THE U.S. ENVIRONMENTAL PROTECTION AGENCY'S HIGH-LEVEL RADIOACTIVE WASTE STANDARDS: FORM OF THE STANDARD AND THE PROTECTED INDIVIDUAL

by

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for the

SSI/EPA Regulators' Workshop
Stockholm, Sweden
September 2001

INTRODUCTION

The United States Environmental Protection Agency (EPA) has issued three sets of standards pertaining to the disposal of radioactive waste storage and disposal: Title 40 of the Code of Federal Regulations (40 CFR) Parts 191, 194, and 197. 40 CFR Part 191 is the Agency's set of generic standards for the management and disposal of spent nuclear fuel, high-level and transuranic radioactive waste (1). 40 CFR Part 194 is the set of regulations which implement 40 CFR Part 191 for the Waste Isolation Pilot Plant (WIPP) (2). (WIPP is a geologic repository for the disposal of defense transuranic radioactive waste. It has operated since 1998.) 40 CFR Part 197 is the set of environmental standards which apply site-specifically to the potential geologic repository for spent nuclear fuel and high-level radioactive waste at Yucca Mountain, Nevada (it is also the most recent set of standards) (3).

In 1992, the Energy Policy Act (EnPA) gave EPA the authority to issue standards for Yucca Mountain. The same act directed EPA to contract with the U.S. National Academy of Sciences (NAS) to provide technical bases for the standards. The NAS provided its findings and recommendations to EPA in 1995 (the NAS Report) (4). As part of those findings and recommendations, NAS recommended the form of the individual-protection standard and made a recommendation on the method for EPA to use to identify the person/people to protect.

The method of identifying members of the public to be protected has changed with the Agency's role. The 1985 standards (40 CFR Part 191) are generic, which means that they are implemented through site-specific regulations (e.g., 40 CFR Part 194 for WIPP). The person being protected in these standards for the period after disposal is the maximally exposed individual, i.e., the person receiving the highest possible dose. (Hereafter, the discussion of the standards refers only to the disposal portion of the 40 CFR Part 197 standards. The storage standard applies to any member of the general population.) As a result of the NAS Report, the approach used in 40 CFR Part 191 has changed for the Yucca Mountain standards. For Yucca Mountain, we use the reasonably maximally exposed individual (RMEI).

A LIMIT ON DOSE OR RISK?

Section 801(a)(1) of the EnPA directs that the EPA standards for Yucca Mountain "shall prescribe the maximum annual effective dose equivalent to individual members of the public from releases to the accessible environment from radioactive materials stored or disposed of in the repository...." (5) The EnPA also requires us to issue our standards "based upon and consistent with" NAS's findings and recommendations. The NAS recommended that we adopt a risk-limit standard to protect individuals, rather than a dose-limit standard, as Congress prescribed. The NAS offered two reasons for its recommendation. First, a risk-limit standard is advantageous relative to a dose-limit standard because it "would not have to be revised in subsequent rulemakings if advances in scientific knowledge reveal that the dose-response relationship is different from that envisaged today" (NAS Report p. 64). Second, a risk-limit standard more readily enables the public to comprehend and compare the standard with human-health risks from other sources.

We reviewed and evaluated the merits of a risk-limit standard as recommended by NAS. However, we chose to adopt a dose-limit standard which is based upon a risk that is within the range of risk recommended by NAS. This approach was chosen for the following reasons. First, section 801(a)(1) of the EnPA specifically directs us to promulgate a standard prescribing the "maximum annual dose equivalent to individual members of the public from releases to the accessible environment from radioactive materials stored or disposed of in the repository." Also, a Congressional conference committee stated that EPA's standards "shall prescribe the maximum annual dose equivalent to individual members of the public from releases to the accessible environment from radioactive materials stored or disposed of in the repository." In a situation such as this, where both the statutory language and the legislative history are clear, we are obliged to implement the clearly stated plain language of the statute and to carry out the unambiguous intent of the Congress. Second, both national and international radiation protection guidelines developed by bodies of non-governmental radiation experts, such as the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP), generally have recommended that radiation standards be established in terms of dose. Also, most national and international radiation standards, including the individual-protection requirements in 40 CFR Part 191, are established in terms of dose or concentration, not risk. Therefore, a risk standard will not allow a convenient comparison with the numerous existing dose guidelines and standards.

The EPA established the level of the dose limit based upon the risk of developing a fatal cancer that, in turn, was based upon the linear, non-threshold, dose-response relationship. The level of risk, about 8.5 fatal cancers per million members of the population per year (see the preamble to the proposed rule at 64 FR 46984), is a level the Agency has judged to be acceptable after taking into account many factors, including existing radiation standards (such as subpart B of 40 CFR Part 191), Congressional action (the WIPP Land Withdrawal Act (6)), and the comments received on the proposed standards.

