STATUS AND OUTLOOK FOR THE USEPA'S ENVIRONMENTAL STANDARDS FOR MANAGEMENT AND DISPOSAL OF SPENT NUCLEAR FUEL, HIGH-LEVEL AND TRANSURANIC RADIOACTIVE WASTES (40 CFR PART 191)

by

RAYMOND L. CLARK and FLOYD L. GALPIN
Office of Radiation Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

for presentation at

Waste Management '91

Tucson, Arizona
February 24 - 28, 1991

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RAYMOND L. CLARK and FLOYD L. GALPIN
Office of Radiation Programs (ANR-460)
U.S. Environmental Protection Agency
Washington, D.C. 20460

ABSTRACT

Since the remand of 40 CFR Part 191 by a Federal Court in July 1987, the EPA has been in the process of revising Part 191 to meet the Court's rulings and to update various aspects of the standards. This standard is unique in that it is the first EPA standard to address a 10,000-year regulatory period and to incorporate a probabilistic risk assessment requirement.

Part 191 is proceeding through review and the internal EPA approval process. This paper reviews the status and selected results of this procedure including discussion of the probabilistic aspects of the standards. We will also summarize the Agency's proposed changes from the original Part 191, as well as the current status of the standards and how EPA plans to proceed with further development and promulgation.

INTRODUCTION

On August 15, 1985, the U.S. Environmental Protection Agency (EPA) promulgated environmental standards for the management and disposal of spent nuclear reactor fuel and high-level and transuranic radioactive wastes (40 CFR Part 191). These standards were designed to provide the overall environmental objectives for the nation's programs to dispose of these materials.

Shortly after the rule was promulgated, several States and environmental groups challenged it in the United States Court of Appeals for the First Circuit ("the Court"). Through rulings issued in 1987, the Court vacated the portion of the rule dealing with disposal (Subpart B) and remanded it to the Agency for further consideration based on problems it found with two sections of the standards. Subpart A (management and storage) was left in effect.

As a result of the Court ruling and the need for such standards, the Agency has established a program to revise 40 CFR Part 191, republish it for public review and comment, and repromulgate it after considering the comments received. The rulemaking is centered on addressing the defects the Court found in the two sections of Subpart B. In addition, we are reviewing other aspects of the standards to see if they need to be updated in response to additional information and to changes in the national disposal programs.

Roles of Federal Agencies

High-Level Waste and Spent Nuclear Fuel. In 1983, President Reagan signed the Nuclear Waste Policy Act (NWPA). The main purposes of the Act were to establish deep geological repositories as the method the Nation will use for disposal of high-level waste (HLW) and spent nuclear fuel, to establish a procedure for choosing the first two HLW repository sites, and to establish the roles of several Federal agencies in developing the disposal system.

The three major agencies named to carry out the provisions of the Act were EPA, the Nuclear Regulatory Commission (NRC), and the Department of Energy (DOE). EPA was assigned the task of issuing generally applicable environmental standards. The NRC was given the task of licensing any civilian repository (as opposed to a repository used exclusively for wastes from defense activities). The DOE was to site, design, construct, and operate any or all repositories which will be built.

The EPA environmental standards, 40 CFR Part 191, were issued on August 15, 1985. Regulations for licensing a repository were issued by the NRC on June 21, 1983 as 10 CFR Part 60. As required by law, the NRC had begun the process to incorporate EPA's standards into 10 CFR Part 60 but, because of the Court remand, NRC has suspended that rulemaking until the new standards are promulgated.

Transuranic Wastes. Virtually all of the transuranic (TRU) waste in the United States comes from defense-related activities and while the NRC will determine the adequacy of the HLW repository, based in part upon the Commission's assessment of whether its performance will meet EPA's disposal standards, they have no jurisdiction over defense-only wastes. The DOE has the same responsibilities for TRU waste disposal facilities as those cited above for the HLW repository. In addition, under current authorities, it is solely responsible for determining compliance with 40 CFR Part 191 for TRU waste facilities.

Subpart B as Originally Promulgated

40 CFR Part 191 was divided into Subparts A and B. Subpart A deals with the management and storage of the subject wastes and is currently in effect. Subpart B dealt with the disposal of these wastes. Disposal was defined to begin when the disposal facility had been backfilled and sealed with no intent to re-enter it.

