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VIA TELECOPIER

February 22, 1994

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Waste Standards and Risk Assessment Branch
Criteria and Standards Division
Office of Radiation and Indoor Air
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Caroline:

Enclosed are comments prepared by our office concerning the draft of compliance criteria which the Agency circulated on January 28, 1994.

We sincerely appreciate the Agency's action in seeking out opinions on its draft and wish to congratulate the Agency on its rapid progress on a massive task.

Some of the issues raised by the Agency in its cover memorandum and in the draft criteria will benefit from further work on our part, and we hope to have additional exchanges with the Agency on such points. Please feel free to discuss these comments with us if you have questions.

Best regards,

Lindsay

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Assistant Attorney General

LAL:mh

Enclosure

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COMMENTS OF THE ATTORNEY GENERAL OF NEW MEXICO
ON DRAFT COMPLIANCE CRITERIA FOR THE WASTE ISOLATION PILOT PLANT
February 22, 1994

The following comments are submitted by the Attorney General of New Mexico concerning the draft compliance criteria circulated by the Environmental Protection Agency ("EPA") on January 28, 1994.

We discuss herein proposed additions and amendments to the draft, set forth in the sequence of the draft. We respond at the appropriate points to the questions in EPA's cover memorandum. For convenience we have assigned section numbers to the individual rules in the draft.

Subpart A -- General Provisions

§194.A-1: Purpose, scope and applicability.

The potential EPA proceedings relating to compliance with the disposal regulation, 40 CFR 191, include the initial certification under §8(d) of the Waste Isolation Pilot Plant Land Withdrawal Act of 1992, Pub. L. 92-579 (the "WIPP Act"); the subsequent §8(f) determinations; and consideration of modification, suspension, or revocation of certification. The "purpose" provision should state that the compliance criteria apply to modification, suspension, and revocation proceedings which follow the initial certification. It should also state that the compliance criteria apply to decisions concerning compliance with conditions of certification.

§194.A-2: Definitions:

The definitions should include the terms "modification", "suspension" and "revocation." We propose:

> "Modification" means any action taken by the Administrator which has the effect of altering any of the terms and conditions of certification pursuant to §8(d).
>
> "Suspension" means any action taken by the Administrator to withdraw, for a period up to one year, the effectiveness of certification pursuant to §8(d).
>
> "Revocation" means the action by the Administrator to terminate or withdraw for a period in excess of one year the effectiveness of certification pursuant to §8(d).

§194.A-3: Communications.

This section should provide that EPA shall issue a list of persons, in addition to EPA, to whom a copy of all

communications by the Department of Energy ("DOE") or others with EPA concerning the criteria or a compliance application shall be sent. Such persons may be known as "parties to the rulemaking." Because of their statutory status under §17 of the WIPP Act, the State, National Academy of Sciences ("NAS"), and Environmental Evaluation Group ("EEG") should be included on such list. Citizen groups who seek listing and establish a continuing interest in the rulemaking should also be included.

§194.A-4: Conditions of compliance certification and determination.

EPA should specify that certain conditions shall be incorporated in any certification so that DOE and EPA can begin to work on appropriate language. We propose that EPA add to subsection (a):

Certification shall include conditions with regard to:

(1) Waste acceptance criteria.
(2) Waste characterization.
(3) Reporting concerning operations, monitoring, and scientific investigations.
(4) Facility construction and maintenance.
(5) Waste handling and related operations.
(6) Closure activities.

We disagree with proposed subsection (b)(3)(A) and (B). As written, this provision will allow DOE to make operational changes of whatever sort (the apparent intended coverage of (A)) or to announce corrections of any kind to the information on which a compliance certification was premised (under (B)), and the only protection that the public would receive is that EPA may thereafter take action. Such a procedure puts the initial burden on EPA and ultimately places a very heavy burden on third parties, such as the State, to compel EPA to undertake rulemaking, when the burden should be placed on DOE.

The rule should provide instead that, if DOE desires to change its operations to depart from the conditions of certification, DOE must apply for a modification, and EPA will reopen the rulemaking to consider DOE's proposal. The rulemaking would then consider whether WIPP meets the disposal regulations under the revised terms of operation.

Further, if DOE determines that scientific data submitted in support of certification are inaccurate, again, the burden should be on DOE to move EPA to reopen the rulemaking and to confirm that WIPP meets the disposal regulations on the corrected scientific record. If EPA concludes that the regulations are not satisfied, certification should be revoked, and the waste should be removed.

It is contrary to the WIPP Act for EPA to conduct procedures affecting the validity or terms of certification in any forum other than an open public rulemaking. Any proposal by DOE to obtain EPA's consent to changes in the terms of certification must be announced to the public; EPA and others must have ample time to obtain information (see §194.C-1) and comment; and EPA must respond to the comments. In particular, to allow DOE to make changes in operations so long as it gives 30 days notice is unacceptable.

The draft language concerning the occurrence or "likely" occurrence of releases to the environment "in excess of what is permitted under the disposal regulations" is unclear, since the disposal regulations speak in terms of specific probabilities. Perhaps EPA intends to refer to the 40 CFR 191, Appendix A, Table 1, quantities. We suggest, first, that a provision governing releases during operations be incorporated into forthcoming compliance regulations governing 40 CFR 191, Subpart A. Second, DOE should be required to notify EPA if DOE determines that the certification (or determination) can no longer be sustained, because scientific information indicates that WIPP will not comply with the disposal regulations. In such event, EPA should have the obligation to reopen the certification rulemaking and determine the appropriate remedy, which may include revocation of the certification and removal of waste.

