

Mr. J. William Gunter, Director
 Criteria and Standards Division
 Office of Radiation and Indoor Air
 U.S. Environmental Protection Agency
 Washington, DC 20460

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Dear Mr. Gunter:

On February 11, 1993, the U.S. Environmental Protection Agency (EPA) published in the Federal Register (58 FR 8029) an advance notice of proposed rulemaking (ANPR). That ANPR solicited comments on EPA's plans to develop criteria for certifying compliance with 40 CFR Part 191, EPA's environmental standards for disposal of transuranic (TRU) and high-level radioactive waste (HLW). EPA's certification criteria would be developed under the authority of the Waste Isolation Pilot Plant (WIPP) Land Withdrawal Act and, presumably, would apply only for EPA's determination of compliance with Part 191 for the WIPP.

Enclosed are the views of the staff of the NRC's High-Level Waste Management Division regarding the questions raised in EPA's ANPR.

Sincerely, *BJ* *BSY*

B. J. Youngblood, Director
 Division of High-Level Waste Management
 Office of Nuclear Material Safety
 and Safeguards

Enclosure:
 Comments on 58 FR 8029

cc: (two copies)
 Docket No. R-92-56
 Air Docket, room M-1500 (LE-131)
 U.S. Environmental Protection Agency
 401 M Street, SW
 Washington, DC 20460

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NRC Staff Comments on
Criteria for Certifying Compliance
with 40 CFR Part 191 at WIPP

On February 11, 1993, EPA solicited public comment on eight questions (see 58 FR 8029). The following are the views of the staff of the NRC's Division of High-Level Waste Management.

1. What is the appropriate analytical "degree of confidence" for determining compliance with the long-term numerical disposal standards (40 CFR part 191)? The question arises because of the uncertainties associated with the long-term assessments required by these standards; unequivocal numerical proof of compliance with the standards is neither necessary nor likely to be obtained. Therefore, it is incumbent upon the Agency [EPA] to define an acceptable level of certainty for compliance with the standards. Should the Agency require a specific statistical test for determining compliance or specify a more general "level of confidence" necessary for compliance?

As EPA recognizes, even the best numerical demonstrations of compliance will include unquantifiable uncertainties, such as the appropriateness of the models used to project releases. EPA uses the term "reasonable expectation" to describe the qualitative level of confidence with which compliance must be demonstrated. EPA's term "reasonable expectation" seems similar to the NRC's concept of "reasonable assurance." However, EPA argued (see 50 FR 38071, dated September 19, 1985) that it is different. The NRC staff strongly encourages EPA to reexamine its "reasonable expectation" concept and to clearly explain the differences, if any, from "reasonable assurance" as used in 10 CFR Part 60.

In 1984, EPA's Science Advisory Board recommended (see 49 FR 19605, dated May 8, 1984) that a 50% level of confidence test be used to evaluate compliance with the standards. However, "level of confidence" is a term of art that implies mathematical precision -- i.e., on the basis of empirical data, a level of confidence of 50% or 90%, for example, that the value of a specified parameter lies within defined limits. In the absence of such empirical data, there can be no meaningful "level of confidence" in the conventional scientific sense. Where insufficient data are available to draw rigorous statistical conclusions, decisions must to a great extent depend upon qualitative judgments and less upon purely numerical analysis. Because a specific statistical test cannot be applied, a more general qualitative "level of confidence" should be the required measure of compliance. DOE should be required to demonstrate (by a preponderance of the evidence) the required level of confidence -- e.g., "reasonable assurance" -- in future performance of the disposal facility.

2. The accuracy of 40 CFR part 191 compliance assessments is based, in part, on the accuracy of the assumed composition of the expected waste inventory. What methods and quality assurance measures should be employed to assure and confirm the accuracy and/or adequacy of the radionuclide inventory estimates assumed for

WIPP compliance assessment? The question arises because of the uncertainties associated with DOE's TRU waste characterization information and approach.

