



**Department of Energy**  
Washington, DC 20585

December 5, 1991

**William G. Rosenberg**  
Assistant Administrator for Air and Radiation  
U.S. Environmental Protection Agency  
Washington, DC 20460

**Dear Mr. Rosenberg:**

This letter is written to provide you with the Department of Energy's (DOE) comments on the Environmental Protection Agency's (EPA) Working Draft 3 of 40 CFR Part 191, "Environmental Radiation Protection Standards for Management and Disposal of Spent Fuel, High-Level and Transuranic Radioactive Waste." Based on the importance of this rule to DOE and the significance of our concerns, we believe that substantial changes and additional justifications are needed to provide technically defensible and implementable standards. Some of these concerns were raised in our comments on Working Draft 2 and in subsequent meetings between our staffs, but they were not addressed by EPA in the preparation of Working Draft 3. Other issues were newly introduced in Working Draft 3 and have been discussed between our staffs. DOE's key comments are provided in Enclosure 1. Enclosure 2 is DOE's responses to the seven questions posed by EPA in the Working Draft.

We urge EPA to consider the revisions which have been recommended by DOE as well as potential revisions which were identified in the Electric Power Research Institute workshop in September. Although it is desirable that EPA have a final rule in the near future, it will not help the process if that rule is not defensible and implementable. EPA should take the time necessary to adequately consider and develop the alternatives to be included in the proposed rule.

We also request the opportunity to review a Working Draft 4 that responds to our concerns before the proposed rule is forwarded to the Office of Management and Budget.

We would like to meet with you to discuss these issues further.  
Please call Ray Berube at 586-5680 to arrange for a followup  
meeting after you have had an opportunity to review our comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Paul L. Ziemer".

Paul L. Ziemer, Ph.D.  
Assistant Secretary  
Environment, Safety and Health

Enclosures 2

## Enclosure 1

### DOE Key Comments on 40 CFR Part 191 Working Draft 3

#### Critical Comments:

- o Clarify in the regulation that repositories are not underground injection. EPA should clarify in the rule, not merely in the preamble to the rule, that geologic repositories do not constitute underground injection as defined in the Safe Drinking Water Act (SDWA). See Working Draft 2 comments for more detail on how this may be done (attached).
- o Separate consideration of human intrusion from the complementary cumulative distribution function (CCDF). DOE believes that the consideration of human intrusion should be separated from the CCDF. Releases resulting from human intrusion dominate compliance analyses and may make it impossible to proceed with any deep geologic disposal site because of the difficulties of assigning and justifying probabilities and consequences of occurrences. DOE believes that this is a critical issue in demonstrating compliance with the performance standard for a repository.

DOE believes that mitigating the probability of occurrence and the impacts of human intrusion are important factors in the design and construction of a repository as well as in the site selection process. The use of active and passive controls and consideration of waste form, spacing, and package orientation should be considered as measures to mitigate the risk to the environment of human intrusion beyond site selection considerations.

As an alternative to considering human intrusion as part of the CCDF, a separate section for the analysis and mitigation of the impacts from human intrusion should be added; Table 1 and the CCDF would then apply to releases from other significant processes and events but not human intrusion.

DOE will provide more detailed comments/suggestions on a desired change after the options being developed as part of the integrated Electric Power Research Institute approach have been finalized.

- o State the basis for the release limits in the rule and allow the use of other methods to demonstrate compliance with the rule as an alternative to release limits. The containment standard seems to be primarily technology based. That is, the containment requirements (expressed as release limits) have been derived based on their presumed achievability by general disposal technology, i.e., geologic repositories. DOE's concern is that EPA may have overestimated the demonstrable capabilities of a repository and set a standard for which compliance cannot be determined with adequate certainty.

In this regard, EPA's derivation of the release limits is technically flawed. The models used to calculate repository performance were simplistic. Not all critical pathways were adequately addressed for different geologic settings, especially an unsaturated site. EPA used many assumptions which were unsupported and likely not amenable to being supported adequately for use in a licensing hearing. It should be emphasized that other methods for demonstrating compliance, as discussed below, are technically defensible and should be recognized. In addition, many of the simplifications and oversights in EPA's derivation resulted in changes in predicted repository performance by factors of as much as 100. These differences go in both directions--some overestimating and some underestimating releases. While it appears that the analysis has more frequently underestimated releases, the errors are so numerous and difficult to quantify that nothing meaningful can be concluded from the analysis about potential repository performance.

A process to demonstrate compliance with the underlying basis for the rule as an alternative to the release limits should be permitted. While specific recommendations will not be provided until after DOE has had an opportunity to further consider and develop alternative concepts identified in the September Electric Power Research Institute workshop, two preliminary alternatives could include:

- Allow site-specific determination of health effects or collective dose as an alternative means of demonstrating compliance.
- Specify release limits for each critical release pathway. Allow site-specific attributes to be used in the calculations to demonstrate compliance with the release limits.

A central point on any of these calculations is that they apply to undisturbed performance only, as discussed in the previous bullet.

- o Revise the carbon-14 release requirements to reflect existing health and industry standards. Releases of gaseous carbon-14 from repositories could potentially violate 40 CFR 191 limits, but the releases would not threaten public health. The 40 CFR 191 limit would yield a maximum individual dose of approximately .00003 millirem/year. This is more than five orders of magnitude more stringent than the industry standard for emissions of radioactive gases (40 CFR 61). Efforts being initiated in an attempt to show compliance with this requirement at Yucca Mountain will be extremely expensive, and given the absence of any threat to public health and safety, are not technically warranted. DOE has provided EPA with information on carbon-14 recently and, under separate cover in response to your request, is providing further information. The current information justifies changing the carbon-14 requirements.

