

APPENDIX A
ANALYSIS OF EPA'S HLW STANDARDS

1. INTRODUCTION

This Appendix discusses several potential uncertainties associated with the 1985 high-level radioactive waste (HLW) standards of the U.S. Environmental Protection Agency (EPA), alternatives to EPA's standards, and efforts by EPA to reduce or eliminate potential regulatory uncertainties.

The principal feature of EPA's HLW standards was a probabilistic limit on cumulative releases of radioactive materials to the environment during the first 10,000 years after disposal. EPA's standards also contained limits on potential dose rates to future individuals, but those limits applied only for the first 1000 years after disposal, and only for conditions involving no disruption of a repository.

The most widely recognized alternative to EPA's standards is the guidance for waste disposal (Publication 46) developed by the International Commission on Radiological Protection (ICRP). In developing this guidance, the ICRP recognized the need for modification of existing guidance on radiation protection. In Publication 46, the ICRP considered many of the same issues that EPA addressed in developing its HLW standards, especially the need for standards for low-probability, high-consequence release scenarios. The following discussion summarizes some of the major features of EPA's 1985 standards, describes possible alternatives to those standards, and provides a comparison with equivalent recommendations of ICRP Publication 46.*

2. RELEASE LIMITS

EPA's containment requirements are expressed in terms of allowable releases of radioactive materials from a repository. EPA's release limits were derived from a health-effects goal, using a generic biosphere model with world-average characteristics. An alternative format would explicitly limit the doses (or health risks) that might result from those releases. For example, the recommendations of ICRP Publication 46 include application of ICRP's basic dose limits for expected releases, as well as limits on projected health risks for releases that are not likely to occur.

The advantage of the release-limit format is that it provides a usable measure of repository performance while significantly simplifying demonstrations of compliance. Regardless of the form of the standards, a major part of an analysis of compliance will consist of evaluating the ability of the repository barriers to reduce releases of radioactive material to the environment. If the standards place limits on releases, the evaluation is complete at that point.

*The Advisory Committee on Nuclear Waste (ACNW) endorsed the individual-dose and risk-limit concepts that the ICRP recommended in a letter from D. Moeller to Chairman Carr, dated January 29, 1991.

If, however, the standards limit doses or health effects, an additional evaluation is needed to estimate the environmental transport and human uptake of the released material. Over the long time period of concern in repository licensing (10,000 years), the parameters involved in dose or health effects estimates can be highly uncertain. For example, the locations where people might live, their dietary habits, the amount of their food obtained locally, and even metabolic characteristics could change, as they have in the past. Elimination of such speculative parameters from a licensing review would be beneficial in terms of reaching a timely licensing decision that adequately protects public health and safety.

One disadvantage of the release-limit format is that it is difficult to compare such a standard with other radiological impacts (e.g., background radiation) or other radiation protection standards. Another disadvantage is that the actual number of health effects to be expected for a repository will probably vary from EPA's goal, since few actual repository sites will conform to the world-average biosphere model used by EPA to derive the release limits. ✓

A standard expressed directly in terms of doses or health effects would have the advantage of facilitating comparison with other radiological impacts and radiation-protection standards. Another advantage is that such a standard would directly limit the potential doses or health risks of concern at a specific site. As noted above, a release-limit standard might allow the actual public-health risk from a repository to vary from EPA's goal if the characteristics of the biosphere surrounding the repository are significantly different from the generic biosphere used by EPA to derive its release limits.

An intermediate alternative would be to express the standards in terms of doses or health effects and to specify, by rule, the assumptions to be made in projecting the doses or health effects associated with releases of radioactive materials to the environment. For example, either EPA or the Commission could specify a "static biosphere," in which current population locations, lifestyles, and metabolic characteristics would be assumed to remain unchanged for the indefinite future. However, such an approach would merely substitute an assumption that present site-specific biosphere conditions are representative of the future in place of the EPA assumption that current world-wide averages are an adequate representation. While this approach would eliminate potential uncertainties, the staff is not convinced that such a specification would be any more accurate than EPA's world-average model. Thus, the staff continues to favor retention of the release-limit format of EPA's standards.

The U.S. Nuclear Regulatory Commission (NRC) staff has long supported EPA's release-limit format for the standards, because it would eliminate many potentially contentious issues from a licensing review. The staff continues to believe that the implementation advantages of the release-limit format far outweigh the disadvantages. ✓

3. POPULATION-IMPACTS BASIS

EPA's standards emphasize protection of populations by imposing "containment requirements" that limit the cumulative amount of radioactive material released over 10,000 years. The cumulative release limits correspond to EPA's population-impacts goal of 1000 premature cancer deaths for a 100,000 metric

tonne (MTHM) repository. Additional, limited protection of individuals is provided for "undisturbed performance" during the first 1000 years. Thus, while the population is protected for most of the circumstances and time period of concern, radiation doses to particular individuals could be either very high or very low, depending on specific circumstances. The alternative to EPA's cumulative release limits, as recommended in ICRP Publication 46, would be limits that emphasize protection of individuals rather than populations.

EPA's decision to base its standards on population impacts rather than on protection of individuals was EPA's most significant departure from the traditional concepts of radiation protection, from the recommendations of international advisory groups, and from the practices of other nations. All national and international criteria and guidance of which the staff is aware use protection of individuals as the primary safety criteria. Evaluation of population impacts is generally required to determine whether such impacts are "as low as is reasonably achievable (ALARA)," but not as a primary measure of facility acceptability. EPA argued that compliance with limits corresponding to protection of individuals might be very difficult to demonstrate and that cumulative release limits would be more practical.* It was also noted that standards based on protection of individuals might encourage selection of disposal sites where any release of wastes would be substantially diluted, even if such sites offered less than optimal containment of wastes.

Recently, the ACNW commented on the population-impacts basis underlying EPA's standards.** ACNW stated, in part:

The projection of collective dose estimates far into the future (as is necessary to comply with the high-level radioactive waste repository standards as proposed by EPA) is extremely difficult. Factors that complicate such estimates include errors in predictions of regional and global population demographics (size and location) and of potential radionuclide pathways (groundwater flow and agricultural practices). In contrast, long-range projections of the locations and living habits of individuals who may reside near a repository are relatively straightforward, and estimates of their potential doses can be made with greater certainty.

