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40 CFR Part 191
Environmental Radiation Protection Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 191

[FRL–4813–5]

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

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is promulgating amendments to the environmental standards for the disposal of spent nuclear fuel, high-level and transuranic radioactive wastes (40 CFR 191.15 and subpart C).

EPA originally promulgated these standards in 1985 pursuant to the Agency's authorities and responsibilities under the Nuclear Waste Policy Act of 1982, as amended, the Atomic Energy Act of 1954, as amended, and § 2(a)(6) of Reorganization Plan No. 3 of 1970 (5 U.S.C. app. 1). In 1987, following a legal challenge, the U.S. Court of Appeals for the First Circuit (hereinafter referred to as "the First Circuit" or "the court") remanded subpart B of the 1985 standards to the Agency for further consideration. *Natural Resources Defense Council, Inc.* v. *United States Environmental Protection Agency*, 824 F.2d 1258 (1st Cir. 1987). Recently enacted legislation, (Pub. L. 102–579) known as the Waste Isolation Pilot Plant Land Withdrawal Act (WIPP LWA), however, reinstates the 1985 disposal standards except "the 3 aspects of §§ 191.15 and 191.16 of such [standards] that were the subject of the remand ordered" by the First Circuit. The WIPP LWA directs EPA to expedite issuance of final disposal standards and specifies that such regulations shall not be applicable to the characterization, licensing, construction, operation or closure of any site required to be characterized under § 113(a) of Public Law 97–425, the Nuclear Waste Policy Act of 1982.

Today's action represents the Agency's response to this legislation and to the issues raised by the court pertaining to individual and groundwater protection requirements. After considering the relevant comments received on the February 10, 1993 proposed rulemaking, the Agency has taken this final action in the form of amendments to part 191 of title 40 of the Code of Federal Regulations. In so doing, EPA has not revised any of the regulations reinstated by the WIPP LWA.

DATES: These amendments will become effective on January 19, 1994. These amendments will be promulgated for purposes of judicial review at 1 p.m. eastern standard time on December 20, 1993.

ADDRESSES: *Background Information:* The technical information considered in developing these amendments is summarized in the final Background Information Document (BID) for the amendments to 40 CFR part 191. In addition, the potential economic costs of these amendments are contained in the Economic Impact Analysis (EIA). Single copies of either of these documents may be obtained by writing to the Waste Standards and Risk Assessment Branch, Criteria and Standards Division (6602J), Office of Radiation and Indoor Air, U.S. Environmental Protection Agency, Washington, DC 20460–0001 or by calling 202–233–9310.

Docket: 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), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC. The docket may be inspected between 8:30 a.m. and 12 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.

FOR FURTHER INFORMATION CONTACT: Ray Clark or Tara Chhay Cameron, Criteria and Standards Division (6602J), Office of Radiation and Indoor Air, U.S. Environmental Protection Agency, Washington, DC 20460–0001; telephone number 202–233–9310.

SUPPLEMENTARY INFORMATION:

Radioactive wastes are the result of governmental and commercial uses of nuclear fuel and other radioactive material. Today's action addresses standards which pertain to the disposal of spent nuclear fuel, high-level radioactive waste (HLW), and transuranic (TRU) radioactive waste, referred to hereinafter as simply "waste." (The Agency has previously issued standards for uranium mill tailings, 40 CFR part 192 and 40 CFR part 61, and plans to issue standards for low-level radioactive wastes to be codified at 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) Commercial nuclear power plants; (2) government-sponsored R&D programs in universities and industry; (3) 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 reactors and other U.S. Department of Defense reactors. 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 facility for reprocessing commercial spent fuel, the Nuclear Fuel Services Plant in West Valley, New York, has operated in the United States; it was closed in 1972. No commercial spent fuel is being reprocessed in the United States at this time. The HLW derived from other reprocessing activities are presently stored on Federal reservations in South Carolina, Idaho, and Washington.

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 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 Colorado, Idaho, Nevada, New Mexico, Ohio, South Carolina, Tennessee, and Washington.

History of Today's Action

Under authority derived from the Atomic Energy Act of 1954, as amended (AEA) (42 U.S.C. 2011–2296), and Reorganization Plan No. 3 of 1970 (5 U.S.C. [app. at 1343]), EPA is responsible for developing generally applicable environmental standards for protection of the general environment from radioactive material.

In December 1976, the Agency announced its intent to develop Federal guidance for the management and disposal of all types of radioactive wastes. Among EPA's first activities in developing this 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. EPA proposed "Criteria for Radioactive Wastes" in 1978 but withdrew the proposed criteria in 1981 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). Shortly thereafter the Nuclear Waste Policy Act of 1982 was enacted which directed that EPA utilize its existing authority to promptly promulgate waste standards pursuant to the AEA. EPA responded on September 19, 1985 by issuing final "Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes" at 40 CFR part 191 (50 FR 38066).

In March 1986, a number of States and environmental groups filed petitions for review of the rule. The petitions for review were consolidated in the First Circuit. The court issued its ruling on July 17, 1987. *NRDC* v. *EPA*, 824 F.2d 1258 (1st Cir. 1987). As discussed below in detail, the First Circuit found certain aspects of EPA's 1985 standards arbitrary and capricious because, although the Safe Drinking Water Act (SDWA) and the part 191 rules addressed similar environmental goals, EPA failed to adequately explain substantive discrepancies in the protective standards of the two programs. Accordingly, the court vacated and remanded:

(1) The Individual Protection Requirements (§ 191.15) for further consideration of their inter-relationship with part C of the SDWA and for further explanation of the 1,000-year time frame for the requirements;

(2) The Ground-Water Protection Requirements (§ 191.16) for insufficient notice; and,

(3) The rest of 40 CFR part 191 even though all except the two sections listed above were either unchallenged or upheld.

On rehearing, the government requested reinstatement of all sections except §§ 191.15 and 191.16. In September 1987, the court reinstated the management and storage standards (subpart A) but left the entirety of the disposal standards (subpart B, which includes §§ 191.15 and 191.16) in remand. *NRDC* v. *EPA*, Nos. 85–1915, 86–1096, 86–1097, 86–1098 (1st Cir.), Order dated September 23, 1987.

On October 30, 1992, the WIPP LWA was enacted. The law reinstated all of the disposal standards issued by the Agency in 1985 that had been remanded by the court in 1987 except the individual and ground-water protection requirements which were the basis of the remand. WIPP LWA, section 8. The WIPP LWA also provides an extensive role for EPA in reviewing and approving various DOE activities at the WIPP including requirements that EPA approve test phase and retrieval plans, and certify whether the performance of the WIPP repository will meet the final 40 CFR part 191 standards. The Agency will conduct separate rulemakings to address those matters.

As required by the WIPP LWA, EPA is today addressing the remand of the 1985 version of 40 CFR 191.15 and 191.16 by promulgating a new § 191.15 and a new subpart C. This represents the Agency's response to the WIPP LWA and to the issues raised in the remand.

It is important to note that under the WIPP LWA, subparts B and C of 40 CFR part 191 will not apply to any disposal site required to be characterized under section 113(a) of Public Law 97–425, the Nuclear Waste Policy Act of 1982 (NWPA). At this time, the only site affected is Yucca Mountain, Nevada. The NWPA required characterization of candidate sites approved by the President after an extensive nomination, recommendation, and evaluation process. Public Law 97–425, sections 112, 113 (1982), 42 U.S.C. 10132, 10133. The 1987 amendments to section 113 of the NWPA limited characterization activities to the Yucca Mountain site only (42 U.S.C. 10133(a)) and defined "Yucca Mountain site" as the candidate site recommended to the President on May 27, 1986 under 42 U.S.C. 10132(b)(1)(B). Public Law 100–203, sections 5002, 5011(e). Thus, 40 CFR part 191 does not apply to the Yucca Mountain site because the Yucca Mountain site is a site that is required to be characterized under section 113(a) of Public Law 97–425.

Finally, the Energy Policy Act of 1992 requires EPA to promulgate public health and safety standards for protection of the public from releases of radioactive materials stored or disposed of in the potential repository at the Yucca Mountain site. Public Law 102–486, section 801(a)(1), 106 Stat. 2921.

Objective and Implementation of Today's Action

Under authorities established by the AEA, Reorganization Plan No. 3 of 1970, the NWPA and the WIPP LWA, the Agency is promulgating amendments to 40 CFR part 191, the Agency's generally applicable environmental standards for the management and disposal of spent nuclear fuel, high-level and transuranic radioactive wastes. As noted above, the WIPP LWA, by operation of law, reinstates the provisions of 40 CFR part 191, as issued in 1985, not specifically found problematic by the First Circuit. The EPA has chosen not to revisit, in this rulemaking, the reinstated provisions. Accordingly, the scope of today's promulgation is strictly limited to the provisions of the 1985 standards vacated and remanded by the court—the individual and ground-water protection requirements.

Currently, three Federal agencies are responsible for implementation of part 191. The EPA, under the authority of the WIPP LWA, will be responsible for, among other items, certifying compliance at the WIPP and will be promulgating criteria for this certification of compliance under a separate rulemaking. The Nuclear Regulatory Commission (NRC) and the DOE will be responsible for implementing and enforcing these standards for other sites to which they may apply, through appropriate regulations or procedures.

Although developed primarily through consideration of mined geologic repositories, 40 CFR part 191, including today's amendments, applies to disposal of the subject wastes by any method, with three exceptions. First, the standards do not apply to ocean disposal or disposal in ocean sediments. Disposal of HLW in this manner is prohibited by the Marine Protection, Research and Sanctuaries Act of 1972, as amended (33 U.S.C. 1401–1445). If the law is ever changed to allow such disposal, the Agency would need to develop appropriate regulations.