**Significant Comments:**

- o **Develop a technically sound basis for establishing TRU waste limits.** In DOE's comments on Working Draft 2 we asked for clarification of the basis and an explanation of the methodology for developing equivalency factors between HLW and TRU waste. In Working Draft 3 EPA has proposed an alternative numerical value for the "equivalency" factor, but has not justified the use of such a factor. Setting TRU waste limits by picking an amount TRU of waste "equivalent" to an amount of HLW is not technically sound. A fundamentally different method should be used to establish TRU waste limits. Additional discussion and alternatives are presented in the response to question 5 in enclosure 2.
- o **Require that resource values be based on current knowledge.** It is important that in the Assurance Requirement section, resources be identified as those which are scarce, accessible, valuable, etc., based on current knowledge to avoid a requirement for insupportable speculation. See Working Draft 2 comments for specific wording changes.
- o **Delete requirement for EPA concurrence for experimental tests with wastes.** The conditions placed on experimental tests with wastes, including the requirement for prior concurrence by EPA, should be deleted. This section exceeds EPA's authority. EPA has no statutory authority to implement the standards or to require concurrence in an implementing agency's determination. Further, the reason for such a requirement is unclear. The Yucca Mountain Project is not planning any tests with radioactive wastes prior to receiving a license. For WIPP, test plans already have been submitted to EPA for review, the DOE has committed to these test plans, and the EPA has indicated that they are in favor of the tests. Thus the WIPP already seems to be complying with these requirements.
- o **Delete specification of use of outside experts.** The guidance for implementation of Subpart B which directs DOE to use experts outside of DOE and NRC is inappropriate. Such direction usurps DOE's prerogatives to plan and manage repository development and the demonstration of compliance.
- o **Delete specification of iterative performance assessments.** The guidance for implementation of Subpart B which directs DOE to conduct iterative performance assessments is inappropriate. Such direction usurps DOE's prerogatives to plan and manage repository development and the demonstration of compliance. It is not guidance related to how to interpret or satisfy the requirements of Subpart B. It seems directed primarily at facilitating the successful

licensing of a repository and is not a general environmental standard.

- o Clarify use of median CCDF. It is our understanding that EPA intended that the median CCDF be used to demonstrate that the containment requirement probability limits are met. This should be specified in the rule.
- o Delete requirement for timing of findings of compliance. The requirements for "Demonstration of Capability to Comply" and for timing of the findings of compliance are inappropriate. It should be noted that when NRC promulgated the procedural rule in 10 CFR Part 60, one key consideration was the appropriate timing for the various review and approval steps in the licensing process. Included among these steps was the determination of compliance and the timing thereof. It was entirely appropriate that NRC, the implementing agency, should make this decision. Specifying such procedural matters is not appropriate for EPA and exceeds EPA's authority.
- o Specify the assumption to be used regarding society's future state of knowledge. EPA should provide specific guidance in the rule regarding society's future state of knowledge (e.g., collapse, same as now, major advance) as a common basis for human intrusion analysis. Such specification would eliminate the need for DOE to analyze insupportable scenarios for the future.
- o Do not incorporate by reference rules for radionuclides in ground water that have yet to be developed. If separate limits for radionuclides in ground water are retained in the 40 CFR 191 rule, the numerical values for those limits should be specified and justified therein. They should not be an incorporation-by-reference of the yet to be finalized Safe Drinking Water Act (SDWA) regulations for the output of public water systems. Those proposed regulations are of concern to DOE in their current form.

### Other Concerns:

- o Make use of qualifying statements concerning degree of proof more explicit and mandatory. The 1985 rule contained several qualifying statements relative to the degree of proof to be required and providing for incorporating performance assessment results into a CCDF only to the extent practicable. These statements should be made more explicit. See Working Draft 2 comments for specific wording.
- o Delete "valuable geologic formations" and "ecologically vital ground water" from the resource list. The sole basis given for the assurance requirements is to provide confidence of compliance with the containment requirements. The purpose for this particular requirement is to avoid areas where there is an expectation that exploration for resources may disrupt a disposal system. However, the presence of resources such as valuable geologic formations and ecologically vital ground water has no direct relation to the purpose for this assurance requirement. The presence of these resources would not cause exploration at the repository site which would disrupt the site. These requirements apparently are not intended to assure the performance of the repository but to protect these specific resources from releases from the repository. The containment requirements will accomplish that. Inclusion of these "resources" in this requirement is without justification, unnecessary and inappropriate. See Working Draft 2 comments for more detail.

Moreover, the assurance requirement on resources contains vague and undefined terms and phrases. Among them are "water for agricultural use" and "valuable geologic formation". See Working Draft 2 comments for more specific concerns. Also, the term "mineral" is not defined and should be replaced by "mineral in character" which has a well developed definition.

- o Expressly provide for use of qualitative judgment in final demonstration of compliance. The standard should be clarified by expressly stating that the final determination of compliance should be based on both performance assessments and qualitative judgments. See Working Draft 2 comments for specific wording.





August 2, 1990

Attachment to  
Enclosure 1

Richard J. Guimond, Director  
Office of Radiation Programs  
U.S. Environmental Protection Agency  
Washington, D.C. 20460

Dear Mr. Guimond:

This is to provide you with the Department of Energy's (DOE) comments on Working Draft 2 of 40 CFR Part 191, Environmental Radiation Protection Standards for Management and Disposal of Spent Fuel, High-Level and Transuranic Radioactive Waste. This draft was placed in your rulemaking docket on January 31, 1990, for information purposes, as part of your efforts to revise 40 CFR Part 191 in response to a remand by the U.S. Court of Appeals for the First Circuit. We hope that you will find the information and preliminary views expressed in our comments useful in developing a proposed rule.

Since the Environmental Protection Agency (EPA) completed its scoping calculations on a set of hypothetical high-level waste repositories as a basis for the standard, much additional information has been developed. For example, specific compliance calculations have proven much more difficult to complete than expected, and the uncertainties in all the models and data sets used in the calculations are much larger than expected. The human intrusion scenarios required by the standard dominate compliance analyses and make all geologic formations look similar. There is now a significant body of data on transuranic and high-level waste and spent fuel and disposal systems. Also, in the years since Part 191 was first promulgated, the qualifying statements in it relative to the degree of proof to be required have been interpreted so as to render them virtually meaningless. Furthermore, the Department cannot emphasize enough the need for uniform, consistent, and compatible regulations at the Federal level. In this regard, we recommend that EPA and the NRC reconcile their regulations to accomplish this objective.

The Department's primary comments on Working Draft 2 are as follows:

- 1) DOE supports the clarification of the definition of undisturbed performance.
- 2) DOE is concerned with the implementability of the containment standards, as they are being interpreted, because of their quantitative, probabilistic nature and the stringency of the numerical release limits.
- 3) The difference between geologic repositories for

radioactive waste and underground injection wells should be clarified.