The staff agrees that long-term projections of collective doses are extremely difficult. As discussed in Section 2 above, a fundamental feature of EPA's standards is the use of limits on the amounts of radioactive material released to the environment. This feature of the standards eliminates the need for difficult dose calculations, and has long been supported by the staff. Nevertheless, ACNW's comment raises a valid question -- would EPA's derivation of the release limits have been more technically rigorous if those release limits had been based on protection of individuals rather than populations? ACNW argues (see Appendix B) that, when monitoring releases from operating

* 50 FR 38077, dated September 19, 1985.

** January 29, 1991, letter from Dade W. Moeller to Chairman Carr.

facilities, collective doses are more difficult to estimate than are individual doses. The staff agrees. However, when projecting hypothetical impacts far into the future, the staff is not convinced that there is a significant difference between release limits based on individual protection versus release limits derived from a population-protection goal. The following discussion examines four measures of repository performance that could have been used by EPA in developing its standards.

3.1 Maximum Individual Dose

Many existing radiation-protection standards, including EPA's environmental standards for the uranium fuel cycle, limit radiation doses received by the maximally exposed individual. An estimate of the maximum individual dose begins with a projection of the location, timing, and rate of release of radioactive material to the human environment. For most releases, the concentration of released material must also be projected. Then, potential pathways of exposure (e.g., drinking water and food chains) must be defined. Finally, the usage rates (e.g., drinking water and food consumption) of the maximally exposed individual must be defined.

Estimation of the maximum individual dose is strongly dependent on the rate of release of radioactive material to the environment, since the rate of release will largely determine the concentrations of radioactive material ultimately reaching an individual. The relative timing of releases of different radionuclides will also be important, since simultaneous release of two or more radionuclides will cause higher doses than would sequential releases. Finally, the estimated doses will depend strongly on whether the location and characteristics of the exposed individual are taken to be projections of current demographics and lifestyles or are defined in a manner that maximizes the doses that reasonably could be hypothesized to occur in the future.

3.2 Average Critical Group Dose

The fundamental radiation protection recommendations of the ICRP now include the concept of the "critical group," (i.e., those who are expected to receive the greatest exposure). The ICRP recommends that its dose limits be applied to the average dose within the critical group, rather than to the maximally exposed individual. Application of the ICRP concept would require essentially the same information as the maximum individual-dose standard discussed above. However, it would also be necessary to define the critical group in terms of size, location, and usage rates for the potential pathways of exposure, and to determine the average dose expected within this group.

3.3 Summation Collective Dose

The most obvious way to estimate the collective dose associated with a repository is to determine the individual dose anticipated for each person exposed to releases from the facility, and then to sum those individual doses. Estimation of the collective dose in this way requires fairly detailed demographic information about the population exposed to a release, including the number of individuals exposed, their locations, and the usage rates for each person for each pathway of exposure. As a practical matter, a truncation of the summation of individual doses may be necessary, either as a function of

distance from the facility or at some de-minimis or "negligible risk" individual dose rate. Some radiation-protection experts extend the "negligible-risk" concept to conclude that truncation is necessary, as a matter of principle, arguing that collective doses composed of very small individual doses are meaningless for regulatory purposes. For example, EPA's release limit for carbon-14 was based on a world-wide collective dose estimate in which each individual dose is only a tiny fraction of natural background radiation levels. However, there is no consensus within the radiation protection community regarding truncation, as illustrated by the directly contradictory advice offered by radiation protection advisory organizations.

The National Council on Radiation Protection and Measurements (NCRP), in its 1987 recommendations (Report No. 91), recommends truncation of collective dose estimates for individual dose contributions below 1 mrem/yr, arguing that such dose rates represent a "negligible individual risk level." The NCRP describes this risk level as "...trivial compared to the risk of fatality associated with ordinary, normal societal activities," and recommends that such risks "be dismissed from consideration." In contrast, the 1990 recommendations of the ICRP state that "The Commission does not recommend the use of this technique" (Publication 60, Paragraph 293). Instead, the ICRP recommends truncation in only two situations: "when the subsequent [individual dose] contributions are common to all alternatives or it is no longer possible to distinguish between options" (Publication 55, Paragraph 149). Perhaps the most practical course of action would be similar to that of NUREG-1150 where collective doses were estimated both within a 50-mile radius of a facility and to the entire regional site population. Differences in the two estimates generally were not substantial. As discussed below, the method used by EPA in deriving its standards did not involve any truncation of individual doses.

Collective dose estimates are not as sensitive as individual dose estimates to the location, timing, and rate of release of radioactive materials to the environment. For example, the sequential release of two radionuclides will produce essentially the same collective dose as simultaneous release of those nuclides, even though individual doses might differ significantly. Therefore, although collective dose estimates require more detailed estimates of biosphere characteristics, there is an offsetting reduction in the needed precision of release estimates derived from geosphere and engineered barrier analyses.

3.4 Collective Dose by EPA's Method

The collective dose estimates used by EPA to develop its high-level waste standards were not produced by summing individual dose estimates. Instead, EPA defined a "world-average" biosphere model, with specified fractions of released radioactive material entering each exposure pathway of the model.* For example, EPA estimated that 1.3×10^4 of the world-wide river flow is consumed as drinking water, and EPA assumed that the same fraction would apply to releases of radioactive material to a river near a repository. Thus, EPA assumed that the release of one curie of any radionuclide results in consumption of 1.3×10^4 curies via drinking water, without regard to whether that activity is consumed by a small or a large number of individuals. Similar

* EPA, "Environmental Pathway Models for Estimating Population Health Effects . . .," EPA 520/5-85-026.

assumptions were made for other exposure pathways, allowing EPA to estimate collective doses without first calculating individual doses.

