WHATEVER BECAME OF 40 CFR PART 191?

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ABSTRACT

In 1985, the United States Environmental Protection Agency issued 40 CFR Part 191, *Environmental Radiation Protection Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes*. These standards set the levels of exposure and release, for the United States, which are permitted in the general environment as a result of the management and disposal of the subject wastes. Those standards were challenged in Federal court and, in 1987, the disposal portion of the standards were remanded to the Agency. Since then, the Agency has worked toward reestablishing the standards. In October 1992, the *Waste Isolation Pilot Plant Land Withdrawal Act* reinstated most of the disposal standards in Part 191 and established a short time period for reestablishment of the entirety of the disposal standards.

The Agency proposed new sections on February 10, 1993; the final sections were published in the December 20, 1993 *Federal Register*. The Agency has limited annual individual doses to 150 microsieverts (15 millirem) committed effective dose received through all pathways. Also, for underground sources of drinking water, there is an annual limit of four microsieverts (four millirem) committed effective dose received from beta- and gamma-emitting radionuclides transported through the ground-water pathway and separate concentration limits on alpha-emitting radionuclides. While not a standard, another important aspect of this rulemaking was the Agency responding to a Court direction to further consider the question of whether geologic repositories are a form of underground injection; the Agency has decided that they are not.

Also, in October 1992, the *Energy Policy Act* was enacted. Section 801 directed the Agency to contract with the National Academy of Sciences (NAS) to conduct a study to provide findings and recommendations on standards for protection of the public health and safety from radioactive materials in the repository at Yucca Mountain. The NAS has established the Committee on Technical Bases for Yucca Mountain Standards to conduct the study called for under the EPA contract. In meetings through December 1993, the discussions were mainly tutorial in nature.

HISTORY

On August 15, 1985, the Administrator of the Environmental Protection Agency (EPA) signed 40 CFR Part 191 (hereinafter, "Part 191"), *Environmental Radiation Protection Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes* (1). These standards were mandated by the *Nuclear Waste Policy Act of 1982* and are the Federal, generic environmental standards which limit releases to the environment and exposures of members of the public from these types of wastes.

In September 1987, a Federal court in Boston, Massachusetts, ruled that problems with Sections 191.15 and 191.16 of Subpart B (Disposal Standards) of Part 191, *i.e.*, the individual and ground-water protection requirements, respectively, were sufficient to vacate and remand the entirety of Subpart B (2). From that time until October 1993, EPA was updating its technical analyses and consulting with interested parties in an attempt to reach as much consensus as possible. Changes were being contemplated for Subpart A (Management and Storage Standards) as well as Subpart B.

On October 30, 1992, the President signed Public Law 102-579, the *Waste Isolation Pilot Plant Land Withdrawal Act of 1992* (WIPP LWA) (3), which made a significant change in the scope and process of repromulgating Part 191. The WIPP LWA reinstated the majority of Subpart B; only Sections 191.15 and 191.16 were not reinstated. In addition, the WIPP LWA set a six-month deadline for finalization. The Act also exempted from 40 CFR Part 191 all sites which are characterized under Section 113(a) of the *Nuclear Waste Policy Act of 1982*. At this time, the only site affected is the proposed site at Yucca Mountain, Nevada.

In response to the WIPP LWA, the Agency proposed amendments to Part 191 in the February 10, 1993 edition of the *Federal Register* (4). Following this, public hearings were held in the New Mexican cities of Carlsbad, Albuquerque and Santa Fe and public comments were accepted through April 12, 1993. The final amendments were signed by the Administrator on December 3, 1993 and published in the *Federal Register* on December 20, 1993 (5).

The WIPP LWA did not forbid changes to the reinstated sections, however, the Congressionally imposed short time frame effectively did. Therefore, only the sections not reinstated by the WIPP LWA, *i.e.*, the individual and ground-water protection requirements, were amended. The issues which needed to be addressed, concerning the two sections, were the level of protection and the length of time over which projections must be made to demonstrate compliance.

Another issue from the court remand involved the underground injection program which has been established under the *Safe Drinking Water Act, as amended* (6). A major conclusion of the Court was that, based upon a succession of interpretations of definitions, underground repositories are "likely" a form of underground injection. The Court directed EPA to consider the issue and to make a finding on whether such repositories are a form of underground injection or not.

FINAL FORM OF THE AMENDMENTS TO 40 CFR PART 191

There are three major parts which constituted the rulemaking to amend Part 191: 1) revised individual protection requirements; 2) a new subpart containing ground-water protection standards; and 3) an Agency position on whether geologic repositories are a form of underground injection.

