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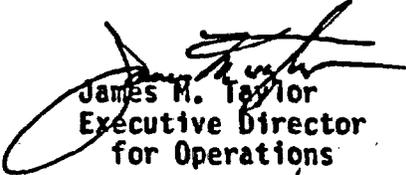
UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

APR 06 1990

MEMORANDUM FOR: The Commissioners
FROM: James M. Taylor
Executive Director for Operations
SUBJECT: FUNDAMENTAL ASSUMPTIONS SUPPORTING EPA AND NRC HLW
CRITERIA (WITS 8900235)

On November 20, 1989, the staff briefed the Commission on recommendations for implementing the U.S. Environmental Protection Agency's (EPA's) standards for high-level waste disposal, as outlined in the staff paper SECY-89-319. At that briefing, you requested that the staff provide you with an "...articulation of the fundamental assumptions in support of the EPA disposal standards and U.S. Nuclear Regulatory Commission (NRC) regulations for high-level radioactive waste, including both the positive and negative aspects of those assumptions, and identification of NRC/EPA consensus and controversy on the fundamental assumptions." (December 14, 1989, Staff Requirements Memorandum)

Enclosed is the information you requested. EPA's Office of Radiation Programs has reviewed the enclosed analysis and agrees with its content. NRC's Offices of Nuclear Material Safety and Safeguards and Nuclear Regulatory Research concur in the enclosure, and the General Counsel has no legal objection to it.


James M. Taylor
Executive Director
for Operations

Enclosure:
Analysis of Fundamental Assumptions

cc: SECY
OGC

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KEY ASSUMPTIONS IN DERIVATION OF
EPA'S HIGH-LEVEL WASTE DISPOSAL STANDARDS
AND NRC'S HIGH-LEVEL WASTE REGULATIONS

1. Agency Jurisdiction

Background. The U.S. Nuclear Regulatory Commission (NRC) and the U.S. Environmental Protection Agency (EPA) agree that EPA's authority to establish environmental standards for high-level waste (HLW) disposal stems from Reorganization Plan No. 3 of 1970. Section 2(a)(6) of the plan transferred to EPA:

The functions of the Atomic Energy Commission under the Atomic Energy Act of 1954, as amended, administered through its Division of Radiation Protection Standards, to the extent that such functions of the Commission consist of establishing generally applicable environmental standards for the protection of the general environment from radioactive material. As used herein, standards mean limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

This authority was referenced by the Nuclear Waste Policy Act of 1982, which directed that:

Not later than 1 year after the date of the enactment of this Act, the Administrator [of EPA], pursuant to authority under other provisions of law, shall, by rule, promulgate generally applicable standards for protection of the general environment from offsite releases from radioactive material in repositories.

Controversy. NRC has taken a relatively narrow view of EPA's authority, arguing that EPA's standards are limited to definition of acceptable levels of environmental impacts, and that the standards may not specify the means to be used by a licensee to achieve compliance with the standards. EPA, on the other hand, has a broader interpretation of its authority. When EPA proposed its HLW standards, seven "assurance requirements" were included which EPA characterized as "...essential for developing the needed confidence that our long-term release limits should be met." These requirements addressed (a) prompt disposal of wastes, (b) restriction of releases to levels "as small as reasonably achievable," (c) use of multiple barriers, both engineered and natural, for waste isolation, (d) restriction of reliance on "active institutional controls" to achieve waste isolation, (e) use of permanent markers and records to identify disposal locations, (f) avoidance of mines and other resource locations as disposal sites, and (g) selection of disposal systems to allow removal of wastes after disposal. The proposed standards also contained "procedural requirements" specifying certain conditions to be

observed when conducting a performance assessment to evaluate compliance with the standards.

NRC's comments on EPA's proposed standards included a strong objection to the "assurance" and "procedural requirements," arguing that those provisions were "clearly within the exclusive jurisdiction of the NRC and beyond the jurisdiction provided for EPA by Reorganization Plan No. 3" (May 11, 1983, letter from Chairman Palladino to Acting Administrator Lee Verstandig of EPA). NRC's position reflects a Presidential Directive of 1973 concerning the respective responsibilities of EPA and the former Atomic Energy Commission.