4) The consideration of human intrusion should be separated from the complementary cumulative distribution function (CCDF) and treated on a qualitative basis using reasonable assumptions regarding future human behavior such as borehole sealing and passive markers.

5) DOE believes that the assurance requirements in section 191.14 are unnecessary, and that their inclusion in the rule would exceed EPA's regulatory authority.

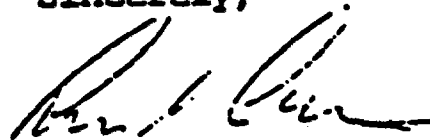
DOE supports EPA's efforts to develop a generic ground water protection strategy and will continue to work with EPA in developing such a strategy. However, for the individual and ground water protection requirements in 40 CFR Part 191, DOE prefers EPA's Option 1A, no separate ground water requirements, in combination with Options 3A and 4A (1,000 year period of applicability and a dose limit of 25 millirem).

These and other important concerns are described more fully in the enclosed set of comments. The DOE is currently developing policy and positions on issues related to the rule, such as the ground water protection strategy. Moreover, because DOE has not seen EPA's discussion and rationale for the suggested rule revisions, these comments cannot represent final DOE positions. DOE expects to submit additional, and possibly revised, comments as the rule is developed.

We believe, and we know EPA shares our belief, that we have a joint responsibility to ensure that the wastes covered by this standard will be disposed of safely. We appreciate the willingness of your staff to work with the DOE in developing the new rule. This will allow the Department's recent data and experience to be considered by EPA. A standard that is technically justified and capable of being implemented is necessary for proper disposal to proceed.

Any questions concerning these comments may be directed to me at 586-8505 or to Edward Regnier of my staff at 586-5027.

Sincerely,



Raymond F. Pelletier  
Director  
Office of Environmental Guidance

Enclosure

cc: Mr. Floyd Galpin  
Mr. Robert Browning, NRC  
Mr. Victor Serrano, GAO

U.S. DEPARTMENT OF ENERGY

COMMENTS ON WORKING DRAFT 2 OF 40 CFR PART 191

DIFFERENCE BETWEEN GEOLOGIC DISPOSAL AND WELL INJECTION

EPA should modify Part 191 to establish unequivocally the difference between the Underground Injection Control (UIC) program under the Safe Drinking Water Act (SDWA) and the 40 CFR Part 191 environmental radiation protection standards for management and disposal of spent nuclear fuel, high-level and transuranic radioactive wastes in geologic repositories. Failure to clarify this important distinction will cause continued controversy over an issue for which the policy and record are clear. Language which specifically explains that emplacement of radioactive wastes in a geologic repository does not constitute underground injection, as defined under the SDWA, should be added to the rule.

Emplacement of non-liquid radioactive wastes in a geologic repository does not constitute underground injection (UI) of fluids subject to regulation under the SDWA. In its Generic Environmental Impact Statement on the Management of Commercially Generated Radioactive Waste (DOE/EIS-0046F, October, 1980), DOE clearly distinguished between the alternative of well injection and the preferred alternative of disposal in geologic repositories.

Injection wells are wells in which fluids flow, normally pumped under pressure, into formations for the purpose of maintaining pressure in the formation (e.g., for secondary oil recovery) or for the irretrievable disposal of hazardous or toxic waste. But, radioactive waste to be disposed of will not be a fluid and will not "flow" into a geologic repository and the waste is retrievable for a substantial period of time.

In the draft 40 CFR Part 193 regulations (April 6, 1989) for the management and disposal of low-level radioactive waste (LLW) EPA expressed an opinion that deep geological disposal is not underground injection subject to regulation under the SDWA. According to the draft regulation:

EPA does not believe that deep geological disposal of LLW constitutes emplacement of a fluid within the meaning of the UIC program.... EPA believes that the time to assess whether the material flows or moves is the time of emplacement and the term "injection" itself connotes delivery by flow. Congress focused on injection practices when directing EPA to control underground injection.... EPA's regulatory program has also focused on the identification and control of

injection practices. Focusing on the practice of injection ties the concept of a fluid directly to the emplacement. This connection is expressed practically by examining the material at the time of injection and, if the injected material flows into the well, then the well is subject to the requirements of the UIC program. Therefore, even if deep geological repositories were considered to be wells within the meaning of the Safe Drinking Water Act, the process of lowering the LLW into a geological formation ... is not considered to be well-injection because the waste is not fluid at the time of injection, i.e., it does not flow into the injection vehicle. The activity therefore is not subject to the regulatory provisions of the UIC program.

A discussion of the differences between injection of fluids into a well and emplacement of radioactive waste in a mined geologic repository should be included in the preamble to the Part 191 regulations to clarify that the SDWA UIC program does not apply to geologic disposal of high-level radioactive waste, spent nuclear fuel, and transuranic radioactive wastes.

In addition, it would be appropriate for EPA to propose the following changes in its definitions for "fluid" and "well" under its SDWA UIC regulations at 40 CFR 144.3 and 146.3 to eliminate ambiguity about the possible application of those regulations to disposal of radioactive wastes and spent nuclear fuel in a geologic repository (changes are highlighted):

"Fluid" means any uncontainerized material or substance which, at the time of emplacement, flows or moves whether in a semisolid, liquid, sludge, gas, or any other non-solid form or state. Radioactive materials associated with spent nuclear fuel or radioactive wastes disposed of in a geologic repository do not constitute fluids for purposes of this Subchapter.

"Well" means a bored, drilled or driven shaft, or dug hole, whose depth is greater than the largest surface dimension. Geologic repositories, for the disposal of spent nuclear fuel or radioactive wastes, are not wells for the purposes of this Subchapter.

Also, add to 40 CFR 144.3 and 146.3 the following definition:

"Geologic repository" means a system which is used for the disposal of spent nuclear fuel or radioactive wastes in excavated geologic media.

Also, add the following to the 40 CFR 144.1 (g)(2) list of items not covered by the UIC regulations:

(vi) Geologic repositories, for the disposal of spent

nuclear fuel or radioactive wastes.