The key sections of Subpart B included the following:

- Section 191.12 which contained the definitions.
- Section 191.13, "Containment Requirements," which, along with Appendix A, specified the nuclide-specific release limits, i.e., the cumulative amount of those nuclides which may be released to the environment over the 10,000 years following closure of a disposal facility. There was also a probabilistic aspect to

this section which required the implementing agency to take into account events, both natural and human-induced, which could disrupt the behavior of the facility. This section required there to be less than one chance in 10 of exceeding the Appendix A quantities and less than one chance in 1,000 of exceeding 10 times those amounts. The different probability levels reflected an attempt by the Agency to separate more likely disruptions from those that are credible but less likely, e.g., normal ground-water flow or human intrusion versus fault movement or breccia pipe formation. There was no requirement to consider events with probabilities lower than one in 10,000; this was in recognition of the large uncertainties involved in estimating probabilities and in the futility of regulating highly improbable events, such as a meteorite impact.

- Section 191.14 which gave several qualitative, common-sense provisions called assurance requirements. The principles embodied in these requirements were important complements to the containment requirements and were intended to ensure that the desired level of protection was achieved.

- Sections 191.15 and 191.16, individual and ground-water protection requirements, respectively, which were both applicable for 1,000 years and assumed undisturbed behavior of the facility. Section 191.15 limited annual doses to members of the public to 0.25 millisieverts (mSv) [25 millirems (mrem)] to the whole body and 0.75 mSv (75 mrem) to any critical organ from radionuclides arriving through all pathways. Section 191.16 applied to water withdrawn from certain sources of ground water and set limits similar to those contained in the National Primary Drinking Water Regulations which pertain to radionuclides.

Court Action Regarding 40 CFR Part 191

In 1986, several environmental groups and States filed petitions for review of 40 CFR Part 191. These suits were consolidated and argued in the U.S. Court of Appeals for the First Circuit which is located in Boston, Massachusetts. The July 1987 Court ruling concerned: (1) potential violation of Part C (underground injection) of the Safe Drinking Water Act (SDWA); (2) inadequate notice and comment opportunity on Section 191.16 (Ground-Water Protection Requirements); and, (3) selection of the 1,000-year time of applicability for Sections 191.15 (Individual Protection Requirements) and 191.16. A very short summary of the findings follows:

Interaction with the SDWA. Reasoning through a series of definitions related to "underground injection," the Court decided that disposal of HLW in geologic repositories "would likely" constitute a form of underground injection. If this is a form of underground injection, the Agency, under the SDWA, is required to assure that underground sources of drinking water

will not be endangered by the injection. i.e., not allow doses higher than those allowed by the National Primary Drinking Water Regulations, i.e., 0.04 mSv per year (4 mrem per year).

Ground Water Protection Requirements. In response to comments mainly from States, Sections 191.15 and 191.16 were added to Subpart B after the Standards were proposed. The Court found that while sufficient opportunity was given for notice and comment on Section 191.15, this was not true for Section 191.16. This section was, therefore, remanded for a second round of notice and comment.

The 1,000-Year Duration of Sections 191.15 and 191.16. These sections set dose equivalent limits for individuals and radionuclide content limits in ground water, respectively. They apply to undisturbed repository performance for the first 1,000 years. The Court found that the 1,000-year period is not inherently flawed but rather that the administrative record and EPA's explanations did not sufficiently support the choice. The 1,000-year criterion was remanded for reconsideration.

THE NEED FOR QUANTITATIVE PROBABILISTIC STANDARDS

Probabilistic standards are necessary because of the long time period over which one must judge the repository's suitability. Without taking the probability of events into consideration, a standard has no meaning for these types of facilities. Assuming careful and prudent site selection, any releases from an undisturbed facility are not expected to be of major concern because of the site's geological integrity. However, as we extend the analysis into the thousands of years, we realize releases of some kind are possible, despite the initial geological integrity. Releases of concern that might occur in the longer term are usually the result of disruptive events external to, but impacting upon, the facility and, therefore, are not susceptible to the classic type of standard that prescribes limits on "routine releases." The releases of concern for any reasonably considered geology generally result from events such as human intrusion or seismic disturbances. To ignore this reality is to develop standards that have no effect on the factors going into the planning for facility performance.

If we were to set only deterministic standards, we would have only two choices for possible events: they either will or will not occur. If we assume they will occur, it will be difficult to find a repository that can pass the test. If we assume they will never occur, or ignore consideration of these events, we will have abandoned having a meaningful standard. Further, if we do not state these criteria in some type of quantitative terms, we will have no yardstick for decision.

Another reason we think that a quantitative standard is necessary is that it provides a criterion against which to judge the adequacy of a licensing decision. We are very much aware of the potentially contentious nature of a repository licensing process. Without quantitative standards in place that have gone through a public review and promulgation process, a proposed site will require extensive justification, much of which will be

subjective. This could result in an unnecessary adversarial situation. By having an existing quantitative measure, much of the contention could be avoided since both the licensing board and any subsequent court will have a yardstick against which to judge the arguments.