Resolution. Controversy over the separation of NRC and EPA jurisdiction was resolved in 1985 when: (1) NRC undertook to revise its regulations so that the substance of all of EPA's "assurance requirements" would be incorporated within Part 60, and (2) EPA specified that the "assurance" and "procedural" requirements were not applicable to disposal facilities licensed by NRC. (This resolution was recorded in a December 2, 1985, letter from Chairman Palladino to Administrator Lee Thomas of EPA.)

2. Type of Impact to be Addressed

Background. Most radiation protection guidance and standards provide limits on potential impacts to the individual most severely affected by a facility or activity. Population impacts are usually addressed, if at all, by an additional requirement that such impacts be "as low as reasonably achievable." EPA's proposed HLW standards were a significant departure from this practice. As proposed, EPA's standards restricted only population impacts, and did so through limits on the total amount of radioactive material allowed to be released to the environment. In the final standards, EPA added provisions for protection of individuals and groundwater supplies, but these sections of the standards were applicable only for shorter times and more limited conditions than were the "containment requirements," which limited population impacts.

Controversy. NRC and EPA have generally agreed on the approach taken by EPA, although individual members of the NRC staff and persons outside NRC have disagreed (see EPA 520/1-85-024-1, "Response to Comments for Final Rule," August 1985). Two controversies are present here. First, some have argued that it would be better to follow the more traditional approach of limiting impacts to individuals rather than basing a standard on population impacts. And, second, EPA's generic translation of its population health effects goal (1,000 premature fatalities over 10,000 years from disposal of 100,000 tonnes of spent fuel) to specific release limits (curies of individual radionuclides) has been criticized as being overly conservative. In this view, the standards should be stated in terms of the health effects goal, allowing larger or smaller releases as permitted by the specific characteristics of a site.

Resolution. Population versus individual impact bases for HLW standards were addressed by NRC as follows in its comments on EPA's proposed standards.

The NRC strongly supports the current form of the containment requirements (Section 191.13) which limit the total amount of radioactivity projected to be released to the environment over 10,000 years. This approach would appropriately protect the environment while limiting the consideration of speculative and unnecessary dosimetry-related issues in a repository licensing review. A standard which specified maximum dose limits to individuals would have two major adverse effects:

- It would encourage dilution rather than containment of wastes (e.g., by siting repositories near prolific aquifers or large rivers), which the NRC considers to be an inappropriate approach to waste disposal, and
- It would needlessly inject into a licensing review questions of individual and societal lifestyles far into the future. These are difficult predictions to make even a few years into the future, and predictions over 10,000 years would be highly speculative. The approach adopted by EPA in developing these standards (limiting total activity released to the environment) would avoid this difficulty while still ensuring that a waste disposal system would achieve its intended function, i.e., long-term isolation of wastes from the environment (May 10, 1983, comment letter signed by John G. Davis).

Regarding conservatism in the relationship between EPA's proposed release limits and the health effects goal from which they were derived, NRC stated:

The NRC staff and its contractors have independently evaluated the relationship between the release limits of the proposed standards and the resulting level of health effects anticipated over 10,000 years. The results of these analyses indicate that EPA's environmental transport analyses may overestimate the number of expected health effects per curie of radioactivity released to the environment. We have not identified any systematic or gross over-conservatism in the models or data used by EPA. However, it appears that a number of marginally conservative assumptions (e.g., cancer risk estimates, fraction of river flow used for irrigation, etc.), when considered together, may result in the acceptance of overly conservative estimates of health effects per curie released. We encourage EPA to reevaluate its environmental transport models and release limits in light of more recent information such as that in NUREG/CR-3235.

EPA did, in fact, review its analyses, and the release limits of many radionuclides were increased by nearly an order of magnitude in the final standards. Because only "marginally conservative assumptions" were identified in the initial analyses, a review of EPA's revised analyses supporting the final standards was not conducted.

3. Bases for the Standards

Background. As support for the standards, EPA developed descriptions of several hypothetical repositories (in salt, basalt, granite and tuff) containing unprocessed spent nuclear fuel. EPA then used relatively simple mathematical models of the repositories to evaluate the ability of these hypothetical repositories to isolate wastes from the environment. These analyses of achievable release levels served as a major part of the technical support for EPA's HLW standards. EPA also developed estimates of the population health effects caused by natural background radiation exposure, unmined uranium ore deposits, nuclear power generation, and nuclear weapons fallout (Draft Environmental Impact Statement, EPA 520/1-82-025, December 1982). When the standards were proposed, EPA stated:

The standards that we are proposing would adequately protect the public from harm. Under them, the risks to future generations from the wastes would be no greater than the risks from equivalent amounts of unmined uranium ore. These risks would also be far less than the risks from other sources of natural background radiation (47 FR 58197, December 29, 1982).