#### SECTION 191.01 -- APPLICABILITY

The highlighted language "(except for transportation)" should not be highlighted as it is not a change from the 1985 rule.

#### SECTION 191.02(1) -- DEFINITION OF RADIOACTIVE WASTE

The definition of "radioactive waste" in Working Draft 2 on page 4 was modified by the addition, without explanation or justification, of the phrase "and any other radioactive waste material managed or disposed of with" high-level or transuranic waste. The phrase "any other radioactive material" should be deleted because, to some degree, all materials are radioactive. This modified definition appears to anticipate the possibility of disposal of greater-than-Class C (GTCC) low-level waste in a geologic repository subject to Part 191. If EPA's intention is to include GTCC radioactive wastes, then the definition should be modified to include that additional term, and only that term. Even though additional waste has been included in the "units of waste" for determining the allowable release to the accessible environment (Appendix B of Subpart B, Note 1), no basis is provided for establishing the equivalency of either 1 million or 100 million curies of this material to 1,000 MTHM.

The data supporting the 1985 rule provides no basis for justifying application of the numerical limits in the rule to GTCC waste. The 1985 rule was developed by assessing the achievability of, and risks from, the disposal of high-level waste and the conclusions of this analysis are not directly transferable to GTCC waste, or to "any other radioactive material."

#### SECTION. 191.03 -- STANDARD

Section 191.03 should incorporate the committed effective dose equivalent concept utilized in Sections 191.15 and 191.16 rather than the outdated dose limits of 25 mrem to the "whole body" and 75 mrem to any critical organ. Dose limits in both Subparts of 40 CFR Part 191 should be in terms of the effective dose equivalent to be consistent with the internationally accepted approach.

#### SECTION 191.12(e) -- DEFINITION OF COMMITTED EFFECTIVE DOSE EQUIVALENT

The definition of the term "committed effective dose equivalent" (CEDE, page 8) is incorrect. The CEDE is not "the total dose equivalent received by an individual.... multiplied by

appropriate weighting factors...." The CEDE is the sum of the doses to specified organs of an individual which have been multiplied by appropriate weighting factors (the multiplication precedes the summation). The established and widely accepted definition of the term in the National Council on Radiation Protection and Measurements (NCRP) Report 91 or EPA Publication EPA-520/1-88-020 should be used.

In addition, the equation for "committed effective dose equivalent" on page 22 should be corrected. Because the time integration is to be carried out first, the equation (with a 50 year dose commitment) should read:

$$H_{T,50} = \sum_T W_T H_{T,50}$$

The period of the dose commitment specified by the International Commission on Radiation Protection (ICRP) and the NCRP is fifty rather than seventy years as proposed in Working Draft 2. Extension of this period to seventy years would require development of new dose conversion factors and is unnecessary considering the low likelihood that individuals would be exposed to the releases for their entire lifetimes and other uncertainties in the calculation of committed effective dose equivalent (e.g., suitability of using the listed values for weighting factors, developed for occupational exposures, for assessing public exposure). DOE recommends that EPA use the ICRP/NCRP approach of 50-year dose commitments in the 40 CFR Part 191 rulemaking.

#### SECTION 191.12(1) -- DEFINITION OF ECOLOGICALLY VITAL GROUNDWATER:

A definition has been added for "ecologically vital ground water" (pages 8-9). This groundwater supplies "an aquatic or terrestrial ecosystem which is located either in a ground water discharge area and supports a habitat for a listed or proposed endangered or threatened species, as designated pursuant to the Endangered Species Act, as amended, or, on Congressionally designated Federal Lands managed for the purpose of ecological protection regardless of the presence of threatened or endangered species." Ecologically vital ground water is one of the resources to be avoided during site selection (p. 12, 191.14(g)). The term also is included in the definition of Class I groundwater under Option 1 for the Individual Protection and Ground Water Protection Requirements (page 14, definition (b)).

DOE has two concerns about the proposed definition of "ecologically vital ground water." First, it is uncertain which species will be endangered or threatened in the future or which lands Congress will designate in the future, as Federal lands managed for the purposes of ecological protection. Therefore,

the word "currently" should be inserted before each of the words: "listed," "proposed," and "Congressionally." Second, the definition is too broad. Under the definition in Working Draft 2, the ground water does not have to be vital, or even important, to the maintenance of the ecosystem. The definition should be revised to read "... ground water providing an essential supply to an aquatic or terrestrial ecosystem which is located either in a ground water discharge area and supports a critical habitat ...." (changes highlighted). Without the word "critical" prior to habitat, any groundwater system discharging into an endangered or threatened species habitat would be classified as ecologically vital, regardless of its importance to the species. If the word "critical" were included, the definition would apply only to ground water systems that were truly vital to an endangered or threatened species.

#### SECTION 191.12(1) -- DEFINITION OF IMPLEMENTING AGENCY

Differences of opinion on the appropriate classification to be assigned to specific ground water supplies may occur. The rule should make it clear that the implementing agency is responsible for classifying the ground water. This clarification would be consistent with the draft 40 CFR Part 193 regulations.

#### SECTION 191.12(n) -- DEFINITION OF MAN-MADE RADIONUCLIDE

A definition has been added for "man-made radionuclide" (page 9). "Mill tailings or other radioactive materials stored or disposed of by man ...." (emphasis added) are expressly included as "manmade radionuclides" for purposes of Subpart B. Virtually all materials stored or disposed of by man have some small amount of radioactivity. No de minimis level has been established to provide appropriate qualification to the term "other radioactive materials". Also, it is unclear whether "man-made radionuclide" includes that portion of background radiation resulting from weapons testing in the 1950s and 1960s. Further, by using the terminology "any radionuclide" instead of "any radioactive material," it is not clear whether this definition would include naturally occurring materials containing radionuclides which, in other circumstances, have previously been classified as byproduct or special nuclear materials. This ambiguity results because the common usage of the term "radionuclide" is to refer to a species of atom. For the above reasons, the proposed definition is too broad, technically questionable, and could set an undesirable precedent. This definition should be deleted from Subpart B.

