute compliance with the SDWA statutory requirements, and the UIC program requirements, not to endanger underground sources of drinking water consistent with this Part, to the extent that such a requirement would otherwise apply to a particular disposal system.

(2) Changes to the definition of the term "implementing agency" to reflect EPA's role under the recently enacted and abovedescribed WIPP LWA.

(3) The addition of several new terms which pertain to the radiation dosimetry used throughout today's proposed individual and ground-water protection requirements;

(4) The addition of several new terms pertaining to the ground-water protection requirements in Subpart C of today's proposed rule; and

(5) The deletion of several terms from the 1985 individual and ground-water protection requirements which are no longer pertinent.

*Individual Protection Requirements (Section 191.15)*

The Agency is proposing to replace the Individual Protection Requirements found at § 191.15 in the 1985 standards with a new set of requirements. A brief history of the development of these requirements follows.

The proposed 40 CFR Part 191 standards, issued in 1982 and which preceded the 1985 standards, did not contain any numerical restrictions on individual doses after disposal. Rather, they relied on the qualitative assurance requirements to reduce the likelihood of such exposures. For instance, 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. Also, another assurance requirement which called for careful evaluation of sites with significant resources was intended to reduce the likelihood of human intrusion even if the information transmitted about the existence of a disposal system was ignored or misunderstood. Another assurance requirement called for employment of multiple barriers, both engineered

and natural, and was intended to reduce the risks if one type of barrier performs more poorly than current knowledge indicates.

This approach to limiting potential individual exposures was highlighted for comment when the standards were proposed in 1982. Comments received persuaded the Agency that quantitative regulatory limits for protection of individuals were also necessary. The Agency was persuaded that reliance on containment requirements, even if supplemented with assurance requirements, could, nevertheless, still result in an unacceptably high risk to individuals in the vicinity of disposal systems. Thus, the Agency decided the best approach would be to supplement (rather than replace) the proposed protection for populations with additional protection for individuals.

Having made the decision to include individual protection requirements, the Agency then had to determine (1) the length of time over which the requirements should apply, and (2) the appropriate dose level for the requirements.

#### *Time Frame of the Individual Protection Requirements*

The final disposal regulations promulgated in 1985 included individual protection requirements which limited annual radiation doses to individuals for 1,000 years after disposal. In selecting the 1,000-year time period for the 1985 requirements, the Agency examined the effects of choosing different time periods. Just as 10,000 years was chosen for the containment requirements because EPA believes 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 is

long enough to ensure that good engineered barriers would be used at disposal sites where some ground water would be expected to flow through a mined geologic repository. Time frames shorter than 1,000 years would not require appropriate engineered barriers even at disposal sites with large ground-water flows.

At the same time, demonstrating compliance with individual exposure limits over time frames longer than 1,000 years appeared to be difficult because of the analytical uncertainties involved. Furthermore, 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, in the 1985 rule, that a 1,000-year period was adequate for the quantitative limits on individual doses after disposal.

As explained above, in 1986, the Natural Resources Defense Council (NRDC) and others challenged EPA's decision to limit the period of the individual protection requirements to 1,000 years as arbitrary and capricious. Petitioners argued that the Agency erred in: 1) setting a 1,000-year period which ensures that the numerical standards expire at the precise moment in time when significant releases to the accessible environment are expected to begin to occur, i.e., as engineered barriers begin to degrade; 2) inappropriately considering population risk in setting the time limit for standards designed to protect individuals; 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.

In 1987, the court held that the Agency's choice of a 1,000-year period was arbitrary and capricious, finding little record evidence that the Agency considered individual risk in addition to population risk in selecting that time frame (a consideration EPA itself had determined must be considered). Thus, the court 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. After re-evaluating the implications of various time frames, the Agency is now proposing to adopt a 10,000-year time frame for the individual protection requirements.

The Agency is proposing 10,000 years as the regulatory period for the individual protection requirements for four primary reasons:

(i) Wastes emplaced into disposal systems will remain radioactive for many thousands of years. Therefore, the Agency believes significant public health and environmental benefits can be gained by selecting a longer time frame for the requirements because a longer time frame can encourage the selection of good disposal sites and the design of robust engineered barriers. The Agency examined potential doses to individuals, for various times in the future, from waste disposal systems. In most of the cases studied, radionuclide releases resulting in exposures to individuals did not occur until more than 1,000 years after disposal due to the containment capabilities of the engineered barrier systems. Beyond 1,000 years, but prior to 10,000 years, as the engineered barriers begin to degrade, releases resulting in doses on the order of a few rems per year appeared for some of the geologic media studied. (The risk, or chance, of causing a premature fatal cancer associated with exposure to one rem/year of low-LET radiation is approximately

four in ten thousand per year ( $4 \times 10^{-4}$ /year) or three in one hundred over a 70-year lifetime ( $3 \times 10^{-2}$ /lifetime). Hereinafter, as used in this document, the term "risk" refers to the chance of developing a premature fatal cancer.) For other, better, geologic media, the Agency's generic analyses estimate no releases for 10,000 years. The Agency believes selecting a 10,000-year time for the requirements will encourage the selection of good sites and the design of robust engineered barrier systems capable of significantly impeding radionuclide releases. These actions, in turn, will serve to reduce the individual risks associated with the disposal of radioactive waste.