NRC did not comment directly on the appropriateness of EPA's projections of repository isolation capabilities. Instead, the NRC staff and contractors conducted independent analyses of the achievability of the proposed release limits. The results of these analyses (NUREG/CR-3235, April 1983) supported EPA's estimates that the proposed release limits would be achievable.

Controversy. Some members of the NRC staff, others outside NRC (including EPA's Science Advisory Board) and, especially, the Waste Management Subcommittee of NRC's Advisory Committee on Reactor Safeguards (ACRS) argued that the release limits of the EPA HLW standards are overly restrictive. This view is based on comparisons with other risks experienced by society and, in effect, rejects the fundamental premise underlying EPA's standards -- i.e., that the release limits of the standards should be determined by the projected isolation capabilities of repositories. More recently, NRC's Advisory Committee on Nuclear Waste (ACNW) has repeated the argument that EPA's standards are overly stringent (December 21, 1989, letter from Dade W. Moeller to Chairman Carr).

EPA's standards have also been criticized by the ACNW for their perceived "risk-averse" nature - a characteristic at odds with the Commission's safety goals for nuclear power plants. Although EPA did not deliberately develop the standards to be risk-averse, EPA's analyses of hypothetical repository performance indicated that large releases were very unlikely. The achievability basis for the standards therefore resulted in a risk-averse formulation for the release limits of the standards.

Resolution. NRC's comments on EPA's proposed standards endorsed EPA's approach for developing the release limits of the standards (SECY-83-137, dated April 14, 1983, and May 10, 1983, comment letter signed by John G. Davis). Despite repeated recommendations by the ACRS Subcommittee and the ACNW, the Commission has not rescinded its earlier endorsement.

4. Part 60 Performance Objectives

Background. When the proposed technical criteria for Part 60 were published for comment, the Commission included the following statement (46 FR 35283, July 8, 1981).

In the course of the Commission's deliberation, it becomes evident that in order to have confidence in the ability of a geological repository to contain and isolate the wastes for an extended period of time, the repository must consist of multiple barriers. In view of the uncertainties that attach to reliance on the geologic setting alone, the Commission believes that a repository should consist of two major engineered barriers (waste packages and underground facility) in addition to the natural barrier provided by the geological setting. The Commission is emphasizing these elements to take advantage of the opportunity to attain greater confidence in the isolation of the waste.

The Commission then went on to propose specific numerical performance objectives for each of the major barriers of a repository system. These performance objectives were to impose upon repository design and site selection a "defense-in-depth" approach analogous to that followed in design of nuclear power plants. By this means, the Commission proposed to attain the level of confidence referred to in the citation above.

Controversy. The numerical performance objectives of Part 60 have been highly controversial, both within and outside NRC (see NUREG-0804, "Staff Analysis of Public Comments...", December 1983). Criticisms have taken two forms. First, some have argued that the repository developer should have unlimited flexibility to determine the level of performance to be achieved by each barrier of a repository, and that subsystem performance objectives are inappropriate. In this view, the only criterion for repository acceptability should be compliance with the overall system performance standard developed by EPA. The Commission's stated concerns about the degree of confidence with which performance can be projected are viewed either as unwarranted, or as capable of being addressed in some other way.

The second criticism admits that subsystem performance objectives may have merit, but argues that there is no logical link between the specific performance objectives of Part 60 and the EPA standards for overall system performance. The supporting analyses of NUREG-0804 showed that the subsystem performance objectives contribute to achieving compliance with the overall system standard. However, NUREG-0804 also showed that the subsystem objectives are not sufficient, by themselves, to ensure compliance nor are they the only means by which compliance could be achieved. This criticism argues that any subsystem performance objectives developed by the Commission should be shown to be either sufficient or necessary for demonstrating compliance with the overall system performance standard.

It should be noted that there is no controversy with EPA regarding the subsystem performance objectives. EPA's comments on the proposed objectives endorsed the multiple barrier concept, and suggested refinements to the

specific objectives proposed (November 16, 1981, comment letter signed by Paul C. Cahill). Also, it should be recalled that Section 121 of the Nuclear Waste Policy Act mandates that NRC regulations provide for the use of a system of multiple barriers in the design of a repository.