Second, as promulgated today, the ground-water protection requirements in subpart C of part 191 do not apply to disposal systems located above or within a formation which within one-quarter (¼) mile of the disposal system contains an underground source of drinking water (USDW). As discussed below, EPA is reserving final action with respect to such repositories in order to explore in greater detail what effect, if any, the prohibition on "Class IV" wells under the SDWA regulations at 40 CFR 144.13 might have on them. The EPA will address this category of disposal systems in the same context as its rulemaking to establish disposal standards for Yucca Mountain pursuant to the Energy Policy Act of 1992.

Third, today's promulgated amendments do not apply to waste

disposal which occurred before the effective date of the 1985 standards. The provisions of the disposal standards are intended to be met through a combination of steps involving site selection, disposal system design, and operational techniques, e.g., engineered barriers. Therefore, the Agency believes that the standards which were in existence from 1985 until the First Circuit decision in 1987 are appropriate to be used for activities which occurred, or were begun, during that time rather than imposing new and different standards on such activities. The effective date for § 191.13, Containment Requirements, and indeed all of 40 CFR part 191, except those provisions being promulgated today, remains November 18, 1985. In accord with this, disposal which occurred on or after November 18, 1985 until the effective date of today's action is subject to the standards as they existed on November 18, 1985.

It is important to emphasize that today's action 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 above-described individual and ground-water protection requirements (40 CFR 191.15, 191.16 and subpart C) and associated definitions. Even though comments were received on other portions of part 191, EPA has not proposed and is not amending subpart A or the reinstated portions of 40 CFR part 191 and is not, therefore, responding to comments received on these specific provisions. See 58 FR 7924, 7925.

Description of the Amendments

The Agency's amendments to 40 CFR part 191 are described in this section.

Definitions

In order to fulfill the regulatory objectives of today's action, the Agency is adding several terms, deleting several terms, and making changes to several others including:

(1) The addition of a new term, "radioactive material," which means materials containing radionuclides that are subject to the Atomic Energy Act and that have half-lives greater than twenty years. There may arise circumstances where radioactive materials not presently classified as spent nuclear fuel, high-level, or transuranic wastes are managed or disposed of with these wastes. For instance, 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 (see 54 FR 22578 codified at 10 CFR part 61). "Greater-than-Class C" wastes are wastes which exceed certain radionuclide concentrations specified by the NRC in 10 CFR part 61. The Agency's definition of radioactive material is intended to ensure that contributions to the radiation dose received by individual members of the public and impacts on ground water from "greater-than Class C" or any other radioactive materials managed or disposed with spent nuclear fuel, high-level and/or transuranic radioactive wastes are covered by the rules being promulgated today;

(2) Changes to the definition of the term "implementing agency" to reflect EPA's role under the WIPP LWA. The list of responsibilities in the definition describes EPA's implementation role under 40 CFR part 191. EPA also has additional implementation responsibilities under the WIPP LWA such as, but not limited to, approval of the test and retrieval plans and determining whether the WIPP complies with other environmental statutes.

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

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

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

Individual Protection Requirements (§ 191.15)

The Agency has replaced 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, did not contain any numerical restrictions on individual doses after disposal. Rather, they relied upon the qualitative assurance requirements to reduce the likelihood of such exposures. For example, the assurance requirement calling for extensive permanent markers and records was intended to avoid exposure to radiation by transmitting information to future generations about the dangers of intruding into the vicinity of a repository.

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 and that reliance upon containment requirements, even if supplemented with assurance requirements, could 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 the length of time over which the requirements should apply and the appropriate dose level for the requirements.

Time Frame of the Individual Protection Requirements

The disposal regulations promulgated in 1985 included individual protection requirements which limited annual radiation doses to individuals for 1,000 years after disposal. Before 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 believed it was 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 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, the difficulty of demonstrating compliance with individual exposure limits over time frames longer than 1,000 years appeared to be greater than the capabilities of assessment technology because of the analytical uncertainties involved. Therefore, the Agency decided, in the 1985 rule, that a 1,000-year period was adequate for the quantitative limits on individual doses after disposal.

In 1987, as noted above, the court held that the Agency's choice of a 1,000-year period was largely unsupported and, therefore, arbitrary. The Agency's reason for not adopting a longer time frame was, generally, that although better engineered "barriers...could provide longer term protection for individuals, they would not provide substantial benefits to populations." See *NRDC* v. *EPA* 829 F.2d at 1287. The court found this argument "deficient

because it purports to justify the Agency's policy choice solely in terms of a variable that the individual protections were not designed to influence." *Id.* at 1289. Thus, the court remanded that portion of the regulations to the Agency for reconsideration or 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 adopting a 10,000-year time frame for the individual protection requirements.

The Agency has decided upon 10,000 years as the regulatory period for four primary reasons:

(1) 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, considering various times in the future, from waste disposal systems in several different geologic media. 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 fatal cancer associated with exposure to one rem/year of radiation having a low level of linear energy transfer (LET), i.e., depositing small amounts of energy per unit length of the absorbing medium (see chapter 5 of the BID for more detail), is approximately four in ten thousand per year (4×10^{-4}/year) or three in one hundred over a 70-year lifetime (3×10^{-2}/lifetime). (Hereinafter, as used in this document, the term "risk" refers to the chance of developing a fatal cancer.) For other, better geologic media, the Agency's generic analyses estimate no releases for 10,000 years. The Agency believes that selecting a 10,000-year time for the requirements, rather than a 1,000-year time frame, will encourage the selection of better sites and/or the design of more 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.

(2) The Agency believes improvements in modeling capability since 1985 have facilitated demonstrating compliance with individual dose limits for 10,000 years. 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 BID supporting today's rulemaking. The BID may be found in the docket supporting this rulemaking (Docket Number R–89–01). 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.

Furthermore, analyses performed prior to 1985 relied upon data derived primarily from generic geological data available in the open literature. Since that time, additional data have been collected during the characterization of potential disposal sites which provide an improved basis upon which to assign values to the various parameters in analyses performed now.

This improved data quality combined with improved computer models allows improved demonstrations of compliance. EPA expects that the quality of data and the capability of computer models will continue to improve. This will facilitate the longer term modeling and supports the choice of a 10,000-year time frame.

(3) 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. The EPA's generic base case analyses of the undisturbed performance of well-sited and well-designed disposal systems estimate that there will be no projected releases for both the 1,000- or 10,000-year time frames. Therefore, 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 assessments indicate that a disposal system design will fail to meet the 10,000-year individual dose standard, more robust engineered barriers to control 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 HLW) but notes that these costs only ensue if a site is selected to host the disposal system which cannot otherwise comply with the standards. 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 regulatory 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 includes undisturbed performance, it could also be used for assessing compliance with the 10,000-year individual protection requirements.

Finally, EPA notes that disposal systems have differing costs of development, i.e., for 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 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, cost more to develop than either salt or unsaturated tuff. (See the Economic Impact Analysis.) 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.

(4) 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 issued under the Resource Conservation and Recovery Act [sec. 3004 (d)(1), (e)(1), and (g)(5), 42 U.S.C. 6924 (d)(1), (e)(1), (g)(5)] for land disposal of untreated hazardous waste (40 CFR 268.6) and for the underground injection of untreated hazardous waste (40 CFR 148.20).

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 action for 10,000 years. The Agency also believes that choosing 10,000 years as the standard is responsive to the issues raised by the First Circuit's 1987 remand. 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 EPA believes that if it is going to regulate over shorter time frames for individuals than for populations it needs 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 such significant difference and has found no convincing rationale as to why the time periods for the two standards should be different. Accordingly, EPA believes it is now possible, and therefore appropriate, 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 replacing the "whole body/specific organ" dose limits in § 191.15 of the 1985 standards with an annual limit of 15 millirems committed effective dose (CED), a different methodology for calculating doses to individuals.

The reason for the change in dose calculation methodology is that the "whole body/specific organ" methodology has been superseded by the CED methodology. 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 to that organ as a result of 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.

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 is conforming to the internationally accepted method for calculating dose and estimating risk.

As noted above, section 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 requirements 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, in 40 CFR 191.15, at 25 millirems per year to the whole body and 75 millirems per year to any critical organ. Thus, the WIPP LWA represents a ratification by Congress of the previously made policy decisions that underlie these numerical standards, including the risk levels they represent. As discussed below, EPA is today reformulating those numerical limits to reflect current practices in measuring and assessing radiation exposure but is not changing the substance of those standards. The EPA has adopted an annual 15-millirem CED requirement which is associated with the same level of risk, about 5×10^{-4}, accepted by the Agency in selecting the 1985 limits. In reviewing the record, EPA has found no convincing reason to alter its basic 1985 decision regarding the appropriate level of protection for individuals for the activities subject to this rulemaking.

The EPA has chosen a 15-millirem CED per year limit because it finds the lifetime risk represented by this level of exposure to present an acceptable risk for the purposes of this rulemaking since it involves only a small number of potential sites and would result in only a small number of people potentially being exposed to the maximum allowed individual risk. While this risk is slightly higher than the risks associated with many other Agency regulations, in general, those risks result from exposures occurring via a single environmental medium or pathway and often from just one pollutant within that medium or pathway. In this case, the Agency is limiting the annual CED from internal exposure to all radionuclides delivered through all pathways, plus the effective dose from any external exposure, to 15 millirems.

In addition, this level is consistent with the ICRP approach of apportioning an overall dose limit from man-made radiation to particular activities, such as waste disposal. The ICRP suggests using an overall limit of one millisievert CED (100 millirems CED) per year. While EPA has not established such an overall limit, the Agency finds that 15 millirem CED per year is today an appropriate and acceptable fraction of the 100-mrem ICRP recommendation because it is small enough to ensure that the total exposure of an individual who was exposed to a number of sources would stay below the overall limit.