The compliance criteria should also recognize that, if EPA initially grants certification, it will actively supervise operating requirements and closure. The certification itself should contain conditions on such points. The regulations should call for periodic reports by DOE about DOE's compliance with the continuing conditions, which EPA should announce in the Federal Register. EPA and others would then have an opportunity to obtain information from DOE about DOE's compliance, which DOE would be required to provide. EPA would then consider by rulemaking whether to approve the reports, would receive public comment, and would announce its decision in the Federal Register. The decision would be subject to judicial review. If a DOE report is disapproved, EPA would be required to suspend, modify or revoke certification. Revocation of certification would require removal of the waste. Only by such a process would EPA oversight and judicial review of compliance with certification conditions be preserved.

§194.A-5: Publications incorporated by reference.

The publications referred to themselves make reference to other potentially relevant materials (e.g., NUREG-1297 refers to 10 CFR 60, Subpart G on quality assurance). EPA should clarify whether it intends to incorporate such second-level references in its rules. It might be clearer if EPA simply reproduced the language it desires to employ as an Appendix to the compliance

criteria.

§194.A-6: Alternative provisions.

The language closely follows former 40 CFR §191.17 and is acceptable.

§194.A-7: Effective date.

EPA should make clear that the date for initiation of judicial review of issuance of the compliance criteria and of any action taken under the compliance criteria is determined by reference to the date of publication of EPA action in the Federal Register.

Subpart B -- Compliance Certification and Determination Applications.

§194.B-1: Completeness and accuracy of compliance applications.

Procedures should be set forth whereby the completeness of the application is determined. The determination of completeness is a significant stage in which public comment will give valuable aid to EPA. Further, DOE will be well served by clear specification of the deficiencies of the application. In addition, regulations should provide that, if the required information is not furnished, the application will be denied. We urge the adoption of language similar to 10 C.F.R. §§2.101(f)(1)-(3), (7), 2.108. This subject is discussed further in connection with Subpart D.

§194.B-2: Submission of compliance applications.

This section should provide for the submission of copies of a compliance application to persons appearing on the list of "parties to the rulemaking." Clearly, §17 of the WIPP Act requires that the State, EEG, and the NAS receive such copies.

§194.B-3: Submission of reference materials.

Reference material should be submitted for the docket and sent to parties to the rulemaking in the same manner as the compliance application and accompanying materials.

§194.B-4: Content of compliance certification application.

This important section should be set forth in terms that apply specifically to WIPP. Generally-stated requirements (e.g., "presence and characteristics of potential pathways for radionuclides") have no clear purpose, when the compliance assessment must describe such subjects very specifically. Similarly, it does not clarify much to say that the application should contain "[a] description of the geology, geophysics, hydrogeology, hydrology, geochemistry, climatology, and meteorology of the disposal system..." Ideally, EPA should outline precisely what data are required about, e.g., the Culebra member, its thickness, areal extent, permeability, porosity, fractures, matrix, clay, and so forth. If it is not yet possible to say what is required in such detail, at least EPA could adopt an outline of data needs so that interested parties could start to work off the same checklist. The current DOE work on a Technical Baseline document is addressed to assembly of relevant data. We have not seen a draft of this document but hope that DOE's work on it and EPA's and others' comments may lead to an acceptable list of data needs.

Several other general principles should govern the application and should be set forth in the compliance criteria: References should not substitute for explanations which contain the data required to support a proposition. Sufficient information about each proposition should be provided to enable EPA and others to reproduce and confirm the calculations made by DOE. The use of "investigator judgment" should be precluded. Any "judgments" employed must be subject to the rule on expert elicitations.

The compliance criteria should recognize that a process of pre-application interchange between DOE and EPA is going forward. Simultaneously with drafting of the compliance criteria, DOE is preparing several presentations of data and compliance plans which, in one way or another, outline the scientific data that DOE will present in proof of compliance. These include: Regulatory Compliance Strategy and Management Plan; Format and Content Guide; Regulatory Criteria Document, 1992 Performance Assessment, Technical Baseline document, Compliance Status Report, Experimental Program Plan. EPA will comment on most such DOE presentations, stating EPA's views as to the scientific data, models, and analytical approaches necessary to demonstrate compliance. We propose that EPA provide in the compliance criteria that DOE's certification application must take account of, and either conform to or explain any departure from, any positions taken by EPA staff in commenting on DOE compliance-related documents. Such a requirement would lend appropriate authority to EPA's statements in pre-application exchanges without excessively constraining either agency.

Subsection (3) should refer to performance assessments

under 40 CFR Part 191, as required by §6(d) of the WIPP Act.

Subsection (4) should refer forward to the compliance criteria sections concerning the assurance requirements (§§194.C-12 through C-17, as numbered herein).

The subsections calling for map data ((6) through (8)) need to describe the area to be covered by such maps. The question of the area is part of the overall question of data requirements. Tentatively, for study of resources, the area of nine townships, T21-23S, R30-32E, should be sufficient. For study of hydrology, the map area should cover the flow and transport model grid and sufficient adjoining area to evaluate the treatment of boundary conditions. We suggest that EPA require that maps separately showing all institutional controls be presented as part of the §194.C-12 and C-14 presentations.

§194.B-5: Content of compliance determination application(s).

