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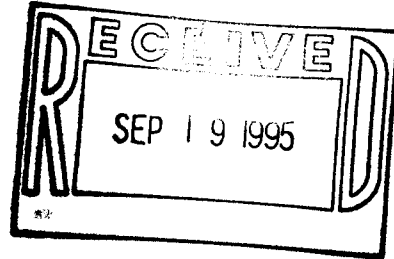
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Environmental Protection Agency
Docket No. A-92-56, Air Docket
Room M-1500 (6102)
401 M Street, S.W.
Washington, D.C. 20460



To The Docket:

Enclosed are comments and draft regulatory language concerning the proposed 40 CFR Part 194 compliance criteria for the Waste Isolation Pilot Plant. These comments and draft language are in addition to those submitted previously, including the submission dated April 28, 1995 and the earlier submissions dated March 30, 1993 and February 22, 1994 as well as the oral comments by the Attorney General at hearings on March 23, 1995. We request that the Agency consider these previous comments as well as those submitted today in deciding on the contents of the final rule.

Among the principal points made in the following comments are:

1. Drilling activities to be considered in assessing the likelihood and consequences of human intrusion may not be limited to exploratory drilling. It cannot be assumed that exploratory drilling would disclose the presence of the repository.

2. The Agency cannot lawfully authorize changes in the terms of certification in a "determination" proceeding pursuant to §8(f) of Pub. L. 102-579.

3. The Agency should articulate criteria for its approval of quality assurance programs for "old data."

4. The rule as to models and codes should require DOE to discuss conceptual models considered and rejected, to include covariance in its models, and to show a high degree of agreement between models and measured data.

5. The waste characterization rule should be redrafted to make clear how a waste characterization study will lead to limiting values for waste acceptance characteristics. It should require the study to be submitted one year in advance of the compliance application.

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6. Future states assumptions cannot be applied to institutional controls.

7. The expert judgment rule cannot be limited to formal elicitations. Further, it must be revised to specify methods to resolve differences among members of the expert panel.

8. Peer review should be required for any part of the compliance demonstration that is not subject to checking by a technical review.

9. The Agency should adopt as final its proposal to measure the radionuclide content of the inventory 100 years after disposal.

10. Human intrusions and activities to be considered cannot be limited to drilling and should include mining, waste water disposal, enhanced petroleum recovery efforts, and other activities.

11. The Agency must require DOE to show compliance with the containment requirement at the level of the 85th to 90th percentile. Probability distribution functions must be supported by data.

12. No credit may be allowed for the supposed effectiveness of passive institutional controls in reducing human intrusion.

13. The engineered barrier requirement must be given independent force. It is not satisfied by a showing of compliance with the containment requirement, because of the uncertainties in such a showing and the nonconservatism of that rule. The engineered barrier study should be submitted one year in advance of the application. Further, the rule should include a quantitative release limit.

14. We supply draft regulatory language for the public participation provisions.

The draft language submitted today concerns certain of the regulations on which we have commented, but not all of them. We have drafted language where such language would assist in making clear the action that the Agency should take.

The Agency originally made known its intention to allow a 60 day public comment period following the submission of the DOE draft compliance certification application; however, only 45 days have been allowed. In consequence, our comments and those of other public participants may not be as effectively presented as they would have been. We regret the Agency's decision to shorten the comment period.

We understand from Agency personnel that it is intended to submit the compliance criteria, in form deemed final by the Agency, for further review by the Office of Management and Budget and other Executive agencies, including the DOE. Such action would be contrary to the intent of Pub. L. 102-579 and the applicable Executive Order, No. 12866. We request that the Agency publish its final regulation without OMB review.

Thank you for considering these comments. We look forward to the Agency's favorable action and stand ready to assist in any way to that end.

Very truly yours,

Lindsay A. Lovejoy Jr. (by AB)

LINDSAY A. LOVEJOY, JR.
Assistant Attorney General

Comments of the Attorney General of New Mexico
on Proposed Compliance Criteria for the Waste Isolation Pilot Plant
September 15, 1995

The following comments concern the proposed WIPP compliance criteria, 40 CFR Part 194, published in the Federal Register at 60 Fed. Reg. 5766 (Jan. 30, 1995). These comments are in addition to those submitted by our office on April 28, 1995:

We discuss the individual regulations in the order of the proposal. Questions on which the Agency requested comment are addressed in connection with the rule to which they pertain:

Subpart A--General Provisions

§194.01: Purpose, scope, and applicability.

The "applicability" statement does not clearly cover proceedings other than the initial certification proceeding and the subsequent determination proceedings. Clearly, there may be other proceedings before the Agency wherein Part 194 will apply, and the applicability of these rules should not be left in doubt.

§194.02: Definitions.

The comments by DOE dated May 5, 1995 ("DOE Comments") request that the definitions of "human activity" and "human intrusion" be limited by the phrase "inadvertent and intermittent exploratory drilling." Such a step would be a serious mistake. The Agency has already determined that the drilling activities to be considered in applying the disposal standards to WIPP "would include, but would not be limited to, exploration for and development of oil and natural gas resources" and "include, but would not be limited to, exploration for potash, withdrawal of water--whether for purposes of drinking, irrigating or controlling dust--and drilling for other resources." (Addendum at 51). DOE may be asserting that it should be assumed that exploratory drilling would disclose the repository (DOE Comments at I-15). Whether such would be the case, examining the question in light of current drilling practices, is at best speculative. DOE's Draft Compliance Certification Application ("DCCA") July 1995 update contemplates that in some circumstances the presence of the repository would go undetected by the driller (Appx. CUTTINGS at 5). It would be erroneous to assume otherwise at the stage of drafting regulations. The Agency has accordingly concluded that "the approach outlined above for assessing the likelihood and consequences of human-initiated processes and events is more appropriate for the WIPP than the method discussed in the guidance [Appendix C]" (addendum at 60).

The comments by Sandia International Laboratories dated April 27, 1995 ("SNL Comments") state that by virtue of the definitions of "human intrusion" and "human activity" the term "undisturbed performance" in 40 CFR Part 191 now includes "human activity."

Such a result is not inappropriate. The exclusion of human intrusion from "undisturbed performance" is necessary because human intrusion may result in large individual doses, and undisturbed performance is the context for analysis of individual and groundwater protection performance. However, the Agency has not found that large individual doses would result from "human activity." Thus, the exclusion of "human activity" from analysis of individual and groundwater protection would not be justified.

Sandia also suggests definitions for the terms "expert" and "expert judgment." (SNL Comments at 194.2, p. 3) We agree that Part 194 should include criteria of professional qualification that one who undertakes to express an expert judgment should meet. They would probably best be placed in §194.26, the applicable rule. We discuss the issue further there. We strongly disagree that judgments to which the rule on "expert judgment" applies can be limited to formal elicitations. If such were the case, important decisions could be made in an informal manner and incorporated into the performance assessment without any demonstrable basis or record.