The individual protection requirements apply only 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 aspect of the standard was included because, if human intrusion occurs, the individuals intruding may be exposed to high radiation doses. No regulatory scheme could prevent this for situations in which large amounts of radioactive material are confined to a relatively small area.

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, with one exception. Ground water withdrawn for consumption directly from within the controlled area need not be included in the analyses because geologic media within the controlled area are an integral part of the disposal system's capability to provide long-term isolation. See *NRDC v. EPA*, 824 F.2d at 1272–74. The resulting potential loss of ground-water resources is very small nationwide because of the small number of such disposal facilities contemplated. However, the movement of contaminated ground water as a result of undisturbed behavior from the controlled area into the surface water system must be included in the analyses.

Standards for Ground-Water Protection (Subpart C)

EPA is also promulgating standards designed to further protect public health by protecting ground-water resources. In general, the standards require disposal systems to be designed so that, for each pollutant, the level of contamination in offsite USDWs will not, for 10,000 years, exceed the applicable maximum contaminant level (MCL) established in 40 CFR part 141 under section 1412 of the SDWA, 42 U.S.C. 300g-1. These provisions are in 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, including those being issued today, are to be implemented in the design phase of a disposal system. Today's rules rely upon the design phase because for long periods of time, such as 10,000 years, it is obvious that active surveillance cannot be relied upon for prevention or remediation of releases or to enforce regulatory limitations on maximum permissible 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 provisions. Further detail and explanation as to the particulars of these standards follow; included is a discussion of the technical and policy rationale underlying subpart C. The reader is also referred to the BID which discusses the technical analyses underlying subpart C in greater detail.

Identification of USDWs

The Agency realizes that there may be instances in which there are multiple steps (or licenses/certifications) to be completed prior to the final closure of a disposal system. This could arise if the licensing/certification process is established to proceed on a stepwise basis. For example, for the WIPP, the EPA will perform an initial certification of compliance and, if the disposal system is found to be in compliance, will recertify compliance every five years thereafter. Identification of USDWs occurs on the date of the first overall approval, by the implementing agency, of the system for use as a disposal system. The designers should have complete knowledge of the area's ground-water system prior to its approval. Therefore, § 191.23 specifies that the USDWs to be considered in the compliance assessment are those which have been identified as of "the date the implementing agency determines compliance with subpart C." Any recertification of compliance will be evaluated to consider USDWs identified at the time of recertification.

Maximum Contaminant Levels to be Applied

Section 191.24 specifies that USDWs are to be protected so that levels of radioactivity in them will not exceed the MCLs which are in force on the effective date of this action. The Agency is currently considering issuing revised MCLs which were proposed on July 18, 1991 (56 FR 33050). However, until that occurs, the Agency believes that it should use the current levels. When MCLs are changed in the future, the Agency will revisit the ground-water protection requirements used in part 191 and revise them, as necessary, to be consistent.

Statutory and Regulatory Background

The WIPP Land Withdrawal and the Nuclear Waste Policy Acts

As noted above, today's action responds to the directive in section 8 of the WIPP LWA that EPA conduct a rulemaking to issue certain radioactive waste disposal regulations at 40 CFR part 191, subpart B. The EPA initially promulgated subpart B in 1985 (50 FR 38084 (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 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 the bases of the remand by the First Circuit). Accordingly, section 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. Today's action responds to that directive by revising the individual protection requirements in 40 CFR 191.15, discussed above, and by adding new ground-water protection standards 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 required to be characterized under section 113(a) of Public Law 97–425, the NWPA. The only section 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. Public Law 102–486 section 801(a)(1) (1992), 106 Stat. 2921.

Notwithstanding this severing of EPA's subpart B regulations from NWPA section 113(a) and, therefore, Yucca Mountain, the genesis of EPA's 1985 subpart B standards 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. The NWPA 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 fundamental 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 health or to minimize danger to life or property." (42 U.S.C. 2201(b)) 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 section 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 section 2201(b)). Furthermore, under the AEA, Reorganization Plan No. 3, and the NWPA, EPA's role is limited to the promulgation of these standards. Today's action is designed to complete the radioactive waste disposal standards that will apply to WIPP, if it is found to be acceptable as a disposal system, the Greater Confinement Disposal facility at the Nevada Test Site, and any other non-NWPA § 113(a) disposal systems for the subject wastes 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 at the WIPP. See WIPP LWA sections 8(c), 8(d) and 9. These compliance criteria are being developed by EPA through a separate rulemaking (58 FR 8029).

The Safe Drinking Water Act

As noted previously, in today's action, EPA is requiring that disposal systems be designed so that contamination in offsite USDWs will not exceed the applicable MCL for radionuclides under the SDWA. The SDWA was enacted to assure safe drinking water supplies and to protect against endangerment of USDWs. SDWA section 1421(b)(1), 42 U.S.C. 300h(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 section 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 (40 CFR parts 141 and 142). These regulations specify either MCLs or treatment techniques and contain "criteria and procedures to assure a supply of drinking water which dependably complies" with such MCLs. SDWA section 1401. The 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 adopting the MCLs for radionuclides as contained in 40 CFR part 141, as they exist on the effective date of this rulemaking, as standards for ground-water protection under 40 CFR part 191.

Subpart B as Promulgated in 1985

As noted above, today's action modifies subpart B of the 1985 version of 40 CFR part 191. From the outset, EPA determined that its 40 CFR 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. 50 FR 38066 (Sept. 19, 1985). High-level waste is produced primarily as a result of reprocessing of spent nuclear fuel from the nuclear weapons program. Transuranic waste consists of equipment, clothing and other items contaminated by radionuclides having atomic numbers larger than 92 (uranium) and is also generated primarily within the nuclear weapons program. The nuclear weapons program is under the direction of the DOE. *Id.* at 38066–38077. 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 section 113(a) facilities are excluded from today's rule, the scope of subpart B, both those reinstated portions and those being finalized 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 40 CFR part 191 on September 19, 1985. See 50 FR 38084. Subpart A of part 191 established standards for the management and storage of the subject wastes, and subpart B, limited portions of which are modified by today's action, established standards for disposal.

As promulgated in 1985, subpart B contained 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 would 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, recordkeeping, 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 protection requirements also called for 1,000 years of protection for "special sources" of ground water.

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 pertaining to flaws it identified in the individual and ground-water protection provisions of subpart B (40 CFR 191.15 and 191.16), the court, on July 17, 1987, vacated and remanded all of part 191 to EPA for further consideration. See generally *NRDC* v. *EPA*, 824 F.2d 1258 (1st Cir. 1987). Following a request by the government, on September 23, 1987, the court reinstated subpart A. That reinstatement and the WIPP LWA reinstatement of most of subpart B left unresolved those provisions which EPA is addressing in today's rulemaking. EPA's 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 the rationale for its ruling, the court emphasized the parallel environmental goals that exist in the SDWA, the NWPA, and the AEA and found that EPA had not adequately explained why the part 191 standards were not consistent with those under the SDWA. The court reasoned that because the SDWA calls for assurances that underground injection not "endanger" USDWs and because the NWPA implicitly adopts the same goal for HLW standards (outside the controlled area), EPA's part 191 standards were arbitrary and capricious since EPA did not adequately explain its choice of a dose limit which might result in less protection than the MCLs for radionuclides under 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. *NRDC* v. *EPA*, 824 F.2d at 1280, citing 42 U.S.C. 10141(a).

Thus, the rules were remanded to EPA for further consideration and explanation. The court explained:

> 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. *Id.* at 1281.

For the reasons set forth elsewhere in this notice, EPA has determined that disposal systems subject to part 191 requirements should not be considered underground injection wells under the SDWA. Today's interpretation of the scope of the underground injection control (UIC) program is, however, neither necessary nor sufficient in assessing the propriety of the part 191 standards with respect to the SDWA. Rather, as reflected in the First Circuit remand decision, in light of the similar environmental goals of the SDWA and part 191 (see 824 F.2d at 1280), there are two key issues: whether the part 191 regulations contain protective standards that are substantively equivalent to those under the SDWA; and, to the extent (if any) that the standards are not equivalent, whether EPA has adequately explained the divergence between the substantive levels of protections afforded by the respective programs. See 824 F.2d at 1293.

Thus, regardless of whether a disposal system is directly subject to UIC requirements, EPA has an obligation to explain any discrepancy in the protective standards of part 191. As explained below, by adopting the MCLs under the SDWA as the protective standard for part 191, EPA has provided substantive equivalence, with the possible exception of the Class-IV-well ban under the UIC program. Accordingly, today's notice reserves final action with respect to disposal systems that might be affected by the Class-IV ban to enable further consideration of this issue.

Legal Rationale for Today's Action

In the manner and for the reasons discussed further below, EPA is conforming the part 191 ground-water protection requirements, through a new subpart C, to the SDWA for USDWs outside the controlled area of a disposal system subject to part 191. Compliance with the new subpart C will provide an equivalent level of radiation protection as would compliance with the SDWA regulations in that both subpart C and the SDWA require adherence to the MCLs. Hence, today's action resolves, with one possible exception discussed below, the substantive inconsistencies between the SDWA program and part 191 that was the basis for the First Circuit's remand.

Furthermore, EPA notes that the First Circuit itself did not resolve the question of whether disposal constitutes underground injection. Although the court stated in dicta that disposal in geologic repositories would "likely" constitute underground injection, the focus of the court's concern was EPA's adoption of inconsistent substantive standards under programs with similar environmental goals. Consequently, the court held that EPA must either conform the substantive regulatory requirements of the two programs or explain any inconsistency. Today's action satisfies the First Circuit remand by issuing amended disposal standards that are consistent with the SDWA MCL limits.