EPA's method is quite attractive for the generic rulemaking purpose to which it was applied by EPA. This method does not require identification of a "critical group," or any other site-specific demographic information. EPA's method is also relatively insensitive to the location, timing and rate of releases. Thus, the performance of the engineered and geologic barriers of a repository need not be estimated with the same precision as would be required for standards based on protection of individuals.

A disadvantage of EPA's method is the lack of any truncation of the contributions to the collective dose estimate, either with distance or at a negligible individual dose rate. This makes it difficult to compare EPA's impact estimates to other risk estimates, where some kind of truncation may have been used. EPA's method will also be seen by many as inappropriate for a site-specific evaluation of collective doses. However, given the very large uncertainties in projections of the sizes, locations, and lifestyles of future populations, EPA's assumption of world-average characteristics might be as good as any other.

3.5 Overall Evaluation

Any of the four measures of repository performance discussed above could have been used by EPA in deriving its HLW standards. Individual dose estimates do not require extensive demographic projections of the populations affected by potential releases, but do require relatively precise estimates of the nature of projected releases, including the location, timing, and rate of release. In contrast, population dose estimates do require demographic projections, but are less sensitive to uncertainties in the nature of the release. Given the sizeable uncertainties in projections of either individual or population doses, EPA's "world-average" biosphere model appears to be a workable approach for deriving generic release standards for HLW disposal.

The principal advantage of EPA's cumulative release limits, as contrasted with release rate or concentration limits derived from an individual protection goal, is that such limits encourage isolation, rather than dilution, of wastes. A significant disadvantage of EPA's cumulative release limits is inconsistency with more commonly applied radiation protection standards, which emphasize protection of individuals. Another disadvantage may be that EPA's cumulative release limits do not recognize any de-minimis level of radiation exposure. Thus, releases that cause very small doses to large numbers of people are considered equivalent to releases that cause larger doses to smaller populations.

The NRC staff has not previously objected to the population-impacts basis for EPA's standards. EPA's decision to protect populations rather than individuals was viewed as a decision properly within EPA's discretion, given EPA's authority to develop generally applicable environmental radiation-protection standards. Moreover, the staff does not believe that the derivation of release criteria corresponding to protection of individuals would be any more technically rigorous than EPA's derivation of its current release limits from a population-protection goal.

The NRC staff does not perceive any significant implementation differences for standards, based on protection of populations or on protection of individuals. If EPA were to base its standards on protection of individuals, a generic biosphere model could be used to translate its radiation-protection objectives into allowable concentrations of radioactive materials permitted to be released to the environment. Such a translation would be very similar to EPA's previous conversion of a population-protection goal into allowable cumulative releases of radionuclides. In either case, the important implementation concern is conversion of a radiation-protection goal to a release-limit format, eliminating speculative long-term environmental transport and dosimetry issues from a licensing review.

4. 10,000-YEAR PERIOD OF CONCERN

Applicability of the containment requirements of EPA's standards is limited to the first 10,000 years after repository closure. In contrast, the recommendations of ICRP Publication 46 are open-ended, restricting individual doses and risks in perpetuity.

The advantage of a 10,000-year limit on releases is that very speculative long-term disruptions need not be evaluated in a licensing review. The disadvantage is the possibility that a significant release might occur after the 10,000-year cut-off, although the subsystem performance objectives and the qualitative siting criteria of 10 CFR Part 60 would limit the potential for, and the size of, any such releases.

The NRC staff has supported EPA's 10,000-year limit on the period of concern. Projections of repository performance for a 10,000-year period will be uncertain, but such projections become significantly more uncertain as the projections are extended over longer periods of time. The staff agrees with EPA that a 10,000-year regulatory test is generally sufficient to evaluate the acceptability of repository performance.

5. ALARA

EPA's standards are notable for the absence of a specific requirement that projected releases be ALARA. EPA's containment requirements, which were derived from analyses of the waste-isolation capabilities of hypothetical HLW repositories, are effectively "generic" ALARA levels. In contrast, an explicit ALARA requirement is a prominent feature of the recommendations of ICRP Publication 46.

The principal advantage of an explicit ALARA requirement would be consistency with other radiation-protection standards. The disadvantage would be significant difficulties in evaluating compliance with such a criterion. In the NRC staff's view, the large uncertainties in projected repository performance would make any case-specific ALARA analysis highly speculative. The NRC staff remains opposed to adoption of an ALARA requirement as a standard for post-closure performance of an HLW repository.

6. STRINGENCY

EPA's containment requirements were derived so as to limit potential health effects from a large repository to 1000 premature cancer deaths over 10,000

Table A1 - Repository Inventory and Allowable Releases
for 100,000 MTHM of Spent Fuel

Table A1

<u>Nuclide</u>	<u>Repository Inventory at 1000 Yr, Ci*</u>	<u>EPA Release Limit, Ci**</u>	<u>Allowable Release, %</u>
Am-241	9.2E7	10,000	1.1E-2
Am-243	1.6E6	10,000	6.3E-1
C-14	1.0E5	10,000	10
Cs-135	2.2E4	100,000	450
Cs-137	1.0	100,000	-----
I-129	3.8E3	10,000	260
Np-237	1.0E5	10,000	10
Pu-238	9.8E4	10,000	10
Pu-239	3.2E7	10,000	3.1E-2
Pu-240	4.4E7	10,000	2.3E-2
Pu-242	1.7E5	10,000	5.9
Ra-226***	2.8E2	10,000	3600
Sr-90	1.5E-1	100,000	-----
Tc-99	1.4E6	1,000,000	71
Th-230***	1.6E3	1,000	63
Th-232	1.3E-3	1,000	-----
Sn-126	5.6E4	100,000	180
U-233***	3.3E2	10,000	3000
U-234	1.9E5	10,000	5.3
U-235	2.0E3	10,000	500
U-238	3.1E4	10,000	32

*These inventory figures and release limits are for 100,000 MTHM (3000 reactor-years) of spent nuclear fuel. The C-14 inventory is from R. A. Van Konyenburg's presentation to ACNW, October 26, 1990. Other inventories are from Arthur D. Little, Inc., "Technical Support of Standards for High-Level Radioactive Waste Management," EPA 520/4-79-007, 1977.