The draft provision concerning recertification procedures provides only generally for the obtaining of additional data to supplement the showing in the certification proceeding. We suggest that DOE be directed to submit, soon after a certification determination, an experimental plan outlining further data to be gathered. EPA should then take public comments, review and direct revisions in such a plan, approve it, and employ data from the experiments in conducting the recertification proceedings.

Subpart C -- Compliance Certification and Determination

GENERAL REQUIREMENTS

§194.C-1: Inspections.

EPA's data access rights are broadly stated, and correctly so. However, other entities are recognized by statute as having an interest in the compliance certification. Section 17 of the WIPP Act specifically directs that the State, the NAS, and EEG shall have free and timely access to data relating to health, safety, or environmental issues at WIPP. Those entities are also authorized to analyze and publish analyses of DOE's plans for compliance with 40 CFR 191 (WIPP Act §17(b)). To enable such statutory participation in EPA's rulemaking EPA should provide in the compliance criteria that the State, NAS, and EEG shall have rights to inspection and access equal to the rights enjoyed by EPA.

We also propose that individuals and citizen groups admitted as parties to the rulemaking have rights of access equal to EPA and the §17 entities. It will ensure public respect for EPA's decision to allow such persons to have access to DOE

information concerning this critical stage.

§194.C-2: Quality assurance.

EPA has inquired in its cover memorandum about quality control and quality assurance requirements. Initially, we suggest that EPA adopt principles similar to those employed by the Nuclear Regulatory Commission ("NRC") in its licensing of nuclear facilities, 10 CFR Part 50, Appendix B. Appendix B outlines principles to be applied in evaluating a quality assurance program for nuclear power plants. These principles include: (a) the applicant's responsibility to establish and execute a comprehensive quality assurance program, (b) a written record of authorities and duties in performing activities and in assuring quality, (c) verifying, such as by checking, auditing, and inspection, that safety-related activities have been carried out correctly, (d) adequate authority and organizational freedom in quality assurance personnel, including independence from cost and schedule when opposed to safety considerations, and including direct access to management, so that they can initiate, recommend, or provide solutions and verify their implementation. Appendix B discusses the specific application of such principles to design control; procurement documents; instructions, procedures and drawings; document control; control of purchased material, equipment and services; identification and control of materials, parts and components; control of special processes; inspection; test control, control of measuring and test equipment; handling, storage and shipping; and related subjects. These principles can be carried over directly to the WIPP project. We question whether all such principles are embodied in the current DOE order on quality assurance, DOE 5700.6C. That order does not provide for a quality assurance authority with sufficient independence from cost and schedule and direct access to management to identify problems and to carry out and verify solutions.

Compliance criteria should require DOE to provide adequate demonstration of compliance with quality assurance standards as part of a certification application. Compliance with future requirements must be established in reports by DOE, as discussed above concerning conditions of compliance certification (§191.A-4).

Certain safety-related activities are not readily subject to verification by "checking, auditing, and inspection." We suggest that matters such as the sufficiency of experimental design are appropriately subject to the peer review requirements of §194.C-7.

§194.C-3: Models and codes.

The term "model" refers to any description of a natural or engineered process or system and, thus, a rule calling for "each model" is difficult to comply with fully. EPA should consider listing each model which, on present information, should be included in the application.

As DOE uses "model" there are four types: conceptual, mathematical, numerical, and computational. EPA's rule should call for a complete description and scientific justification of each type of model for its intended purpose: conceptual models describe the environment, mathematical models translate the conceptual relations into mathematical relationships, numerical models represent a process or system using a sequence of arithmetic operations, and computational models are the computer-applicable instructions which carry out calculations in accordance with the numerical models.

The model justification should include inter alia, a description of alternative conceptual models examined and rejected in the process of performance assessment and the reasons for their rejection. Further, present models contain arbitrary limitations, e.g., as to the timing and number of human intrusions. Compliance criteria should require that any such limitations be justified or be demonstrated to be conservative. Similarly, matters such as the size and configuration of transport grid blocks, boundary adjustments, and other mathematical simplifications of the natural world must be shown to be conservative assumptions.

The reference to model "validation" raises, among many other things, the question of extrapolation. EPA cannot assume that observational data from two or four years "validate" a model which depicts 10,000 years of behavior or behavior in circumstances varying from those observed. It is appropriate to add to (a)(2)(D): "including extrapolation to the relevant time period and circumstances."

As models are now used in performance assessment, certain parameters are fixed, and others are treated as variable parameters with a range and a median. The variable parameters are subjected to Latin hypercube sampling within the given range. Compliance criteria should require an explanation and justification of (a) the selection of fixed and variable parameters, (b) the establishment of range, median, and probability distribution of variable parameters, (c) the sampling methods, including any probability judgments implied thereby.

Subsection (d) correctly requires EPA access to computer facilities to carry out computer simulations. Again, similar access should be furnished to the State, NAS, and EEG to carry out the mandate of §17 of the WIPP Act. Computer models are plainly

"data relating to health, safety or environmental issues at WIPP" (WIPP Act §17)--indeed, they may ultimately be the most important such data, since they will determine whether the facility is used at all. Access should be mandated by regulation. Similar access should be made available to other parties to the rulemaking.

§194.C-4: Waste characterization.

The draft rule is somewhat ambiguous. It begins by requiring "detailed" characterization of all waste proposed for disposal at the time of the certification application, but such requirement applies to both existing and future waste, leaving unclear whether characterization is to be based on actual examination of waste -- which is impossible as to future waste -- or something else.