The definition of "population of CCDFs" needs clarification as to whether it means the entire population of CCDFs which would be generated from sampling values of parameters through an infinite number of iterations, or the CCDFs generated from sampling of particular values and generation of specific vectors using the sampling results--the "parameter values used in compliance assessments." It seems likely that the first meaning is intended, and the language could be clearer. Further, the SNL comments seek to change the standards of §194.34(b) in the definitional provisions, i.e., by inserting the criterion of 90th percentile and 90% confidence. If the substantive provisions are to be changed, such should be done in the rule itself. We discuss the issue further there.

The same comments apply to the request to modify the definition of "population of estimates."

It should be reemphasized that a "modification" cannot properly be adopted in a "determination" proceeding, since such a proceeding has the sole purpose of determining whether WIPP "continues to be in compliance" and does not incorporate rulemaking or judicial review. We add this cautionary note, since it is clear that DOE is seeking authority to change waste characterization requirements, and to admit waste previously prohibited, in a determination proceeding (DOE Comments, at II-7).

§194.04: Conditions of compliance certification or determination

DOE proposes a major change in the certification procedure established by the WIPP Land Withdrawal Act of 1992 (the "WIPP

Act") in the guise of a minor rulemaking alteration. DOE proposes that the Agency authorize itself to make a "modification" of the terms of certification in a WIPP Act §8(f) determination proceeding, in which there is no rulemaking, public comment, or judicial review. Thus, DOE candidly states that it may seek to "modify the application to include wastes that were not contained in the original application for disposal at WIPP." (DOE Comments at II-7). Such action would be illegal. We have already explained at length that phased certification conflicts with the terms of the WIPP Act. (see our April 28, 1995 comments at 42-46).

If, however, the Agency were permitted by law to consider groups of waste in phases, it surely would need to do so by rulemaking. The sole purpose of a §8(f) determination--which is issued without a rulemaking--is to find whether WIPP "continues to be in compliance with the final disposal regulations" (WIPP Act §8(f)(2)). Such a finding is to be made on the basis of "documentation of continued compliance"--i.e., information that the condition and activities at the facility to date comply with applicable law and regulations. There is no authority to employ §8(f) to seek approval of new hypothetical future conditions and activities, and any attempt to do so would be a serious evasion of the law's requirements.

The Agency should also reject DOE's request for express recognition of authority to apply for and receive authorization for "phased disposal" (DOE Comments at II-9). "Phased disposal" is contrary to law and should not be authorized by regulation.

DOE also requests that it be relieved of the requirement that, in event certification is revoked, waste would be retrieved to the extent practicable (DOE Comments, at II-7). But to assume that revocation might be considered without weighing the alternatives is unrealistic. On the other hand, to allow waste to remain at a site where certification has been revoked is unthinkable. The provision (subsection (b)(1)) should remain.

Sandia would have waste be removed in event of revocation only if its removal would not violate existing regulations that protect occupational health and safety (SNL Comments at 194.4 p. 1). Probably waste removal could be carried out lawfully, if desired; thus, the condition is unnecessary. In any case, if there is a conflict of regulations, the Agency should have the authority to resolve it.

Sandia also asks that the Agency add terms, stating that a "reversible potential violation" of §191.13 is grounds for suspension, and an "irreversible potential violation" is grounds for revocation of certification (SNL Comments, at 194.4 p. 2). The concept of "reversibility" may help to guide the Agency in considering action in event of a probable violation, and we agree with this suggestion. Sandia requests that the rules require that

a suspension be lifted on "submittal and implementation" of an approved remedial plan. "Implementation" is not defined; we believe it would be best to say that the suspension will be lifted when its cause has been resolved.

DOE complains that the obligation to report that "a release of waste from the disposal system to the accessible environment in excess of what is permitted under the disposal regulations has occurred or is likely to occur" is a duty that has nothing to do with the disposal standards and instead belongs in guidance for Subpart A. Although we have suggested clarification of the term "permitted," DOE's objection is unfounded, because the rule plainly asks for reports when DOE learns that an impermissible release is "likely," i.e., will probably occur post-disposal. For example, DOE might learn that data underlying the certification were in error, and a violation is likely. Clearly, DOE should be obligated to report such a fact.

Subpart B--Compliance Certification and Determination Applications

§194.11: Completeness and accuracy of compliance application

The Agency has sensibly noted that the one-year period to act on a certification application pursuant to §8(d) of the WIPP Act cannot begin until DOE has submitted a complete "application for certification of compliance" (§8(d)(1)(A)). DOE objects that the statute requires EPA to act within one year of receiving the application, even if it is not complete (DOE Comments at II-11). However, the process of determining the completeness of an application is a familiar one in the permitting context. For example, the Agency's permitting procedures state that "[t]he Director shall not begin the processing of a permit until the applicant has fully complied with the application requirements for that permit." (40 CFR §124.3(a)(2)). Further, "[t]he effective date of an application is the date on which the Regional Administrator notifies the applicant that the application is complete as provided in paragraph (c) of this section." (40 CFR §124.3(f)). Common sense calls for the same practice here.

The requirement that the application be found accurate simply reflects an aspect of completeness. If the material contained in the application is inaccurate, the Agency faces a process of amendment and supplementation, the length of which is indeterminate and largely controlled by DOE. Because of the one-year deadline, the Agency must find that that process is not needed before deeming the application complete.

§194.14: Content of compliance certification application

The proposed rule states that the applicant may be required to set forth "additional information" considered necessary for a determination of compliance. We agree that the Agency must retain

the authority to require submissions of information not previously required. It should be noted, however, that when the application is supplemented at the Agency's request or otherwise, the public shall have an opportunity to comment on the new matter.

DOE's comments suggest the use of notices of deficiency (NOD) or requests for additional information (RAI) to obtain further information from the applicant. We have pointed out the importance of public opportunity to comment on the completeness of the application. Should the occasion arise for the Agency to consider seeking further information, the public should have an opportunity to comment on the scope and form of the request.

Subpart C--Compliance Certification and determination

GENERAL REQUIREMENTS

§191.21: Inspections

DOE objects to the Agency's proposed authority to inspect the WIPP site and locations which generate compliance-related data, asserting that there is no statutory authority for such powers before a certification application is filed (DOE Comments at II-15). However, DOE and EPA have engaged in exchanges of technical data for many months, and DOE has now submitted a draft application to EPA, seeking comment. The pre-application processes should be more thoroughly regulated, not less so. When the Agency is engaged in a review of a draft application, it plainly has use for inspection powers, and they should be retained. Indeed, we have pointed out the need to allow post-certification access to the Agency as well (see our April, 28, 1995 comments, at 7).

The importance of data access by third parties, particularly the parties named in §17 of the WIPP Act, must be emphasized. The compliance process is moving at an accelerated pace, and quick access to information is becoming quite important. Congress has provided in the WIPP Act for access to information. The Agency, as the responsible regulatory agency, should adopt provisions effectuating the statutory data access.