**The EPA standards require that a "sum-of-the-fractions" rule be applied if more than one radionuclide is released. "Unlikely" releases are allowed to be 10 times larger than the limits listed here.

***Inventory increases after 1000 years.

years. EPA argued that this level of impacts is comparable to the impacts that might have occurred if uranium ore had never been mined for use as nuclear fuel, and that the level of impacts is therefore clearly acceptable. EPA's critics have charged that the level is excessively stringent and that the costs of achieving this level of safety will be excessive. An alternative commonly suggested is to increase the release limits by a factor of 10, as recommended by EPA's Science Advisory Board.

A different perspective on the stringency of EPA's standards is provided by Table A1, which compares EPA's allowable release limits to the inventory of a repository. (If more than one radionuclide is released, a "sum-of-the-fractions" rule applies that effectively reduces the individual release limits of Table A1. If a release is unlikely, the release limits are 10 times larger than the Table A1 values.) Table A1 indicates that EPA's release limits are significantly restrictive only for the isotopes of americium (Am) and plutonium (Pu). Permissible releases of neptunium (Np), uranium (U) and carbon-14 (C-14) are a few to several percent of the repository inventory, whereas permissible releases of all other radionuclides may approach or exceed the entire repository inventory. (Table A1 assumes, of course, that no release of waste to the accessible environment occurs within the first 1000 years.) Thus, the staff believes that EPA's standards are not particularly stringent in terms of the performance required of a repository.*

7. PROBABILISTIC FORMAT

The "containment requirements" of EPA's standards prescribe two sets of release limits. Releases more likely than 1 chance in 10 (over 10,000 years) must not exceed the levels specified in a table of release limits, whereas releases less likely than 1 chance in 10 may be up to 10 times larger. Releases less likely than 1 chance in 1000 are not restricted at all by the standards. EPA's standards require that the probabilities of disruptive processes and events be estimated with sufficient precision to determine that a projected release falls within one of the two ranges of likelihood addressed by the standards. Uncertainty exists regarding acceptable methods for estimating the probabilities of potentially disruptive processes and events.

In contrast to EPA's dual-release limits, ICRP Publication 46 recommends that the risk to any individual be limited to a specified level. In this context, "risk" means the product of the probability that an individual will receive a radiation exposure, and the probability that the resulting exposure will cause a fatal health effect. Thus, ICRP recommends a continuum of acceptable release levels, dependent on the likelihood that a release will occur.

*A virtually identical table is presented by Thomas H. Pigford in "Actinide Burning and Waste Disposal," UCB-NE-4176, October 5, 1990. Pigford also predicts the fractions of several radionuclides likely to be released from spent fuel at the Yucca Mountain repository. For U, Np, Pu and Am, the predicted release fractions are 3 to 5 orders of magnitude less than allowed by EPA's standards.

EPA's containment requirements have been criticized by NRC and by others, because they require numerical predictions of the probabilities of human-initiated disruptions and of rare geologic events (those with probabilities on the order of one chance in 1,000 over 10,000 years). EPA's critics believe that the inability to estimate such probabilities in a scientifically rigorous way will preclude determination of compliance with the standards in a licensing review.

A range of alternatives exists for the probabilistic format of EPA's containment requirements. For example, EPA could limit applicability of the standards to relatively likely releases, as is the case for EPA's uranium fuel cycle standards. NRC would then need to develop some type of implicit or explicit safety standard for evaluating the acceptability of unlikely releases. Alternatively, EPA could replace its dual category standard with a pure risk standard, as recommended by the ICRP in its Publication 46. Such a standard would benefit from conforming more closely with other radiation protection standards. However, it would require probability estimates for disruptive processes and events that are at least as precise as the probability estimates required by the current standards. Other alternatives include a qualitative (rather than a numerical) description of the release categories, or elimination of release categories so that a single release limit would apply to any release regardless of its likelihood.

The NRC staff believes that some type of probabilistic formulation is needed for EPA's standards in order to accommodate the large uncertainties in potential geologic evolution, climate change, and human activities. At the same time, the staff is sensitive to the difficulties that would be associated with the numerical probability estimates required by the current EPA standards and, perhaps to an even greater extent, by ICRP Publication 46. As an alternative, the staff has suggested to EPA wording for the containment requirements that would retain essentially the same level of safety sought by EPA, but would eliminate the need for precise numerical predictions of the probabilities of unlikely processes and events. This alternative is discussed below.

8. ALTERNATIVE PROBABILISTIC FORMAT

The staff's recent comments to EPA, on "Working Draft No. 2" of EPA's standards,* included a recommendation for alternative wording for the probabilistic "containment requirements" of EPA's standards. This alternative retains the probabilistic format of the current standards for likely releases, but addresses unlikely releases with a deterministic consequence limit. (Extremely unlikely releases would continue to be unregulated.) Thus, precise numerical probability estimates would not be needed for unlikely external processes and events.**

*August 27, 1990, letter from R. Browning to R. Guimond.

**As used here, "external processes and events" are potentially disruptive occurrences external to the repository system, (i.e., outside the boundary of the controlled area). Phenomena occurring within the repository system, such as waste-package corrosion, would be incorporated into models that simulate the performance of the repository system in response to external processes and events.

Using the staff's recommendation, processes and events potentially affecting a repository would be divided into three categories.

-**"Likely conditions,"** for which both the probabilities of occurrence and the effects on repository performance would be evaluated numerically. This category would include those processes and events that are so likely to occur that they must be considered to be part of normal operation ("anticipated operational occurrences" in reactor licensing). "Likely conditions" might include processes and events with likelihoods greater than about one chance in 10 over the regulatory period of interest.

-**"Unlikely conditions,"** for which the effects on repository performance would be evaluated numerically, but probabilities would only be qualitatively estimated as necessary to distinguish from "likely" or "very unlikely" conditions. This category would include processes and events that, although unlikely to occur, are nevertheless sufficiently likely that they are relevant to a safety analysis. "Unlikely conditions" might include processes and events with likelihoods greater than about one chance in 1000 or one chance in 10,000 over the regulatory period of interest.