The Department of Energy (DOE) seems to have at least three choices: (i) accurately characterize the waste composition through a reasonably thorough sampling study, (ii) carry out compliance assessments based on "worst-case" composition assumptions, as determined from a more limited sampling study, or (iii) process the wastes into controlled physical and chemical forms. (Of course, different options could be used for various subsets of the total waste inventory.) It is not clear that EPA should specify the option(s) to be used. Instead, EPA should require DOE to demonstrate that the option(s) used will produce source term estimates sufficiently accurate to demonstrate compliance with EPA's standards.

3. Compliance with the 40 CFR part 191 disposal standards involves modeling projections of disposal system performance. What types of models (e.g., geo-chemical, ground-water flow, transport, etc.) should be used to demonstrate compliance and how should EPA determine that those models are adequate?

EPA should not take on the burden of determining which models are appropriate for use. Instead, EPA should insist that DOE thoroughly study the WIPP site and repository components, develop a good understanding of the physical and chemical phenomena of importance, and demonstrate to EPA that the models used by DOE are appropriate.

EPA will need to develop a sufficient level of technical expertise to conduct a meaningful review of DOE's safety assessment, including evaluating the appropriateness of the models used by DOE. In developing such expertise, it would be very helpful if EPA could have an active oversight role while DOE is conducting its site characterization and waste testing studies, analogous to the NRC's involvement in the site characterization process for Yucca Mountain. EPA should not expect, however, that rigorous acceptance criteria can be developed for evaluating the appropriateness of models. In our experience, judging the validity of a model depends on the purpose for which a model is to be applied, as well as the nature of the model and its accuracy in describing a physical or chemical process. Some conservative or "bounding" models are inherently inaccurate, yet they may be very suitable for projecting some aspect of repository performance. Determining whether a model is sufficiently accurate for the purpose to which DOE proposes to apply it will be a complex judgmental decision for which development of rigorous acceptance criteria may be impractical.

In raising this question, EPA seems to be using the term "model" to refer to a mathematical model, probably embedded in a computer code. Developing an adequate conceptual model of a repository system is a necessary prerequisite for determining the adequacy of the mathematical models that might be used to project system performance. A conceptual model would include identification and description of the physical and chemical phenomena important for projecting performance, definition of the boundary conditions of the system, and determining (at least qualitatively) the sensitivity of the system to outside perturbations. Clearly, a projection of repository performance can be no better than the conceptual model used to approximate the real repository. EPA should insist that

DOE develop an adequate conceptual model of the WIPP repository before developing the more detailed models of specific physical and chemical phenomena.

4. What methods or procedures should be employed to assure the quality and completeness of data used in determining WIPP's compliance with 40 CFR part 191?

The NRC's quality assurance criteria are contained in Appendix B to 10 CFR Part 50. To the extent that DOE uses (or has used) an equivalent QA program, the quality of DOE's data should be adequate to support a safety assessment. For data that were not developed under an equivalent QA program, guidance in NUREG-1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories," might be helpful.

5. Compliance with 40 CFR part 191 is determined by evaluating the degree to which various processes and events affecting the performance of a disposal system are likely to lead to radionuclide releases and radiation doses to members of the public. The Agency is interested in any suggestions for guidance or criteria (e.g., simplifying assumptions) aimed at reducing uncertainty or undue speculation which may be associated with these assessments.

EPA should consider two possibilities. First, EPA could specify, by rule, some of the assumptions to be made when demonstrating compliance. As an example, the human intrusion guidance now contained in Appendix B of Part 191 could be codified in EPA's compliance certification criteria for WIPP. Other assumptions used to derive the release limits of Part 191 could also be codified, to the extent that EPA continues to believe that those assumptions are appropriate.

A second possibility would be to specify, also by rule, acceptable methods for developing probability or release estimates. When EPA developed the release limits of Part 191, specific methods were used to estimate parameters such as the probability of volcanism. EPA could endorse use of the same methods for WIPP by codifying the methods in the WIPP certification criteria.

6. EPA's 40 CFR part 191 disposal standards include a set of qualitative Assurance Requirements (See 40 CFR 191.14) designed to provide the confidence needed for long-term compliance with the quantitative requirements of the standards. The Assurance Requirements address such things as institutional controls at disposal sites, monitoring and the use of engineered barriers to isolate wastes from the environment. In what ways, or pursuant to what processes, should EPA specify criteria which addresses [sic] compliance with these requirements?

