OGC
JRG
JPK
KSD
File

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

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

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.

Radionuclide	Release Limit per 1,000 MTHM
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

Nuclide	Repository Inventory at 1000 Yr, Ci*	EPA Release Limit, Ci**	Allowable Release, %
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 background[3] requires a significant extrapolation 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 mrads/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^{-5} 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

[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").

[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.