Resolution. Although this was by far the most controversial issue involved in development of Part 60, numerical subsystem performance objectives were adopted by the Commission, as explained in NUREG-0804.

5. Detailed Assumptions Underlying the EPA Standards

Assumption. Exposure to ionizing radiation will continue to impose risks on future human beings in the same way it does today, and future societies will value those risks as ours does today.

Discussion. Some people have suggested that future radiation exposures should be "discounted," analogous to economic discounting in monetary calculations. EPA rejects this suggestion by assuming that all future radiation exposures should be valued the same as current exposures. Implicit in this assumption is also an unwillingness to speculate on such future events as a potential cure for cancer. During EPA's rulemaking, this assumption was not an issue.

Assumption. Only detrimental processes and events need be considered in the technical analyses supporting EPA's HLW standards.

Discussion. As EPA described its hypothetical repositories, "undisturbed performance" resulted in little, if any, release of radioactive material to the environment. Consequently, the NRC staff projects that there would have been little effect on the amounts of radioactive waste projected to be released, even if EPA had included potentially beneficial processes and events in its analyses. Nevertheless, consideration of favorable conditions, such as those of Section 60.122 of Part 60, is not precluded by EPA's standards.

Assumption. "Active" institutional controls may not be relied on for more than 100 years.

Discussion. An assumption of limited reliance on "active" institutional controls (e.g., guarding or monitoring a disposal site, or performing maintenance activities at the site) is widely accepted in national and international radioactive waste disposal standards. (See, e.g., IAEA Safety Series No. 99, "Safety Principles and Technical Criteria for the Underground Disposal of High Level Radioactive Wastes.") However, the specific wording in EPA's standards, while not applicable to a licensed repository, is at variance with the Part 60 definition of "unanticipated processes and events," where it is presumed that remedial actions will be taken by future institutions.

Assumption. A repository capable of meeting EPA's release limits for 10,000 years is likely to continue to perform well for periods beyond 10,000 years.

Discussion. NUREG/CR-3235 extended analyses of repository performance to 50,000 years to test this assumption. No significant deterioration of repository performance was found for the hypothetical repositories evaluated in NUREG/CR-3235. The "favorable" and "potentially adverse" siting criteria of Part 60 are intended to preclude location of a repository at a site where sudden degradation of isolation capability could occur. Nevertheless, analyses in the U.S. and in other countries have shown that, with very long-lived radionuclides in an apparently good site, the peak releases don't occur until well after 10,000 years.

Assumption. EPA selected 10,000 years as the period for assessing repository performance for two reasons: (1) it is long enough for releases through groundwater to reach the environment, and (2) it is short enough to avoid consideration of the types of major geologic changes that occur only over much longer periods of time.

Discussion. The NRC staff agrees that 10,000 years is an appropriate period of time to assess repository performance for regulatory purposes. It appears to be long enough to distinguish good repositories from poor ones, especially when used in conjunction with the performance objectives and siting criteria of Part 60. Moreover, assessments over longer periods would be so uncertain as to have little value for evaluating the acceptability of repository performance.

Assumption. Health effects associated with specific releases were estimated using very general models of environmental transport and a linear, nonthreshold dose-effect relationship to project premature deaths from cancer.

Discussion. The linear, nonthreshold dose-effect relationship is well-accepted for regulatory purposes. Possible conservatisms in the environmental transport models are discussed in Item 2, above.

Assumption. World average environmental parameters, such as river flow rates and consumption of foods, can be used for generic determinations of health effects expected from releases of radioactive materials to the environment.

Discussion. For generic standards, this assumption seems reasonable. However, specific repository sites may be located where the population potentially affected by a release is small. If so, EPA's generic health effects calculations would over-estimate the number of health effects that would be expected at an actual site.

Assumption. A geologic barrier to waste migration, called the "controlled area," may be permanently committed for use as part of a geologic repository. Determination of compliance with the standards consists of calculating projected releases of radioactive materials from this barrier into the "accessible environment." The size of the controlled area is limited to 100 km², and the area may extend no more than 5 km in any direction from the actual waste disposal location.

Discussion. This assumption recognizes that a geologic barrier is a major part of a geologic repository. This assumption also places reasonable bounds on the size of that barrier.