Some Agency personnel have commented that a rule providing discovery rights would give little practical benefit, since the party seeking disclosure would be required to satisfy the Agency that the materials sought are pertinent to a compliance determination, and in such case the Agency would demand them anyway under the existing rules and would require that the materials be put in the docket. However, discovery rights, once put in place, are often self-enforcing. Thus, it cannot be assumed that such rights will require the Agency's intervention at every turn.

Moreover, the current system, under which third parties may convince the Agency that certain information is important to the

compliance decision, is not effective. Frequently, Agency staff simply are not pursuing the same inquiries on the same schedule as third parties and do not choose to look into a new issue. As a result, the importance of a given document is simply not assessed. Existing practice is no substitute for disclosure rights, such as those available in NRC proceedings (see 10 CFR §§2.740-2.744).

§194.22: Quality assurance

The proposal states that data and information collected before implementation of the §194.22(a) QA program may be qualified by a QA program equivalent in scope and implementation or "an alternative method approved by the Administrator for use at the WIPP." No criteria are supplied for the Administrator's approval. As the 1995 Background Information Document states, ASQC E4 requires that "any data obtained from sources that did not use a quality system equivalent to ASQC E4 shall be assessed according to approved and documented procedures" (1995 BID at 4-18). If the proposed rule is adopted there still will be no approved and documented procedures for the use of old data.

DOE (DOE Comments at II-19) and Sandia (SNL Comments at 194.22 p.2) propose language to describe criteria, but the factors to be considered are described only generally, and sometimes unsatisfactorily; Sandia suggests as sufficient quality assurance publication in peer-reviewed professional literature and confirmation by the original investigator, neither of which is well-defined or on its face sufficient. Further, the standard suggested by DOE prescribes that "[t]he organization using the data shall establish procedures for the data qualification process considering both technical and quality assurance program criteria." (NQA-3 Supplement 3 SW-1, at 12).

In this situation, DOE may develop and apply a review process for old data which it will present for public comment only at the time of the application. It is the intent of the WIPP Act that the Agency articulate criteria for approval of the application before the application is submitted. The Agency has not done so to date. In February 1995 the Agency held a technical workshop at which one of the principal issues studied was the qualification of existing data. The background materials for the session emphasized that available guidance documents do not contain implementation procedures:

"The U.S. Nuclear Regulatory Commission (NRC) has issued NUREG-1298 (Generic Technical Position, Qualification of Existing Data for High-Level Nuclear Waste Repositories). NUREG-1298 identifies alternative methodologies for qualification. However, NUREG-1298 is a general guidance document and does not provide detailed implementation guidance as to how to apply these methodologies or how the decisions to qualify or disqualify data are to be determined. There is no industry experience available at

this time for the QED process to qualify existing data for the nuclear waste repositories. Therefore, NUREG-1298 generally serves as a starting point for both DOE and EPA on this matter." (Qualification of WIPP Existing Data, prepared for US EPA Technical Workshop, Feb. 14-16, 1995).

The current Sandia National Laboratories QA procedure, QAP 20-3, suggests the range of issues to be addressed in the necessary rule. Information to be assembled concerning existing data includes the work plan, procurements, test methods and procedures, qualifications and training records, construction records, equipment used, calibration records, sample descriptions and handling, data acquisition systems, data records, any reports generated about the work, any correspondence, and records of any verifications and assessments. The rule should so require.

Further, there are important issues to be addressed involving issues such as (a) independence of the initial reviewers, (b) necessary tests to be met by data which are deemed qualified (such as the nature of QA procedures deemed equivalent), (c) QA requirements to be met by corroborative data, (d) relationship of corroborative data to data in question, (e) QA requirements as to confirmatory data, (f) independence of peer reviewers, and (g) criteria for peer review of data which, by hypothesis, do not meet current standards.

The hard questions, in our view, involve data which are not found self-qualifying. We do not expect that such data can effectively be confirmed by other data, since the other data will either be independently sufficient for the purpose, or it will be irrelevant. Corroboration must, in other words, be direct.

Peer review is likely to be much-used, and the rule must call for true independence and adherence to NUREG-1297, Peer Review for High-Level Waste Repositories. However, peer review is at best awkward in reviewing data that are, by assumption, not fully supported. Peer review is generally used to address issues of judgment, after methods of checking through testing, alternate calculations, or reference to previously established standards or practices have been exhausted (NUREG-1297 at 2). But the issues with old data may concern not judgment but the absence of data or records of various kinds. "Peer reviews should not be used as a substitute for readily collectible data. Conclusions based on inadequate or limited data cannot be improved by subjecting those conclusions to the peer review process." (NUREG-1297, at 5) How problems of the absence of data or records can be cured by having other scientists look at the existing records is not clear.

It will be important for the peer reviewers to have a clear statement of the precise question to which they are expected to address their judgment and to articulate their conclusion. Peer

review is not the exercise of intuition, and so there must be a record of it. (see NUREG-1297, at 4-5).

The final rule should also make clear, as does the proposal in subsection (b), that its restrictions apply to the application, not to comments and submissions made by members of the public.

The DOE comments object to the requirement of information establishing compliance with certain quality indicators, listed in subsection (c) (DOE Comments at II-17). The DOE comments do not convey the problem clearly, stating only that the requirements are "difficult" to apply to data already collected, that comparability and verification are "technically impossible to apply to existing data," and that validation is "not applicable" because of the 10,000 year period.

DOE's statements should not be grounds for amending the proposal. The 1995 Background Information Document states that the Agency's QA publication, EPA QAMS-005/80, has been adopted voluntarily by DOE (at 4-2, 4-7, 4-36). Moreover, EPA QAMS-005/80 requires that each QA project plan be prepared based on consideration of inclusion of "QA objectives for measurement data in terms of precision, accuracy, completeness, representativeness, and comparability" (§3, p.4). Further, "[s]pecific routine procedures to be used to assess data precision, accuracy, and completeness of specific measurement parameters involved" are a mandatory requirement (id. 2). A plan must also describe criteria used to validate data integrity (§5, p.12). The document states that a QA plan as described is mandatory for WIPP: "Each intramural and extramural project that involves environmental measurements must have a written and approved QA Project plan. All 16 items described previously must be considered and addressed." (§8, p.1). Consequently, the elements of proposed §194.22(c) are effectively required already and should be retained in the final rule.

The suggestion by DOE and Sandia (DOE Comments at II-18; SNL Comments at 194.22, p.1) to add the qualifier "where applicable" simply begs the question, where are the requirements applicable? It is no solution simply to suggest that in some undescribed circumstances the requirements may not apply. The suggestion should be rejected.

§194.23: Models and computer codes

DOE objects to the requirement of a listing of the conceptual models considered and rejected, saying that, taken literally, the rule would call for a list that is infinitely long (DOE Comments at II-21). However, the question of conceptual model uncertainty is so important and otherwise neglected that the requirement should be retained. The practical problem is not so unmanageable as DOE claims. The models to be discussed can be limited to those that

limits. Data in the Baseline Inventory Report is so doubtful that projections of the performance of the repository cannot be made from it. Moreover, if limits (waste acceptance criteria) are placed on certain characteristics, the values in an inventory report would change because of covariance. How will this be dealt with?