The draft rule identifies characteristics to be quantified but then adds an open-ended item: "[a]ny other characteristics that could affect the transport of radionuclides toward the accessible environment." The draft does not state how such characteristics are to be identified.

The draft says that characterization of existing waste should be based on "physical sampling" which is "statistically representative" or worst-case assumptions should be made. It says only that characterization of future waste must "accurately quantif[y]" that waste.

There is a separate requirement of a demonstration that waste received at WIPP "will not differ" from application data so as to increase the mobility of radionuclides.

Thus, the draft is confusing as to the parameters to be quantified, the nature of the data to be furnished about such parameters (quantities? ranges? probability distributions?), how data are to be obtained, especially as to future waste, and how EPA will oversee the gathering of such data.

This rule should be rewritten to call upon DOE to submit characterization data as follows. Briefly, waste characterization must start from an identification of the characteristics which are important to a demonstration of compliance. The performance assessment has not been refined to the point where such characteristics can be identified. For example, without a valid model of spallings releases, we do not know what parameters in such a model are the sensitive ones. Without a complete gas generation model and backfill data, we cannot identify the sensitive gas-generation parameters. Thus, it is too soon for EPA to write a complete rule specifying all relevant characteristics (although those listed in the draft seem to be correct). The burden should be placed on DOE instead.

When the sensitive parameters (and their range, median,

and distribution) have been identified, DOE should develop waste characterization parameters which will ensure that the inventory has the required characteristics, or range and distribution of characteristics, to support the assumptions of a compliance demonstration. Existing waste must be shown in the certification application to meet the criteria based on examination and statistical analysis, because EPA should not authorize WIPP to operate based only on hypotheses about the nature of the existing waste. As to future waste DOE must show that the waste characterization parameters will be satisfied or the waste will not go to WIPP.

We question the utility of "worst-case" assumptions as to existing waste. It is hard to decide what the "worst case" is without knowing what parameters are relevant and defining a reasonable range. Instead, EPA should call for data characterizing existing waste containing a supportable range and distribution of sensitive parameters.

It is unclear whether subsection (c)(4) is meant to refer to existing or future waste or both. In any case, DOE cannot provide "information demonstrating" future events. DOE should demonstrate in its certification application that waste acceptance criteria, if followed, will support the assumptions of a performance assessment, both as to existing and future waste. But such criteria might not be followed, and compliance criteria must therefore provide for EPA's ongoing supervision of waste characterization. Ongoing supervision must be carried out with full public participation, which is probably not obtainable in "audit and inspections." Public participation can be provided through semi-annual reports by DOE as to waste received, together with statistical analysis establishing that such waste is within the limits set by the waste acceptance criteria. Such reports must trigger a public rulemaking, in form to modify the compliance determination to reflect the introduction of additional wastes.

Another aspect of waste characterization that EPA needs to deal with in the compliance criteria is the method of measuring the curie content of the inventory to establish radionuclide release limits. Since release limits must be known to carry out a compliance analysis, the curie content must be established (or a maximum set) at the time of the certification proceeding. The factors of rapid radionuclide ingrowth and decay contend for the establishment of a fixed date for determination of curie content. WIPP may well be in an operational phase for 30 years or more, waste may be kept in a retrievable state for an extended period after that, and DOE will certainly assert the effectiveness of institutional controls in preventing releases for 100 years after disposal. To establish a uniform measuring point we propose that the curie content of TRU waste for purposes of long-term performance analyses be calculated at the time 100 years after disposal. We note that in the Final Supplement to Environmental

Impact Statement (DOE/EIS-0026-FS), Jan. 1990, DOE asserted that in assessing the long-term performance of the repository the 100 year curie content was the appropriate value to use. (Appx. B. page B-19 and Table B.2-14).

§194.C-5: Future state assumptions.

It is, of course, arbitrary and nonconservative to assume that the future will resemble the present for 10,000 years. The appropriateness of such an assumption must be considered in the context of the analyses contained in a compliance determination.

If the probability and consequences of human intrusion, under the containment requirement, are to be evaluated solely through the structured approach outlined in §194.C-10 (discussed below), and without consideration of possible future changes in the location of populations, political control, resource uses, and scientific knowledge, it may be feasible to disregard changes in such factors. In so doing, EPA must be constantly on guard to avoid inconsistencies in basic assumptions, e.g., analyzing probability of intrusion under assumptions of changes in technology but consequences under assumptions that technology does not change.

However, there is no reason to apply fixed "future states" to other parts of the disposal regulation. Such assumptions supposedly reduce the role of speculation in a quantified demonstration of compliance. But, since such assumptions are unreal, a compliance determination based upon them is to that extent unreal. For such reasons, among others, additional regulatory requirements need to be imposed as a defense in depth, viz: the assurance requirements. Whether fixed future states should be assumed in applying the assurance requirements is a separate issue. For example, in evaluating engineered barriers pursuant to §194.C-15 for their ability to impede the release of radionuclides or to mitigate the consequences of human-induced processes and events, there is no need to simplify the analysis by assuming unrealistic future states. The analysis under §194.C-15 is an open-ended analysis of DOE's choice among means of "defense-in-depth." Such analysis should assume a range of changes in technology and society affecting the probability, severity and consequences of intrusions i.e., the challenges that engineered barriers will have to deal with in the real world. The same principle applies to analyses of active institutional controls (§194.C-12), monitoring (§194.C-13), passive institutional controls (§194.C-14), and resources on site (§194.C-16).