#### SECTION 191.12(q) -- DEFINITION OF UNDISTURBED PERFORMANCE

DOE agrees with the modified definition of "undisturbed performance" (page 10) used in Working Draft 2. The application of this definition would limit consideration of scenario

probabilities to the containment requirements in Section 191.13. Eliminating required consideration of disruptive external natural events in determining compliance with individual and ground water protection requirements removes unnecessary uncertainty from the dose calculations. DOE recommends that appropriate language from the guidance in Appendix C be more explicitly reflected in the definition itself.

#### SECTION 191.13 -- CONTAINMENT REQUIREMENTS

The DOE is concerned with the implementability of the containment requirements as they are being interpreted. A literal interpretation of the requirements would preclude the use of qualitative judgment by the implementing agency as intended by EPA. Without a significant measure of qualitative judgment allowed by the rule, the combination of the quantitative, probabilistic nature of the standard and the stringency of the numerical limits for allowable releases would make it difficult to demonstrate compliance at any site. In addition, risk levels implied by these release limits are inconsistent with the criteria and methodologies established by the International Commission on Radiological Protection (ICRP) - the internationally recognized body for establishing radiation protection standards. The standards should be consistent with the principles and criteria established by the ICRP; any inconsistencies should be technically justified and fully documented.

Given the current probabilistic nature of the standard, DOE believes that some wording changes are needed to assure that the containment requirements are not misinterpreted and a more stringent requirement imposed than originally intended. The August 1985 rule contained several qualifying statements relative to the degree of proof to be required and providing for incorporating performance assessment results into a complementary cumulative distribution function (CCDF) only to the extent practicable. These qualifying statements were believed essential to the implementability of the standard. Unfortunately, the NRC staff, and others, seem to have overlooked and/or misinterpreted these qualifying statements so as to render them virtually meaningless. DOE believes that the following additions to the proposed rule are necessary to assure that the rule is implemented as EPA intends (changes highlighted):

191.13(a) Disposal systems for spent nuclear fuel or high-level or transuranic radioactive wastes shall be designed to provide a reasonable expectation, based upon performance assessments and qualitative judgments, that the cumulative releases ---.

191.13(b) Complete assurance that the requirements of 191.13(a) will be met is not required. --- Instead what is required is only a reasonable expectation, based on



qualitative judgments and performance assessments, that compliance with 191.13(a) will be achieved.

In Appendix C the following should be added after the first paragraph: In determining compliance with these regulation the standard of proof required is a "reasonable expectation." This standard of proof is not the same as "reasonable assurance," as that term is used in NRC regulations in Title 10. A "reasonable expectation" allows a substantially greater degree of uncertainty than does "reasonable assurance." This is appropriate because of the uncertainties associated with predicting environmental conditions and geologic and hydrological phenomena over unprecedented periods of time. The terms are not interchangeable.

Appendix C, Compliance with Section 191.13. Add following the first sentence: It is intended that the above qualifier, "whenever practicable," be applied in a manner to give it significant effect and to facilitate implementation of this rule. The Agency expects that there will likely be instances where it is not practicable to assemble the results of performance assessments into a CCDF, for example, due to unavailable data, uncertainties in data, or inadequacy of models for describing long term future events and processes. The resulting impracticality could be either a practical inability to execute the calculations or a CCDF with such a large band of uncertainty surrounding it as to make it essentially meaningless.

Revise the last sentence of the first paragraph of Appendix C, compliance with Section 191.13, as follows: The Agency assumes that a disposal system can be considered to be in compliance with Section 191.13 if, considering this single distribution function and relevant qualitative factors, there is a reasonable expectation that the disposal system will meet the requirements of Section 191.13(a).

#### Human Intrusion Considerations

The standard should be revised so that consideration of human intrusion is separated from the CCDF. In 1985, the methodology proposed for evaluating compliance could be tested only in theory. Since that time, data and understanding have been developed by the Department to complete a preliminary analysis for the WIPP repository. This first real-system analysis shows that the human intrusion considerations in the containment requirements dominate the analysis. It is not technically possible to use human-intrusion analyses to compare geologic formations for siting repositories because the intruding borehole bypasses the host formation and removes it as a barrier to radionuclide transport. Analysis of the probability of human intrusion requires projection of future societal requirements and activities. Uncertainties in these projections dominate and are

propagated throughout the analyses. The unfortunate result is that the standard provides little incentive to locate a repository in a site with favorable geologic properties, and minimizes these properties in the performance process.

This is exactly opposite EPA's stated intent that the human intrusion scenario provide a basis for comparing alternate sites. Thus, the standard should be revised so that consideration of human intrusion is separated from the CCDF and treated on a qualitative basis using reasonable assumptions regarding future human behavior such as borehole sealing and passive markers. The Department is continuing to evaluate human intrusion issues and will provide more specific suggestions in the near future. For example, the Department is in the process of analyzing the implications of future societal requirements and activities for the WIPP Project. This effort should provide useful insights into the feasibility of evaluating human intrusion scenarios. A report discussing the impacts of human intrusion on the containment analysis and on the repository design is expected to be available within a few months.

#### SECTION 191.14 -- ASSURANCE REQUIREMENTS

The Department believes that the Assurance Requirements in Section 191.14, which are applicable only to facilities not regulated by the Commission, are unnecessary and that their inclusion in the rule exceeds EPA's regulatory authority to establish generally applicable environmental standards for radiation protection under the Atomic Energy Act of 1954 and Recorganization Plan No. 3. Requirements for site selection, for design of disposal systems, for monitoring and for permanent markers are the responsibility of the implementing agency, not EPA. Although DOE intends to incorporate the requirements of these assurance requirements into its planning, the Department objects to EPA imposing the requirements as a part of the 191 Standards.

In addition to exceeding EPA's authority, the new 40 CFR 191.14(e) is unacceptably ambiguous. The term "maximum achievable control technology" (MACT) in the context of 40 CFR Part 191 is unclear. The technical community, including the NRC, is in agreement that the release limits specified in Table 1 are so restrictive as to constitute de facto compliance with the ALARA concept. Applying a new concept of MACT to a geologic repository is inappropriate, primarily because of the passive nature of such a facility and its functional lifetime. This requirement would make the natural system itself subject to MACT: an unwarranted and unworkable extension of the concept. The DOE strongly opposes the use of MACT in Section 191.14(e) and understands from discussions with EPA staff that EPA plans to eliminate this assurance requirement from the next draft. DOE strongly supports deleting this assurance requirement; however, it should not be replaced with a requirement for ALARA. An ALARA

requirement would be inappropriate because of the extremely low release limits in the rule and is inappropriate for geologic systems and for time frames where action cannot be taken to control unplanned releases.