(ii) The Agency believes improvements in modeling capability since 1985 have facilitated demonstrating compliance with individual dose limits over time frames longer than 1,000 years. Out of necessity, analyses performed prior to 1985 relied on data derived primarily from generic geological data available in the open literature. Since that time, additional data have been collected, during characterization of potential disposal sites, which provide an improved basis on which to assign values to the various parameters in analyses performed now.

As indicated in the documentation supporting the promulgation of 40 CFR Part 191 in 1985 (EPA 520/1-85-023), the NWFT/DVM computer code was used to estimate risks to individuals from disposal systems. This computer code has undergone considerable improvement since 1985. It has evolved into the NEFTRAN-S computer code and is used to perform EPA's updated analyses of individual risk which are found in the draft Background Information Document (BID) supporting today's rulemaking which may be found in the docket supporting this rulemaking. In particular, NEFTRAN-S incorporates improved capabilities for

modeling the transport of radionuclides through a geologic medium, including use of the distributed velocity method for modeling dispersive or diffusive transport through porous media. NEFTRAN-S also incorporates added capability to perform statistical analyses required in sensitivity and uncertainty analyses. (See Sandia Report SAND90-1987, UC-502.) Both NRC and DOE also use the improved NEFTRAN methodology.

(iii) In contrast to earlier estimates, EPA now believes that the financial cost of providing additional protection for individuals and ground water by imposing a 10,000-year regulatory time frame will be reasonable. EPA's analyses of the performance of well-sited and well-designed disposal systems indicate that there will be zero releases for either a 1,000- or 10,000-year time frame. In fact, EPA's analyses show that, under conditions of normal ground-water flow, time frames much longer than 10,000 years are achievable for geologic repositories in some settings. (See Chapter 7 of the draft BID.) As such, there should be no additional compliance costs associated with a 10,000-year time frame at well-selected disposal sites. There may, however, be costs associated with the procedures used to demonstrate compliance although EPA believes that for well-selected and well-designed systems these costs will also be minimal.

If compliance assessment indicates that a disposal system fails to meet the 10,000-year individual dose standard, more robust engineered barriers to contain releases of radionuclides may be required. EPA acknowledges that the costs of more robust engineered barriers could be high (one preliminary estimate by DOE is \$3.2 billion for 10,000-year containers for commercial spent fuel and high-level waste) but notes that these costs only ensue if a poor site is selected to host the

disposal system. EPA's standards are designed, in part, to encourage the selection of good sites for disposal systems.

It is possible that extending the time frame for individual dose calculations could increase the costs by making additional modeling necessary. While it is difficult for EPA to estimate the costs of additional modeling, EPA believes the costs will be insignificant when compared to the multibillion dollar costs to develop disposal facilities. Furthermore, many of these costs will have to be incurred, in any case, under the provisions reinstated by the WIPP LWA. In particular, under the containment requirements now in effect under 40 CFR Part 191, compliance must be demonstrated over a period of 10,000 years. That demonstration requires an analysis of the movement of radionuclides out of the repository and into the environment. Because this analysis is at the heart of the proposed 10,000-year individual protection requirements, it can also be used for assessing compliance therewith.

Finally, EPA notes that disposal sites have differing costs of development, i.e., mining and construction, associated with them. Coincidentally, the geologic media which are least expensive to develop--salt and unsaturated tuff--are also the media which appear most capable of limiting releases of radionuclides, beyond 10,000 years, in a manner that keeps expected doses to individuals low. On the other hand, other media, e.g., basalt, which, EPA's analyses show, will not contain radionuclides for 10,000 years, costs more to develop than either salt or unsaturated tuff. (See the Economic Impact Analysis accompanying this proposal.) These costs could dwarf any increase in cost that may be associated with selecting a 10,000-year, rather than a 1,000-year, time frame. This reinforces EPA's view

that extending the time frame for the individual and ground-water protection requirements will not add significantly to the costs of disposal system development.

(iv) Incorporating a 10,000-year time frame in these requirements is consistent with the time frame adopted for the containment requirements in § 191.13 and with 10,000-year modeling guidance and requirements in other EPA regulatory programs such as "no-migration" determinations for the underground injection of untreated hazardous waste (40 CFR Part 148.20) and "no-migration" determinations issued under the Resource Conservation and Recovery Act (42 U.S.C. 6905, 6912(a), 6921, and 6924) at 40 CFR 268.6.

For the reasons stated above, EPA believes that the individual protection requirements should apply for 10,000 years. (These reasons also support EPA's decision to apply the ground-water protection requirements in Subpart C of today's proposal for 10,000 years.) EPA also believes that, to be responsive to the issues raised by the court remand of 40 CFR Part 191, it must choose 10,000 years as the standard. When the court ruled on the subject of the time frame associated with the 1985 individual and ground-water protection requirements, it made note of the fact that EPA used a 10,000-year standard for the containment requirements in the rule. The court stated that if EPA was going to be less protective for individuals than for populations it would have to explain why factors peculiar to the protection of individuals, calculated over time, justify a different time period than for protection of the overall population. EPA has concluded that there is no significant difference between these calculations in terms of the time frame involved and, hence, there is no convincing reason why the two types of standards should be different. Accordingly, EPA believes it is necessary to make the time

periods for the containment, individual and ground-water protection requirements the same.

*Dose Limits in the Individual Protection Requirements*

The individual protection requirements in § 191.15 of the 1985 standards 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 from all pathways of exposure. Today, the Agency is proposing to replace § 191.15 of the 1985 standards with individual protection requirements which adopt a different methodology for calculating doses to individuals.