The draft rule contains an exception from future state assumptions for geologic, hydrologic or climatic conditions, which is correct. There should also be an exception for the acts of man in constructing and operating the repository and in bringing about any potential release scenario. It would not be correct, for

example, to discount or reject a potash-mining scenario on the theory that 1994 potash prices do not justify mining for potash in the area, nor to exclude a reservoir-construction scenario on the theory that evaporation problems have not economically been solved. Scenarios which pass screening requirements should not be eliminated on "future states" grounds.

§194.C-6: Expert judgment.

We previously suggested principles which should govern "expert" elicitations (see the New Mexico Attorney General's comments to the NACEPT Subcommittee, Sept. 22, 1993) and note that the draft omits some important items. The record of expert judgment elicitation should include a clear statement of the question, so that the answer may be clearly understood, especially when probabilities are estimated. Panels should not be elicited collectively; individuals should be required to express their own views as confirmation of their expertise. Issues should be decomposed into a decision or event tree. Panelists should be required to assign fractile probability values to high, low and intermediate levels of the variable in question; in other words, the exercise should be focused on the creation of a probability distribution function which may be incorporated into a performance assessment. Panelists should be required to explain and justify their judgments.

Some rule changes are required to ensure that experts are neutral. Members of the "team of investigators" requesting or using the judgment are properly precluded. The rule should make clear that these terms exclude all Sandia employees or consultants on the WIPP performance assessment, whatever their connection with the issue of the expert elicitation. Moreover, the requirement of "at least one-half" non-DOE members is insufficient to ensure neutrality. We suggest that two-thirds independent membership is necessary to ensure general acceptance of panel judgments. Further, the requirement that most of the membership of any panel not be employed directly or indirectly by DOE should include as "employed" any person whose professional work is significantly dependent upon DOE. Moreover, all members should give their personal assurance that their views will not be affected by their financial dependence.

The rule should state that expert judgments offered "to support compliance application(s)" include not only estimates as to the range and distribution of parameters or probability estimates but also intermediate judgments used in preparing an application, such as conclusions as to the adequacy of an experimental design, the appropriateness of a given sampling technique, or the appropriateness of adjustments to experimental data.

§194.C-7: Peer review.

There is an ambiguity as to the scope of necessary peer review. Subsection (a) refers to certain activities ("expert elicitation...") as requiring peer review. Subsection (b) calls for peer review processes to be "compatible with NUREG-1297," which has its own scope definition (§IV(1)(a)). We suggest that EPA employ language in subsection (a) similar to that in NUREG-1297, §(V(1)(a), and add: "including but not limited to any expert elicitation...."

NUREG-1297 refers to evaluation of DOE's peer review process from inception through the issuance of a report (see §V). It is not clear how EPA intends to perform this function. If EPA will be making ongoing decisions about the adequacy of peer review, the process needs to be public and should comply with rulemaking requirements.

§194.C-8: Consideration of controlled area.

The "controlled area" as defined in the WIPP Act appears to exclude rights held under certain oil and gas leases (see WIPP Act §§3, 4(b)(5)), whereas 40 CFR §191.12(g) defines "controlled area" to include the entire subsurface. By stating here that the controlled area encompasses "no more than" the area specified under the WIPP Act, is EPA attempting to change the definition in 40 CFR 191?

CONTAINMENT REQUIREMENTS

§194.C-9: Scope of performance assessments.

The compliance criteria should describe how scenarios are selected, screened and defined. At present summary scenarios are screened based upon low probability, physical unreasonableness, lack of consequence, and regulatory exclusions. (Preliminary Comparison with 40 CFR Part 191, Subpart B, Dec. 1991, SAND 91-0893, v. 1, at 4-12). The compliance criteria should reduce uncertainty as to the correct process of scenario selection. For example, certain scenarios have been screened on the questionable assumption that climate changes in the 10,000 year period will not exceed certain ranges (SAND 91-0893, v. 1, at 4-15 through 4-19). Scenarios deemed to have a low probability or consequence should be incorporated in the base "undisturbed performance" case. Moreover, scenario selection and design must be peer-reviewed.

The exclusion in the draft of categories of processes and events estimated to have a chance of less than 10^{-4} of occurring over 10,000 years reflects an erroneous assumption of the nature of scenario selection and definition. Any potential release

scenario can be redefined to comprise individual scenarios, each of which has a probability of less than 10^{-4} (SAND 91-0893, v. 1, at 4-5). Thus, EPA should delete this exclusion.

§194.C-10: Consideration of human-initiated process and events.

It is not clear whether the approach described in subsection (c) is intended to be exclusive as to consideration of any human-initiated processes and events. The approach outlined focuses only on "exploratory activity" by the specific means of "drilling." However, certain scenarios involving other human activities clearly must be considered. DOE has retained for analysis the scenario involving mining beyond the controlled area, and EPA has pointed out the need to analyze mining within the controlled area and above the waste panels (EPA Comments on the December 1992 Preliminary Performance Assessment, volumes 1-3, Jan. 7, 1994, at 9). Injection wells and withdrawal wells remain to be analyzed. Other scenarios involving irrigation, impoundments, and repository-induced events (panel caving, nuclear criticality) have been credibly suggested. Such scenarios should not be excluded by rule.

Subsection (b) excludes "intentional" human intrusion. We agree that future generations must take responsibility for their deliberate actions. However, performance assessments should consider the likelihood of intrusions by persons who have vague or incomplete information about the presence of radioactive materials but either disbelieve such reports or assume that they can avoid any risks. The appropriate rule would exclude intrusions by persons to whom the content of information contained in passive institutional controls has effectively been communicated.