The final reason for quantitative standards is that we do not believe that the disposal of high-level radioactive waste can be approached on the basis of just doing the best job that we can; even the most experimental of engineering designers must have in mind some design goal. The country started out on this best-possible-job approach with the result of withdrawing the proposed repository near Lyons, Kansas; it is now agreed that the Lyons site would not have provided adequate long-term isolation. Furthermore, we do not believe that the public is willing to accept a qualitative standard as adequately protective of their health and the environment.

REGULATORY ALTERNATIVES

The principal objective of this rulemaking is to address the defects cited by the Court. The Agency does not plan to change any major aspects of the standards that were not challenged. For example, we do not plan to review the 10,000-year time frame used for the containment requirements or the need for qualitative assurance requirements to complement the numerical standards.

However, there are several issues that the Agency is considering to ensure that the final rule is as sound as possible; these include the following:

Ground-Water Protection Standards

The ground-water protection standards, as promulgated in 1985, were based on the Agency's Guidelines for Ground Water Classification which have since been withdrawn. The need for changes in the ground-water classification system are being reviewed. We believe that the best approach to meeting the Court's ruling is to be consistent, as far as possible, with the provisions of the SDWA regulations, with the exception of the underground injection section which we do not consider to be applicable to DOE's geologic repositories (this is covered in more detail later in this paper). Therefore, the leading contender for a new section is consistent with the dose and concentration limits found in the National Primary Drinking Water Regulations (40 CFR Part 141).

In addition, there will also be consideration of both 1,000- and 10,000-year time frames. As noted above, the Court asked for further justification of the 1,000-year time frame in Sections 191.15 and .16 which some people read as asking why was 10,000 years not chosen. Consideration of the longer time period is based upon consistency with the containment requirements time frame as well as, it appears that the 10,000-year period may be achievable for a variety of geologic settings if the repository is

carefully sited and designed. Therefore, we are interested in gathering comments on the advisability and implementability of both time frames.

Individual Protection Standards

As in the previous section, it is likely the Agency will seek comments on two alternatives for the length of time that the individual protection standards will be applicable, 1,000 and 10,000 years. In addition, there will likely be comments requested on two annual effective dose equivalent (ede) limits, 10 and 25 mrem. Recent trends in radiation protection have been toward lower allowable levels because of increases in dose response estimates. In addition, the 10-mrem ede limit is consistent with the levels found in the most recent EPA radiation regulations which were issued under the Clean Air Act.

Implementation Considerations

As noted earlier, we are considering potential implementation problems as we develop the individual and ground water standards. In particular, do uncertainties in projecting exposures or ground-water concentrations over long periods of time affect the feasibility of different options? For example, could an individual exposure standard be practical to implement over 1,000 years but not over 10,000 years -- even for a repository that appears to provide adequate protection?

In addition, to help us evaluate the practicality and stringency of our standards, we are incorporating new data into updated models to evaluate repository performance to see if there need to be changes made to the containment requirements. The analyses for the 1985 standards centered on salt, basalt, and granite. We are using updated computer programs to model ground-water behavior and radionuclide transport and we have access to much more data on geologic media than were available during the early 1980's when the original 40 CFR Part 191 was being developed.

Demonstration of Compliance

Since 1985, there has been confusion over when in the facility development process it is necessary to show compliance with Part 191. In an attempt to clarify this issue, two new sections, patterned after requirements in the Nuclear Waste Policy Act of 1982 pertaining to waste emplacement at the Yucca Mountain repository site, are being considered. The first new section requires that compliance with Part 191 be shown prior to the emplacement of any radioactive wastes.

The second new section allows an exception to this for the purpose of experimental emplacements. This could be done, however, only after several conditions were met, viz., preliminary performance assessments are available to guide the experiments, the purpose of the tests and the amount of waste required are in written form along with a time schedule, there are pre-established plans and tested procedures for removal of the wastes, and the approval of the Administrator is given in cases where the NRC is not the licensing authority.

Qualitative Performance Comparison

An additional, potential assurance requirement would make a qualitative comparison of potential releases due to undisturbed performance from alternative sites over a 100,000-year time frame. We believe this is important to provide, early in the site selection process, a long-term comparison of the sites' potential strengths and weaknesses and give some assurance that a site will perform adequately beyond the 10,000-year time frame required by the quantitative standards. This provision is consistent with the DOE's site selection guidelines in 10 CFR Part 960. Here again, we will be interested in receiving comments on the utility of projecting, even qualitatively, performance for 100,000 years.