Finally, we did not receive any comments in favor of a risk-limit standard that provided either a compelling technical or policy rationale for promulgating such a standard (see the Response to Comments document). Therefore, for this and the other reasons cited in this section, EPA chose to use a limit on dose rather than risk.

WHO IS PROTECTED?

As noted earlier, NAS recommended a method of identifying who should be protected. Relative to this issue, NAS said:

> "Although not strictly a scientific issue, we believe that the appropriate objective is to protect the vast majority of members of the public while also ensuring that the decision on the acceptability of a repository is not unduly influenced by the risks imposed on a very small number of individuals with unusual habits or sensitivities. The situation to be avoided, therefore, is an extreme case defined by unreasonable assumptions regarding the factors affecting dose and risk, while meeting the objectives of protecting the vast majority of the public. An approach that is consistent with this objective, and is used extensively elsewhere in the world, is the critical-group approach. We recommend that the critical group approach be used in the Yucca Mountain standards."
> (NAS Report p. 5)

Thus, NAS recommended that EPA use the risk imposed upon a critical group (CG) as the basis for the individual-protection standard. The NAS described the CG as the group of people: (1) that based upon cautious, but reasonable, assumptions, has the highest risk of incurring health effects due to releases from the disposal system; (2) within which the distribution of risks is homogenous (i.e., within a factor of 10); and (3) small enough to be homogenous with respect to diet and behavior (NAS Report pp. 53-54). In its report, NAS discussed two specific examples of CGs. The NAS considered the probabilistic CG, based upon a present-day farming community, to be more appropriate and less reliant upon speculative assumptions than the other CG it discussed, which was based upon subsistence farming.

The NAS probabilistic CG. The NAS probabilistic CG approach uses a theoretical population distribution which would be developed by using the Monte Carlo method. The other parameters would be present-day biosphere and environmental parameters, including soil quality, land slope, growing season, depth to the aquifer, and population distribution and lifestyles. The individuals who comprise the CG would represent a variety of economic lifestyles and activities. The analysis would then use the variability of the values of those parameters in the region around Yucca Mountain to arrive at the characteristics of the population for the calculation of radiation exposure. This theoretical population would then be combined with Monte Carlo simulations of the distribution of contaminated ground water in time and space (NAS Report p. 148). Each simulation would generate a plume path which could be overlain on a map of potential farm density or water use to determine a potential exposure area. Each of these potential plume paths is known as a ''realization.'' For each plume realization of the contamination in the aquifer, the results of the exposure simulations are combined to give a spatial and temporal distribution of maximum exposures for the locations likely to be inhabited. This approach would use a large number of simulations of plume realizations to identify critical subgroups with the highest risk. It would then be used to calculate the arithmetic average of the risk in all subgroups over all plume realizations to estimate the risk for the CG.

We considered proposing the probabilistic CG approach but are not doing so for the following reasons. First, there is no relevant experience in applying the probabilistic CG approach. Second, the approach is very complex and difficult to implement in a manner that assures it would meet the requirements of defining a CG. Third, we are concerned that this approach does not appear to identify clearly who is being protected. Fourth, a probabilistic CG implies some, or even many, locations of the members across a broader geographic area than the plume covers. This dispersal inescapably involves additional decisions for combining dose estimates for the group members and comparison against regulatory limits and could average some, or many, doses with a zero magnitude. Indeed, given the characteristics of the plume of contamination projected by DOE (a relatively narrow plume), a dispersed CG would be very likely to include members who incur no dose. Such a situation would be inconsistent with the basic concept of a CG. Finally, a significant majority of the public comments that we received opposed the probabilistic-CG approach.

The NAS subsistence-farmer CG. The other approach discussed in the NAS Report specified one or more subsistence farmers as the CG. It made assumptions designed to define the farmer at maximum risk to be included in the CG. The subsistence-farmer CG is a highly exposed segment of the larger, exposed population. The subsistence farmer would be assumed to: (1) be a person with eating habits and response to doses of radiation that would be average for present-day people and (2) obtain all potable water and grow all of his or her own food using water withdrawn from the aquifer contaminated with radionuclides from the disposal system. The water used by this CG would be withdrawn at a location downgradient from and outside the footprint of the repository at the point of maximum potential concentration of ground water contamination, provided that no natural geologic features preclude drilling for water at that location. (The footprint of the repository is the circumscription of the outermost, original emplacement locations of the waste.) Concentrations of radionuclides in the extracted ground water may be smaller than in undisturbed ground water due to pumping; this effect could be included when projecting exposures (NAS Report p. 155). As a result of uncertainty, there will be probabilistic distributions of radionuclide concentrations, as they vary in time and space in the aquifer outside the repository footprint, which are the input variables needed to estimate the risk. Any assessment of the potential doses from the repository must consider the probability of processes and events that influence eventual concentrations of radionuclides in aquifers supplying water to the CG.