In the 1985 standards, EPA's dose standards were specified in terms of limits on specific organ doses and the "whole body dose." This methodology is no longer in keeping with current practices of radiation protection; 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. (52 FR 2822) The methodology was originally developed by the International Commission on Radiological Protection (ICRP) and is now used by EPA and other Federal agencies.

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, i.e., multiplied by, the risk represented by that dose. These weighted organ doses are then added together and that total is the CED. In this manner, the risk of radiation exposure

to various parts of the body can be regulated through use of a single numerical standard.

The weighting factors for the individual organs and procedures for calculating annual CEDs are specified in Appendix B of today's proposal. A discussion of the basis for the EPA factors is included in the BID prepared in support of this proposal.

The CED is simple to implement, is more closely related to risk than the system of limiting doses to the whole body and to specific organs, and is recommended by the leading national and international advisory bodies. By changing to this new methodology, EPA will be conforming this rule to the internationally accepted method for calculating dose and estimating risk.

As noted above, § 8 of the WIPP LWA reinstates those aspects of the 1985 version of 40 CFR Part 191, Subpart B, not specifically found problematic by the First Circuit in NRDC v. EPA. The First Circuit had only one concern pertaining to the existing individual protection requirements: EPA failed to adequately explain its decision to limit the duration of the individual protection requirement to 1,000 years given the arguments of petitioners and the 10,000-year period in the containment requirements. The court neither addressed nor commented upon the numerical standard itself, which the 1985 standards set at 25 millirem per year to the whole body and 75 millirem per year to any critical organ. See 40 CFR 191.15. Thus, the WIPP LWA arguably represents an endorsement by Congress of the policy decisions that underlie these numerical standards, including the risk levels they represent. As discussed below, EPA is today proposing to reformulate those numerical limits to reflect current practices in measuring and assessing radiation

exposure. EPA is proposing an annual 15-millirem effective dose requirement which reflects an equivalent level of risk identified by the Agency in selecting the 1985 limits. In so doing, EPA sees no reason to alter its basic 1985 decision regarding risk to individuals and the appropriate level of protection. Rather, as discussed further below, EPA is only reconsidering the durational component.

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 15 millirem. EPA chose a 15-millirem dose limit because it is most consistent with the level of risk associated with the individual protection requirements of the 1985 standards (about  $5 \times 10^{-4}$ ) and because, as in 1985, it believes that this level is sufficiently protective for situations where no more than a few individuals are likely to receive the maximum dose.

In addition, the Agency believes it is reasonable to adopt a standard that allows a slightly higher level of risk when the dose is being received through all exposure pathways, e.g., direct exposure, food ingestion, water ingestion, and inhalation, and all environmental media, e.g., air and water, than when regulating doses received through a single environmental medium, e.g., a 10-millirem committed-effective-dose per year standard for air emissions (40 CFR Part 61).

The individual protection requirements in today's proposal apply to the undisturbed performance of the disposal system, including consideration of the uncertainties in that performance. Undisturbed performance means that the disposal system is not disturbed by human intrusion or the occurrence of unlikely disruptive natural events. This assumption is made because, if human intrusion

occurs, the individuals intruding may be exposed to high radiation doses which regulations cannot prevent.

In assessing the performance of a disposal system with regard to individual exposures, all pathways and routes through which radioactive material or radiation can travel from the disposal system to people must be considered. Ground water use within the controlled area need not be assumed, however, because geologic media within the controlled area are an integral part of the disposal system's capability to provide long-term isolation. The potential loss of ground-water resources is very small because of the small number of such disposal facilities contemplated.

#### *Standards for Ground-Water Protection (Subpart C)*

EPA is also proposing separate regulatory provisions designed to further protect public health by protecting ground-water resources. In general, EPA is proposing that disposal systems be designed to provide reasonable assurances that levels of contamination in off-site underground sources of drinking water will not, for 10,000 years, exceed the applicable maximum contaminant level (MCL) established in 40 CFR Part 141 under the SDWA, 42 U.S.C. 300g-1. These provisions are proposed for inclusion as a new Subpart C in 40 CFR Part 191 and will apply only to disposal (not management and storage). The disposal-related aspects of 40 CFR Part 191 are to be implemented in the design phase of a disposal system. For long periods of time, such as 10,000 years, the Agency believes that active surveillance cannot be relied upon for prevention or remediation of releases or to enforce levels of radiation in the environment.

Discussed below are the statutory and regulatory backgrounds, interpretive caselaw in the First Circuit, and the legal rationale for these proposed provisions. Further detail and explanation as to the particulars of the proposal follows, including a discussion of the technical and policy rationale underlying inclusion of Subpart C. The reader is also referred to the draft BID which discusses the analyses underlying Subpart C in greater detail.

### **Statutory and Regulatory Background**

#### ***The WIPP Land Withdrawal and the Nuclear Waste Policy Acts***

As noted above, today's proposal responds to the directive in § 8 of the WIPP LWA that EPA conduct a rulemaking to issue certain radioactive waste disposal regulations at 40 CFR Part 191, Subpart B (Subpart B). Under § 8(b)(1) of the WIPP LWA, EPA is to issue the required regulations within six months of enactment pursuant to rulemaking under 5 U.S.C. 553, i.e., informal rulemaking under the Administrative Procedure Act. EPA initially promulgated Subpart B in 1985 (50 FR 38,084 (Sept. 19, 1985)), but those regulations were subsequently vacated in whole as part of a remand order issued by the First Circuit in 1987 (discussed further above and below). See NRDC, Inc. v. EPA, 824 F.2d 1258 (1st Cir. 1987).