Further, the new assurance requirement added for a 100,000 year projection of undisturbed performance when comparing alternative sites [Section 191.14(f)] is unacceptable. Predictions beyond 10,000 years are extremely speculative and not justified on the basis of protection of human health or the environment. This requirement addresses the site selection process. Involvement in site selection is not an appropriate role for EPA. Moreover, the U.S. Court of Appeals in the decision vacating and remanding this rule specifically found that the 10,000 year time period of consideration was adequately justified.

The only stated purpose for the assurance requirements in 191.14 is "To provide the confidence needed for long term compliance with the requirements of 191.13 ---." The only basis suggested in the rule for the assurance requirement in 191.14(g) - avoidance of areas where there is an expectation of exploration for resources - is to reduce the chances that people may inadvertently disrupt a disposal system. Although it is not clear, the term "valuable geologic formation" would seem to refer to valuable in an aesthetic or academic sense and not to economic value, because mineral, petroleum, gas and water resources are covered in other clauses.

In Section 191.14(g) "water for agricultural use" and "ground waters that are ecologically vital" have been added to the list of resources to be considered during site selection.

The requirements to avoid valuable geologic formations, ground water which may be extracted outside the controlled area for drinking or agricultural use, and ecologically vital ground water, are without justification because such resources would not make disruption by exploration at the site any more likely. These requirements apparently are intended, not to assure the performance of the repository, but rather to protect the resources. It is not clear that EPA has authority to promulgate regulations protecting "valuable geologic formations" and (as defined under ecologically vital) "endangered species" and "Federal lands managed for the purpose of ecological protection ---." In any event, no basis has been provided to establish that location of a repository or any potential releases of radioactive material from a repository would cause unacceptable harm to these resources. Therefore, the above enumerated resources should be deleted from the list of those to be avoided.

Further, the identification of the ground waters to be considered in this section is unnecessarily complicated because the term "water for agricultural use" has not been defined in Section 191.12 and terminology found in existing legislation has not been

used. As previously discussed, DOE recommends that all of Section 191.14 be deleted. However, if it is retained, DOE suggests that the Section 191.14(g) requirement should be reworded as follows (changes highlighted):

Places where there has been mining for resources, or where there is a reasonable expectation of exploration for resources that, based on current knowledge, are predictably scarce or easily accessible, or where there is a significant concentration of any material that is not widely available from other sources, should be avoided in selecting disposal sites. Resources to be considered shall include minerals, petroleum or natural gas of currently recognized economic value or strategic importance; ground waters inside the controlled area that are currently either a sole source of drinking water as defined in the Water Quality Act of 1987 and the Clean Water Act of 1977 as amended or ground waters which serve an area classified as prime farmland subject to provisions of the Farmland Protection Act. Such places ---.

The above suggested changes more precisely define resources to be avoided.

#### SECTIONS 191.15 & 191.16 -- INDIVIDUAL AND GROUND-WATER PROTECTION REQUIREMENTS

DOE recommends the adoption of Option 1A for Section 191.15 and 191.16. DOE cannot support either Options 1B, or 2B as outlined in the Working Draft 2 proposal. They should be deleted from the proposed rule for the following reasons:

1. There is no adequate rationale for the dual dose-limiting standards under Options 1B and 2B of 4 mrem/yr for ground-water pathways and 25 or 10 mrem/yr for all pathways combined. Both sets of standards govern the same radioactive waste disposal activity. In Options 1B and 2B, EPA proposes to formulate a separate ground water pathway requirement even though the 25 mrem/yr individual dose limit would control the dose from all pathways combined, including the ground water pathway. EPA has provided neither a health-based justification nor a cost-benefit optimization rationale for a separate ground water provision.
2. There is no statutory requirement for a separate ground water pathway standard.
3. EPA has not presented any rationale or technical justification for the Option 1B proposed zero degradation standard for Class I ground water. Also, many qualitative terms in the definitions of the ground-water classes are vague. For example, the term "interconnected" in the definitions for Class IIIA and IIIB ground waters under

Option 1 (page 14) is vague and should be defined to avoid compliance demonstration problems. The quantitative measures associated with determinations of "potable ground water" and "high-yield aquifer" have not been peer reviewed or otherwise technically justified.

4. Option 1B relies on EPA's internal ground-water protection strategy, which has never been formally proposed and is undergoing revision. This classification system, which divides ground waters into various classes based on qualitative and quantitative measures, should be appropriately justified and established by rulemaking before its incorporation into any other regulations.
5. Preexisting background radiological dose from natural or man-made radionuclides should not be incorporated into the proposed Section 191.16 standards (Options 1B and 2B). If EPA decides to include separate ground-water standards in the rule, DOE strongly believes that the standards should be applied only to radionuclides and pathways from the disposal system itself.

DOE generally supports Option 1A because it does not rely on the draft ground-water classification system and contains one standard for all pathways of exposure. Option 1A should be the only regulatory approach presented in the proposed rule. Although Option 2A is a similar standard, the term "high-yield aquifer" is more precisely defined and more restrictive than "potable water." Formations may contain potable water, but may be over 2,500 feet below the land surface and not able to produce significant quantities of water for human use. However, it is not apparent that the quantitative measures defining a "high-yield aquifer" are appropriate. For example, the limit of 10,000 mg/L total dissolved solids may not be appropriate for all types of dissolved solids. Limits for individual species (e.g., carbonates, phosphates, brine) may be more appropriate. Under Option 1A, DOE supports a dose limit of 25 mrem (Option 4A) and a time period of 1,000 years (Option 3A) as part of the Individual and Ground Water Protection Requirements. Other options are inappropriate and should not be presented in the proposed rule. DOE believes that the 25 mrem dose limit for all pathways combined provides an adequate margin of safety in protecting the public health. Extension of the Individual and Ground Water Protection Requirements to 10,000 years would likely complicate demonstration of compliance without necessarily increasing the degree of public protection due to the increased uncertainty in the projection of performance. Although Appendix C provides additional clarification on implementation of the standard, projecting climatic changes and socio-cultural factors, such as population, agriculture, and lifestyle statistics, over 10,000 years with any certainty, is not likely to be possible. At a minimum, this difficulty is appropriately addressed in Appendix C's recognition of the need for "expert judgment." In addition, because the NRC is not bound by the language in the

appendix, it is not certain that EPA's assumptions regarding qualifying statements and strictness of interpretation will be reflected in NRC's licensing process.