The ‘‘expected’’ risk for the average member of this CG would be about one-half that of the most-exposed subsistence farmer (NAS Report p. 158). This average risk to the members of the CG would be compared with the standard to determine compliance.

We considered the subsistence-farmer CG approach, but decided that it would be inappropriate, since we could not find, nor did any other party demonstrate, that there is the subsistence-farmer lifestyle at, or downgradient from, Yucca Mountain.

EPA's Protected Individual. The EPA chose an approach, for this case, that is consistent with other Agency programs and which it believes provides a level of protection substantially equivalent to that which would be achieved by the CG concept. The Agency conceived of an individual who would be representative of the most highly exposed individuals. This individual is called the reasonably maximally exposed individual (RMEI). The RMEI in the Yucca Mountain standards is a representative of a group termed “rural-residential.” This means that the person lives downgradient from Yucca Mountain, but works elsewhere and brings in some food and drink from outside, uncontaminated sources. This RMEI also drinks 2 liters per day of water from the aquifer and grows a garden using that same source of water. The Agency believes that this life style is characteristic of the life style downgradient from Yucca Mountain.

The RMEI is characterized using all the necessary parameters to calculate the dose incurred by an individual. The parameter values are based upon characteristics of the current population downgradient. Of the critical parameters, one (or more) is set at its high value, while the others are set at their mean values. To be effective, the RMEI approach must avoid incompatible combinations of parameter values, such as, low body weight used in combination with high intakes. The EPA intends for this procedure to project doses that are within a reasonably expected range rather than projecting the most extreme case. However, the procedure is also meant to identify an individual dose which is well above the average dose in the exposed population. The ultimate goal and purpose is to estimate a level of exposure that is protective of the vast majority of individuals at a site, but is still within a reasonable range of potential exposures. The EPA specified two of the parameters and their maximum values – the water drinking rate (2 liters per day) and the location of the RMEI (about 18 kilometers from the repository). The Agency also requires the assumed diet to be based upon surveys of the current population in the Town of Amargosa Valley, Nevada.

In both the RMEI and CG approaches, the objective is to determine the magnitude of the potential dose using reasonable, but not extreme, assumptions to find a dose that is high within the group of highest exposed people, but is not the highest theoretical dose. Both approaches are designed to account for differences in age, size, metabolism, habits, and environment to avoid heavily skewing the results based upon personal traits that make certain people much more or less vulnerable to radiation releases than the average within the group. Considering this, and the reasons summarized in the next paragraph, we believe that the RMEI approach is more prudent for Yucca Mountain.

In summary, there are several reasons that EPA chose the RMEI approach. First, this approach is consistent with widespread practice, current and historical, of estimating dose and risk incurred by individuals even when it is impossible to specify or calculate accurately the exposure habits of future members of the population, as in this case where it is necessary to project doses for very long periods. Second, we believe that the RMEI approach is sufficiently conservative and fully protective of the general population (including women and children, the very young, the elderly, and the infirm). The risk factor for fatal cancer upon which the dose level was established is 5.75 chances in 10,000,000 per millirem (mrem) (5.75 in 100,000,000 per microsievert). Third, it provides protection similar to the CG recommended by NAS. This belief was supported by NAS in its comments on the proposed 40 CFR Part 197. The NAS agreed that EPA's RMEI approach is basically consistent with its report's recommendations. Fourth, it is possible to build the desired degree of conservatism into the model through choices of assumed values of "reasonable maximum exposure" parameters. However, these values must be within certain limits because EPA requires the use of Yucca Mountain-specific characteristics in choosing those parameters and their values. In subpart B of 40 CFR Part 197, EPA established a framework of assumptions for NRC to incorporate into its implementing regulations. Fifth, the RMEI approach is more straightforward in its application than the CG approach (particularly the probabilistic CG). The important difference between the RMEI and probabilistic-CG approaches is in the assumed distribution of the group members relative to the projected path of radionuclide contamination from the repository. Sixth, and finally, the RMEI approach is used in other EPA regulations, but not the CG approach. For example, the WIPP certification criteria (40 CFR Part 194) use an approach involving estimating doses incurred by individuals rather than a CG.

REFERENCE

1. *Environmental Radiation Protection Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Waste*, Part 191, Title 40, Code of Federal Regulations.
2. 40 CFR Part 194*, Criteria for the Certification and Re-certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations*, *Federal Register,* Volume 61, No. 28, pp. 5223-5245, February 9, 1996.
3. 40 CFR Part 197, *Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada*, *Federal Register,* Volume 66, No. 114, pp. 32073-32135, June 13, 2001.
4. *Technical Bases for Yucca Mountain Standards*, National Research Council, National Academy Press, Washington, DC, 1995.
5. *Energy Policy Act of 1992*, Public Law 102-486, 106 Stat. 2921.
6. *Waste Isolation Pilot Plant Land Withdrawal Act,* Public Law 102-579.