How will the Agency determine the maximum amount of a "category" of waste that may be emplaced in a container, room, panel, etc.? What components of the study will give rise to such requirements?

How will the uncertainty of DOE's future compliance with the values, ranges, maxima, and other waste acceptance limits be determined? How will such data be fed into the study and into the subsection (d) showing?

There is discussion of a "system of controls" to enforce the ranges (and presumably the values and maxima) applicable to waste characteristics and categories. However, the criteria that such a system must meet are not clear. The Agency should require that the system be applied in fact to existing waste, and the results supplied, so that the Agency can assess the effectiveness of the characterization methods and the validity of the characterization data underlying the PA and the study. If the existing waste is not characterized for purposes of the application, the Agency must demand other and far stronger support for assertions of the accuracy and uncertainty achieved by the characterization methods.

Rather than simply stating that the Agency may oversee characterization compliance by audit and inspection, the rule should state also that regular reports on compliance with waste characterization requirements shall be made by DOE, that they shall operate, when submitted, to reopen the certification rulemaking, and that the Agency must approve or disapprove the report. Thus, the public will be allowed to comment on the results of waste characterization--something they are otherwise precluded from doing if the Agency does not require waste characterization before the compliance determination--and to seek judicial review if necessary of the issue of DOE's compliance with such requirements.

The question of waste characterization is so complex that we suggest that the Agency require the study to be completed one year before the compliance certification application is submitted. The additional time will enable the Agency and the public to comment on the study as originally done, to suggest refinements (e.g., study of alternative combinations of waste acceptance ranges and limits), and will enable DOE to check the feasibility of characterization methods for the likely waste acceptance criteria. The revised study may then be submitted with the application.

§194.25: Future state assumptions

were actually the subject of study and discussion, including models suggested by third parties. The explanation of the reason the models were not used should include an assessment of the probability that the rejected model is the valid one for the site and repository.

The Agency should reject DOE's suggestion that models and codes not be required to handle covariance (DOE Comments at II-23; see also SNL Comments, at 194.23, p. 3). If covariance is not accounted for, the sample vectors will incorporate values which either could not coexist or are highly unlikely to do so. Such vectors will generate a CCDF curve which is not equally likely, with other curves, to depict the behavior of the repository.

DOE's objections are without substance. DOE says that there are no empirical data on which to base a treatment of covariance, but it does not say that such data could not be obtained. It may be that, in some sense, covariance is not consistently related to conservatism, but the fact is that we do not know whether it is conservative or not to omit covariance, because representing covariance has not been attempted. To omit covariance simply compromises the validity of the sampling methods and renders the models less accurate to an uncertain degree. Because covariance can be handled, it should be done.

The Agency requests comment on the factors to consider in evaluating models (60 Fed. Reg. at 5771, col. 1) In this connection, the proposal has dropped the requirement, contained in the preliminary draft, that a high degree of agreement exist between the model and measured data, if observational data are available (Jan. 28, 1994 preliminary draft, at 15). The requirement should be put back. Part 191 requires a performance assessment which "examines the effects of ... processes and events on the disposal system ..." (40 CFR §191.12), an assessment which implies accurate modeling. Thus, there must be "reasonable projections of the protection expected from all of the engineered and natural barriers of a disposal system" (Appx. C). The argument (e.g., SNL Comments, at 194.23, p. 3) that agreement cannot be required because of the length of the 10,000 year period modeled amounts to a statement that extrapolation is, in principle, indefensible, which cannot be accepted.

If a model is conservative, in the sense that it leads to an overstatement of releases in all circumstances, it should be accepted also. However, the Agency must be cautious about judging a model conservative based on a top-of-the-head assessment, in light of the number of coupled nonlinear processes involved.

§194.24: Waste characterization

The rule needs revision, which should begin with a statement of the objectives of the rule. We suggest the following aims:

1. To cause DOE to adopt a waste characterization process which will confirm that the waste population (either of the repository or some subset such as drum, canister, room, panel) corresponds in relevant respects to a projection of its characteristics, on the basis of which the Agency found that the repository will comply with the disposal regulations.

2. To enable the Agency, in considering a compliance certification application, to compare different waste characterization plans as they may affect certainty of compliance.

3. To furnish assurance that a proposed characterization plan is practically achievable.

The rule in its present form does not achieve these objectives. The Agency needs to redraft it with these aims in mind. Part of the task is the need to recognize that PA will employ probability distribution functions as to various waste characteristics. Thus, the 1992 PA was premised on a range and probability distribution of the volume fraction of combustibles and the volume fraction of metals and glass (see 1992 PA Vol. 3, at 3-60, 3-61). Presumably, the final application, which will be the basis for the certification decision, will contain probability distribution for such characteristics and perhaps others. Moreover, DOE presumably controls waste characteristics and therefore can be required to comply with certain rules governing those characteristics.

The question then arises of deciding on the rules. Such rules are likely to take the form of a value, range of values, or maxima for relevant characteristics or categories, as the proposed rule suggests. The proposal states that these rules will be derived from a study by DOE of characteristics important to the containment of waste and that DOE will show that the repository will comply with the disposal regulations for "all combinations of waste" falling within the range allowed by the rules (subsections (b) and (c)).

What the proposed regulation does not explain is how the study is to give rise to values, ranges of values, and maximum amounts of waste categories. A performance assessment, showing compliance based on projections of the probabilities of certain waste characteristics, does not lead directly to the specification of any absolute limits on such characteristics. Discussions with EPA staff suggest that they intend the study to go beyond a probabilistic analysis (as to waste characteristics) to examine repository performance using fixed assumptions as to various waste characteristics. The regulation should explain how such a study will be designed and how the alternative assumptions as to waste characteristics will be developed.

As proposed, the rule seems to place the burden on the applicant to show that a particular characteristic is not important to containment, but it applies only to certain named characteristics and to characteristics which affect solubilization and mobilization of radionuclides, colloid formation, gas production, criticality, and heat generation. There may be different views on what affects those factors to what extent. How will the differences be resolved?

Who will pick the various combinations of possible waste characterization limits that will be studied? What likelihood of achievability (theoretical and practical) must the various combinations have? How will the sensitivity of containment to various waste characteristics be measured and compared?

How will the "value or range of values for characteristics identified as important to the containment of waste" be established on the basis of the study? Will the values apply to the contents of the repository as a whole, or to the contents of a room, panel, or container? Will the limits be absolute or proportional? Note that the limits might be both per container and for the entire repository.

In the study what values will be assumed for waste characteristics other than those assumed fixed or limited in the study? Will the study be based on waste inventory data such as the current Baseline Inventory Report or on more defensible data?