Individual Protection Requirements

The individual protection requirements in 1985 were 250 microseiverts (μSv) [25 millirem (mrem)] per year (yr) to the whole body and 750 μSv (75 mrem)/yr to any critical organ. These limits covered doses received through all pathways and required that an individual be assumed to drink two liters per day from certain sources of ground water. The doses were to be calculated assuming undisturbed performance and projected over 1,000 years. The 1993 requirements are 150 μSv (15 mrem) committed effective dose (CED)/yr projected over 10,000 years, still calculated assuming undisturbed performance.

The new requirements are based upon updated dose-to-risk conversion factors. This has resulted in increases in the risk (of developing a fatal cancer) per unit of dose received. Also, the new requirements have incorporated into them the internationally accepted CED dose-calculation methodology (7). This level is, today, associated with the same risk as was the dose level in the 1985 standards, 5×10^{-4}. The Agency believes that nothing has changed since 1985 to make this risk level unacceptable today. The choice of this level was underlain by examining the levels of risk allowed by other Agency regulations. In addition, the Agency is trying to be consistent with the approach endorsed by the International Commission of Radiological Protection to apportion an overall individual dose limit of 1 mSv (100 mrem) CED/yr (8). The Agency believes that 150 μSv (15 mrem) CED/yr is an appropriate and acceptable fraction of that limit for this practice. All of these factors have resulted in the selection of the annual limit of 150 μSv (15 mrem) CED.

As mentioned previously, the time over which doses are to be projected has been increased to 10,000 years. The reasons that the 1,000-year period was chosen in 1985 were that it was believed that it would encourage more substantial engineered barriers than might be used without such a requirement and that the capability of assessment technology was judged to be inadequate to go beyond a 1,000-year projection. The Agency now believes that advances in modeling together with greater amounts of site-specific data, as opposed to the generic data used almost exclusively in 1985, and data of higher quality now make a 10,000-year projection feasible. Further, the Agency believes that these factors will continue to progress and further facilitate the longer projection.

There are three other reasons for the choice of 10,000 years. First, the results of the Agency's generic analyses showed that, for some geologic media, releases which resulted in significant doses began to occur after 1,000 years but before 10,000 years. However, for other media, no releases were projected over 10,000 years. (9) The purpose, then, of the new time frame is to encourage the selection of better sites and the design of robust engineered barriers which in turn should reduce risks to individuals.

Second, the Agency's generic, base-case analyses of well-sited and well-designed disposal systems indicate no projected releases for 10,000 years. Therefore, there should be no additional compliance costs because of the extended period. There could be some additional costs for demonstrating compliance if additional modeling is needed but these costs are believed to be insignificant when compared to the overall cost of disposal system development (10). In addition, the analyses required by the reinstated standards include the undisturbed-performance analysis and could be used for this purpose as well.

Third, and finally, the new 10,000-year time frame is consistent with the time frame in the reinstated containment requirements as well as in other EPA regulatory programs, *e.g.*, "no-migration" determinations and the underground injection of untreated hazardous waste, both under the *Resource Conservation and Recovery Act* (RCRA) (11). Overall, the Agency concluded, based upon a finding that there is no significant difference in protecting populations and individuals and having found no convincing rationale for a different time frame, that it is possible and appropriate to extend the time frame.

Ground-Water Protection Standards

The ground-water protection requirements in 1985 were based upon the limits in the Interim National Primary Drinking Water Regulations which had been established under the *Safe Drinking Water Act* -- 40 μSv (4 mrem)/yr to the whole body or any organ from beta- and gamma-emitting radionuclides plus a few, separate concentration levels in the water for alpha-emitting radionuclides. These are known as maximum contaminant levels (MCLs) and define the level of water quality which the Agency believes is acceptable for consumption from public water supplies. In addition, the 1985 requirements applied to only certain sources of ground water. These sources, though based on an Agency classification system which is now withdrawn, were unique to Part 191 and did not cover all sources of potable ground water. Like the individual protection requirements discussed above, doses and concentrations were to be assessed based upon 1,000 years of undisturbed performance of the disposal system and an assumed drinking-water consumption rate of two liters per day per person.