Section 8(a)(1) of the WIPP LWA reinstates those portions of Subpart B except §§ 191.15 and 191.16 which were remanded by the First Circuit. Accordingly, § 8(a)(2)(A) of the WIPP LWA exempts the requirements at 40 CFR 191.15 (individual protection) and 191.16 (ground-water protection) from the statutory reinstatement. Section 8(b)(2) addresses these non-reinstated provisions

by directing that EPA promulgate final regulations within six months. This proposal responds to that directive by proposing revised individual protection requirements in 40 CFR 191.15, discussed above, and by proposing new groundwater protection requirements as 40 CFR Part 191, Subpart C (discussed below).

The WIPP LWA also limits the applicability of the reinstated standards and the revisions being made today so that they will not apply to sites characterized under § 113(a) of the NWPA. The only § 113(a) site currently under consideration is Yucca Mountain, Nevada. The radioactive waste disposal standards that will apply there are to be developed by EPA pursuant to specific provisions in the Energy Policy Act of 1992, Pub. L. 102-486, which, among other things, requires EPA to formally consult with the National Academy of Sciences before proposing standards.

Notwithstanding this severing of EPA's Subpart B regulations from NWPA § 113(a) and, therefore, Yucca Mountain, the genesis of EPA's 1985 Subpart B standards and, thus, today's proposal, resides in significant part in the NWPA.

As noted above, the NWPA was enacted in 1982, amended in 1987, and is amended again by the Energy Policy Act of 1992. In general, the NWPA directs DOE and NRC to endeavor to establish repositories for spent nuclear fuel and HLW and directs EPA to "promulgate generally applicable standards for protection of the general environment from offsite releases from radioactive material in [such] repositories." 42 U.S.C. 10141(a). The NWPA does not independently authorize these rules, but instructs EPA to act pursuant to its "authority under other provisions of law." *Id.*

*The Atomic Energy Act and Reorganization Plan No. 3*

EPA's regulatory authority is provided by the AEA and Reorganization Plan No. 3 of 1970. The AEA authorized the Atomic Energy Commission (the predecessor of the NRC) to "establish by rule, regulation, or order, such standards ... to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable ... to protect public health or to minimize danger to life or property." When EPA was created in 1970 by Reorganization Plan No. 3, President Nixon transferred to EPA's jurisdiction:

"[t]he functions of the Atomic Energy Commission under the Atomic Energy Act of 1954, as amended, ... to the extent that such functions of the Commission consist of establishing generally applicable environmental standards for the protection of the general environment from radioactive material. As used herein, standards mean limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material." Reorganization Plan No. 3 at § 2(a)(6).

Thus, EPA is authorized to promulgate the generally applicable environmental standards called for by the NWPA [through reference to the AEA, including § 2201(b)].

Under the NWPA and the WIPP LWA, the contemplated disposal systems are to be built and operated by DOE. NRC has a licensing role under the NWPA, which, as discussed above, currently is focused exclusively upon Yucca Mountain.

Under the AEA, Reorganization Plan No. 3, and the NWPA, EPA's rulemaking role is limited to the promulgation of generally applicable environmental standards. Today's proposal is designed to complete the radioactive waste disposal standards that will apply to DOE's WIPP and any other non-NWPA disposal systems that may be selected in the future. Under the WIPP LWA, EPA must also promulgate regulations setting forth criteria for certifying DOE's compliance with these regulations. See WIPP LWA §§ 8(c), 8(d) and 9. These criteria are being developed by EPA through a separate rulemaking.

#### *The Safe Drinking Water Act*

As noted previously, in today's action EPA is proposing that disposal systems be designed to provide reasonable assurances that contamination in off-site underground sources of drinking water will not exceed the applicable maximum contaminant level for radionuclides (MCL) under the SDWA. The SDWA was enacted to assure safe drinking water supplies and to protect against endangerment of underground sources of drinking water. SDWA § 1421 and 42 U.S.C. 300(h) and (b)(1). "Endangerment" occurs if an underground injection "may result in the presence of underground water which supplies or can reasonably be expected to supply any public water system of any contaminant, and if the presence of such contaminant may result in such system's not complying with any national primary drinking water regulation or may otherwise adversely affect the health of persons." 42 U.S.C. 300h(d)(2).

Pursuant to § 1412 of the SDWA, EPA has promulgated National Primary Drinking Water Regulations (NPDWRs) for contaminants in drinking water which

may cause an adverse effect on the health of persons and which are known or anticipated to occur in public water systems. Pursuant to SDWA § 1401, these regulations include MCLs and "criteria and procedures to assure a supply of drinking water which dependably complies" with such MCLs. MCLs are the enforceable standards under the SDWA and represent the level of water quality that EPA believes is acceptable for consumption from public drinking water supplies. EPA is today proposing to adopt the MCLs for radionuclides as contained in 40 CFR Part 141.

*Subpart B as Promulgated in 1985*

As noted above, today's proposal modifies the rulemaking that resulted in the 1985 version of 40 CFR Part 191, Subpart B (a large portion of which is reinstated by the WIPP LWA). The authority for this proposal and the 1985 standards exists in the AEA and Reorganization Plan No. 3, as EPA had commenced developing those rules even before the NWPA was enacted in 1982. See 50 FR 38,066, 38,067 (Sept. 19, 1985) (Preamble to 1985 standards). However, the NWPA certainly informed and played a vital role in EPA's 1985 rulemaking and, thus, deserves reference here.