What criteria will be used by the Agency in assessing the sufficiency of the "value or range of values"? What role will the Agency play in selecting among various combinations of values and ranges of values for various waste characteristics? The study may show compliance as to more than one combination of waste acceptance criteria, but the certainty of compliance may be higher as to one combination than another. How will the combination that is incorporated in a certification be selected, and on what basis?

What is meant by the rule calling for a demonstration of compliance for "all combinations of waste whose characteristics fall within the range"? Is this a probabilistic analysis, with the distribution functions modified to reflect the permissible ranges, or some other kind of analysis? The rule suggests that it is to be a worst-case analysis as to the waste characteristics. However, DOE may argue that the analysis should take the existing probability distribution functions and impose a cutoff at the limit of the permitted range. Such would be erroneous, since a certification subject only to a range or limit would allow the entire waste inventory to hit the limit of the range.

In the study will all waste characteristics be analyzed using ranges and limitations? Presumably not, but if not, attention must be paid to the characterization of the factors not subject to

The proposed regulation states that it is assumed that "characteristics of the future remain what they are today." However, other compliance criteria state that active institutional controls shall not be assumed to make any contribution for more than 100 years after disposal (§194.41(b)) and that passive institutional controls shall be assumed to have only such effect as is supported by a demonstration in the application (§194.43(c)). The rule on future states should prevent any conflict with the other provisions by stating simply that future states are assumed to remain, "Provided, That such characteristics are not related to geologic, hydrologic, or climatic conditions; or to institutional controls."

There must also be some concern about how the current conditions and practices will be established. See, for example, the documents concerning well abandonment practices referred to by the EEG (EEG Comments, at 9). As to that aspect of drilling activities, there may be no single current practice. The rule should state that the applicant bears the burden of establishing the current state as to each point of fact asserted as the basis for a future state assumption. Proof should take the form of systematically gathered and defensible data. Variable parameters must have a defensible range and distribution, and where a point value is used, it must be defensible as the invariable current practice or as clearly conservative.

DOE and Sandia suggest that the consideration of future climate changes should be limited to effects of recharge, rather than precipitation or evapotranspiration (DOE Comments, at II-28; SNL Comments, at 194.25, p. 2). There is already information in the docket about the possible future effects of recharge on flow direction and dissolution within rock bodies (see material presented by Prof. Roger Anderson at Feb. 16, 1995 EPA workshop). The Agency should not insert a proviso which would have the effect of limiting consideration of such factors.

§194.26: Expert judgment

The Agency has solicited comment on the way in which expert judgment can be incorporated into compliance assessment (60 Fed. Reg. at 5773, col. 2). We have submitted comments prepared by Prof. Elisabeth Pate-Cornell, addressed, inter alia, to the elicitation of expert opinions. As discussed therein, the aggregation of opinions of multiple experts should be carried out by a process which includes means to reduce or eliminate the range of disagreement, including requirements that all experts (a) agree on the substance of the question, (b) consider and account for all available data, and (c) articulate the relationship between the data and their judgment as to the probability of the various models. In addition, to aggregate separate opinions, there should be an interactive process wherein the experts (d) discuss the data, (e) explain their models, (f) discuss the probability of each of

the models, (g) assess such probabilities, and (h) generate a composite distribution. We have incorporated these concepts in the draft rule submitted with these comments.

Sandia suggests (SNL Comments, at 194.2, p. 3) that an expert be defined as one who qualifies as a peer under NUREG-1297, §§III and IV(3), i.e.: "The technical qualifications of peer reviewers, in their review areas, should be at least equivalent to that needed for the original work under review and should be the primary consideration in the selection of peer reviewers. Each peer reviewer should have recognized and verifiable technical credentials in the technical area he or she has been selected to cover. The technical qualifications of each peer, and hence of the peer review group as a whole, should relate to the importance of the subject matter to be reviewed." (§IV(3)). The first sentence of the definition does not suit the situation exactly, because the main purpose of expert judgment is not to review original work. However, the rest of the definition is quite appropriate and should be included in the rule on expert judgment.

DOE's proposal (DOE Comments, at II-29,-30), if accepted, would mean that expert judgment could be used in support of a compliance application without any restriction upon the selection of experts, the manner in which judgment is rendered, or the occasions on which such judgment may be used. Sandia's proposal is effectively similar (SNL Comments, at 194.26, p. 3). Expert judgment would be available under the DOE proposal to substitute for scientific data for such key purposes as "development of conceptual models or of appropriate assumptions to use in the calculations." It is only when a formal elicitation is conducted--which occurs "when the applicant deems it appropriate"--that the protections of the rule apply. Such a change would eviscerate the rule.

The limitation on use of expert judgment is imposed to prevent DOE from introducing what function as demonstrated facts or data into the compliance application, when no experimental results or observations support them, and no formal process gives rise to such facts or data. The provisions should remain which allow such judgments to be used only when information could be obtained through data collection or experimentation, and which call for a structured process of elicitation.

DOE also requests that the rule be changed to allow participation by individuals employed by DOE or a contractor, provided that he or she demonstrates an absence of a conflict of interest (DOE Comments at II-31). However, it is precisely because it is so difficult to prove or disprove bias that a presumption is appropriate here. If expert elicitation is used, it should not remain unclear whether the result will be objectionable for bias. A clear rule which excludes certain persons on the grounds of

presumed bias is preferable to one which leaves uncertain the status of an important judgment.

Last, DOE would restrict the right of third parties to present information to the expert panel. Certainly, the opportunity to present such information would add to the credibility of a dubious process. It should not be deleted.

§194.27: Peer review

The Agency proposed a list of issues as to which peer review would be required to be conducted. Briefly, they were:

1. engineered barrier study
2. scenario selection
3. quality assurance
4. models and codes
5. data supporting models and codes
6. waste characterization.

Since then the Agency has convened a meeting of the WIPP NACEPT subcommittee, stating in the materials that it is considering a new list of guidelines, calling for peer review of "critical program areas", which we paraphrase:

1. experimental design and selection of elements for study
2. methodology of data collection
3. studies, use of good science
4. scientific basis of understanding of natural processes
5. experimental data validity, especially critical data
6. assumptions made in performance assessment, conservatism

DOE objects generally to peer review, citing the cost and delay which would allegedly result (DOE Comments, at II-33). It should also be noted that DOE has had in place since 1986 a Performance Assessment Peer Review Panel. The panel has met since 1987 and has reviewed all published performance assessments, including the 1992 PA. That peer review has primarily concerned the documentation of the PA rather the data, modeling, and calculations.

Sandia also requests that the Agency drop the peer review rule, claiming that further peer review is redundant, since Pub. L. 102-579 provides for peer review by EEG and the NAS WIPP Committee. However, to say that peer review as structured under NUREG-1297 may--or may not--be carried out by EEG or the NAS, neither of which is controlled by DOE, is not the same as requiring that DOE demonstrate peer review as part of its compliance application. In fact, DOE has taken the position that the NAS "will not be able to meet the prerequisites for peer review defined in the proposed 40 CFR Part 194" (DOE Comments at II-49).