The 1993 requirements are more inclusive and have a new projection period; however, the undisturbed-behavior assumption has remained. While the 1993 Part 191 adopts the existing MCLs which, therefore, remain at the same levels as those upon which the 1985 standards were based, the volume of ground water protected under Part 191 has increased to include any underground source of drinking water. The Agency has not taken a position on whether or not the *Safe Drinking Water Act* applies to any particular disposal system. However, given the similarity of purpose between it and the *Atomic Energy Act, as amended* (12), the new standards are designed to provide an equivalent level of protection as would occur if the *Safe Drinking Water Act* MCLs did directly apply to a particular disposal system. It is noted that EPA has formally proposed revisions to the current MCLs; should these proposed revisions (or any others not consistent with Part 191) be finalized, Part 191 will be amended to become consistent.

The new projection period is 10,000 years. The reasons for this change are the same as those discussed in the *Individual Protection Requirements* section above.

One issue under this section has been left open for later resolution. In assuring substantive equivalence between the *Safe Drinking Water Act* regulations and Part 191, the Agency found that it was necessary to examine a provision in the *Safe Drinking Water Act* regulations in the perspective of the current situation. The provision bans so-called Class-IV injection wells, *i.e.*, those injection wells which are used to dispose of radioactive waste into or above a formation which contains an underground source of drinking water within one-quarter

mile of the well. [The subject of underground injection is discussed further later in this paper.] Part 191 does not contain such a ban; the Agency currently believes this is appropriate. The intent of the ban in the *Safe Drinking Water Act* regulations was to preclude routine well injection. The Agency does not believe, at this time, that disposal systems subject to Part 191 constitute disposal so routine that it is appropriate, at least without further consideration, to apply "a blunt instrument akin to the Class-IV-well ban" to the disposal of wastes subject to Part 191. In addition, the Federal court recognized that the *Nuclear Waste Policy Act of 1982* superseded the *Safe Drinking Water Act*, allowing radioactive contamination of ground water near the disposal system. The Agency intends to resolve this issue through another rulemaking which should be starting within the next year.

Are Geologic Repositories a Form of Underground Injection?

In its ruling which vacated Part 191 and remanded it to EPA, one of the key findings was that Part 191 potentially allowed endangerment of underground sources of drinking water by allowing radiation dose levels to individuals in excess of the MCLs. This was brought about because the Court believed that repositories were "likely" a form of underground injection. The Court stated, "...the HLW regulations either should have been consistent with the SDWA [Safe Drinking Water Act] standards...or else should have explained that a different standard was adopted and justify that adoption." As explained earlier, the Agency has adopted the MCLs as its ground-water standards in Part 191, however, the Agency disagrees that repositories are a form of underground injection.

The *Safe Drinking Water Act* defines "underground injection" as "the subsurface emplacement of fluids by well injection." The Agency has concluded that the underground disposal of containerized radioactive waste in geologic repositories is not a form of underground injection 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, are enclosed in barrels or other types of containers. The Agency does not believe the *Safe Drinking Water Act*'s reference to "subsurface emplacement of fluids" was intended to address the subsurface disposal of solid or containerized materials because the legislative history addresses only the injection of liquid materials that flow or move at the time they are emplaced in the ground. Legislative history of the *Safe Drinking Water Act* and Agency policy, supported by the legislative history, discuss parameters such as volume, rate, degree of fluid saturation, and fluid pressure. This supports the interpretation that these documents do not address the subsurface emplacement of containerized radioactive wastes but they do address noncontainerized liquids as the object of concern.

Reflecting the statutory approach, EPA's underground injection control regulations similarly do not treat containerized radioactive wastes as fluids or liquids for the purpose of control under the underground injection control 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 underground injection control regulations. There is no mention of this activity in the preambles to the proposed or final underground injection control regulations. On the contrary, the fluids regulated by EPA's underground injection control 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. 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 underground injection control regulations.

Finally, EPA has never interpreted its underground injection control regulations to include the subsurface emplacement of containerized wastes or solid materials that do not flow or move. The EPA stated instead that placement of such containerized hazardous waste in geologic repositories such as underground salt formations, mines, or caves, is regulated under Subtitle C of the RCRA hazardous waste program. Similarly, the Part 191 disposal standards regulate the disposal of radioactive wastes including containerized radioactive wastes. Thus, the Agency recognized that there would be some disposal practices that might potentially contaminate ground water that would not be covered under the underground injection control program.

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."

The EPA's underground injection control 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." A "well" is defined as "a bored, drilled, or driven shaft, or a dug hole, whose depth is greater than the largest surface dimension." 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 *Safe Drinking Water Act* or EPA's underground injection control regulations. In addition, the overall configuration of a repository is far different from a "drilled," "driven," or "dug" injection well. 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 bedded-salt 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.