DOE supports the guidance provided by Appendix C in Working Draft 2, particularly the concept of "undisturbed performance" (related to gradual processes) and "best estimate predictions" (used to analyze compliance).

#### SECTION 191.17 -- DEMONSTRATION OF CAPABILITY TO COMPLY

Working Draft 2 added a new Section 191.17 on demonstration of capability to comply. The new section requires preliminary performance assessment calculations (which are undefined), written test plans for experiments, plans and tested procedures for the removal of the waste, and concurrence of the EPA Administrator before temporary emplacement of the waste when the implementing agency is not the Commission. For WIPP, test plans already exist; the DOE has committed to plans and tested procedures for waste removal; and the EPA has indicated that they are in favor of the tests. Thus the WIPP already seems to be complying with these requirements; and, by the time this rule is promulgated testing should be well underway. However, this section exceeds EPA's authority and should be deleted. EPA has no statutory authority to implement the standards or to require concurrence in an implementing agency's determination.

#### APPENDIX B NOTE 1 -- UNITS OF WASTE

Several independent assessments of health effects of HLW and TRU wastes have arrived at different equivalencies for some of the radionuclides in the table. To clarify the basis for the equivalency factor used, EPA should explain its methodology for determining that 1000 MTHM HLW is the equivalent, for the purposes of this standard, of 1,000,000 Ci TRU waste.

Note 1(e) should be revised to include additional nuclides as follows:

- (e) an amount of transuranic (TRU) waste containing 1,000,000 total curies of 1) alpha emitting transuranic radionuclides with half-lives greater than 20 years, 2) radionuclides with half-lives less than 20 years which produce regulated daughters with half-lives longer than 20 years, and 3) any other regulated radionuclides contained in the (nominally) TRU waste.

This language would include plutonium-241 (half-life 14+ years) and other like radionuclides in the waste unit. Plutonium-241 emplaced in the repository rapidly decays to become regulated radionuclides with half-lives greater than 20 years. The nuclides described in 2) and 3) above will comprise about half of

the initial inventory in the repository.

## APPENDIX C -- GUIDANCE FOR IMPLEMENTATION OF SUBPART B

### Compliance with Section 191.13

It is not clear whether the guidance suggests combining multiple distribution functions into a single function or consideration of multiple distribution functions instead of using a single distribution function. Some ambiguity has resulted from the reference to a single distribution function in the first paragraph while referring to distribution function(s) in the second paragraph. This could be clarified by revising the second paragraph to read:

"--- use prevalent expert judgement to assist it in determining which distribution function(s) to consider and whether to combine them in evaluating compliance with 191.13."

### Frequency and Severity of Inadvertent Human Intrusion into Geologic Repositories

After the second sentence insert the following:

"These parameters represent the most pessimistic upper bound that ever need be assumed. They are not required to be used by the implementing agency. Instead of assuming these parameters, the implementing agency is encouraged to develop and use a probability distribution function for borehole drilling rates which is justified for application at the particular site under consideration."

Revise the last sentence to read:

... newly sealed in accordance with the least protective practices required by current law for exploratory drilling... These consequences represent an upper bound and are the most pessimistic that ever need be assumed. They are not required to be used by the implementing agency which is encouraged to develop and justify the use of other consequences. For example, the permeability of an intruding borehole may be represented by a distribution for uncertainty analysis.

## Enclosure 2

### Responses to Questions in Working Draft 3 of 40 CFR Part 191

**Question 1:** Two options are presented in Sections 191.03 and 191.14 pertaining to maximum exposures to individuals in the vicinity of waste management, storage and disposal facilities: a 25 millirems/year ede limit and a 10 millirems/year ede limit. Which is the more appropriate choice and why?

**Response:** DOE supports the use of the 25 millirems/year ede individual dose limit because it is consistent with other source-specific standards (e.g., fuel cycle and low-level waste). Pathway-specific standards are typically a fraction of this level (e.g., air, 10 millirems/year).

The ICRP recommends 100 millirems/year for the maximum individual dose rate from all anthropogenic sources of radiation, excluding medical. It recommends that some fraction of this limit be allocated for radioactive waste disposal but declines to set the fraction, explicitly leaving that decision to the member nations. In the United States the NCRP has indicated that a fraction of 25 percent is appropriate for fuel cycle activities. This fraction, or a greater one, is appropriate for a geologic repository; considering that a repository's remote location makes exposure to multiple sources of anthropogenic radiation unlikely.

The uncertainties in the analyses to predict doses for 10,000 years will be far greater than the factor of 2.5 difference between the two limits under consideration. None the less, the standard is a specific numerical value with which compliance must be shown with a given degree of assurance. This degree of assurance will not change with a change in the numerical standard. The high uncertainty in being able to demonstrate compliance dictates that the limit should be 25 millirems/year, not 10.

**Question 2:** A new assurance requirement is presented in Section 191.13 that would require a qualitative evaluation of expected releases from potential disposal systems over a 100,000-year time frame. Are such evaluations likely to provide useful information in any future selecting of preferred disposal sites?

**Response:** No. It is not clear what a qualitative comparison of projected releases is, since it is difficult to project releases without numerical modeling. Predictions beyond 10,000 years are extremely speculative and not justified on the basis of protection of human health or the environment. Although such calculations can be mechanically executed, the uncertainties in



the input parameters, and thus the results, are so high that no useful information is provided. Moreover, the U.S. Court of Appeals in the decision vacating and remanding this rule specifically found that the 10,000-year period of consideration was adequately justified.

In addition, DOE believes that the addition of this new assurance requirement exceeds EPA's regulatory authority to establish generally applicable environmental standards for radiation protection under the Atomic Energy Act of 1954 and Reorganization Plan No. 3. The requirement as stated is concerned about information for site selection. According to the Nuclear Waste Policy Act, DOE has sole responsibility for site selection.