The Nature of Subpart C

Subpart C requires that a prospective disposal system demonstrate that it will comply for 10,000 years with the SDWA MCLs for radionuclides as currently codified at 40 CFR 141.15 and 141.16 or until such time that subpart C of part 191 is amended to be consistent with new MCLs. This means that disposal systems subject to subpart C shall be designed such that they will not cause the amount of radionuclides in USDWs, in the accessible environment, to exceed the MCLs. Implementation of subpart C will occur before any waste is actually disposed and, thus, these resources will not be "endangered" within the meaning found in part C of the SDWA. In recognition of the uncertainties involved with projecting performance over 10,000 years, as with the containment requirements in subpart B, unequivocal numeric proof of compliance is neither necessary nor likely to be obtained.

Authority for Today's Action

As authority for this rulemaking, EPA is relying upon the AEA, Reorganization Plan No. 3, the WIPP LWA, and the NWPA. The express statutory authority for taking this action is provided by the AEA. Included therein is the authority to "establish by rule * * * such standards * * * as the Commission [now EPA] may deem necessary or desirable * * * to protect health or to minimize danger to life or property." 42 U.S.C. 2201(b). Furthermore, the NWPA, which has 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.* Other provisions of law include the AEA, Reorganization Plan No. 3, and the WIPP LWA. In other words, EPA is to promulgate those standards it deems necessary or desirable to protect the general environment, including health, life, and property, from dangers presented by radioactive material at locations outside the boundaries of the sites where such materials were originally located.

The SDWA provides additional reason for EPA's action as it reflects Congressional policies and purposes. Whether or not the SDWA applies as a matter of law for a particular repository, the Congressional purposes that the SDWA advances are consistent with those underlying national radioactive waste disposal programs. Under the SDWA, EPA is to publish regulations (that the States will 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 NPDWRs 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." 42 U.S.C. 300f(3)

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. "[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." *NRDC* v. *EPA*, 824 F.2d at 1280. Thus, the

standards in subpart C respond to the entire range of statutory mandates. They are directed to ground water in the accessible environment, outside the "controlled" area of the repository, and are intended to protect a valuable resource in the environment, and, in that way, protect health, life, and property from radioactive materials. They do this by establishing requirements such that releases, as a result of disposal, will not (considering the background concentration) "endanger" ground water for 10,000 years, as measured by the MCLs.

Subpart C Radiation Protection Is Equivalent to Radiation Protection Under the SDWA

Given the confluence of purpose of the AEA and the SDWA, subpart C is designed to provide an equivalent level of protection as would occur if the SDWA regulations for MCLs applied directly to a particular disposal system. The underlying substantive requirement in the SDWA is that ground water, which is or can reasonably be expected to be a source of drinking water, not be endangered by the presence of any radionuclide which may cause a violation of the applicable MCLs or may otherwise adversely affect the health of persons. This is accomplished by the requirement in subpart C that before disposal may occur, a determination must be made that radionuclide levels in such ground water will not exceed the applicable MCLs for 10,000 years. As discussed elsewhere, EPA is addressing potential discrepancies between the part 191 requirements and the Class-IV-well ban under the SDWA by deferring final action on those disposal systems that might be affected by the Class-IV-well prohibitions.

Policy and Technical Rationale for 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 upon 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). Thirty-four of the 100 largest U.S. cities rely completely or partially on ground water. In addition, ground-water contamination is of concern to EPA because of its potential impact upon the ecosystem.

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 sets forth an effective approach for protecting the Nation's ground-water resources. The approach will be reflected in EPA policies, programs, and resource allocations and is intended to guide EPA, State and local governments, and other parties in carrying out ground-water protection programs. The Agency has also issued "The Final Comprehensive State Ground Water Protection Program Guidance." This document provides guidance to States for establishing a coordinated approach to their ground water.

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. Adverse effects mean those risks that are significant to the affected population and determined, where appropriate, under relevant statutes to be unreasonable. Ground water needs to be protected to ensure that the Nation's currently used and potential sources of drinking water are preserved for present and future generations. In addition, ground water should be protected to ensure that ground water that is closely hydrologically connected to surface water does not interfere with the attainment of surface-water quality standards, which is necessary to protect human health and the integrity of associated ecosystems. The Strategy also recognized, though, that efforts to protect ground water must also consider the use, value, and vulnerability of the resource, as well as social and economic values. In carrying out its programs, the Agency uses 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 or other appropriate reference point 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, adding a new subpart to the 40 CFR part 191 standards—"Subpart C, Environmental Standards for Ground-Water Protection." This subpart applies to radioactive waste disposal facilities and parallels the MCL dose-limit requirements under 40 CFR part 141.

The EPA is promulgating separate ground-water protection requirements because ground water is unique and deserving of pollution controls separate from other environmental media. Agency analyses indicate that, of all the potential environmental pathways, travel through ground water is the most likely pathway to lead 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 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 may be large. All of which favor effective ground-water protection so that the pollution may be prevented in the first instance.

The Agency believes that it is prudent to protect ground-water resources from contamination through prevention rather than rely upon clean-up. This approach avoids requiring present or future community water suppliers 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 expensive clean-up by future generations.

Today's subpart C limits radioactive contamination in USDWs 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 standard pertains to USDWs located outside the controlled area surrounding radioactive waste disposal systems. See *NRDC* v. *EPA*, 824 F.2d at 1274.

This 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 parts 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.

Subpart C protects what is known as an "underground source of drinking water" (USDW). The definition of "USDW", and indeed all of the definitions pertinent to subpart C, are taken directly from the Agency's underground injection control regulations found in 40 CFR parts 144 through 146. These definitions are designed to be consistent with the SDWA requirements. The definition of USDW 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 USDWs warrant inclusion in the definition. This reflects a policy to protect ground water that is to be used in the future.

As a guide to the Agency, the Committee Report suggested that aquifers with fewer than 10,000 milligrams per liter of total dissolved solids (TDS) be included. H.R. Rep. No. 1185, 93d Cong., 2d Sess. 32 (1974). The Agency has reviewed the current information on the use of aquifers for drinking water which contain high levels of TDS. 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. 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 up to 10,000 milligrams per liter TDS as potential sources of drinking water.

The provisions found in subpart C 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.

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, considering the uncertainties in the analysis, that the undisturbed performance of the disposal system, over a 10,000-year period, will not cause releases which could result in the radionuclide MCLs being exceeded.

For consistency among today's individual protection requirements, the reinstated containment requirements, and the SDWA underground injection requirements, the Agency is adopting 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 USDW outside the controlled area beyond the radionuclide MCLs.

Compliance With Part 191 as Compliance With the Underground Injection Control Requirements

In addition to proposing amendments to the disposal standards of 40 CFR part 191, EPA proposed to add a provision to the Agency's Underground Injection Control Program regulations at 40 CFR 144.31(a) which stated that compliance with 40 CFR part 191, subparts B and C, would constitute compliance with regulations under the SDWA. (58 FR 7924, February 10, 1993). In light of EPA's determination that nuclear waste disposal systems should not be considered underground injection, the Agency has decided to withdraw the proposed amendment to the UIC regulations.

In the preamble to the proposed rule, the Agency stated that the protection offered by proposed subpart C provided the same substantive protection and similar significant procedural components as those under SDWA regulations. 58 FR 7932 Comments on the proposed rule made a point-by-point comparison of proposed 40 CFR part 191 and requirements under the SDWA. These comments asserted that the 40 CFR part 191 requirements do not precisely correspond to the SDWA requirements because they lack some of the SDWA's provisions which include reporting requirements, judicial review procedures, citizen suit provisions, monitoring requirements, recordkeeping requirements, and permitting conditions and requirements.

In addition, the preamble to the proposed rule stated that the review process for the WIPP facility was extraordinarily elaborate and that such an intensive and thorough process would be applied for any other disposal system covered by these regulations. Comments on the proposal pointed out, however, that a facility exists for which this is allegedly not the case, the Greater Confinement Disposal (GCD) facility which has been operated at the Nevada Test Site. This facility has not been subject to the extensive review process which is being applied to both WIPP and the potential site at Yucca Mountain and has received considerably less public attention than these potential disposal sites. Also, unlike at WIPP or a HLW repository, DOE alone implements 40 CFR part 191 at the GCD. This is not necessarily a unique situation. It is conceivable that other facilities could be proposed in the future which are in the same category in that they would not receive as high a degree of scrutiny as the current potential repositories. The EPA's February 10, 1993 proposal addressed the UIC issue by deeming that compliance with part 191 would constitute compliance with regulations under the UIC program. Given EPA's conclusion regarding the applicability of the UIC program to disposal systems and, as set forth below, consequent withdrawal of the proposed revisions to 40 CFR 144.31(a), the comments regarding proposed revisions to part 144

are moot. Nevertheless, EPA is responding in order to provide a fuller understanding of the Agency's action.

As discussed elsewhere, the thrust of the First Circuit's 1987 remand decision was to require that EPA either adopt the substantive protections of the SDWA program in its part 191 regulations or explain any discrepancies. EPA has provided substantive equivalence through its adoption of the MCLs. (Potential discrepancies at some facilities with respect to the SDWA's Class-IV-well ban will be addressed in a future rulemaking.) The First Circuit did not address the details of the procedural provisions of the SDWA or compare them to the procedures under part 191 and associated provisions (such as NRC disposal procedures). EPA believes that the court's focus on substantive protection was appropriate in light of the general administrative law principle that an agency is bound to explain a departure from previously established substantive norms. See 824 F.2d at 1282 (citing, e.g., *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mutual Life Ins. Co.*, 463 U.S. 29 (1983)).

