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August 27, 1990

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.

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.

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). 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."