Assumption. Potentially disruptive processes and events, including human-initiated disruptions, can be identified and their probabilities and consequences can be evaluated numerically, with sufficient accuracy to permit determination of compliance with probabilistic standards.

Discussion. This is one of the most contentious issues regarding EPA's HLW standards, and is discussed extensively in SECY-89-319.

Assumption. EPA's descriptions and analyses of hypothetical repositories are realistic representations of the waste isolation capabilities of real disposal facilities. At the same time, EPA's descriptions and analyses are somewhat conservative in the sense of over-estimating expected releases. Thus, real repositories should be able to comply with EPA's standards "...with little, if any, effort beyond that already planned." (50 FR 38070, September 19, 1985)

Discussion. The analyses of NUREG/CR-3235 supported EPA's view that the standards should be achievable by real repositories. Nevertheless, those analyses were also based on hypothetical data. An actual demonstration of compliance with EPA's standards cannot be made until real data are acquired for a real site through the site characterization process.



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

August 27, 1990

NRC Comments -
Draft # 2
001.6 (36)

Richard Guimond, Director
Office of Radiation Programs, ANR-45P
U.S. Environmental Protection Agency
Washington, D.C. 20460

Dear Mr. Guimond:

Enclosed are the comments of the staff of the U.S. Nuclear Regulatory Commission (NRC) on Working Draft Number 2 of the U.S. Environmental Protection Agency (EPA) environmental standards for management and disposal of high-level and transuranic radioactive wastes.

As you know, the Commission plans to issue "conforming amendments" to our regulations (10 CFR Part 60) to adopt the requirements of your standards. Ideally, I would like to propose those amendments to Part 60 concurrently with proposal of your standards, so that both documents can be reviewed by the public simultaneously. In order to achieve this goal, significant interactions between our staffs will be needed. A starting point for these interactions might be the development of a common set of terms for use in both regulations, as addressed in our comments. I propose that our staffs meet as soon as practical to work toward development of the common terminology.

reduce limit meaning
I am concerned that there continues to be considerable controversy regarding the perceived stringency of your standards. Many have argued that the standards are excessively conservative when compared with other accepted standards. We recommend that EPA provide further insight into the basis for the standards to permit a comparison with other regulatory standards and guidance, as well as with other risks experienced by society. I strongly encourage you to explicitly and thoroughly describe the basis for your standards in such a way that the level of safety can be evaluated in public comments, and questions of excessive stringency may be resolved.

(2)
Considerable controversy also exists, both within the NRC and outside, about the probabilistic format of your standards and the potential difficulty of implementing them. In the enclosed comments, we reiterate (with slight modification) the same concern expressed in our 1983 comments. We once again suggest rewording the "containment requirements" in a manner that should achieve a level of safety comparable to that sought by EPA. Modifying the text as recommended would, at the same time, eliminate the need for numerical predictions of the probabilities of highly unlikely processes and events. I strongly encourage you to adopt this text as a way to end the debate surrounding the standard's probabilistic format.

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Thank you for the opportunity to review and comment on Working Draft Number 2.
We look forward to working closely with EPA during reissuance of your standards.

Sincerely,

RF Browning
Robert F. Browning, Director
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

COMMENTS ON WORKING DRAFT NO. 2
OF EPA'S HIGH-LEVEL WASTE STANDARDS

General

1. There continues to be considerable controversy regarding the stringency of the U.S. Environmental Protection Agency's (EPA's) environmental standards for disposal of spent nuclear fuel, high-level radioactive wastes (HLW) and transuranic radioactive wastes (TRU).¹ This controversy results, at least in part, from concerns over the very low levels of risk which underlie release limits imposed by EPA's standards, particularly when compared to other federal health and safety standards. We are concerned that a clear understanding and acceptance of the standards will not be achieved until EPA has explicitly documented the acceptable risk level that underlies the release limits of the standards and the way in which the release limits were derived from that risk level. The Commission is concerned about this issue. So that the Commission might better understand the basis for the proposed standards and evaluate the stringency issue, we encourage EPA to clearly and concisely document the risk basis for its standards.