When EPA inquires as to the scope of appropriate peer review, its question must be understood within the purpose and scope of peer review described in NUREG-1297, Peer Review for High-Level Waste Repositories, which is cited in the proposed rule. So understood, the question almost answers itself. Peer review is appropriate for issues which are not satisfactorily checked by a technical review under agreed standards:

"A peer review should be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods essential to showing that the repository system meets or exceeds its performance requirements with respect to safety and waste isolation cannot otherwise be established through testing, alternate calculations or reference to previously established standards and practices." (NUREG-1297, at 2)

NUREG-1297 outlines several instances in which peer review should be used:

"Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing

"Decisions or interpretations having significant impact on performance assessment conclusions will be made

"Novel or beyond state-of-the-art testing, plans and procedures, or analyses are or will be utilized

"Detailed technical criteria or standard industry procedures do not exist or are being developed

"Results of tests are not reproducible or repeatable

"Data or interpretations are ambiguous

"Data adequacy is questionable--such as, data may not have been collected in conformance with an established QA program." (NUREG-1297, at 2-3)

It should be apparent that nearly all aspects of the performance assessment of the repository qualify for peer review under NUREG-1297. DOE suggests that the design, testing, development, and use of computer software may be reviewed for technical adequacy under existing practice (DOE Comments at II-33), and DOE should be allowed to so demonstrate and be relieved from a further peer review. However, few other aspects of the PA could be excused from peer review. For example, DOE says that conceptual models cannot be validated because of the long spans of time involved (DOE Comments at II-17); such situation calls for peer review.

Responding to the list in the recent peer review position paper, peer review is appropriate under the tests of NUREG-1297 for experimental design, data collection methodology, technical studies (such as studies of seals, engineered barriers, waste characterization, drilling methods, institutional controls, monitoring, resource site considerations, waste removal plans), scientific basis for scenario selection and construction, scientific basis for conceptual models, use of experimental data in constructing conceptual models and parameters, and conservatism of assumptions.

Peer review under NUREG-1297 includes a documented record of the review, a report by the peer reviewers, and a response to comments by the principal investigators. See NUREG-1297, at 4-5.

CONTAINMENT REQUIREMENTS

§194.31: Application of release limits

The Agency has proposed that the radionuclide inventory be determined on the basis of the calculated content of the waste at a time 100 years after disposal and seeks comment (60 Fed. Reg. at 5774, col. 1). As the Agency states, the content of the repository after 100 years will primarily constitute radionuclides with long half-lives, which should be the focus of attention in assessing the long-term performance of the repository. We concur with the Agency's approach.

DOE objects that the use of a 100-year value conflicts with the underlying logic of the approach developed for Part 191 (DOE Comments, at II-35). To the contrary, the use of a 100-year inventory actually fulfills the Agency's stated objective to "require alpha-emitting radioactivity from either high-level or transuranic wastes to be isolated with about the same degree of effectiveness." (47 Fed. Reg. at 58200, Dec. 29, 1982).

The Agency's contractor, Neil Numark, studied the application of the principle of equal effectiveness and concluded that to apply the Table 1 release limits to the same initial number of curies that is in 1000 metric tons of heavy metal does not lead to equal

isolation, because TRU waste and spent fuel contain different radionuclides, which decay at different rates, so that applying the release limits to the same initial curie content that is in 1000 MTHM means applying them to different amounts later. (Numark presentation, International High-Level Radioactive Waste Management Seminar, April 14, 1992). Numark suggested applying the Table 1 limits to the integrated curies over 10,000 years (id.).

A detailed paper by Numark and Phelps points out: "Equating initial inventories would mean that the Table 1 release limits would actually apply to different amounts of different waste streams later in the isolation period." (N. Numark and S. Phelps, Equivalence to 1000 MTHM of Spent Fuel: Application of 40 CFR Part 191 to Other Wastes, Feb. 1992, at 3). Thus, the one million Curie TRU unit, if applied at the date of disposal, would impose a standard on TRU waste that is only 12% as stringent as spent fuel at the 100 year point, 8% as stringent at 1000 years, and 16% as stringent at 10,000 years (N. Numark and S. Phelps, Feb. 1992).

Since 40 CFR Part 191 does not specify the time at which radionuclide content is to be determined, the Agency should fix that time in the compliance criteria. It is necessary, in doing so, to consider the effects of ingrowth and decay; indeed, that is why a date is needed. The 100 year date, based on studies by Numark and others, will bring the protections of 40 CFR Part 191 for TRU waste much closer to parity with the protections for spent fuel than would the suggestion to use the initial inventory. The 100 year date follows logically from the determination that active institutional controls may not be deemed effective after that point (see §194.41(b)). DOE objects to the use of a 100 year inventory but does not contest the fundamental point that it would bring the rule for TRU waste much closer to parity (DOE Comments at II-34, II-35, III-1, III-2).

§194.32: Scope of performance assessments

DOE asserts that the use of the term "sequences" would require that scenarios be constructed which reflect all possible sequences of all features, events, and processes which may affect the disposal system (DOE Comments at II-36). A reading of the rule shows that it does not so require. To be sure, in the construction of scenarios, all relevant sequences of events and processes must be considered, but the rule does not prescribe all possible sequences.

§194.33: Consideration of human-initiated processes and events

Comments by EEG make the important point about the need to consider solution mining, in addition to other methods of mining, in performance assessment (EEG Comments at 7). Further, EEG notes the possibility of an underground blowout as one consequence of the engagement of blowout preventers (at 8). EEG also mentions events

involving brine injection and enhanced petroleum recovery, which should be included (id.). Their comments also point out the possibility of crossflow between formations, resulting from drilling and ultimately causing dissolution of salt formations (id.). Such consequences of future drilling in the area should be examined.

The Agency must make clear how the "current practice in the Delaware Basin" (§194.33(b)(6)) and the borehole sealing (§194.33(b)[sic](1)) will be established. There must be systematically gathered data, not anecdotal evidence, for the relevant practices, and the applicant must bear the burden of proof. It will not be sufficient if DOE presents data that fail to examine the entire relevant time span and area.

The Agency must also note that the demonstration of current practice may not include activities which are sustained by active institutional controls past the 100 year point, nor may it include activities sustained by passive institutional controls without a demonstration, in addition, that such controls will survive and be effective at the relevant times. In that connection, see our comments on passive institutional controls, below.

DOE objects to the Agency's decision to include both exploratory and development holes in the calculation of drilling rates. The Agency has decided clearly that both types of drilling should be included (Addendum at 51). DOE claims that there has been a change from the basis that was used in the development of the disposal standards (DOE Comments, at II-37). In fact, in the analysis leading to Part 191 the Agency was aware of the prospect of development drilling but projected very little such drilling, because it assumed that the sites chosen would not be likely development targets (see the discussion in our comments dated April 28, 1995, at 18-19). There is no indication that the Agency wanted development drilling to be disregarded if a site were likely to experience it. Further, the guidance contained in Appendix C is specifically nonbinding and evolved well after the release limits were developed. The Agency is not bound to Appendix C.