It is not clear from subsection (c) whether EPA intends to require a particular design of scenarios in calling for calculation of the rate of intrusion for each "specific type" of "exploratory activity" and a "total rate of human intrusion." Scenario design should not be constrained by the compliance criteria. The purpose of calculating a "total rate" is not clear, since scenarios must be analyzed separately.

The term "exploratory activities" needs to be defined. It suggests a process of identification of resources for extraction; thus, its application to scenarios involving injection wells or withdrawal wells is not clear. Certain release scenarios may also include drilling of "development" or "extraction" wells, and presumably the history of such (non-exploratory) drilling would be used to project future drilling of such nature. It may not be possible to find out whether certain historical wells should be deemed "exploratory." It would be better to use a term without vague connotations, such as "drilling activities."

There is a question as to how analyses should consider the likelihood that the intruders -- although not informed by passive institutional controls -- might learn that their drilling raises special risks and terminate their intrusion. Previously, the Guidance has contained certain assumptions in this regard, but they should not be retained. First, EPA should not make regulatory assumptions about the effectiveness of passive institutional controls; the effectiveness should be established based upon a specific plan which has undergone expert review. Second, it should not be assumed, without specific analysis, that events during drilling would inform the driller of the presence of the repository sufficiently so that either (a) any further intrusion is effectively intentional or (b) the driller will become alarmed, stop drilling, and prevent any further releases. The likelihood of intruders learning of, and then curtailing, intrusion must be carefully analyzed on the basis of the relevant drilling practices, which should be reviewed by knowledgeable persons at the scenario selection and design stage.

We inquire also whether EPA should prescribe that future drilling events shall be assumed to be random in time and space. Information obtained in drilling one hole certainly affects the likelihood that a second hole may be drilled.

EPA has inquired in its January 28, 1994 cover memorandum as to the extent to which passive institutional controls can be relied upon to deter human intrusion and how such factor may be considered in a performance assessment. A few points can be made in response:

First, to attempt to calculate the contribution of passive institutional controls conflicts with one of EPA's premises in the draft compliance criteria. EPA proposes that in projecting the likelihood of releases, "characteristics of the future remain what they are today" (§194.C-5), and in projecting the likelihood of human intrusion EPA proposes to assume that current-day drilling rates continue (§194.C-10). We take it that EPA has adopted such limitations in an effort to keep speculation out of the performance assessment. However, it is impossible to assess the effectiveness of passive controls, using an assumption of unchanged future states. The very issues are whether markers and other controls <u>will</u> change and whether peoples' ability to interpret them <u>will</u> change. The only published examination of the issue, Expert Judgment on Markers to Deter Inadvertent Human Intrusion into the Waste Isolation Pilot Plant, SAND 92-1382 (Nov. 1993), considers varying levels of technology as they may affect the likelihood that markers may survive and be understood (see Ch. 5). The treatment of the survival and understandability of the markers is dealt with inadequately in only ten pages but suggests the range of factors to be weighed. A thorough analysis will implicate such issues as the prospects for changes in political control, population concentrations, resource exploitation, communications, climate,

underground detection methods, and understanding of radioactivity.

Second, it is already nonconservative to assume, as EPA has done, that intrusion methods will be limited to those available today. It errs still further to assume, inconsistently, that technology will change and may develop in ways which enhance the survival and understandability of markers. Such nonconservative inconsistency should be avoided.

We have no quick answer to EPA's problem. Previously we have counseled against nonconservative "future states" assumptions (New Mexico Attorney General's comments to the NACEPT Subcommittee, Sept. 22, 1993). EPA has nevertheless taken that course. In this situation we suggest, first, that the burden of persuasion rests upon DOE, which must convince EPA that a historically prevailing drilling rate will not resume after the expiration of 100 years of active institutional controls. Superficial speculation, such as that contained in chapter 5 of SAND 92-1382, cannot possible convince EPA to make major reductions in drilling rates. Since EPA has elected a supposedly comparable historical proxy area and time span to establish the rate of drilling disregarding passive controls, presumably DOE is free to adduce proof of the durability and effectiveness of such controls by presenting equally comparable historical proxies for such factors, but of course omitting any role for active institutional controls. The evolution of the compliance criteria may lead to more definite answers to this question.

§194.C-11: Compliance.

The idea that compliance is to be determined based on the mean CCDF curve contradicts the frequent statements that compliance cannot be judged from a single curve. Commentators such as EEG have emphasized the need, rather, to depict the full range of uncertainty reflected by analyses to understand the weight to be given to the mean and any other curve in a compliance demonstration. (EEG Preliminary Comments, Sept. 13, 1993, at 2). At the December 1993 NAS WIPP Panel meeting one eminent member said that if 8% of the CCDF iterations are above the CCDF limit, "I don't call that a reasonable expectation." EPA must change a lot of minds before it can make compliance depend on the mean, standing alone.

EPA asks in its January 28, 1994 cover memorandum for comment on the proposed selection of the mean curve and the direction for 300 CCDF's. We do not yet have the expertise to address these issues completely. It would seem that the answer requires mathematical analysis of the level of assurance obtained from a mean derived from multiple generations of CCDF's. It would also appear that the validity of the proposal depends upon the way in which the range and probability distribution of variable

parameters were established and what sampling methods were used. Thus, in focusing on the mean the draft rule makes numerous unstated assumptions about the generation of CCDF's and what is shown by such curves. EPA must state more clearly what is meant by the "mean," i.e., a mean generated by what processes. For example, it is not sufficient to state simply that when "parameter values are imprecisely known, mathematical techniques [must] consider the full range of potential values" without stating how such range shall be established and "considered." For instance, what if any weighting based on the probability of different values is required to be used?