To the extent that we understand EPA's development thus far, it consisted of the following:

- a) EPA determined that radiological impacts from disposal of HLW should be no greater than those experienced by individuals and populations today. EPA therefore surveyed the radiological impacts of natural background radiation exposure, nuclear weapons testing fallout, unmined uranium ore deposits, and nuclear power operations to provide benchmarks for evaluating the waste isolation capability of HLW repositories.
- b) EPA described several hypothetical HLW repositories and conducted performance assessments to evaluate their waste isolation capabilities. EPA has asserted that these performance assessments demonstrate that repositories are able to restrict population impacts to less than 1,000 health effects over 10,000 years -- a level comparable to or less than the benchmarks surveyed in step a), above. Individual radiological impacts were found to be very low.

¹ (see Remarks of Leo P. Duffy, Commission Briefing, December 20, 1989; Letter from Dade W. Moeller to Chairman Carr, December 21, 1989; First Report to the U.S. Congress and the U.S. Secretary of Energy from the Nuclear Waste Technical Review Board, March 1990, p. 31; Rethinking High-Level Radioactive Waste Disposal, National Research Council, July 1990.)

c) Because of the large uncertainties involved in calculations of radiation doses far into the future, EPA used a generic environmental model to translate its 1,000 health effects goal into a table of allowable limits for releases of radioactive materials to the environment. While these release limits might correspond to fewer than 1,000 health effects at an actual repository site, EPA's Science Advisory Board found this translation to be appropriate for a generic analysis. In EPA's view, any conservatism involved in developing the table of release limits is justified in light of the implementation difficulties that would be involved if the standards required long-term projections of population locations, sizes, and lifestyles.

d) In view of the long regulatory time period of interest and the sizeable uncertainties involved in projecting releases over that time period, EPA elected to use the term "reasonable expectation" to describe the level of confidence required for a demonstration of compliance with the standards. As EPA stated (50 FR 38071, September 19, 1985), "[t]his phrase reflects the fact that unequivocal numerical proof of compliance is neither necessary nor likely to be obtained."

2. Another reason for the concern over the excess stringency is the technical basis for the standards. We understand that EPA developed descriptions of several hypothetical repositories, and used relatively simple analyses to project the performance of those facilities. The release limits of the standards were then set so as to require actual repositories to perform approximately as well as EPA's hypothetical repositories. We are concerned that standards developed in this way may be overly stringent for the following reasons:

a) In setting the standards, EPA has stated its belief that real repository sites can be found that can be shown to perform as well as its hypothetical sites. But, experience to date in the HLW repository program reveals that real sites that have been investigated are much more complex than EPA's hypothetical sites, and projected performance is much less certain. EPA's release limits may be too restrictive to accommodate the uncertainties at these sites, or more generally, at any real site.

b) EPA's analyses of repository performance are very simplistic. EPA's models are not able to accurately simulate some of the phenomena potentially important for projecting repository performance, such as groundwater flow and contaminant transport in fractured, unsaturated media, and the effects of waste-generated heat on the geochemical, hydrologic, and mechanical properties of a repository. Again, EPA's release limits may be too restrictive to

accommodate the uncertainties that will be inherent in more realistic analyses of repository performance.

c) EPA has not considered a complete range of release scenarios in its supporting analyses. Some processes and events were omitted from EPA's analyses, such as the gaseous release pathway for unsaturated repository sites. Also, combinations of processes and events, such as fault movement followed by drilling, were not considered. These omissions caused the release limits to be set at a level that might rule out repositories capable of providing an adequate level of protection of public health and safety.

In the NRC staff's view, there are several actions that need to be taken to respond to these concerns. EPA should reexamine the stringency of the standard in light of other risks experienced by society and risk levels used as the basis for other safety standards, particularly those for the uranium fuel cycle. When presenting its releases limits, EPA should also place increased emphasis on comparisons with other regulatory standards and guidance, and with other risks experienced by society. EPA's analyses of hypothetical repository performance would then play a less prominent role in supporting the standards. Additionally, we recommend that EPA modify the standards in the manner discussed below (comment no. 7) so as to reduce potential difficulties in demonstrating compliance with the standards for low probability events.