Conversely, the First Circuit's silence on procedural aspects of the SDWA was in keeping with another firmly established principle of administrative law, namely, that in the absence of constitutional constraints, specific statutory directives, or extremely compelling circumstances, agencies are free to fashion procedures that they deem appropriate to the task at hand. Consequently, while comments regarding a potential lack of procedural equivalence at potential disposal sites other than the WIPP may have some merit, they have no bearing on the outcome of this part 191 rulemaking. As stated by the Supreme Court in *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 524 (1978), "the formulation of procedures was basically to be left within the discretion of the agencies to which Congress had confided the responsibility for substantive judgments." In accordance with the doctrine of Vermont Yankee, the procedures applicable to a decision to emplace nuclear waste into a given disposal system will be determined by applicable statutes governing such procedures and the discretion of the relevant agencies. In addition, NRC licensing of Yucca Mountain and WIPP compliance requirements are both extensive. To overlay those procedural requirements with possibly redundant UIC program procedural requirements could be considered duplicative and unnecessary. See *NRDC* v. *EPA*, 937 F.2d 641, 648 (D.C. Cir. 1991) (upholding EPA decision not to regulate based on Agency's conclusion that EPA regulations would be redundant given "roughly similar" Interior Department regulations providing equivalent benefits).

Disposal of Radioactive Waste in Geologic Repositories Is Not Underground Injection

In the preamble to the proposed part 191 amendments, EPA stated that it was not necessary to address whether the disposal of radioactive waste in a geologic repository covered under part 191 constitutes underground injection under the SDWA since the proposed part 191 standards conformed with the MCL standards for radionuclides under the SDWA. EPA maintains this position in today's final action. EPA also noted that in *NRDC* v. *EPA*, 824 F.2d at 1258, the First Circuit itself did not resolve the underground injection issue, stating only in dicta that disposal in geologic repositories would "likely" constitute underground injection. However, a number of commenters specifically raised this issue expressing both support for, and opposition to, the regulation of such disposal in geologic repositories as underground injection. EPA has carefully considered these comments. The Agency also has reviewed the SDWA and its legislative history and the regulations governing the underground injection control (UIC) program. The Agency has concluded that the underground disposal of containerized radioactive waste in geologic repositories subject to the part 191 standards does not constitute underground injection within the meaning of the SDWA or EPA's regulations governing the UIC program.

Section 1421 of the SDWA defines "underground injection" as "the subsurface emplacement of fluids by well injection." 42 U.S.C. 300h(d)(1). The statute defines neither "fluids" nor "well injection." Moreover, neither the statute nor the legislative history directly addresses whether the underground disposal of containerized radioactive waste constitutes the "subsurface emplacement of fluids by well injection." Even though the legislative history states, "[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. 31 (1974), the legislative history does not specifically address whether the underground disposal of containerized radioactive waste into geologic repositories of the type covered by these part 191 rules constitutes the "subsurface emplacement of fluids by well injection."

The EPA has concluded that the underground disposal of containerized radioactive waste in geologic repositories subject to part 191 does not constitute underground injection both because the materials to be emplaced are not "fluids" and because the mode of emplacement of these materials is not "well injection."

The EPA does not consider the type of containerized radioactive wastes which are covered under part 191 to be "fluids." Instead, the wastes, which consist almost entirely of solid materials themselves are enclosed in barrels or other types of containers. The Agency does not believe the SDWA's reference to "subsurface emplacement of fluids" was intended to address the subsurface disposal of solid or containerized materials. As noted above, the statute does not specifically address this activity and the legislative history also does not address the subsurface emplacement of containerized materials or solids. On the other hand, the legislative history does address the injection of liquid materials that flow or move at the time they are emplaced in the ground. For example, in floor debate, Sen. Domenici stated that "the [UIC] regulations would cover all types of injection wells, e.g., industrial and nuclear disposal wells, oil and gas wells, solution mining wells or any hole in the ground designed for the purpose of injecting water or other fluids below the surface." See 126 Cong. Rec. 30189 (November 19, 1980) (remarks of Sen. Domenici, emphasis added). Indeed, in amending the SDWA in 1985, Congress stated "underground injection is the process of forcing liquids underground through a well." H.R. Rep. No. 168, 99th Cong., 1st Sess. 540 (1985) (emphasis added). Moreover, it is clear from the legislative history of the SDWA that Congress intended to ratify EPA's policy on deep-well injection contained in Administrator's Decision Statement #5, entitled "Subsurface Emplacement of Fluids," published at 39 FR 12922 (April 9, 1974). H.R. Rep. No. 1185, 93rd Cong., 2d Sess. 31–32 (1974). Administrator's Decision Statement #5 contained parameters for well injection including, among other things, data requirements for volume, rate, and injection pressure of the fluid, degree of fluid saturation, and formation and fluid pressure. 39 FR 12923 (emphasis added). Like the legislative history itself, the policy does not mention the subsurface emplacement of containerized radioactive wastes but it does address the injection of

noncontainerized liquids as an object of regulatory concern.

The legislative history of the SDWA indicates that Congress was concerned about contamination of ground water from a variety of sources that produce noncontainerized liquids and sludges. Quoting from a U.S. Department of Health, Education and Welfare report entitled "Human Health and the Environment—Some Research Needs," Representative Rodgers noted in floor debate that ground-water pollution was rapidly increasing from sources including ". . . waste-water sludges and effluents...mine drainage, subsurface disposal of oil-field brines, seepage from septic tanks and storage transmission facilities, and from individual on-site waste-water disposal systems." 123 Cong. Rec. 22460 (July 12, 1977) (remarks of Rep. Rodgers). Later in 1985, Congress made clear its intent that there would be early detection of fluid migration into or in the direction of a USDW. H.R. Rep. No. 168, 99th Cong., 1st Sess. 540 (1985) (emphasis added). Again, there is no mention that Congress intended that the SDWA cover the subsurface emplacement of containerized radioactive wastes.

Reflecting this statutory approach, EPA's UIC regulations similarly do not treat containerized radioactive wastes as fluids or liquids for the purpose of control under the UIC program. The EPA regulations at 40 CFR 146.3, tracking the legislative history, define "fluid" as "material or substance which flows or moves whether in a semisolid, liquid, sludge, gas, or any other form or state." In adopting this regulatory definition of fluid, EPA did not consider the emplacement of containerized radioactive wastes in geologic repositories to be fluids subject to the UIC regulations. There is no mention of this activity in the preambles to the proposed or final UIC regulations. On the contrary, the fluids regulated by EPA's UIC program include, for example, brines from oil and gas production; hazardous and industrial waste waters; liquid hydrocarbons (gasoline, crude petroleum, and others); solution mining fluids from uranium, sulfur, and salt solution mining; and sewage and treated effluent. See 40 CFR 144.6; 45 FR 33329 (May 19, 1980). All of these are materials that can flow or move at the time they are emplaced in the ground. There is no indication that EPA intended that containerized materials be covered as fluids under the UIC regulations.

Finally, EPA has never interpreted its UIC regulations to reach the subsurface emplacement of containerized wastes or solid materials that do not flow or move. As explained in greater detail below, EPA has stated instead that placement of such containerized hazardous waste in geologic repositories such as underground salt formations, mines, or caves, is regulated under the Subtitle C of the Resource Conservation and Recovery Act (RCRA) hazardous waste program. Subtitle D of RCRA regulates the disposal of containerized nonhazardous wastes pursuant to the regulatory provisions at 40 CFR 257.1.[1] Today's part 191 disposal standards regulate the disposal of radioactive wastes including containerized radioactive wastes.

In *NRDC* v. *EPA*, 824 F.2d at 1258, the First Circuit was concerned that radiation itself might be considered a fluid within the meaning of the SDWA and EPA's UIC regulations at 40 CFR 146.3. The Agency believes that radiation itself does not meet the UIC regulatory or statutory definition of "fluid." Radioactivity is a specific characteristic of the waste but does not define the form of the waste. Radioactivity results in the emission from the waste of ionizing radiation in the form of electromagnetic energy or subatomic particles. Electromagnetic radiation is a form of energy, not a "material or substance," and hence not a "fluid." Subatomic particles, such as alpha and beta particles, will either be absorbed in the waste or the container and, therefore, not travel beyond the container, or will travel very short distances in comparison to the distance to the boundary of the controlled area. In any event, as is set forth above, EPA believes that since the activity at geologic repositories consists of the emplacement of containers of radioactive wastes underground, this is emplacement of solid materials, not "fluids." Even though these materials may eventually disintegrate or dissolve and release some radiation, liquids, or gasses, the activity in question still consists of emplacement of containers and solid materials that will not flow or move at the time of emplacement underground.

Moreover, EPA does not consider the emplacement into geologic repositories of containerized and solid wastes that do not flow or move to be subsurface emplacement "by well injection." For example, at the WIPP, a potential repository subject to part 191, containerized waste will be placed in a mined underground repository, located in a salt bed formation approximately 2150 feet below the earth's surface. The waste containers are lowered down a vertical elevator shaft. Once underground, the waste containers are transported and placed in rooms mined into the formation or in underground horizontal boreholes in the salt formation. Once enough containers are accumulated, the room is sealed. To date, approximately 15 acres of underground disposal rooms have been mined.

The EPA's UIC regulations define "well injection" as "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." 40 CFR 146.3. A "well" is defined as "a bored, drilled, or driven shaft, or a dug hole, whose depth is greater than the largest surface dimension." *Id.* Although transmission of the materials underground in geologic repositories such as the WIPP involves waste handling "shafts," or "holes," these are elevator shafts or other shafts that transmit containerized solid materials, not "wells" into which fluids are being "injected" within the meaning and intent of the SDWA or EPA's UIC regulations. In addition, the overall configuration of a repository is far different from a "drilled," "driven," or "dug" injection well.