-**"Very unlikely conditions,"** for which neither probabilities nor effects on repository performance would be evaluated numerically. This category would include processes and events that are so speculative and unlikely that numerical consideration as part of a safety analysis would not be meaningful. Processes and events with probabilities less than about one chance in 1000 or one chance in 10,000 over the regulatory period of interest could be classified as being of "negligible likelihood."

Classification of processes and events as indicated above comports with the quality of information typically available for safety analyses. In the first category, sufficient information is likely to be available to predict both probabilities and consequences with some confidence. In the second category, one can "bound" the consequences, but numerically estimating probabilities may be very difficult, because the processes and events are so rare. Finally, in the "very unlikely" category, only qualitative estimates for both probabilities and consequences can be made.

If EPA were to adopt the staff's alternative wording for the "containment requirements," a performance assessment for a repository would consist of the following steps.

1. All conceivable processes and events potentially affecting the repository would be listed.
2. Each process or event would be assigned to one of the three categories just discussed. The criteria for assignment could be numerical, as suggested above, or could be qualitative. Processes and events assigned to the third category (very unlikely) would not receive further analysis.
3. Scenarios would be constructed from the remaining list of processes and events (i.e., those in the first two categories). The construction process would use an event tree (or similar) methodology to ensure that the scenarios would be mutually exclusive.

4. The set of scenarios would receive a second screening, analogous to "pruning" an event tree, to eliminate those judged to be too unlikely to warrant further consideration. Screening could be based on "rough" numerical probability estimates or on purely qualitative considerations.

5. Consequences (releases) would be estimated for each remaining scenario. The staff's proposal would not allow any scenario to cause releases exceeding 10 times EPA's current table of release limits.

6. For each of the more likely scenarios, probabilities would also be estimated, and the probability and release estimates would be combined to produce a "complementary cumulative distribution function" estimating the likelihood of exceeding EPA's table of release limits. The likelihood would be compared to the (current) one chance in 10 limit of EPA's standards.

A critically important concept in the staff's alternative is the construction of mutually exclusive scenarios (Step 3) and application of EPA's current consequence limit to each (Step 5). Because scenarios would be mutually exclusive, only one of them could occur, and total releases in the future therefore could be no greater than 10 times EPA's table-of-release limits. This is the same magnitude of releases permitted under EPA's current probabilistic standards. The only difference between the staff's alternative and EPA's current standards is that the staff's proposal would not require probability estimates for releases in the unlikely category. The staff's proposal would not alter EPA's current probabilistic treatment of relatively likely releases.

9. OVERALL EVALUATION

Several features of EPA's HLW standards are intended to facilitate implementation of the standards in a licensing review, including the release-limit format, the 10,000-year cut-off for application of the release limits, and the absence of a requirement that releases be ALARA. NRC staff has long supported these features of the standards.

Other features of the standards, including the population-impacts basis for the release limits and the level of stringency, are considered to be within EPA's discretion, given EPA's authority to develop generally applicable environmental radiation-protection standards. NRC staff considers EPA's release limits to be achievable (with the possible exception of carbon-14 at an unsaturated site), but has not commented on whether EPA's standards are more or less stringent than other radiological or non-radiological safety standards. (The staff has recommended that EPA provide comparisons with such standards when the HLW standards are reissued.)

The most significant potential implementation problem associated with EPA's standards is the probabilistic format of the "containment requirements." If EPA retains the probabilistic format, the staff will continue to encourage adoption of alternative wording for the standards that would eliminate the need for precise numerical probability estimates for unlikely processes and events.



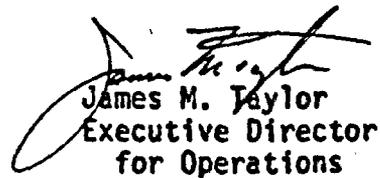
UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

✓ Vol. 16 - 15
JAG
JK
KSD
All

June 12, 1992

MEMORANDUM FOR: The Chairman
FROM: James M. Taylor
Executive Director
for Operations
SUBJECT: RESPONSES TO QUESTIONS FROM JUNE 11, 1992, BRIEFING

As a result of the briefing you and Commissioner Curtiss received on June 11, 1992, covering the status of the repository program at Yucca Mountain, you asked seven questions. The staff response to those questions is provided in the enclosure.


James M. Taylor
Executive Director
for Operations

Enclosure: As stated

cc: Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
Commissioner de Planque
SECY
OGC

12 JUN 11 11 03

~~91101050180~~

Question 1. What are the release limits of the EPA High-Level Waste Standards, 40 CFR Part 191?

Answer 1.

For 10,000 years after disposal, there must be

(a) less than one chance in ten that releases will exceed EPA's table of release limits, and

(b) less than one chance in one thousand that releases will exceed ten times EPA's table.

If more than one radionuclide is released, a "sum-of-the-fractions" rule is to be applied. For example, suppose that only two radionuclides were projected to be released, with the Am-241 release at 50% of its limit and the Am-243 release at 60% of its limit for a total of 110% of EPA's table.

Then the repository would fail to meet EPA's standards unless the likelihood of those releases was less than one chance in ten. The release limits of EPA's standards are listed below, and a more extensive table comparing those release limits to the radionuclide inventory of a spent fuel repository is attached.