Applicability

3. The applicability statements of 40 CFR 191.01 and 191.11 are limited to spent nuclear fuel, HLW and TRU. In 40 CFR 191.02, however, the term "radioactive waste" also includes any other radioactive material managed or disposed of with spent fuel, HLW or TRU. This definition suggests that EPA intends to avoid the potential for two or more different standards to be applicable to a single repository, if both HLW and non-HLW are disposed of in that facility. If that is actually EPA's intent, it can be accomplished by revising the applicability statements to refer to ". . . radioactive waste as defined herein at any facility that is intended to be used for, or may be used for, the permanent disposal of high-level radioactive waste, transuranic radioactive waste, or spent nuclear fuel . . ." The NRC staff would support such a broadened statement of applicability for the standards, provided it was accompanied by an explicit exemption from other EPA radioactive waste standards (e.g., low-level waste standards) that might otherwise be applicable.

Subpart A

4. The NRC staff notes that Subpart A continues to specify dose limits in terms of individual organ doses even while Subpart B proposes to adopt the newer "effective whole body dose equivalent" concept. The NRC staff supports use of the newer concept, and notes that the Commission's regulations for radiation protection, 10 CFR Part 20, have been amended to adopt the updated concepts. EPA's Supplementary Information should explain either the reason for the different treatment in 40 CFR Part 191 or EPA's plans for updating the format of Subpart A.

Definitions

5. The NRC staff is considering proposals to revise 10 CFR Part 60 by substituting new terms for the current definitions of "anticipated" and "unanticipated processes and events." The new terms would serve the same purpose in the rule as the current terms -- i.e., to specify the design conditions for the engineered barriers in 10 CFR 60.113 and the range of conditions for analysis of overall system performance in 10 CFR 60.21. The NRC staff is particularly interested in working with EPA to try to develop a common set of terms that could be used in both agencies' regulations.

6. Although EPA's definition of "ground water" comports with common use (see, e.g., Webster's New Collegiate Dictionary), the NRC staff notes that the term is defined and used differently in Part 60. EPA's definition includes only subsurface water in a zone of saturation, whereas NRC's definition includes all subsurface water. Discussions are needed between EPA and NRC staff to try to develop a common definition.

Containment Requirements

7. As EPA is aware, the Commission continues to be concerned about the workability of standards that require numerical probability estimates for very unlikely processes and events. In our formal comments on EPA's proposed standards, we suggested alternative wording for the containment requirements that would ease potential implementability problems while retaining approximately the same level of safety sought by EPA. That alternative would have required development of a complementary cumulative distribution function (CCDF) only for the more likely disruptive processes and events (those now defined as "anticipated" in 10 CFR Part 60). Very unlikely processes and events ("unanticipated" in Part 60 parlance) would be restricted by a release limit applied event-by-event, rather than

cumulatively. With this structure for the containment requirements, there would be no need to develop precise numerical probability estimates for very unlikely processes and events. The following text for 40 CFR 191.13 illustrates the concept recommended in the Commission's earlier comment:

191.13 Containment Requirements

(a) Disposal systems . . . shall be designed to provide a reasonable expectation that, for 10,000 years after disposal:

(1) anticipated performance will not cause cumulative releases of radionuclides to the accessible environment to have a likelihood greater than one change in 10 of exceeding the quantities calculated according to Table 1 (Appendix B); and

(2) the release resulting from any process, event, or sequence of processes and events that is sufficiently credible to warrant consideration will not exceed ten times the quantities calculated according to Table 1 (Appendix B).

The Commission would, of course, need to evaluate compliance by means of appropriate performance assessments. This would involve analyses that: (1) identify all processes and events that might affect the disposal system and are "sufficiently credible to warrant consideration," and (2) estimate the releases of radionuclides caused by those processes and events. For anticipated performance, a performance assessment would also (3) estimate the probability of likely processes and events, and (4) to the extent practicable, combine the release and probability estimates for likely processes and events into an overall probability distribution of cumulative release.

We strongly recommend that EPA reconsider adopting this concept for the containment requirements, because it would impose almost exactly the same level of safety on a repository, while avoiding the potential pitfalls of probability estimation for very unlikely and speculative events that could occur far in the future.

8. The NRC staff also notes that EPA continues to use the term "reasonable expectation" in the text of the containment requirements. In our previous "conforming amendments," we found that DOE and some other commenters perceived "reasonable expectation" to be a much less stringent standard than "reasonable assurance," as used in Part 60. A dialogue is needed between EPA and NRC staff to identify a single term to be used in both regulations.