The EPA noted in the preamble to the proposed rules setting forth the definitions of "well" and "well injection" that the definitions cover not only "conventional" deep wells, but also drilled, bored, and driven wells. Dug wells and non-residential septic tanks also fall under the term. See 44 FR 23738, 23740 (April 20, 1979). EPA further stated, however, that "although the definition is broad, it is not without limitation." *Id.* For example, EPA stated that the term does not cover simple depressions in the land or single-family domestic cesspools or septic systems, nor does it cover surface impoundments. *Id.* Although EPA had been concerned initially about whether the UIC regulations should impose conditions on surface impoundments, generally referred to as "pits, ponds, and lagoons," since they pose a threat to ground water, the Agency noted that standards to control such contamination would be covered under the RCRA hazardous waste management program. 44 FR 23740. Thus, the Agency recognized that there would be some disposal practices that might potentially

[1] EPA's regulations at 40 CFR 257.1(c)(9) provide that the solid waste criteria do not apply to disposal of solid waste by underground well injection subject to the UIC part 146 regulations. This provision does not imply that the UIC program regulates emplacement of all solid materials. The UIC program covers only the subsurface emplacement by well injection of those solid wastes that "flow or move" and thereby fall within the definition of a "fluid."

contaminate ground water that would not be covered under the UIC program.

Similarly, EPA does not believe that the emplacement of containerized waste by conveyors or elevators down a shaft should be covered under the UIC program. Such emplacement is in no way similar to the pressurized or gravity-fed flow of fluids, liquids, or sludges injected into a well that has been the traditional focus of the UIC program. *See* e.g., 41 FR 36726, 36732 (August 31, 1976). Even Class-V wells, a general category of injection wells not included in Classes I–IV, are not used for the disposal of containerized waste. Class V covers the subsurface emplacement of fluids, usually by gravity flow, into the injection well. Although Class-V wells include some types of wells that may not traditionally be thought of as injection wells (e.g. septic systems), all of these well types do involve the emplacement of noncontainerized fluids into drilled, bored, dug, or driven wells, typically through gravity flow rather than pressurized flow.

The Agency specifically addressed the status of containerized waste under RCRA and SDWA in the preamble to the final rule promulgating standards for hazardous waste miscellaneous units under subpart X of the RCRA regulations at 40 CFR part 264. In the preamble to the final rule EPA stated,

> Placement of containerized hazardous waste or bulk non-liquid hazardous waste in geologic repositories such as underground salt formations, mines, or caves, either for the purpose of disposal or long-term retrievable storage, is included under subpart X. 52 FR 46946, 46952 (December 10, 1987).

EPA promulgated the subpart X regulations to address hazardous waste management technologies not covered under 40 CFR part 264 (RCRA regulations for the disposal of hazardous waste) or 40 CFR part 146 (UIC program technical criteria and standards). As EPA indicated in the preamble to the subpart X regulations, the 40 CFR part 146 technical standards do not address practices other than the injection of noncontainerized liquids, slurries, and sludges, and do not fully address some potential disposal or storage practices that may fall under EPA's regulatory definition of well injection. 52 FR 46953. In the subpart X rule, EPA provided that, to the extent that miscellaneous disposal practices subject to subpart X may be determined to be underground injection, a subpart X permit would constitute a UIC permit for well injection of hazardous waste for which current part 146 technical standards are not generally appropriate. The Agency stated, however, that it was not "specifying that these miscellaneous management practices constitute underground injection." *Id.*

Thus, EPA has never expressed an intent that the disposal of containerized waste, including containerized radioactive waste, in geologic repositories is an activity covered by the UIC program. Instead, injection wells have been described as facilities at which wastes, in a fluid (usually liquid) state, are injected into the ground under a pressure head greater than the pressure head of the ground water into or above which they are injected for the purpose of disposal. Discharge to the ground water is either direct or by direct seepage of leachate from the well outlet. See 46 FR 11137–11138 (February 5, 1981).

Moreover, the regulatory criteria and standards applicable to underground injection, contained in 40 CFR parts 144 and 146, have never been intended to apply to a geologic repository. The concepts of area of review, pressure buildup and pressure monitoring, restrictions on injection pressure and other operating requirements and mechanical integrity testing of injection wells that are included in the part 146 regulations are meaningless as applied to geologic repositories. As noted above, some of the repositories, like the WIPP, may be mined containment areas in which humans operate mechanical equipment to emplace waste packaged in containers surrounded by both engineered and natural barriers designed to isolate such waste from the environment. The UIC regulations are directed at injection of fluids by pressure or gravity flow; this activity is far different from an engineering perspective from the subsurface emplacement of containerized wastes.

Finally, as is explained elsewhere in this preamble, part 191 sets technical standards that are adequate to protect the environment from the radiation effects of underground disposal of these containerized radioactive wastes. Thus, it is not necessary to expand the scope of the UIC program to cover this activity.

Deferral of Final Action Regarding Disposal Systems Above or Within a Formation Which Within One-Quarter (¼) Mile Contains a USDW

As stated elsewhere, today's action assures, with one possible exception, substantive equivalence between the SDWA and part 191 through the adoption of the MCLs as the protective standard under subpart C of part 191. That possible exception relates to the provision of 40 CFR 144.13 banning "Class IV" injection wells. As defined in § 144.6(d), such wells include those which dispose of radioactive waste into or above a formation which contains a USDW within one-quarter (¼) mile of the well. As promulgated today, the part 191 regulations contain no such across-the-board ban. EPA's tentative position is that this discrepancy is appropriate in light of differences in the purposes of the UIC and part 191 programs. The UIC regulations mandate minimum requirements for State programs to prevent underground injection which endangers USDWs, while part 191 standards are directed to ground water in the accessible environment, outside the controlled area of a repository, and establish requirements for performance of disposal systems, including natural or engineered barriers that prevent or substantially delay movement of water or radionuclides toward the accessible environment. Nevertheless, EPA believes it is appropriate to consider this matter further, in the context of its upcoming rulemaking regarding HLW disposal standards for Yucca Mountain in accordance with the Energy Policy Act of 1992. Accordingly, EPA is deferring final action at this time regarding subpart C with respect to those disposal systems that could conceivably fall within the Class-IV ban if it were applicable to radioactive waste disposal systems.

Before discussing the reasoning for this partial deferral, it is important to emphasize that EPA's deferral of final action does not affect disposal systems that do not dispose of hazardous or radioactive waste into or above a formation which within one-quarter (¼) mile of the disposal system contains a USDW. Hence, it does not affect the applicability of part 191 to the WIPP. In addition, because disposal facilities required to be characterized by NWPA § 113(a) are not subject to part 191 requirements, such facilities, which include Yucca Mountain, are also not affected by this deferral. Finally, today's deferral is limited to subpart C. It does not affect other provisions of part 191 which will apply to all disposal systems.

The Class-IV-well ban is part of the UIC program, and is recognized at section 3020 of RCRA. As explained elsewhere in this notice, the UIC program was intended to address routine "well injection" in the common sense meaning of that term. In contrast, the part 191 regulations address permanent emplacement of radioactive wastes. Two of the waste disposal systems currently being studied (WIPP and Yucca Mountain) are mined repositories subject to extremely sophisticated site characterization,

design, engineering, containerization, and operational requirements intended to ensure that the applicable protective standards in part 191 will be met. Given such intense scrutiny, applying a blunt instrument akin to the Class-IV-well ban as a siting mechanism appears to be both unnecessarily restrictive and a poor substitute for more sophisticated site characterization studies that may preclude siting of a disposal facility for reasons other than those embodied in the Class-IV restriction. In addition, as the First Circuit recognized, the environmental goals of regulations under the NWPA at least in part differ from and supersede the SDWA in allowing radioactive contamination of ground water within the controlled area of the disposal system.

Taken together, these distinctions are arguably sufficient to justify nonapplicability of a prohibition akin to the Class-IV well ban under the SDWA. Nevertheless, EPA believes it is appropriate to consider this matter further before making a final determination. The Agency plans to do so, and to make any appropriate revisions to part 191, at the same time that it addresses disposal standards for Yucca Mountain. In accordance with the Energy Policy Act of 1992, those standards are required to be promulgated within one year of receipt of a related report, from the National Academy of Sciences, which is presently planned for completion in December, 1994.

Economic Impact of Today's Action

The impact of today's action is described in the EIA for this rulemaking. As a result of the WIPP LWA reinstatement of portions of the disposal standards and the exclusion of sites developed under the NWPA, the analysis concentrates upon the impact of the individual and ground-water protection requirements upon the disposal of TRU wastes. The analysis emphasizes one generic method of TRU waste disposal, emplacement in salt, because this is the only disposal medium for which reasonably substantive cost estimates are available. Other media were analyzed in the BID for this rulemaking and are briefly discussed but cannot be analyzed as deeply because of the lack of cost data. The EPA's generic, base-case, performance analyses for undisturbed performance in all media yields an estimate of no projected releases over 10,000 years. This leads to the conclusion that there is no significant economic impact because of this rule. There may be small costs to DOE since they must now show compliance with these amendments in addition to the remainder of subpart B. Any additional cost is likely to be small and, certainly, a very small fraction of the total cost of disposal. The Agency's experience in environmental pathway modeling suggests that the cost of this effort should not exceed one million dollars.

Response to Comments

The Agency heard the statements of about 175 people during the four days of hearings held in New Mexico in February 1993 and received approximately 90 comment letters. This section responds to the major issues in the comments which the Agency received; responses to all substantive and relevant comments are in the Response-to-Comments document which was made available concurrently with today's action.