DOE may be asserting that exploratory drilling would necessarily disclose the repository, so that any development drilling would be intentional intrusion (see DOE Comments, at I-15). However, the DCCA states that in some circumstances the repository may be penetrated without the driller being aware of its presence (see DCCA, July 1995 update, Appx. CUTTINGS, at 5).

As Sandia points out, the upper and lower limits of the drilling rate proposed by the Agency to constrain the analysis of human intrusion are "not the result of scientific or statistical observation. They are rough estimates by members of the Arthur D. Little, Inc. staff who have experience in resource exploration and recovery." One concern is that EPA is requiring an analysis of

historical data and bounding the results with generic 'rough estimates'." (SNL Comments, at 194.33, p. 9). Thus, Sandia does not support the limits in the proposed rule.

The Agency has sought comment on the definition of the Delaware Basin to be used in calculating relevant drilling rates (60 Fed.Reg. at 5774, col. 3). We reviewed Hills, J.M., Sedimentation, Tectonism, and Hydrocarbon Generation in Delaware Basin, West Texas and Southeastern New Mexico (1984), and suggest that the area depicted therein in Fig. 1 as the Delaware Basin should be the area of concern. The rule should state that the Delaware Basin includes all the surface and subsurface areas within the central basin area and the area overlying the Capitan Reef. The article examines the sedimentary history of the Basin with specific regard to hydrocarbon formation. Most of the Basin's hydrocarbons formed in Permian and earlier strata, and most formed at great depth. See Figure 13, which illustrates the depth of formations in which oil and gas have formed. It can be seen from the cross sections in Figures 3 and 4 that the hydrocarbon zones extend to and beyond the edges of the basin as defined in Figure 1 and do not end at the Capitan Reef.

DOE asserts that the area within the basin but excluding the Capitan Reef is "more like" the WIPP area than the area overlying the Capitan Reef, but DOE offers no data in support (DOE Comments at I-16). Sandia asserts that the area to be considered in calculating drilling rates should exclude the Capitan Reef (SNL Comments at 194.33, pp. 4, 13). It claims that the Capitan Reef has much higher resource production and potential than the sedimentary rocks enclosed within the reef (id. 13). However, Sandia neither cites nor supplies data supporting such assertions.

§194.34: Results of performance assessments

The selection of the determinative curve should be made with knowledge of the level of assurance which the Agency contemplated compliance would be shown. When 40 CFR Part 191 was originally adopted in 1985 it was seen primarily as the regulation covering disposal of spent fuel and high-level waste and only secondarily as the rule for transuranic waste. At the same time, EPA clearly intended to require that transuranic waste be isolated with about the same degree of effectiveness as spent fuel (47 Fed. Reg. at 58200, Dec. 29, 1982).

It is clear from the history of the regulation that EPA intended that compliance be demonstrated with a level of assurance higher than a simple preponderance, or better-than-even, probability. An EPA witness in hearings before the Science Advisory Board ("SAB") subcommittee noted that the Agency had not made its final decision, but the choice was clear between the "standards as constructed, such that one can comply with it by the normal type of use of reasonable assurance," meaning high

confidence, or, on the other hand, a test using nominal or expected values (Tr. July 13, 1983, at 72-73). The hearing participants generally equated the NRC standard of "reasonable assurance" with 90% certainty and expected that such would be the level of assurance required by the NRC (See Tr. Aug. 29, 1983, at 69; Tr. Sept. 20, 1983, at 18, 14). The EPA witness stated clearly that "reasonable assurance" does not mean 50% confidence (Tr. Sept. 20, 1983, at 11).

After the SAB report EPA issued several working drafts of 40 CFR Part 191, addressing the level of assurance. Working Draft No. 2 (which predated the SAB report) had called for determination of compliance on the basis of mean or "best estimate" values (Nov. 1, 1983, at p. 13). The SAB report had requested that EPA make clear that compliance by the median--i.e., a showing of a less than 50% chance of noncompliance--is the test (SAB Report, Jan. 1984, at 3).

The Agency did not adopt the median and in fact proposed that compliance be tested by the mean plus one standard deviation, which the Agency equated with 85% confidence in the case of a normal distribution (Working Draft No. 3, Feb. 1, 1984, at 15). Working Draft No. 4 (May 21, 1984) contained similar language, limited to projections made to support sealing and closure of the disposal system (at 81). The preamble stated that "the Agency believes that there should be an 85 percent expectation that the results would be in compliance with the disposal standards." (at 55). Continuing, the preamble stated that "the Agency believes that its intent can adequately be met if the implementing agencies determine, within a judgmental 'reasonable expectation,' that the numerical standards will be met." (at 55-56). Thus, in the Agency's thinking, "reasonable expectation" approximates 85% assurance.

Working Draft No. 5 (March 21, 1985) omits the reference to 85% assurance but retains the "reasonable expectation" language (at 12). Working Drafts No. 6 (June 15, 1985) and No. 7 (July 5, 1985) contain similar terms.

In issuing the final rule EPA stated that it "agrees with those commenters who suggested that allowing a 50 percent chance of exceeding the containment requirement release limits would not provide adequate confidence of achieving the desired protection of public health." (Response to Comments, Vol. II, at 2-5) Thus, there was a clear intent by the promulgating Agency to require something more than a preponderance of likelihood that the repository would comply.

The choice of determinative curve in the draft Part 194--the mean curve plus the 95% confidence factor--does not imply any specific fractile of the distribution or level of confidence. Some of the Agency's past remarks (e.g., in Working Draft No. 4) equate a mean plus standard deviation with a given level of assurance, but the current proposal does not expressly state a level of assurance.

The Agency has noted that with skewed distributions the mean may exceed certain percentiles, and the confidence limit will exceed the mean (1995 BID at 3-44), but the Agency has selected no percentile as appropriate and states that it "would be extremely difficult to justify any specific higher [than 50%] value" (Addendum at 65).

We have discussed in our previous comments the suitability of various tests of compliance. It is apparent from review of the history of the regulation that the Agency had a value in the area of 85% to 90% assurance as the target for determination of compliance. The submission by Prof. Paté-Cornell illustrates, from the viewpoint of scientific risk assessment, the need to analyze the assumptions contained in the compliance demonstration and, accounting for such assumptions, to show that the unconditional assessment provides "reasonable assurance" of compliance.

The Agency must articulate compliance criteria, and in this instance that means it must make a quantified statement of the level of assurance called for in demonstrating compliance with the containment requirement. We propose that the Agency start from the goal that the unconditional risk assessment have the aim of proving compliance to the level of 90% certainty--"reasonable assurance"--and from there establish the level of certainty called for in the conditional risk assessment.