From the outset, EPA determined that its Part 191 standards would apply to spent nuclear fuel, high-level and transuranic radioactive waste. Spent nuclear fuel is mainly produced by commercial nuclear power plants which are licensed by the NRC. *Id.* at 38,066. HLW is mostly produced as a result of reprocessing of spent nuclear fuel from the nuclear weapons program. Transuranic waste, on the other hand, consists of equipment, clothing and other items contaminated by

radionuclides heavier than uranium and is also generated primarily within the nuclear weapons program. The nuclear weapons program is under the direction of the DOE. Id. at 38,066-077. As EPA developed its rules prior to passage of the NWPA, the Agency was aware that DOE was developing plans for disposing its transuranic waste at the WIPP. After enactment of the NWPA, which is directed at NRC-regulated wastes, EPA continued to develop rules that would also apply to the DOE's transuranic waste including that targeted for disposal at the WIPP. (Even though NWPA facilities are now excluded from today's rules, the scope of Subpart B, as reinstated and proposed today, continues to include the full range of waste.)

EPA concluded its rulemaking effort, in part in response to the directive in the NWPA and related litigation, by promulgating final standards on September 19, 1985. See 50 FR 38,084. Subpart A of those rules established standards for the management and storage of radioactive wastes, and Subpart B, limited portions of which are modified by today's proposal, established standards governing disposal.

As promulgated in 1985, Subpart B consisted of four categories of requirements: containment (40 CFR 191.13), assurance (40 CFR 191.14); individual protection (40 CFR 191.15), and ground-water protection (40 CFR 191.16). The containment requirements called for disposal systems to "be designed to provide a reasonable expectation" that releases of radionuclides be controlled to specified levels for 10,000 years. The assurance requirements supported the containment requirements by calling for a period of active maintenance and monitoring, permanent markers, record-keeping, redundant barriers against the movement of water and radionuclides toward the environment, and other

measures. The individual protection requirements limited individual doses for 1,000 years, and the ground-water requirements also called for 1,000 years of protection but for only a small category of ground water ("special sources").

The WIPP LWA reinstates the containment and assurance requirements of Subpart B. Thus, those provisions are not being re-opened or revisited by today's proposal, the scope of which is strictly limited to the individual and ground-water protection requirements.

### *The First Circuit Opinion*

Several petitions to review the 1985 standards were filed by environmental groups and states; the cases were consolidated in the First Circuit. For reasons peculiar to the individual and ground-water protection provisions of Subpart B (40 CFR 191.15 and 191.16), the court granted the petitions on July 17, 1987, initially remanding all of Part 191 to EPA for further consideration. See generally NRDC, Inc. v. EPA, 824 F.2d 1258 (1st Cir. 1987). As discussed above, the WIPP LWA reinstates all of Subpart B except those provisions for which EPA is to address the court's ruling through today's rulemaking. EPA's proposed response regarding individual protection is set forth above, while ground water is addressed below, beginning with a brief description of the court's ruling in this regard.

In granting the petition, the court emphasized the parallel environmental goals that exist in the SDWA, the NHPA, and the AEA and found that EPA had not adequately explained why the Part 191 standards were less stringent than those under the SDWA. The court reasoned that because the contemplated repositories will "likely" constitute underground injection under the SDWA, and

because the SDWA calls for assurances that underground injection not "endanger" underground sources of drinking water, i.e., ground water, EPA's standards were arbitrary and capricious because EPA did not adequately explain its choice of a level of protection less stringent than the SDWA for ground water outside the controlled area of the repository. The court stated:

[T]he SDWA is no mere incidental provision. It reflects a national policy and standard relative to the country's water supplies. Safeguarding such resources and their users is likewise implicit in the EPA's duty under the NWPA to promulgate HLW standards for the protection of the general environment from offsite releases from radioactive material in repositories.' 42 U.S.C. 10141(a). Id. at 1280.

Thus, the rules were remanded to EPA for further consideration and explanation:

To be rational, the HLW regulations either should have been consistent with the SDWA standards -- or else should have explained that a different standard was adopted and justify such adoption. As matters now stand, the DOE may be encouraged to expend large sums on site selection, design and construction only to discover itself embroiled in a dispute as to whether the EPA's HLW standards excuse it from securing a state underground injection permit based on the EPA's different, more [or, in some circumstances, less] stringent standards [emphasis added]. These are matters the EPA, relying on its expertise, should face and clarify in the HLW regulations; otherwise

the HLW regulations will be on a collision course with the SDWA regulations. *Id.* at 1281.

### **Legal Rationale for Today's Proposal**

In the manner and for the reasons discussed further below, today, EPA is proposing to conform the Part 191 ground-water protection requirements, through a new Subpart C, to the SDWA for underground sources of drinking water outside the controlled area of a disposal system subject to Part 191. Under this proposal, compliance with the new Subpart C will provide an equivalent level of protection as would compliance with the SDWA regulations. Thus, as also provided in today's proposal to revise regulations under the SDWA, compliance with Subpart C will constitute compliance with the SDWA to the extent -- if at all -- such compliance would otherwise be required for a particular disposal system.