<u>Radionuclide</u>	<u>Release Limit per 1,000 MTHM</u>
Americium-241 or 243	100
Carbon-14	100
Cesium-135 or 137	1,000
Iodine-129	100
Neptunium-237	100
Plutonium-238, 239, 240 or 242	100
Radium-226	100
Strontium-90	1,000
Technetium-99	10,000
Thorium-230 or 232	10
Uranium-233, 234, 235, 236 or 238	100
Any other alpha-emitting nuclide	100
Any other radionuclide	1,000

Table A1 - Repository Inventory and Allowable Releases
for 100,000 MTHM of Spent Fuel

Table A1

<u>Nuclide</u>	<u>Repository Inventory at 1000 Yr, Ci*</u>	<u>EPA Release Limit, Ci**</u>	<u>Allowable Release, %</u>
Am-241	9.2E7	10,000	1.1E-2
Am-243	1.6E6	10,000	6.3E-1
C-14	1.0E5	10,000	10
Cs-135	2.2E4	100,000	450
Cs-137	1.0	100,000	----
I-129	3.8E3	10,000	260
Np-237	1.0E5	10,000	10
Pu-238	9.8E4	10,000	10
Pu-239	3.2E7	10,000	3.1E-2
Pu-240	4.4E7	10,000	2.3E-2
Pu-242	1.7E5	10,000	5.9
Ra-226***	2.8E2	10,000	3600
Sr-90	1.5E-1	100,000	----
Tc-99	1.4E6	1,000,000	71
Th-230***	1.6E3	1,000	63
Th-232	1.3E-3	1,000	----
Sn-126	5.6E4	100,000	180
U-233***	3.3E2	10,000	3000
U-234	1.9E5	10,000	5.3
U-235	2.0E3	10,000	500
U-238	3.1E4	10,000	32

*These inventory figures and release limits are for 100,000 MTHM (3000 reactor-years) of spent nuclear fuel. The C-14 inventory is from R. A. Van Konynenburg's presentation to ACNW, October 26, 1990. Other inventories are from Arthur D. Little, Inc., "Technical Support of Standards for High-Level Radioactive Waste Management," EPA 520/4-79-007, 1977.

**The EPA standards require that a "sum-of-the-fractions" rule be applied if more than one radionuclide is released. "Unlikely" releases are allowed to be 10 times larger than the limits listed here.

***Inventory increases after 1000 years.

Question 2. What does Part 60 require as subsystem performance objectives?

Answer 2.

(a) Containment of HLW within waste packages must be substantially complete for 300-1,000 years, assuming anticipated processes and events. (The exact time period is to be determined by the Commission considering age and nature of waste, etc.)

(b) After the containment period, the release rate of each radionuclide from the engineered barrier system is to be less than one part in 100,000 per year, again assuming anticipated processes and events.

(c) The pre-emplacement groundwater travel time from the disturbed zone to the environment is to be at least 1,000 years.

(d) On a case-by-case basis, the Commission may approve some other containment period, release rate, or travel time.

Available information indicates that the current performance objectives are likely to be achievable without undue cost, except possibly for the release rate of gaseous carbon-14 from the engineered barrier system. However, perceived uncertainties about the meaning of terms associated with "substantially complete containment" and "pre-emplacement groundwater travel time" may cause difficulties in implementation, and may require revisions to the current performance objectives. The staff has projects in place to evaluate these matters.

Question 3.

Could we propose a dose standard today to substitute for the EPA release standard?

Answer 3.

Yes. A simple dose standard could be phrased: "Releases from the repository by any reasonable pathway shall not cause any individual to receive an effective dose equivalent exceeding X millirem in any year in the future." Such a limit would protect any individual in the future from significant individual risk from direct exposure. In fact, EPA is likely to include a similar requirement for undisturbed performance (25 millirem/yr for 10,000 years) when its standards are reissued.

There might be two significant drawbacks to the simple dose standard suggested above. First, a "static biosphere" assumption would need to be specified to avoid uncertainties about future locations and lifestyles of humans. Second, this type of individual protection standard does not take into account the potential for a distributed risk of very small exposures to a large population. Typically, such risks are limited by requiring that releases be "as low as reasonably achievable." However, application of an ALARA provision in repository licensing is likely to be very difficult.

Question 4. Does assured retrievability of waste packages for as long as 100 years offer any better approach to achieve a 1000-year package requirement?

Answer 4.

The most reliable and useful information for projecting waste package performance is expected to be that obtained under controlled laboratory test conditions. For example, the ability to conduct tests under a wide range of physical, chemical and radiological conditions will be helpful in developing extrapolation methods for projecting waste package performance for times longer than those over which the tests were conducted.

Substituting in situ studies for laboratory tests is not likely to produce data that would be any more reliable or useful. Collection of in situ information, even if carried out for 100 years, would cover only 10-30 percent of the required waste package lifetime, so there would still be a need to develop methods for extrapolation of observed performance. In addition, it would be difficult and expensive to retrieve and sample a statistically significant number of the 10,000 to 20,000 waste packages expected for a repository.

To some extent, the retrievability and package lifetime criteria of 10 CFR Part 60 are linked. Part 60 requires that a performance confirmation program be carried out before and during repository operations (roughly 50 years). This program would provide information on

the actual performance of waste packages in the repository environment. If that performance were significantly different from the performance initially projected from laboratory data, the waste packages could be retrieved and remedial measures taken. The ability to retrieve wastes is important in allowing a relatively long-term performance confirmation program to be carried out, confirming projections based on short-term laboratory data.

The staff does not anticipate that retrievability can or should be maintained for periods longer than about 100 years. A fundamental principle of repository development has been non-reliance on long-term institutional controls as a means to achieve safe waste disposal. For this reason, periodic retrieval and inspection of waste packages would not be appropriate.

Question 5. Is there an alternative to deal with the potential for carbon-14 releases to exceed EPA's release limits?

Answer 5.

Several alternatives are available, all of which would be based on the very small individual doses that could be caused by carbon-14 releases. First, EPA could include an alternative dose standard such as: "Releases shall not exceed Table 1 unless it can be shown that individual doses will not exceed a small fraction of individual safety limits (less than a few mrem/yr EDE)." Second, EPA could restrict application of the Table 1 release limits to releases to groundwater or to the land surface. DOE has suggested that EPA's existing NESHAP (Clean Air Act) standards for airborne releases (10 mrem/yr) would be applied to gaseous releases from a repository. Finally, EPA could revise the carbon-14 release limit (or delete it), based on a recognition that there is no potential for carbon-14 releases to cause any significant dose to any individual. The staff considers that any of these alternatives would provide a workable solution.

Question 6. What is the issue with radioiodine?