Four of the assurance requirements may need attention by EPA. First, EPA should determine how it will address the potential for natural resources and any favorable compensating characteristics under the provisions of 191.14(e). Both potash and petroleum deposits are known to be present at or near the site, but it is unclear how EPA would judge the significance of those deposits (and favorable compensating characteristics) when evaluating compliance with 191.14(e).

Second, EPA should clearly describe what the term "engineered barrier" means in the context of 191.14(d). For the WIPP site, some people have referred to shaft seals as engineered barriers. However, such seals might also be viewed as repairs to one of the natural barriers (the salt deposits) of the site rather than as independent engineered barriers. Similarly, it is unclear how other concepts, such as bentonite mixed with salt as a backfill material, would be viewed by EPA when evaluating compliance with 191.14(d). In addition to developing qualitative descriptions of the types of engineered barriers EPA would find acceptable for WIPP, EPA will need to decide whether to develop more detailed performance or design criteria to judge the adequacy of the engineered barriers that will be used at WIPP.

Third, the requirement of 191.14(f) to "select" disposal systems so that "removal of most of the wastes is not precluded for a reasonable period of time after disposal" requires clarification for application to WIPP. How long is "a reasonable period," what means of "removal" are allowed, and how much waste is "most of the wastes?"

Finally, the requirement of 191.14(b) for post-closure monitoring needs elaboration. It is particularly important for EPA to specify whether the goal of monitoring is to confirm the validity of the modeling projections used by DOE to demonstrate compliance or to serve as an independent means of assuring the safety of the public. EPA also needs to specify the means to be used to determine when "there are no significant concerns to be addressed by further monitoring." Since DOE needs to demonstrate compliance with this criterion by designing a monitoring program before the WIPP facility is placed in operation, EPA needs to specify the goal(s) and duration(s) of monitoring that will be considered acceptable.

In our view, it would be appropriate for EPA to address each of these four subjects by rule in the compliance criteria to be developed for WIPP. Less rigorous mechanisms, such as development of non-binding guidance, are unlikely to fully address concerns about these subjects.

7. The U.S. Nuclear Regulatory Commission has issued regulations and guidance establishing procedures, criteria, terms and conditions for licensing low-level and high-level radioactive waste disposal facilities. (See 10 CFR part 61 and 10 CFR part 60.) To what extent should EPA consider adopting, with or without modification, these NRC requirements in our compliance criteria?

The specific technical criteria of NRC's low-level waste regulation, 10 CFR Part 61, are clearly inappropriate since they were developed for near-surface waste disposal facilities. Significant concerns addressed in developing Part 61 were protection of casual intruders and maintenance of a stable cover over the closed disposal facility, both of which are presumably of little concern for a deep disposal facility like WIPP.

Since Part 60 applies to deep geologic repositories, some of its criteria may be more appropriate for WIPP, including section 60.21 which describes the information to be included in a license application. However, some modifications would be needed. Part 60 anticipates a multi-step licensing process consisting of site characterization, construction, repository operations, closure and

license termination. The first two steps have already been completed for WIPP, so EPA may need to develop criteria for reviewing those activities retroactively. Similarly, application of the quality assurance criteria of 10 CFR Part 50 (incorporated into Part 60 by reference) might be different than anticipated in Part 60 if retroactive reviews of existing data are needed. Finally, the subsystem performance objectives of Part 60 may not be appropriate for a transuranic waste repository, especially the waste package objective which was developed for heat-generating, high-level wastes.

8. Are there other issues EPA should address in proposing compliance criteria?

EPA's proposed amendments to 40 CFR Part 191 (58 FR 7924, dated February 10, 1993) would limit contamination of groundwater to whatever EPA drinking water standards are in effect at the time when compliance is demonstrated. Following EPA's initial certification of compliance with 40 CFR Part 191, EPA is to recertify compliance at five year intervals throughout the life of the WIPP facility. EPA needs to specify whether any changes in EPA's drinking water standards following the initial certification will be imposed on WIPP at the time of a later recertification.