In support, EPA notes that it does not believe there are persuasive scientific or policy reasons for going forward with a level of protection for these sites less stringent than would apply under the SDWA. However, in issuing today's proposal, EPA emphasizes that it is not revisiting the issue, litigated before the First Circuit, of whether disposal at a covered repository, either at the WIPP or elsewhere, constitutes underground injection under the SDWA. By conforming the two sets of standards, EPA does not believe that it is necessary to reach or resolve the question of whether disposal constitutes underground injection. EPA notes that the First Circuit itself did not resolve that issue, stating only in dicta that disposal in geologic repositories would "likely" constitute underground injection. What the court held was that, in any event, EPA could not rely on a narrow legal

conclusion that disposal of radioactive waste was not covered under the SDWA, even if that conclusion were correct. Instead, because the Part 191 and the SDWA programs called for essentially similar protective standards, EPA's duty was to either conform the substantive regulatory requirements of the two programs or explain any inconsistency. Today's proposal fully satisfies the First Circuit remand by proposing disposal standards that are consistent with the SDWA standards.

### *The Nature of the Proposal*

As proposed, Subpart C will require that a prospective disposal system demonstrate that it will comply for 10,000 years with the primary SDWA regulations for radionuclides -- the MCLs, currently codified at 40 CFR 141.15 and 141.16, in effect at the time the implementing agency determines compliance with Subpart C. Subpart C provides an additional measure of public health protection by limiting the sites or methods for disposal so that no degradation of off-site underground sources of drinking water in excess of the MCLs will occur.

Implementation of Subpart C will occur before any waste is actually disposed and, thus, these resources will not be "endangered" within the meaning of the SDWA.

These requirements will apply whether or not any particular disposal system constitutes underground injection. Thus, it is not necessary in this rulemaking to analyze the composition or method of disposal for any particular disposal system, such as the WIPP, to determine whether it is the sort of activity covered by the underground injection provisions in the SDWA.

### *Authority for Proposal*

As authority for this proposal, EPA relies upon the AEA, Reorganization Plan No. 3, the WIPP LWA, and the SDWA. Although, as described above, EPA's specific authority for Part 191 derives from the AEA and Reorganization Plan No. 3, that authority is also informed by the NWPA which provided the impetus for the 1985 standards, portions of which were reinstated by the WIPP LWA. The SDWA provides additional reason for EPA's proposal as it reflects Congressional policies and purposes, regardless of whether they apply as a matter of law, that are consistent with those in the authorities for Part 191. In other words, in exercising its rulemaking authority under the AEA and the WIPP LWA (as further informed by the NWPA), EPA is reconciling that action with Congressional purposes in the SDWA.

As noted above, at its inception, EPA's jurisdiction was defined to include the "establishment of generally applicable environmental standards for the protection of the general environment from radioactive material." Reorganization Plan No. 3 at § 2(a)(6). These standards are directed to radiation levels, concentrations, and exposures "in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material." *Id.* The express statutory authority for taking this action is provided by AEA. Included therein is the authority to "establish by rule ... such standards as the Commission [now EPA] may deem necessary or desirable ... to protect public health or to minimize danger to life or property." 42 U.S.C. 2201(b). And the NWPA, which played an integral role in the development of Part 191, directed that EPA promulgate "standards for protection of the general environment from offsite

releases from radioactive material in repositories." 42 U.S.C. 10141(a). In so doing, EPA is to act pursuant to its "authority under other provisions of law." Id. (e.g., the AEA). In other words, EPA is to promulgate those standards it deems necessary or desirable to protect the general environment, including public health, life, and property, from dangers presented by radioactive material at locations outside the boundaries of the sites where such materials were originally located.

Whether or not the SDWA applies as a matter of law for a particular repository, the Congressional purposes it advances are consistent with those underlying the national disposal program. Under the SDWA, EPA is to publish regulations (that the states will then, ordinarily, implement) to "prevent underground injection which endangers drinking water sources." 42 U.S.C. 300h(b)(1). Endangerment is broadly defined to occur whenever:

such injection may result in the presence in underground water [i.e., groundwater] which supplies or can reasonably be expected to supply any public water system of any contaminant, and if the presence of such contaminant may result in such system's not complying with any national primary drinking water regulation or may otherwise adversely affect the health of persons.

42 U.S.C. 300h(d)(2). In pertinent part, the national primary drinking water regulations include MCLs, 42 U.S.C. 300g-1, which are defined as the "maximum permissible level of a contaminant in water which is delivered to any user of a public water system."

The purposes advanced by this statutory scheme -- protection of the nation's drinking water resources so as not to adversely affect public health -- is in substantial accord with the purposes underlying EPA's authority for radioactive waste disposal regulations. See NRDC, 824 F.2d at 1280 ("[The SDWA] reflects a national policy and standard relative to the country's water supplies. Safeguarding such resources and their uses is likewise implicit in the EPA's duty under the NWPA to promulgate 'standards.'"). Thus, the proposed rules at Subpart C respond well to the entire range of statutory mandates. They are directed to ground water in the general environment, outside the "controlled" area of the repository, and are intended to protect a valuable resource in the environment, and, in that way, protect public health, life, and property from radioactive materials. They do this by conditioning disposal in a particular repository upon reasonable assurances that such use will not "endanger" groundwater for 10,000 years, as measured by the MCL then in effect.