Answer 6.

The only radioisotope of iodine which persists in HLW is I-129 which has a very long half-life, 15.7 million years. Iodine is expected to be relatively soluble and mobile in a geologic environment. Therefore, assessments of repository performance often show I-129 to be one of the first radionuclides to be released to the environment. Because of its long half-life (and resulting low specific activity), I-129 poses virtually no individual risk, but only the risk of collective dose from slight exposures of large numbers of people over many of its long half-lives.

Some performance assessments for hypothetical repositories, including the Swedish Project 90, have found I-129 to cause the largest individual doses for a wide range of potential release scenarios. It is important to note that the projected I-129 doses are quite small (nanorem/year), and the reason I-129 causes the largest doses is because most other radionuclides are retained by the repository for a long enough time to allow virtually complete radioactive decay. The dominance of I-129 is not an indication of its hazard, but of the ability of a repository to provide essentially complete isolation of other radionuclides.

Question 7. What is the basis for the Linear Hypothesis?

Answer 7.

In the NRC's BRC Policy Statement, the linear hypothesis was defined as follows:

"Linear, no-threshold hypothesis" refers to the theory that there is a proportional relationship between a given dose of radiation and the statistical probability of the occurrence of a health effect (such as latent cancers and genetic effects), and that there is no dose level below which there is no risk from exposure to radiation.

Additional information from the BRC Policy Statement is attached.

APPENDIX—DOSE AND HEALTH EFFECTS ESTIMATION

I. Dose Estimation

In estimating the dose rates to members of the public that might arise through various practices for which exemptions are being considered, the Commission has decided to apply the concept of the "total effective dose equivalent." This concept, which is based on a comparison of the delayed health effects of ionizing radiation exposures, permits the calculation of the whole body dose equivalent of partial body and organ exposures through use of weighting factors. The concept was proposed by the International Commission on Radiological Protection (ICRP) in its Publication 26 issued in 1977. Since that time, the concept has been reviewed, evaluated, and adopted by radiation protection organizations throughout the world and has gained wide acceptance. The "total effective dose equivalent" concept is incorporated in "Radiation Protection Guidance to Federal Agencies for Occupational Exposure—Recommendations Approved by the President," that was signed by the President and published in the Federal Register on January 27, 1987 (52 FR 2822). The Commission recognizes that, in considering specific exemption proposals, the total effective dose equivalent must be taken into account.

II. Estimating Health Effects From Radiation Exposure

A. Individual Risks.

In the establishment of its radiation protection policies, the Commission has considered the three major types of stochastic (i.e., random) health effects that can be caused by relatively low doses of radiation: cancer, genetic effects, and developmental anomalies in fetuses. The NRC principally focuses on the risk of fatal cancer development because (1) the mortality risk represents a more severe outcome than the nonfatal cancer risk, and (2) the mortality risk is thought to be higher than the risk associated with genetic effects and developmental effects on fetuses.² However, even though radiation has been shown to be carcinogenic, the development of a risk factor applicable to continuing radiation exposures at levels equal to natural background³ requires a significant extrapolation

² Further discussion of these topics is provided in "Sources, Effects and Risks of Ionizing Radiation," United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), 1988 Report to the General Assembly with Annexes.

³ Natural background radiation can vary with time and location. In Washington, D.C., natural background radiation (excluding radon) results in individual doses of about 90 mrem per year (0.9 mSv/yr), while in Denver, Colorado, the value is about 160 mrem per year (1.6 mSv/yr). In both cases, naturally occurring radioactive material in the human body contributes approximately 40 mrem per year. Radiation from inhalation of the daughter products of radon contributes an average additional dose of 200 mrem per year (2 mSv/yr) to members of the U.S. population (NCRP Report No. 93, "Ionizing Radiation Exposure of the Population of the United States").

from the observed effects at much higher doses and dose rates.⁴ This results in significant uncertainty in risk estimates as reflected by the views of experts in the field. For example, the Committee on the Biological Effects of Ionizing Radiation (BEIR III) of the National Academy of Science cautioned that the risk values are "...based on incomplete data and involve a large degree of uncertainty, especially in the low dose region." This Committee also stated that it "...does not know whether dose rates of gamma or x-rays (low LET; low linear energy transfer radiation) of about 100 mrad/year (1 mGy/year) are detrimental to man." More recently, the BEIR V Committee of the National Academy of Science/National Research Council stated that it "recognizes that its risk estimates become more uncertain when applied to very low doses. Departures from a linear model at low doses, however, could either increase or decrease the [estimation of] risk per unit dose." The Commission understands that the Committees' statements reflect the uncertainties involved in estimating the risks of radiation exposure and do not imply either the absence or presence of detrimental effects at such low dose levels.

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) stated in their 1988 Report to the General Assembly that "...there was a need for a reduction factor to modify the risks (derived at high doses and dose rates)...for low doses and dose rates....[A]n appropriate range (for this factor) to be applied to total risk for low dose and dose rate should be between 2 and 10." This factor would lead to a risk coefficient value between 7×10^{-3} and 3.5×10^{-4} per rad (7×10^{-3} and 3.5×10^{-2} per Gy) based on an UNSCEAR risk coefficient of 7.1×10^{-4} per rad (7.1×10^{-2} per gray) for 100 rad (1 gray) organ absorbed doses at high dose rates. The report also stated, "The product of the risk coefficient appropriate for individual risk and the relevant collective dose will give the expected number of cancer deaths in the exposed population, provided that the collective dose is at least of the order of 100 person-Sv (10,000 person-rem). If the collective dose is only a few person-Sv (a few hundred person-rem), the most likely outcome is zero deaths."