Individual Protection Requirements

Many commenters said that an annual 15-millirem CED limit was higher than necessary; those who suggested alternative levels generally suggested between 0 and 10 millirems CED annually. EPA has adopted an annual 15-millirem CED requirement, which is associated with the same level of risk, about 5×10^{-4}, accepted by the Agency in selecting the 1985 limits. In reviewing the record, EPA has found no convincing rationale to justify altering its basic 1985 decision regarding the appropriate level of protection for individuals from the activities subject to this rulemaking. While this risk is slightly higher than the risks associated with many other Agency regulations, in general, those risks result from exposures occurring via a single medium or pathway and often from just one pollutant within that medium or pathway whereas these individual protection requirements limit the annual CED from exposure to all radionuclides delivered through all pathways.

In addition, this level is consistent with the ICRP approach of apportioning an overall dose limit from manmade radiation to particular activities. The ICRP suggests using an overall annual limit of one millisievert CED (100 millirems CED). While EPA has not formally established such an overall limit, the Agency has found that 15 millirems CED is an appropriate and acceptable level for the activities subject to 40 CFR part 191, under the ICRP concept.

Ground-Water Protection Standards

The Agency proposed to apply the SDWA MCLs to USDWs. The comments received on the proposed subpart C covered a spectrum from eliminating the subpart to allowing no degradation of any ground water. There was also a request that the limits be applied incrementally, i.e., that only those doses resulting from releases from the disposal system be compared to the standards with no consideration of any existing contamination.

The Agency has chosen to incorporate the current USDW MCLs as the quantitative measure for the protection of USDWs. The Agency has not been convinced that limits different from those acceptable in the regulations developed under the SDWA are justified for the situations covered in this rulemaking. The EPA considered applying the MCLs incrementally but in those situations where there are pre-existing concentrations of radionuclides, this approach would not prevent contamination of a USDW while the Agency-chosen approach would prevent this contamination without imposing an unreasonable burden on siting or licensing disposal facilities. However, the Agency recognizes that there may be situations in which a potential disposal site is located in the vicinity of one or more USDWs which contain elevated levels of radionuclides.

Under the current standards, a potential disposal system could be precluded from consideration in an area with elevated levels of radionuclides, even if the site would be otherwise attractive for a facility, based upon its superb capability for isolating such waste, because of the difficulty—or impossibility—of adequately demonstrating that not a single atom or molecule would be released.

Accordingly, the Agency believes that it could be appropriate for the Administrator to develop alternative provisions, for example in situations in which nearby USDWs contain elevated levels of radionuclides. New § 191.26 of subpart C of part 191 sets forth procedures under which the Administrator could develop alternatives to subpart C provisions, should this situation arise. Any such changes would have to proceed through the usual notice-and-comment rulemaking process. Section 191.26 stipulates that such a rulemaking would require a public comment period of at least 90 days, to include public hearings in the affected areas of the country. Addition of this section is consistent with § 191.16 in subpart B of part 191 which contains identical provisions.

Furthermore, the approach adopted here for part 191—incorporation of the MCLs as the quantitative measure for protection of USDWs—is not intended to preclude different uses of MCLs or

different approaches to protection of human health and the environment in other situations or regulatory programs that do not address spent nuclear fuel or high-level or transuranic radioactive wastes. For example, the Resource Conservation and Recovery Act (RCRA) prohibits land disposal of hazardous waste unless it can be shown that there will be "no migration" of hazardous constituents from the disposal unit for as long the wastes remain hazardous. See, e.g., 42 U.S.C. 6924(g)(5). Under EPA's Land Disposal Restrictions No-Migration Variances, the Agency has affirmed that the "appropriate focus is on whether constituents ever migrate at hazardous levels," and the Agency has in the past used or proposed using MCLs or other health-based levels as the no-migration standard which the disposal unit must meet without regard to total environmental loading (including background) of the hazardous constituent. 55 FR 13073 (April 6, 1990) See also 55 FR 47715 (November 14, 1990); 55 FR 35942 (August 11, 1992) (notice of proposed rulemaking). As explained above, however, EPA is not adopting such an approach in this rule.

Use of the Term "Reasonable Expectation"

As the result of a comment, the term "reasonable expectation" and expanded explanatory sections have been added to §§ 191.15(c) and 191.24(b) which are consistent with their use in the Containment Requirements in § 191.13. This action comes in response to comments made requesting the inclusion of the term and maintains consistency among all parts of the standards. The intention of the Agency, since 1985, has not and does not change with this action. The Agency's intent, both before and after proposal, is for the term to reflect the fact that unequivocal numerical proof of compliance is neither necessary nor likely to be obtained. A similar test, that of "reasonable assurance," has been used with NRC regulations for many years. Although the Agency's intent is similar, the NRC term 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 in 40 CFR part 191. The use of a different test of judgment is meant to acknowledge the unique considerations likely to be encountered upon implementation of these standards. In its role under the WIPP LWA, EPA will determine what "reasonable expectation" is for the WIPP during its compliance-criteria rulemaking.

Time Frame

Comments regarding the time frame for the individual and ground-water protection requirements suggested a range from 1,000 years to "forever". The Agency has decided to apply the requirements for 10,000 years following disposal. The Agency finds that 1,000 years is not sufficient to encourage finding acceptable disposal sites or designs for robust engineered barriers but, as explained above, does believe that improvements in modeling capability and the availability of better data allows for an extension from the 1,000-year time frame in 1985 to 10,000 years today.

Underground Injection

Many commenters expressed the concern that the EPA proposed amendment to part 144 would preempt the States from enforcing requirements under the UIC program. The Agency also received comments that geologic repositories are clearly not a form of underground injection and should be exempted from the UIC requirements. In addition, one commenter challenged EPA's assertion that facilities which will be subject to 40 CFR part 191 will receive extraordinarily elaborate review with the result being that 40 CFR part 191 would provide protection equivalent to that under the SDWA.

After considering these comments, EPA has concluded that many disposal systems which are subject to 40 CFR part 191 will receive "extraordinarily elaborate" review. However, there could also be future disposal systems not subject to such widespread and thorough review. An example is the GCD, located on the Nevada Test Site, which has not received widespread national or regional attention. The Department of Energy is responsible for ensuring compliance with part 191 for this disposal system since it is not subject to NRC licensing and, unlike at the WIPP, EPA has been given no oversight or approval authority for radioactive materials in the disposal system. Therefore, EPA cannot conclude that the requirements of part 191 under the AEA would provide a degree of oversight and review equivalent to that which would be provided by the corresponding requirements of 40 CFR part 141 under the SDWA. For the reasons stated previously, however, EPA's decision to withdraw its proposal to deem compliance with part 191 to constitute compliance with the UIC regulations, plus the fact that part 191 does provide equivalent protective standards is dispositive of this comment.

EPA has explained elsewhere in this notice its conclusion that the underground disposal of containerized radioactive waste in geologic repositories subject to part 191 does not constitute underground injection. The preemptive effect of this determination, if any, cannot be determined in this rulemaking, but rather must be addressed by the parties to any future proceeding that seeks to apply State underground injection provisions to disposal systems.

Applicability Date

Based on a comment which requested that the new sections not be applied retroactively, the Agency has changed the date of applicability for the individual and ground-water protection sections to January 19, 1994. Part 191 was in effect from November 18, 1985 until July 17, 1987 at which time the Court vacated and remanded the entirety of part 191 including, of course, the individual and ground-water protection sections. With today's repromulgation of the individual and ground-water protection provisions, the Agency believes that it is more reasonable to require compliance with them only for waste disposed of after the effective date of these amendments.

However, the Agency believes that it is reasonable, due to the design nature of the 40 CFR part 191 standards, that the standards which were in existence from 1985 until the First Circuit decision in 1987 are appropriate to be used for activities which occurred, or were begun, during that time rather than imposing new and different standards on such activities. The effective date for § 191.13, Containment Requirements, and indeed all of 40 CFR part 191, except those provisions being promulgated today, remains November 18, 1985. In accord with this, disposal which occurred on or after November 18, 1985 until the effective date of today's action is subject to the standards as they existed on November 18, 1985.

Since there is no indication that Congress intended to allow a regulatory gap in this important area, EPA interprets section 8(a) of the WIPP LWA as reinstating part 191 Subpart B except for those aspects that were remanded by the court, retroactive to July 17, 1987, the date of the First Circuit decision vacating part 191. Any facilities at which disposal-related activities were initiated after the date of the First Circuit decision might not be covered by the ground-water and individual protection requirements of part 191 as promulgated in 1985, which were vacated by the court and not reinstated

by Congress. However, EPA is not aware of any such facility.

EPA informed the Department of Energy, prior to the First Circuit decision in 1987, that the 1985 version of part 191 was applicable to any disposal activities at the Greater Confinement Disposal (GCD) Facility. Therefore, any radioactive waste as defined in § 191.02 that was disposed of at the GCD facility is subject to all of the requirements of 40 CFR part 191 promulgated in 1985, and neither the First Circuit decision, the WIPP LWA, nor today's promulgation of revised regulations change that determination.

Finally, it continues to be the Agency's intention that any waste which was disposed prior to the effective date of today's action is not exempt from subparts B and C of 40 CFR part 191 if it is exhumed and redisposed. That disposal will be subject to all the provisions of 40 CFR part 191 as they exist at the time of redisposal.

Revision of Appendix B Organ-weighting Factors

A few commenters stated that EPA had been premature for proposing to use organ- weighting factors published by the ICRP in their Publication Number 60 (ICRP 60). Commenters observed that these factors are inconsistent with the organ-weighting factors currently accepted by all Federal agencies and that EPA should use the factors in ICRP Publication Number 26 (ICRP 26). There was one commenter who supported the use of the ICRP 60 organ-weighting factors.