*Compliance with Proposed Subpart C Constitutes Compliance with the SDWA*

Given the confluence of purpose between the authorities for regulating HLW disposal and the SDWA, as well as EPA's assessment that there is no scientific or policy reason not to require conformance, Subpart C is designed to provide an equivalent level of protection as would occur if the SDWA regulations applied directly to a particular disposal system. The underlying substantive requirement in the SDWA is that ground water not be endangered through degradation above the levels of the applicable MCLs. This is accomplished by the proposed requirement in Subpart C that before disposal may occur, reasonable assurances

must be provided that ground water will not be degraded to radionuclide levels above the MCLs for 10,000 years. For this reason, EPA is today proposing an amendment to its SDWA regulations for the UIC program (40 CFR 144.31(a)) stating that compliance with the Part 191 standards, including Subpart C, will constitute compliance with the SDWA, to the extent that that statute would otherwise apply at a particular disposal system.

In issuing today's proposals, EPA acknowledges that not only is the substantive protection in Subpart C equivalent, but also that the significant procedural components of the SDWA are likewise assured. EPA has reviewed the procedures available under the SDWA and compared them to the extraordinarily elaborate process that exists for the only disposal systems currently being considered for use, such as, the WIPP. This review reveals extensive procedural requirements for these disposal sites, including the preparation of detailed engineering plans and site assessments, long-term projections of performance, oversight by independent scientific boards and committees, historically high Congressional interest, and review by the public and several federal agencies, over the course of many years, before disposal may occur. Based thereon, it is EPA's belief that any decision to dispose of radioactive wastes in these, or any other, disposal systems will be subject to intensive and thorough public scrutiny under the national disposal program that is at least equivalent to that which might otherwise occur through direct application of the SDWA. In other words, EPA has identified no shortfall in the process that might jeopardize or interfere with the benefits and purposes underlying the SDWA.

As noted above, EPA has no need to address, and is not addressing, whether disposal at some or all of the facilities potentially covered by these rules constitute underground injection under the SDWA. Instead, EPA has determined for policy reasons to propose provisions that provide an equivalent level of protection as would be provided by regulation under the SDWA. In promulgating the AEA, the NWPA, and the WIPP LWA, Congress has articulated a comprehensive scheme for regulating radioactive waste disposal. The Congressional purposes underlying the pre-existing SDWA are consistent with those authorities. Thus, today's proposal advances both purposes -- it comprehensively regulates radioactive waste disposal in a manner that protects ground-water resources as effectively as the SDWA.

Nevertheless, as part of this rulemaking, EPA seeks public comment on how, if at all, implementation of Subpart C, in lieu of direct compliance with the SDWA regulations, to the extent that that statute applies for a particular disposal system, if at all, would not be equivalent to direct application of the SDWA. These comments may address procedural and substantive concerns.

## **Policy and Technical Rationale for Proposed Subpart C**

### ***EPA Approach to Ground-Water Protection***

Since the time of the court's decision in NRDC v. EPA, the Agency has been developing an overall ground-water protection strategy. 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 those for camps or restaurants serving a transient population). Finally, 34 of the 100 largest U.S. cities rely completely or partially on ground water.

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 effective approach for protecting the Nation's ground-water resources. 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 the overall goal to prevent adverse effects on human health and the environment and protect the environmental integrity of the nation's ground-water resources. Ground water needs to 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 uses 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 are relied upon to protect ground water to the maximum extent practicable. Detection of a percentage of the MCL at an appropriate monitoring location is used to trigger consideration of additional action, e.g., additional monitoring, or restricting or banning the use of the potential contaminant. Breaching the MCL would be considered a failure of prevention.

For all these reasons, protection of ground water is a critical factor in devising a regulatory approach for waste management and disposal. EPA is, therefore, proposing to add a new Subpart to the 40 CFR Part 19191 standards-- Subpart C, "Environmental Standards for Ground-Water Protection." These proposed requirements apply to radioactive waste disposal facilities and parallel the MCL dose-limit requirements under 40 CFR Part 141.

As discussed herein, EPA is today proposing separate ground-water protection requirements because, as discussed below, ground water is unique and deserving of pollution controls separate from other environmental media. (Although, § 191.15 of today's proposal limits the total risk to individuals from radiation doses received through all environmental media.)

For instance, Agency analyses indicate that, of all the potential environmental pathways, travel through ground water is the most likely to the accessible environment at most disposal sites. Moreover, because ground water is

not directly accessible, its contamination is far more difficult to monitor and/or clean-up than is contamination in other environmental media.

In addition, ground water generally moves slowly; velocities are usually 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 other environmental media like air or surface water--generally move in a plume with relatively little mixing or dispersion, so concentrations can remain high. These plumes of relatively concentrated contaminants move slowly through aquifers and may be present for many years--sometimes for decades or longer--potentially making the resource unusable for extended periods of time. Because an individual plume may underlie only a very small part of the land surface, it can be difficult to detect by aquifer-wide or regional monitoring. Of course, over thousands of years, monitoring is unlikely, avoidance will be difficult, and the area affected by be large. All of which argues in favor of effective ground-water protection so that the pollution may be avoided in the first instance.

The Agency believes that it is prudent to protect ground-water resources from contamination rather than rely upon clean-up. Stringent controls can help prevent releases from radioactive waste disposal facilities from causing present or future community water suppliers to have to implement expensive clean-up or treatment procedures and protects individual users, as well. Moreover, absent protection, the disposal system could find itself subject to the clean-up requirements under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (Superfund).