In December 1989, the BEIR V Committee published a report entitled "Health Effects of Exposure to Low Levels of Ionizing Radiation," which contained risk estimates that are, in general, similar to the findings of

⁴ The health effects clearly attributable to radiation have occurred principally among early radiation workers, survivors of the atomic bomb explosions at Hiroshima and Nagasaki, individuals exposed for medical purposes, and laboratory animals. Natural background radiation causes an annual dose that is at least two orders of magnitude less than the dose received by human populations from which the cancer risks are derived. Experiments at the cellular level, however, provide similar indications of biological effects at low doses.

the 1988 UNSCEAR report. The BEIR V report's estimate of lifetime excess risk of death from cancer following an acute dose of 10 rem (0.1 Sv) of low-LET radiation was 8×10^{-3} . Taking into account a dose rate effectiveness factor for doses occurring over an extended period of time, the risk coefficient is on the order of 5×10^{-4} per rem, consistent with the upper level of risk estimated by UNSCEAR.

In view of this type of information, the NRC, the Environmental Protection Agency, and other national and international radiation protection authorities have established radiation protection standards defining recommended dose limits for radiation workers and individual members of the public. As a matter of regulatory prudence, all these bodies have derived the value presumed to apply at lower doses and dose rates associated with the radiation protection standards by a linear extrapolation from values derived at higher doses and dose rates. This model is frequently referred to as the linear, no-threshold hypothesis, in which the risk factor at low doses reflects the straight-line (linear) dose-effect relationship at much higher doses and dose rates. In this respect, the BEIR V report notes that "in spite of evidence that the molecular lesions which give rise to somatic and genetic damage can be repaired to a considerable degree, the new data do not contradict the hypothesis, at least with respect to cancer induction and hereditary genetic effects, that the frequency of such effects increases with low-level radiation as a linear, non-threshold function of the dose."

The Commission, in the development of the BRC policy, is faced with the issue of how to characterize the individual and population risks associated with low doses and dose rates. Although the uncertainties are large, useful perspective on the bounding risk associated with very low levels of radiation can be provided by the linear, no-threshold hypothesis. Consequently, such risk estimates have been a primary factor in establishing individual and collective dose criteria associated with this policy. The estimations of the low risk from potentially exempted practices can be compared to the relatively higher potential risks associated with other activities or decisions over which the NRC has regulatory responsibility. Through such comparisons, the Commission can ensure that its radiation protection resources and those of its licensees are expended in an optimal manner to accomplish its public health and safety mission.

In this context, the risk to an individual as calculated using the linear, no-threshold hypothesis is shown in Table 1 for various defined levels of annual individual dose. The values in the hypothetical lifetime risk column are

based on the further assumption that the annual dose is continuously received during each year of a 70-year lifetime. To provide further perspective, a radiation dose of 10 mrem per year (0.1 mSv per year) received continuously over a lifetime corresponds to a hypothetical increase of about 0.25% in an individual's lifetime risk of cancer death. Ten millirem per year (0.1 mSv per year) is also a dose rate that is a small fraction of naturally occurring background radiation and comparable to the temporal variations in natural background radiation due to fluctuations that occur at any specific location.

The Commission prefers to use factors of ten to describe such low individual doses because of the large uncertainties associated with the dose estimates. Use of values such as 0.7 or 12 imputes a significance and sense of certainty that is not justified considering the levels of uncertainty in the dose and risk estimates at these low levels. Thus, order of magnitude values such as 1 and 10 are preferable to avoid providing analysts and the public with a sense of certainty and significance that is not commensurate with the actual precision and certainty of the estimates.

B. Collective or Population Risk

In the application of the fundamental principles of radiation protection, collective dose provides a useful way to express the radiological impact (i.e., potential detriments) of a practice on the health of the exposed population. Because of the stochastic nature of risk, analysis of exposures of large groups of people to very small doses may result in calculated health effects in the population at large. Collective dose is the sum of the individual total effective dose equivalents resulting from a practice or source of radiation exposure. It is used in comparative cost-benefit and other quantitative analytical techniques and, therefore, is an important factor to consider in balancing benefits and societal detriments in applying the ALARA principle. For purposes of this policy, individual total effective dose equivalents less than 0.1 mrem per year (0.001 mSv per year) do not need to be considered in the estimation of collective doses. The Commission believes consideration of individual doses below 0.1 mrem per year imputes a sense of significance and certainty of their magnitude that is not justified considering the inherent uncertainties in dose and risk estimates associated with potentially exempted practices. The Commission also notes that doses in the range of 0.01 to 0.1 mrem per year correspond approximately to lifetime risks on the order of one in a million. The NRC has used collective dose, including rationales for its truncation, in a number of rulemaking decisions and in resolving a variety of generic safety issues.

Table 1

Incremental Annual Dose*		Hypothetical Incremental Annual Risk**	Hypothetical Lifetime Risk From Continuing Annual Dose**
100 mrem	(1.0 mSv)	5×10^{-5}	3.5×10^{-3}
10 mrem	(0.1 mSv)	5×10^{-6}	3.5×10^{-4}
1 mrem	(0.01 mSv)	5×10^{-7}	3.5×10^{-5}
0.1 mrem	(0.001 mSv)	5×10^{-8}	3.5×10^{-6}

- * The expression of dose refers to the Total Effective Dose Equivalent. This term is the sum of the deep [whole body] dose equivalent for sources external to the body and the committed effective [whole body] dose equivalent for sources internal to the body.
- ** Risk coefficient of 5×10^{-4} per rem (5×10^{-2} per Sv) for low linear energy transfer radiation has been conservatively based on the results reported in UNSCEAR 1988 (Footnote 2) and BEIR V (see also NUREG/CR-4214, Rev. 1).

III. Dose and Risk Estimation

The Commission recognizes that it is frequently not possible to measure risk to individuals or populations directly and, in most situations, it is impractical to measure annual doses to individuals at the low levels associated with potential exemption decisions. Typically, radionuclide concentrations or radiation dose rates can only be measured before the radioactive material is released from regulatory control. Estimates of doses to members of the public from the types of practices that the

Commission would consider exempting from regulatory control must be based on input of these measurements into exposure pathway models, using assumptions related to the ways in which people might become exposed. These assumptions incorporate sufficient conservatism to account for uncertainties so that any actual doses would be expected to be lower than the calculated doses. The Commission believes that this is an appropriate approach to be taken when determining if an exemption from some or all regulatory controls is warranted.