While not rejecting the validity of the ICRP 60 factors, the Agency has determined that the proposal was premature and has adopted the organ-weighting factors in ICRP 26 for purposes of this rulemaking.

Open the Entirety of 40 CFR Part 191 to Comment

Several commenters stated that the Agency should reopen the entirety of 40 CFR part 191 to comment rather than just a few amendments since Congress did not prohibit EPA from making changes to the reinstated provisions. The argument was also made that Congress had required that the entirety of the disposal standards be reproposed.

The Agency does not agree that Congress required EPA to repropose either the entirety of the disposal standards or any portion thereof, except those being promulgated today. The Congress exercised its legislative powers when it reinstated much of subpart B but did not require any further action by the Agency regarding the reinstated provisions.

The Agency does agree that it is not prohibited from considering and amending other provisions of subpart B. In fact, prior to enactment of the WIPP LWA, the Agency was considering whether changes to other provisions would be appropriate. The Agency's decision not to make such changes today has been influenced by considering the statutory deadline for this action and the reinstatement provisions of the WIPP LWA. By setting a short time frame for issuance of final disposal regulations, Congress expressed its preference for expeditious promulgation of the regulations, and, by reinstating 40 CFR part 191, subpart B (except for the three aspects of §§ 191.15 and 191.16 which were the subject of the court remand), Congress expressed its preference for narrowing the number of issues to be considered. In legislative debate on the WIPP LWA, Senator Bennett Johnston stated, "by reinstating the 1985 standards, the conferees are seeking to narrow the issues that must be revisited by the Environmental Protection Agency so that the Agency will be able to meet the six-month deadline for repromulgation of the remaining portions of the final standards." 138 Cong. Rec. S17,956 (daily ed. Oct. 8, 1992). Thus, the Agency has chosen to amend the individual and the ground-water protection requirements based upon recently available information and advancing scientific capabilities and has solicited comments on those changes. At the same time, to comply with the Congressional deadline as closely as possible, the EPA has limited its consideration of comments to those that apply to the amended provisions. 58 FR 7924, 7932, 7934 (Feb. 10, 1993).

Review of 40 CFR Part 191 in the Future

The Energy Policy Act of 1992 requires EPA to contract with the National Academy of Sciences (NAS) to provide advice to EPA on the development of standards for Yucca Mountain and to develop standards which are consistent with that advice. Realizing that this might result in a form of standards considerably different than those in 40 CFR part 191, several commenters asked that EPA commit to reviewing 40 CFR part 191 following the development of standards for Yucca Mountain to make it consistent with the Yucca Mountain standards.

In developing standards for Yucca Mountain, EPA will need to consider several factors, including the referenced NAS study. In addition, for the same reasons that today's action must take into account standards developed under the SDWA, EPA must consider the part 191 standards as well as SDWA requirements in developing the Yucca Mountain standards. Such consideration will give due regard to any differences in the environmental goals of the respective programs. As stated previously, EPA will consider revisions to part 191 in parallel with the Yucca Mountain rulemaking under the Energy Policy Act of 1992 in order to address today's reservation of final action under part 191 with respect to disposal systems above or within a formation which within one-quarter (¼) mile of the disposal system contains a USDW. The Agency believes that it is premature to make any further commitment on its future actions regarding this question. It is first necessary to see the results of the NAS study; at that time, EPA will make a judgment as to the need for other revisions of 40 CFR part 191.

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 action 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 promulgated standards. This action was submitted to OMB for review under Executive Order 12291 and cleared by OMB under Executive Order 12866.

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 action 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, Radionuclides, Uranium, Transuranics, Waste treatment and disposal.

Dated: December 3, 1993.

Carol M. Browner,

Administrator.

The Environmental Protection Agency is hereby amending part 191 of title 40, Code of Federal Regulations, as follows:

SUBCHAPTER F—RADIATION PROTECTION PROGRAMS

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

1. The authority citation for part 191 is revised to read as follows:

Authority: The Atomic Energy Act of 1954, as amended, 42 U.S.C. 2011–2296; Reorganization Plan No. 3 of 1970, 5 U.S.C. app. 1; the Nuclear Waste Policy Act of 1982, as amended, 42 U.S.C. 10101–10270; and the Waste Isolation Pilot Plant Land Withdrawal Act, Pub. L. 102–579, 106 Stat. 4777.

2. 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, 96 Stat. 2201.

3. Section 191.12 is amended by removing the paragraph designations for all definitions and placing them in alphabetical order; by removing the definitions *community water system, significant source of ground water, special source of ground water,* and *transmissivity;* revising the definition of the term *implementing agency;* and adding the following definitions, in alphabetical order, to read as follows:

§ 191.12 Definitions.

* * * * *

Annual committed effective dose means the committed effective dose resulting from 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 of this part.

* * * * *

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:

(1) The Commission for facilities licensed by the Commission;

(2) The Agency for those implementation responsibilities for the Waste Isolation Pilot Plant, under this part, given to the Agency by the Waste Isolation Pilot Plant Land Withdrawal Act (Pub. L. 102–579, 106 Stat. 4777) which, for the purposes of this part, are:

(i) Determinations by the Agency that the Waste Isolation Pilot Plant is in compliance with subpart A of this part;

(ii) Issuance of criteria for the certifications of compliance with subparts B and C of this part of the Waste Isolation Pilot Plant's compliance with subparts B and C of this part;

(iii) Certifications of compliance with subparts B and C of this part of the Waste Isolation Pilot Plant's compliance with subparts B and C of this part;

(iv) If the initial certification is made, periodic recertification of the Waste Isolation Pilot Plant's continued compliance with subparts B and C of this part;

(v) Review and comment on performance assessment reports of the Waste Isolation Pilot Plant; and

(vi) Concurrence by the Agency with the Department's determination under § 191.02(i) that certain wastes do not need the degree of isolation required by subparts B and C of this part; and

(3) The Department of Energy for any other disposal facility and all other implementation responsibilities for the Waste Isolation Pilot Plant, under this part, not given to the Agency.

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.

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

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

* * * * *

4. 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 to provide a reasonable expectation 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 paragraph (a) of this section 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. Instead, what is required is a reasonable expectation, on the basis of the record before the implementing agency, that compliance with paragraph (a) of this section will be achieved.

(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 January 19, 1994.

§ 191.16 [Removed]

5. Section 191.16 is removed.

§§ 191.17 and 191.18 [Redesignated as §§ 191.16 and 191.17]

6. Sections 191.17 and 191.18 are redesignated as §§ 191.16 and 191.17.

7. Subpart C is added to part 191 to read as follows:

Subpart C—Environmental Standards for Ground-Water Protection

Sec.
191.21 Applicability.
191.22 Definitions.
191.23 General provisions.
191.24 Disposal standards.
191.25 Compliance with other Federal regulations.
191.26 Alternative provisions.
191.27 Effective date.

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 the effective date of this subpart; 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, 96 Stat. 2201.

§ 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:

(1) Any collection, treatment, storage, and distribution facilities under control of the operator of such system and used primarily in connection with such system; and

(2) 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 (filterable) 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.

§ 191.24 Disposal standards.

(a) Disposal systems.

(1) *General.* Disposal systems for waste and any associated radioactive material 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, in the accessible environment, to exceed the limits specified in 40 CFR part 141 as they exist on January 19, 1994.

(2) *Disposal systems above or within a formation which within one-quarter (¼) mile contains an underground source of drinking water.* [Reserved]

(b) Compliance assessments need not provide complete assurance that the requirements of paragraph (a) of this section 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. Instead, what is required is a reasonable expectation, on the basis of the record before the implementing agency, that compliance with paragraph (a) of this section will be achieved.

§ 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 Alternative provisions.

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

(a) The alternative provisions have been proposed for public comment in the **Federal Register** together with information describing the costs, risks, and benefits of disposal in accordance with the alternative provisions and the reasons why compliance with the existing provisions of this subpart 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.

§ 191.27 Effective date.

The standards in this subpart shall be effective on January 19, 1994.

8. The heading of Appendix A is revised to read as follows:

Appendix A to Part 191—Table for Subpart B

9. Appendix B is redesignated as Appendix C to part 191 and the heading is revised to read as follows:

Appendix C to Part 191—Guidance for Implementation of Subpart B

10. A new Appendix B to part 191 is added to read as follows:

Appendix B to Part 191—Calculation of Annual Committed Effective Dose

I. Equivalent Dose

The calculation of the committed effective dose (CED) begins with the determination of the equivalent dose, H_T, to a tissue or organ, 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] See paragraph A14 in ICRP Publication 60 for the choice of values for other radiation types and energies not in the table.

II. Effective Dose

The next step is the calculation of the effective dose, E. The probability of occurrence of a stochastic effect in a tissue or organ is assumed to be proportional to the equivalent dose in the tissue or organ. 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 the tissue or organ to the total risk when the whole body is irradiated uniformly and H_T is the equivalent dose in the tissue or organ, T, in the equation:

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

TABLE B.2—TISSUE WEIGHTING FACTORS, w_T [1]

Tissue or organ	w_T value
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	[2] 0.30

[1] The values are considered to be appropriate for protection for individuals of both sexes and all ages.

[2] For purposes of calculation, the remainder is comprised of the five tissues or organs not specifically listed in Table B.2 that receive the highest dose equivalents; a weighting factor of 0.06 is applied to each of them, including the various sections of the gastrointestinal tract which are treated as separate organs. This covers all tissues and organs except the hands and forearms, the feet and ankles, the skin and the lens of the eye. The excepted tissues and organs should be excluded from the computation of H_E.

III. 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 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 $H_T(t)$ is the relevant equivalent-dose rate in a tissue or organ at time t. For the purposes of this part, the previously mentioned single intake may be considered to be an annual intake.

IV. 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, $E(\tau)$:

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

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