Update of the Dose Equivalent Calculation Method

In 1985, the annual dose limits in the standards, were generally based on the critical-organ dose calculation method. During the development of the original standards this was the accepted method, however, this method is no longer consistent with current practices of radiation protection. The current dose-calculation method is known as the effective dose equivalent system. Therefore, all individual doses will now be required to incorporate that system.

ISSUES UNDER CONSIDERATION

Gaseous Releases

The analyses for the 1985 standards did not consider a gaseous release pathway from a disposal facility. While we believe that the issue has not been adequately addressed as to technical alternatives, geochemical conditions which could affect the releases, and chemical form of the radionuclides, we are examining the basis of our release limits and considering possible approaches. For example, one alternative is rather than calculate doses to the world population, as is now done, consider a distance limit for the population. A second possibility is to establish a lower bound on individual doses below which their contribution need not be included. No decision has been reached at this time.

Basis of the Release Limits

It has been brought to our attention that an alternative to the basis of our 1985 release limits may be a useful change which would allow for flexibility in assessments of disposal system performance but which would not compromise the original level of protection. The 1985 release limits were based on a particular geological and environmental pathway model. This model may not accurately portray the situation at all sites. While we have no intention of eliminating the release limits, we are considering alternatives. One example being the use of a collective dose limit which is equal to the 1,000 health effects over 10,000 years from 100,000 metric tons of heavy metal which is the basis of the 1985 release limits.

Underground Injection

One basis of the Court's remand of Subpart B was that geologic repositories may be a form of underground injection under the SDWA. We believe that the basis of a determination of whether a material flows or moves is the waste form and method of emplacement. On this basis, we intend to show that the geologic repository operations envisioned by DOE, i.e., the process of lowering massive pieces of solid material down a shaft on an elevator or some human-controlled (i.e., not gravity or pressure-driven) conveyance and, upon reaching the emplacement level, either emplacing them or transporting them via some form of mechanical transport to their emplacement location, do not constitute underground injection.

An Alternative to the Probabilistic Approach in Section 191.13

The Agency is considering a suggestion from the NRC regarding the probabilistic approach in Section 191.13, the Containment Requirements. Rather than requiring all potential release scenarios to be assigned specific probabilities and be assembled into a CCDF, this system would require a CCDF only for those likely events, defined, for example, as having a probability greater than 0.1 over 10,000 years of exceeding the standard. Events with probabilities estimated in a range of say 0.1 to 0.0001 of exceeding the standards would be analyzed individually and compared to the release limits and, as is true in the 1985 standards, events below 0.0001 need not be considered. Considering the difficulty in assigning specific probabilities to very improbable events, some believe that this approach would assure some flexibility in the licensing system while not affecting the safety goal of the standards.

Negotiated Rulemaking

Based on suggestions from the National Academy of Sciences and the Nuclear Waste Technical Review Board, the Agency is currently assessing the feasibility of conducting a negotiated rulemaking for Part 191. At this time, the contractor is preparing to interview potential participants in order to determine under what conditions they would be willing to enter the process. This is anticipated to be completed by May 1991.

FUTURE ACTIVITIES

Review of this rule is proceeding in accordance with EPA procedures. We have and will continue to interact frequently with the appropriate NRC and DOE offices, States, environmental groups, industry representatives, and others during the development of the rule whether the negotiated rulemaking occurs or not. Two drafts of the rule have been entered into Public Docket Number R-89-01 at EPA Headquarters in Washington, DC. A third draft will be submitted soon.

We are preparing regulatory support documents which will be available when the proposed standards are published in the *Federal Register*. They will include a Draft Background Information Document (BID), which will

provide information on the risk assessment including sources of radiation exposures, routes of exposures, methodology of assessments, and individual and population risk estimates, and a Draft Regulatory Impact Analysis (RIA), which will have a presentation of the costs of the controls and cost-effectiveness of the regulatory options. In addition, the *Federal Register* notice will include the proposed standard, listing the requirements discussed earlier, and a preamble to the rule which discusses the Agency's decision-making procedure and the rationale for its regulatory judgments. The rulemaking process will include a notice of proposed rulemaking, a public comment period, and public hearings; all will provide important mechanisms for public input to help guide the final decision-making. The final rulemaking documentation will include final versions of the preamble to the standards in the *Federal Register*, RIA, and the BID along with a volume which summarizes EPA's response to public comments.

We were planning to propose the Standards in the Spring of 1991 with finalization occurring in 1992. The date of proposal will now be delayed and will be dependent on the outcome of the negotiated rulemaking investigation.