Today's proposal limits radioactive contamination in both public and private underground sources of drinking water to the MCLs found in the Agency's NPDWRs for radionuclides (40 CFR 141.15 and 141.16). Consistent with the 1987 First Circuit ruling, the proposed standard pertains to underground drinking water sources located outside the controlled area surrounding radioactive waste disposal facilities.

In proposing this approach, the Agency notes that, at most sites, releases of radionuclides into, and subsequent transport through, ground water is the most likely pathway to the accessible environment and to people. Once contaminated, an aquifer remains polluted for a relatively long time and it may be extremely difficult to restore the quality of the water in the aquifer. At the same time, while it is often feasible to limit the impact of polluted ground water on human health and the environment, the same may not be true of other polluted environmental media.

This proposed approach 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. This approach is reflected in Agency regulations pertaining to hazardous waste disposal (40 CFR Part 264), municipal waste disposal (40 CFR Part 257 and 258), underground injection (40 CFR Parts 144, 146, and 148), and uranium mill tailings disposal (40 CFR Part 192). The Agency's analyses demonstrate that these objectives are scientifically and technically achievable assuming well-selected and well-designed disposal sites and systems, respectively.

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 underground sources of drinking water warrant inclusion in the definition. This reflects a policy to protect ground water that is to be used in the future by today's proposal.

As a guide to the Agency, the Committee 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 ground water containing as much as 9,000 milligrams per liter TDS is currently supplying public water systems. EPA 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, with fewer than 10,000 milligrams per liter TDS, which currently or potentially could supply a public water system.

Proposed Subpart C protects USDWs in the vicinity of waste disposal systems by requiring that the disposal systems be designed so as to assure that ground water will not be contaminated above the MCLs. In other words, before disposal may occur, the implementing agency must determine that the undisturbed performance of the disposal system, over a 10,000-year period, will not result in releases which exceed the MCLs.

For consistency among today's proposed individual protection requirements, the reinstated containment requirements, and the SDWA underground injection requirements, the Agency is proposing a 10,000-year time frame for the duration of the ground-water protection requirements pertaining to disposal facilities. The disposal standards in Subpart C are design standards. Implementing agencies will determine compliance by evaluating 10,000-year projections of the disposal system performance. The implementing agency must determine that the natural and engineered features of a disposal facility, not disrupted by human intrusion or the occurrence of unlikely natural events, will prevent degradation of any underground source of drinking water outside the controlled area beyond the radionuclide MCLs.

The Agency is not soliciting comment on the UIC program requirements. Most of these requirements were promulgated in the 1970s and 1980s and were subject to extensive notice and comment procedures at that time. However, the Agency is soliciting comment on the broader issues of the appropriateness and

desirability of making the ground-water protection provisions found in 40 CFR Part 191 consistent with the UIC program protection requirements.

As noted earlier, it is important to emphasize that today's proposal does not address Subpart A or the portions of 40 CFR Part 191 which were reinstated by the WIPP LWA; it is strictly limited to the abovedescribed individual and ground-water protection proposals (40 CFR 191.15 and Subpart C) and associated definitions. Thus, EPA will not respond to comments on Subpart A or the reinstated portions of 40 CFR Part 191.

#### **Questions for Comment**

The Agency is requesting comment on the proposed amendments to 40 CFR Part 191 found in today's proposal. As noted previously, however, the scope of today's rulemaking does not extend to other provisions of Part 191. With that stipulation, EPA invites comment on whether today's proposal adequately protects public health and the environment from releases of radioactive material to the general environment. In addition, there are several specific issues on which the Agency would like commentors to focus.

1) Are there reasons for adopting a different regulatory time frame for the individual and ground-water protection requirements than the 10,000-year period of analysis associated with the containment requirements of 40 CFR 191.13?

2) In Subpart C, the Agency proposes to prevent radioactive contamination of "underground sources of drinking water" beyond the limits found in 40 CFR Part 141—the National Primary Drinking Water Regulations. The Agency is aware, however, that there could be some types of ground water that warrant additional

protection either because they are of unusually high value or are more susceptible to contamination. Should the Agency adopt non-degradation requirements for especially valuable ground water? If so, what types of ground water warrant this extra level of protection?

## **Regulatory Analyses**

### ***Regulatory Impact Analysis***

Under Executive Order No. 12291, the Agency must judge whether a regulation is "major" and thus subject to the requirements of a Regulatory Impact Analysis. The notice published today is not major because the rule will not result in an effect on the economy of \$100 million per year or more, will not result in increased costs or prices, will not have significant adverse effects on competition, employment, investment, productivity, and innovation, and will not significantly disrupt domestic or export markets. Therefore, the Agency has not prepared a Regulatory Impact Analysis under the Executive Order. The Agency has, however, prepared an Economic Impact Analysis which assesses the costs of today's proposed standards.

### ***Regulatory Flexibility Act***

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires each Federal agency to consider the effects of their regulations on small entities and to examine alternatives that may reduce these effects. The nature of this proposal is to limit releases from the disposal of radioactive waste. Since the disposal will only be carried out by the DOE and the waste is being stored and managed by DOE and

electric utilities that own and operate nuclear power plants, the Agency certifies that this regulation will not have a significant impact on a substantial number of small entities.

*Paperwork Reduction Act*

There are no information reporting or recordkeeping requirements associated with this rule.

**List of Subjects in 40 CFR Part 191**

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