Therefore, DOE believes that this requirement is both unproductive and exceeds EPA authority.

**Question 3:** Two options are presented in Section 191.14 and 191.23 pertaining to the length of time over which the individual and ground water protection requirements would apply: a 1,000 year duration and a 10,000 year duration. Which is the more appropriate time frame and why?

**Response:** Extension of the individual and ground water protection requirements to 10,000 years would likely complicate the demonstration of compliance due to the increased uncertainty in the projection of performance without necessarily increasing the degree of public protection. Projecting climatic changes and socio-cultural factors, such as population, agriculture, and lifestyle statistics, over 10,000 years with any certainty, may not be possible.

If EPA insists on extending the compliance demonstration time period to 10,000 years, it should provide criteria for limiting the number of biosphere changes that need to be considered in the analyses. It might be appropriate to use present day human behavior, generic biosphere conditions, and site-specific geosphere factors to calculate potential doses from 1,000 to 10,000 years. To ensure reasonable closure on the number and scope of the analyses that need to be conducted, EPA should include recommendations for the type of biosphere conditions (including changes) that need to be considered.

**Question 4:** In Subpart C the Agency proposes to prevent degradation of "underground sources of drinking water" beyond the concentrations found in 40 CFR 141--the National Primary Drinking Water Regulations. The Agency is aware, however, that there may be some types of ground waters that warrant additional protection because they are of unusually high value or are more susceptible to contamination. Should the Agency develop no-degradation requirements for especially valuable ground waters? If so, what types of ground waters warrant this extra level of protection?

**Response:** While DOE believes that potential sources of ground water should be protected, non-degradation requirements are not warranted for any type of water. Once deep geologic disposal of high-level radioactive waste was chosen as this nation's method of disposal and a site is selected on the basis of avoidance of especially valuable ground waters, little is to be gained by limiting releases of a repository to zero release. A zero-degradation standard requires that performance assessment models prove that for 10,000 years not even one radioactive atom would reach the "valuable ground water." Because of the uncertainties in these models such proof is not possible. DOE believes that the nation's needs for high-level waste disposal facilities must be balanced with the nation's goals to protect ground water. In light of the fact that there will be two, perhaps three, deep geologic disposal facilities built for high-level radioactive waste disposal, DOE believes that the protection of especially valuable ground water should be considered in the site selection process and that further requiring proof of zero degradation is counterproductive.

**Question 5:** Two options are presented in Notes 1(d) and (e) of Appendix B pertaining to the transuranic waste unit: a 1,000,000 curies option and a 3,000,000 curies option. Which is the more appropriate TRU waste unit and why?

**Response:** Neither is appropriate. EPA should reevaluate the purpose of the equivalent waste unit. There is no TRU waste unit that would be "equivalent" to a HLW waste unit except for a single combination of waste modes. Three million curies was computed by the EPA as a quasi-equivalent TRU waste unit, and it was later rounded off to the nearest integer power of ten (1 M Ci). Neither option complies with EPA's stated purpose for the equivalent unit, neither is based on risk potential, and neither is based on expected times of release or risk.

The method which has been used to set TRU waste limits by picking an amount of TRU waste "equivalent" to an amount of HLW is not technically sound. The risk/benefit relationship for commercial HLW does not apply to government TRU waste and there is no reference TRU waste unit that is comparable to the ton of reactor fuel that is used in the HLW fundamental criteria. However, the HLW fundamental criterion is presently being used in 40 CFR 191 along with a quasi-equivalent TRU waste unit that is based on initial activity of only long lived transuranic radionuclides. Equating initial activity of two repositories does not equate risks, so neither equivalency value proposed by EPA is appropriate.

Two possible options which should be further developed and seriously considered are:

- 1) Develop a fundamental criteria for TRU waste based on acceptable risk to the populace.
- 2) Equate the collective risks from a TRU repository with those of either the standard EPA commercial HLW repository or with the Yucca Mountain Project. One way to implement this would be to use the same total normalized release limit for both repositories.

**Question 6:** The Agency is investigating the impacts of gaseous radionuclide releases from radioactive waste disposal systems and whether, in light of these releases, changes to the standards are appropriate. To assist us in this effort, we would appreciate any information pertaining to gaseous release source terms, chemical forms, rates, retardation factor, mitigation techniques and any other relevant technical information.

**Response:** Carbon-14 is the only potential gaseous release of concern to DOE. Releases of gaseous carbon-14 ( $^{14}\text{CO}_2$ ) could easily violate 40 CFR 191 limits, but the release would not threaten public health. (The 40 CFR 191 limit would yield a maximum individual dose of approximately .00003 millirem/year.) This limit in particular needs to be revised.

DOE contractors provided EPA staff with a list of 43 references on carbon-14 at the recent EPRI workshop. Further information is being supplied under separate cover in response to EPA's letter to DOE requesting information related to the carbon-14 concerns.

**Question 7:** EPA requested comments on an attachment to Working Draft 3 of an alternative approach to the probabilistic section of the containment requirements similar to a suggestion by the NRC.

**Response:** DOE believes that the consideration of human intrusion should be separated from the CCDF. Notwithstanding this position, the meaning or significance of several terms and phrases used in describing the suggested approach need to be clarified before it will be possible to determine the appropriateness of the approach. These include:

"Anticipated performance." We hope that this is not analogous to NRC's "anticipated processes and events" which are not well defined. DOE requests that this term be defined to exclude human intrusion and any event or process with a likelihood of less than one chance in ten of occurring.

"Projected releases that have a likelihood" versus "processes and events that have a likelihood." Paragraph (a) of the approach assigns a probability to releases, and paragraph (b) assigns a probability to process and events that cause the releases. The text explains that the "proposed rewording of the containment requirements retains the previous probabilistic formulation for relatively likely releases, i.e., those events with probabilities of one chance in ten or greater over 10,000 years." This incorrectly equates event or process probability with release probability. A repository's integrity may survive the process. Consequences depend on processes' severity, not their existence.

"Process, event or sequence of processes and events" (in paragraph (b) of the approach). These terms could have any number of meanings which would give very different results. This must be clarified.