Assurance Requirements

9. The NRC staff objects to the two new assurance requirements of Working draft No. 2, and would not recommend to the Commission that it add comparable provisions to its regulations as implied by the parenthetical statement of 40 CFR 191.14. The Commission's views on the impracticality of an "as low as reasonably achievable" (ALARA) requirements were discussed extensively in the Supplementary Information accompanying the technical criteria of 10 CFR Part 60 (48 FR 28194, 28198, June 21, 1983). There the Commission noted that the substantial uncertainties involved with predicting long-term repository performance, the already low EPA limits and the already stringent geologic performance requirements make it doubtful that the ALARA concept could be applied in a meaningful way.

10. The 100,000-year comparison of alternative sites seems superfluous given the previous identification for site characterization of the Yucca Mountain site and selection of the Waste Isolation Pilot Plant (WIPP) site. More importantly, calculations of repository performance over such long periods of time would involve such large uncertainties that they could have little value for judging repository safety. "Undisturbed performance," as defined in Working Draft No. 2, provides little useful information for selecting a preferred site from a slate of alternatives, and could even be counter-productive if it diverted attention away from potentially disruptive features of the sites. In any case, under the provisions of the Nuclear Waste Policy Act, as amended, repository site selection is the responsibility of the Department of Energy, not the Commission. For these reasons, the NRC staff would not propose addition of a comparable provision to the Commission's regulations.

11. The NRC staff also notes that the assurance requirement dealing with natural resources substitutes "ecologically vital" for the previous phrase "vital to the preservation of unique and sensitive ecosystems." Neither concept relates to the Atomic Energy Act policies underlying the standards. Instead, this appears to be a subject for evaluation in DOE's environmental impact statement (which Congress has directed the NRC to adopt to the extent possible) for a repository. The NRC staff would continue to view this as beyond the scope of 10 CFR Part 60 and would not propose that the Commission's regulations be changed.

Individual and Ground Water Protection Requirements

12. The NRC staff prefers those options (1.A and 2.A of EPA's Working Draft No. 2) that would combine the individual and ground water protection requirements into a single standard. Separate ground water protection standards would not provide any significant improvement in public health or environmental protection, but would add substantial complexity to the standards, with a resulting potential for increased difficulties in implementing the standards.

13. The NRC staff finds the definition of the term "man-made radionuclide" confusing since it clearly includes radionuclides that are not man-made. The staff is also puzzled by EPA's use of the term (to refer to concentrations of radioactive materials in ground water) since it does not follow the jurisdictional scheme of the Atomic Energy Act. A better explanation of EPA's intent is needed. Alternatively, we note that the staff's preferred options for ground water protection (1.A and 2.A) would eliminate the separate ground water standards where this term is used.

14. The NRC staff objects to any EPA ground water protection requirement that would be applicable within the controlled area. As the staff interprets the language of Reorganization Plan No. 3, EPA's standard-setting authority is limited to releases to the general environment which, in this instance, would exclude activity retained within the controlled area.

15. The NRC staff recommends that EPA reexamine the reasonableness of the part of the individual protection requirement that specifies an assumption of continual ground water use at the boundary of the controlled area. The passive institutional controls permitted by the standards would seem to provide at least some protection against such uninterrupted ground water use. The effectiveness of such controls is in any event a matter of implementation committed to the independent judgment of the Commission.

Demonstration of Capability to Comply

16. The new 40 CFR 191.17, "Demonstration of Capability to Comply," clearly is not a "generally applicable environmental standard" within the meaning of Reorganization Plan No. 3 and therefore is outside EPA's jurisdiction. Two remedies are possible: (1) delete the entire section, or (2) add a statement that the section does not apply to facilities regulated by the Commission (analogous to 40 CFR 191.14).

Appendix C - Guidance for Implementation

17. We recommend that EPA reevaluate the technical base underlying the guidance on frequency and severity of intrusion. It is our understanding that EPA has, to date, limited its consideration to petroleum exploration. Exploration for non-petroleum resources may take much different forms. For example, multiple, closely spaced boreholes may be drilled, the frequency of drilling will be highly site-specific, and borehole sealing may be absent or ineffective. Guidance based on petroleum industry practice may not be representative of other exploratory drilling practices -- especially for borehole sealing.

18. This Appendix to the standards suggests use of "prevalent expert judgment" to select an appropriate analytical model to use for performance assessments. Of course, the Commission will consider expert judgment for all appropriate purposes, but it must arrive at its own conclusions taking into account the persuasiveness of the testimony, including the force of the underlying arguments, and not use expert judgment merely because it is "prevalent."