ASSURANCE REQUIREMENTS

§194.C-12: Active institutional controls.

EPA does not describe how assumptions as to the effectiveness of active institutional controls are to be formed. Such effectiveness must be established by expert judgment elicitation, subject to peer review.

§194.C-13: Monitoring

The disposal regulation states that monitoring shall be continued "until there are no significant concerns..." §191.14(b). That time will not arrive until the radioactivity has decayed to a level at which intrusion creates no concern. The compliance criteria should indicate specifically that the monitoring plan must cover such an extended period, which may exceed 10,000 years.

The monitoring plan presumably must also demonstrate compliance with §191.14(b) in that it does not "jeopardize the isolation of the waste." The relevant subsection of the compliance criteria should so state.

Further, an effective monitoring plan should include guidelines as to the levels of monitored parameters that will trigger further action. DOE's plan to monitor radionuclides should indicate levels, detection of which will cause DOE to notify EPA and reopen the certification rulemaking. Similarly, DOE's plan should require it to report to EPA any variations in monitored parameters from the assumptions which underlie a compliance certification or determination.

§194.C-14: Passive institutional controls.

The draft requires only markers that furnish "identification of the controlled area." The actual need is for markers that communicate the danger of the wastes, the elements

contained in them, their configuration, their location, and the general plan of the repository. The recent markers panel report, SAND 92-1382, illustrates broadly what is required. The rule should specify such requirements.

The rule should also require permanent records off the WIPP site in case the on-site records are destroyed or ignored. All such records should be designed to survive a major discontinuity in civilization.

In addition, the rule should require much more detailed records, showing the nature and location of the wastes, their emplacement, their risk, and the potential means of release (as described in draft subsection (a)(2)(v)) to be placed in numerous libraries throughout the world, suitably marked to prevent discard.

Finally, information conforming to the content and needs of land record systems should be required to be placed in such systems. Such information will not be as detailed as the library records but should refer to such records.

§194.C-15: Engineered barriers.

The stated criterion for performance of engineered barriers is "to prevent or substantially delay the movement of waste or radionuclides...." The rule should quantify the concepts of "prevent" and "substantially delay." "Prevent" presumably means totally isolate; this should be said explicitly. "Substantially delay" should be defined in terms of a release rate. In a similar context the NRC has required that, after an initial period of containment, any release be gradual, resulting in release of small fractions of the inventory over a long period. NRC has said that an initial period of substantially complete containment will be fixed by NRC at between 300 and 1,000 years. EPA should similarly specify the time period during which releases will be "prevented." Such period should be defined by the period of most significant radioactivity, i.e., 1,000 years. NRC has defined gradual releases as no more than one part in 100,000 per year of the inventory calculated to be present at 1,000 years; a similar quantification would be appropriate here. See 10 C.F.R. §60.113. With quantified standards the evaluation called for by subsection (b) will have an objective target, serving the interest of all parties in reducing uncertainty.

EPA should also require that, pending compliance certification, DOE undertake no actions rendering it substantially more difficult for DOE or EPA to apply the engineered barrier requirement. For example, DOE should not repack waste or mine waste rooms in such a way that an engineered alternative such as shredding or different disposal room dimensions becomes more expensive, thereby prejudicing an analysis based in part on "total

system costs."

We have already pointed out that the evaluation of engineered barriers should not be limited by future states assumptions (see §194.C-5).

§194.C-16: Consideration of the presence of resources.

It is not clear how the evaluation of "favorable characteristics" is to be done; the term implies a comparison, and sites to be compared are not identified. EPA should specify hypothetical disposal systems to be built in areas which are not exploration targets. Analysis of such systems would be based on the assumption of no human intrusion. Comparison of sites should be based upon some objective measure, such as area under the CCDF curve. Unless an objective test is stated, this requirement, which has been in effect since 1985, would become a dead letter.

The provision calling for analysis of human intrusion "in search for all known resources" is correct and properly belongs in §194.C-10. It should be made clear that "resources" include minerals and other substances that are not currently of market value but may become so; indeed, so much is required by §191.14(e).

§194.C-17: Removal of wastes.

The requirement of a plan for removal of waste is appropriate but must include a measure of time, such as during 50 years after disposal, to describe the task. The basic purpose of this requirement is to ensure that waste can be removed regardless of the condition of the shafts, drifts, and rooms.

INDIVIDUAL AND GROUNDWATER PROTECTION REQUIREMENTS

§194.C-18: Consideration of protected individual.

The draft says that the protected individual presumably resides in the accessible environment at the point of highest exposure. It would be better to say that he/she resides at such location, provided that it is on the surface.

§194.C-19: Consideration of exposure pathways.

The draft language is consistent with the revised Part 191 and carries forward parameters contained in the former §191.15.

§194.C-20: Consideration of underground sources of drinking water.

The draft appropriately directs consideration of all underground sources of drinking water and interconnections between bodies of water. EPA should clarify that its use of the word "likely" does not imply a simple more-than-50% probability and that the standard remains that of a "reasonable expectation."

§194.C-21: Consideration of undisturbed performance.

We take it that the $>10^{-1}$ probability is intended to draw the line demarking "unlikely natural events," §191.12(p) (1985). As written, the rule calls for consideration of categories of events or processes which collectively have a greater than 1 in 10 chance of occurring, even if the events individually have a less than 1 in 10 chance of occurring.