Therefore, the Agency does not believe that the emplacement of containerized waste by conveyors or elevators down a shaft should be covered under the underground injection control 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 underground injection control program.

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 underground injection control program. 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. The underground injection control regulations are directed at the injection of fluids by pressure or gravity flow; this activity is far different, from an engineering perspective, than the subsurface emplacement of containerized wastes.

Finally, 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 underground injection control program to cover this activity.

THE NAS COMMITTEE ON TECHNICAL BASES FOR YUCCA MOUNTAIN STANDARDS

The *Energy Policy Act* (13) was enacted in October 1992. Section 801 of that Act directed the Agency to issue site-specific, environmental standards to protect public health and safety of the public from releases of radioactive materials stored or disposed of in the potential repository at the Yucca Mountain site. This is unprecedented for EPA under the *Atomic Energy Act*. Until now, the Agency has been limited to writing generic environmental standards, *i.e.*, standards which could be applied to a category of nuclear facilities or releases, *e.g.*, all nuclear reactors, the entire uranium fuel cycle, or disposal systems for entire categories of radioactive wastes. Section 801 also directed EPA to contract with the National Academy of Sciences (NAS) to conduct a study to provide findings and recommendations for EPA to use in writing the Yucca-Mountain-specific standards. Section 801 further mandated answers to three specific questions. To quote from Section 801, the NAS is to provide findings and recommendations on reasonable standards including:

"A whether a health-based standard based upon doses to individual members of the public from releases to the accessible environment...will provide a reasonable standard for protection of the health and safety of the general public;

B whether it is reasonable to assume that a system for post-closure oversight of the repository can be developed, based upon active institutional controls, that will prevent an unreasonable risk of breaching the repository's engineered or geologic barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits; and

C whether it is possible to make scientifically supportable predictions of the probability that the repository's engineered or geologic barriers will be breached as a result of human intrusion over a period of 10,000 years."

To carry out the Congressional directive and the contract with EPA, the NAS has established the Committee on Technical Bases for Yucca Mountain Standards which is being administered by the Board on Radioactive Waste Management. This committee has fifteen members including the chairman, Dr. Robert W. Fri of Resources for the Future. The members are a mixture of personnel from academia, contractors, consultants, and one member from a foreign radioactive waste management program.

There have been four meetings through January 1994 with the first being held in May 1993. The discussions held during public sessions were mainly tutorial in nature. Many outside experts made presentations in their areas of specialization. The general subjects discussed have been the scientific considerations of technology-based versus health-based standards, estimating radiation doses, radionuclide releases to and through the accessible environment, radiation effects, effect on the repository of disturbing events and processes (*e.g.*, vulcanism, earthquakes, and human intrusion), passive and active institutional controls to mitigate the effects of human intrusion, scientific considerations of assessments of undisturbed performance of the repository, and engineered and natural barriers.

The Committee set aside time for public input at each meeting and intends to do so at any future open meetings. For example, at the first meeting, representatives of EPA, NRC, DOE, the State of Nevada, the nuclear power industry, environmental groups, and Nye County, Nevada made presentations. The Committee will continue its deliberations which will lead to its final report. The meetings in the future could either be held entirely in executive or in partially open session. The Agency expects to receive the report in December 1994.

The Committee clearly does not see its charge as limited to the issues posed by Congress. As stated by the Committee Chairman on May 27, 1993, "...we are free to question all assumptions and evaluate all options with regard to the technical bases for EPA's standards. Everything is on the table. We have no preconceptions about the subject of our study." (13) The Agency supports this approach but has asked the Committee to provide its rationale and underlying assumptions for all of its findings and recommendations. We believe this is the only way that their input will be useful in our future rulemaking for the Yucca Mountain standards.

On a related matter, the Agency has been asked to commit to revising Part 191 to make it consistent with the Yucca Mountain standards and the NAS report. However, Part 191 is a set of generic standards and, therefore, basically different than a set of site-specific standards. In both cases, *i.e.*, Part 191 and the Yucca Mountain standards, EPA needs to consider many factors only one of which is the NAS report. Therefore, the Agency believes that it is premature to make any commitment on its future actions. As can be inferred from the Chairman's statement, the recommendations for the form of the Yucca Mountain standards could be considerably different or very similar to Part 191. Given such a spectrum of possibilities, the Agency will first study the NAS report and then assess the needs for Part 191 and the Yucca Mountain standards.

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