§194.C-22: Compliance.

Our comments on draft §194.C-11 in general apply here. Moreover, to the extent that the specifics of a probabilistic risk assessment are set forth in §194.C-11 to give content to the concept of "reasonable expectation," they should also be set forth here for the same purpose.

Subpart D -- Public Participation

§194.D-1: Advance Notice of Proposed Rulemaking.

The entire subpart concerning public participation needs to be rewritten to give the public an effective role in the process. Moreover, the draft fails to recognize the inevitable sequence of events.

Any application for certification is almost certain to be incomplete. Both the public and EPA staff will wish to address that initial issue and to comment on DOE's efforts to fill the gaps. A process should be adopted like that in 10 C.F.R. §2.101(f)(1)-(3), whereby EPA will treat an application as tendered, make it public, announce the tendering in the Federal Register, accept comments on the tendered document, issue one or more notices of deficiencies to DOE, receive supplemental materials, and ultimately determine whether the tendered application is complete or should be denied as incomplete. There is no point in requiring persons to file comments and demand a public hearing concerning the first incomplete submittal by DOE, and in denying them such opportunities concerning the application on which EPA may ultimately act.

Further, there is no provision in the draft for access to information. As stated above (see §194.C-1) EPA, the State, NAS, and EEG ought to have regulatorily-conferred access to DOE

information concerning the compliance determination. In addition, other "parties to the rulemaking" should have rights of access to DOE information similar to those enjoyed by the State, NAS, and EEG.

If EPA determines that the application, as supplemented, is complete it should so state publicly (i.e., in the Federal Register) and invite comments and requests for a public hearing on the application. The time period for submission of comments should not begin to run until the application is deemed complete by EPA and DOE has responded to all information requests.

Before EPA issues a proposed decision it should hold a public hearing at which DOE proponents of the application appear in person to explain their compliance presentation. We strongly suggest that the DOE proponents be required at that time to answer questions by EPA staff members, the State, NAS, EEG, and any other parties to the rulemaking. We suggest just as strongly that EPA accept and respond to written or oral comments by qualified experts without regard to time or page limitations that may apply to public comments generally.

This rule should recognize that after initial certification issues may arise involving compliance with conditions of certification, modification or revocation of certification, noncompliance with the factual predicate for certification, or occurrence of releases in violation of the disposal standards. The rule should state that all such postponed "pieces" of the compliance certification must be determined in accordance with the procedures governing the initial certification.

§194.D-2: Notice of Proposed Rulemaking.

Any EPA determination must contain a detailed discussion of the issues raised by the application and, if certification is granted, will contain numerous conditions. Many such determinations and conditions will be new to the public. Again, opportunity for access to information from DOE must be provided. After such disclosure, parties must have an opportunity to comment, including the submission of extended written or oral expert statements. The time period for submission of comments should not begin until information has been furnished. Again, a public hearing must be held, and EPA staff and parties to the rulemaking must be able to ask questions of the DOE proponents of the certification.

EPA must, of course, respond to comments on its proposed rulemaking. The draft rule does not state when, but such response should be provided no later than the final rule. The rule should also state that EPA shall respond to comments made pursuant to the Advance Notice of Proposed Rulemaking at the same time it responds

to comments on its proposed rule.

Again, this rule should apply to post-certification proceedings involving conditions, modifications, revocations and the like, and it should so state.

§194.D-3: Notice of Final Rule.

The notice must contain a full statement of the factual premises for the certification decision and the conditions to such certification.

As stated above, the same procedure will apply to determinations of compliance with conditions of certification, modification, or revocation of certification and other post-certification issues. (see §194.D-1). The rule should so state.

EPA's final rule should also state when the determination shall be deemed made for purposes of judicial review pursuant to §18 of the WIPP Act. The compliance criteria should require such a statement.

§194.D-4: Documentation of continued compliance.

The same comments apply here as to §194.D-1 concerning the filing of the initial application. Again, access to information should be provided. The initial documentation filed by DOE is almost certain to be incomplete, and the process of completing the filing must be publicly conducted. Only after access to information has been afforded and the application has been determined by EPA to be complete should the time for comments start. The comment period should be at least 120 days, not 30.

The draft fails to provide for a public hearing. Why there should be no public process is unexplained. Questions will have arisen concerning the premises of EPA's initial certification and DOE's compliance with conditions of such certification. EPA staff will certainly desire to ask questions of the DOE proponents of recertification. Such a process should be conducted publicly. That being so, there is little to be gained by excluding the public from commenting or asking questions of the DOE proponents.

The draft calls for a publication of EPA's decision on recertification but no response to comments, no statement of reasons by EPA, and no public hearing. These omissions are wholly unjustified and do not do justice to the significance of EPA's task. EPA should follow the usual procedure of issuing its proposed decision, taking public comment, and issuing its final rule thereafter. The WIPP Act does not preclude EPA from receiving public comment, and the absence of judicial review does not excuse unnecessary short-cuts.

§194.D-5: Dockets.

The rule should provide that dockets shall be maintained in timely manner in New Mexico (i.e., filings completed within three business days of filing in Washington, D.C.). To enable prompt filing in New Mexico, DOE and others should be required to send copies of filed materials direct to the New Mexico dockets. Further, dockets should be maintained in three locations in New Mexico, which we suggest should be Albuquerque, Carlsbad, and Santa Fe, and the rule should so provide.