This regulation also deals with the formulation of probability distribution functions. It has been noted that the formulation of probability distribution functions is not effectively constrained in the performance assessment process and that it may have dramatic effect on the outcome. For example, William W.-L. Lee shows in A Perspective on the 1992 Performance Assessment for the Waste Isolation Pilot Plant that the formulation of a probability distribution for plutonium solubility spanning a wide range not supported by data "resulted in a downward bias in estimating plutonium solubility, resulting in non-conservative consequences." (at 3) When solubilities are set at levels supported by data, the position of the mean CCDF is significantly changed (see Fig. 4).

Numerous probability distribution functions in the 1992 PA are derived similarly to that for plutonium solubility. Volume 3 of the 1992 PA describes each such variable parameter and its derivation. Under Sandia's procedures, subjective estimation plays a large role in development of probability distribution functions (see id. pp. 1-16, 1-17). Agency personnel pointed out recently that certain gas generation values for forthcoming analyses were arrived at "arbitrarily" (see Appx. E to SPM Iteration 2 Baseline Position Paper: Gas Generation in the Waste Isolation Pilot Plant, March 17, 1995). There is clear need for application of regulatory constraint to this process. We suggest that requirement of a minimum number of data points would usefully inhibit the formulation of probability distribution functions which are

entirely subjective. Possibly more important is the requirement that the form and parameters of the probability distribution function be justified objectively by its proponents. We include these suggestions in the draft rule.

DOE questions the Agency's requirement of a 95% level of confidence as to the high quantile (99%) CCDF. DOE states that a classical tolerance limit is not appropriate for a skewed distribution, such as the expected CCDF distribution here. DOE analyzes the number of samples required and concludes that 6.8 years of processing time would be required to meet the requirement of 95% confidence that the maximum CCDF exceeds the 99th percentile. We submit that DOE should present more than unsupported assertions as to the nature of the distribution and the time to perform iterations. If, on examination, the specified confidence level requires an unattainably large amount of computer time, we suggest that the Agency adopt a dual test for the high percentile: 95% confidence that the 95th percentile is reflected, and 75% confidence that the 99th percentile is reflected.

The Agency requests comment on the alternative of basing compliance on a single realization. We recommend against such course. The performance assessment includes multiple coupled nonlinear processes. To arrive at a "best estimate" value for each of many variable parameters would be very difficult. Moreover, the result may well be misleading, since it would ignore the range of possible values and interactions. As an example, a calculation was made in 1994 using "best guess" values for numerous parameters. "This calculation was made to show the non-linear relationship that exists between the input parameters and the model consequences after 10,000 years. As expected, the results from the "example" run did not match the mean or median of the consequences from the 50 runs with samples input parameters." Memorandum, Stoelzel, et al., to Anderson, Summary of 1993-94 WIPP Preliminary Undisturbed Repository Calculations, at 1 (Feb. 21, 1994). The memorandum noted: "The maximum migration distance reached for the Example Problem was 866 meters from the repository edge in Anhydrite A&B South. This was significantly less than the mean and median distances of the 50 consequences for that layer. Once again, this illustrates the extreme non-linearity of the system, and the value of the Monte-Carlo sampling method when experimental input data is unavailable." (id. at 4). The best-estimate approach, moreover, achieves no specific level of assurance of compliance. If this is the idea on which the Agency desires comment, we see little to recommend it.

ASSURANCE REQUIREMENTS

§194.42: Monitoring

DOE objects that a requirement of pre-closure monitoring is included, claiming that it exceeds the Agency's powers under

§191.14(b), concerning post-closure monitoring (DOE Comments at II-45). However, the power to require pre-closure monitoring derives from the Agency's authority to determine compliance with the containment and individual and groundwater protection requirements. Under Pub.L. 102-579, §8(f), the Agency has the obligation to entertain applications for a periodic recertification of continued compliance. It is appropriate for the Agency to require that DOE obtain monitoring data for use in such redeterminations.

It is also appropriate for the Agency to seek to obtain monitoring data before a determination of compliance, for the purpose of assisting the compliance determination. Such a provision was contained in the Agency's draft rule before it went to the OMB for review, and it should be reinstated.

§194.43: Passive institutional controls

The Agency must delete the proposed subsection (c), allowing credit for the effectiveness of passive institutional controls. As DOE itself notes (DOE Comments at II-47) there is no criterion in the proposed rule for allowance of quantitative credit for effectiveness. Consequently, the rule as proposed does not disclose the criteria that the Agency would use in allowing credit and does not qualify as a compliance criterion pursuant to Pub. L. 102-579, §8(c).

The Agency has long recognized the lack of a credible system to assess credit for the effectiveness of passive institutional controls, but it has never developed such a system. Daniel Egan of EPA testified to the SAB in 1983 that the issue of credit had not been resolved: "What credit we might take analytically for passive controls, I don't know yet but that's something we'll probably play with ...I don't know what good numbers would be. But, that's one thing we want to play with." (Tr. July 12, 1983, at 160-61). One of the subcommittee members commented that there was no coherent approach to the issue: "This is one topics, another one of those topics in which people talk a lot but don't have much information that's helpful. I mean you're just kind of at sea, bullshitting around beers or something." (Id. 162). Mr. Egan recognized that there are unanswered questions of projecting the ability of markers to survive and deter intrusion (Id. 166). He remarked later that he did not agree with the approach taken by the NRC in 10 CFR Part 60, under which intrusion would be discounted: "I personally disagree with, if you read Part 60 carefully, they seem to feel that passive institutional controls have the potential to be perfect over 10,000 years. And I can't buy that....And they further say that even if they are not perfect, that they kind of universally categorize human intrusion as a very unlikely event, with some rough comments as to what we consider to be a very unlikely event. And my own assessment is, I also don't believe the probability of human intrusion is likely to be that low." (Tr. July 13, 1983, at 141).

Drafts of Part 191 initially directed the assumption that passive institutional controls "can keep the chance of inadvertent human intrusion very small as long as the Federal Government retains such passive control of disposal sites." (Working Draft No. 2, Nov. 1, 1983, at 14). Later drafts stated that it should not be assumed that passive controls can eliminate the chance of inadvertent intrusion (Working Draft No. 3, Feb. 1, 1984, at 16; Working Draft No. 4, May 21, 1984, at 84). Notably, in developing the Appendix stating assumptions concerning human intrusion, the Agency estimated that after taking into consideration each repository's site, design, and passive controls, drilling might be assumed to occur at a rate of 30 drillholes per square kilometer per 10,000 years (at 89); thus, the assumption that the rate of intrusion would be "very small" was still consistent with significant levels of drilling.

In Working Draft No. 5 (March 21, 1985) the Agency dropped the statement that passive controls can keep the chance of inadvertent intrusion "very small" and said only that the Agency "believes" that passive institutional controls "can substantially reduce the chance of inadvertent human intrusion as long as such passive institutional controls endure and are understood" (at 23)--a statement that is both inherently weaker and expressly conditioned on the survival and comprehensibility of the controls.

In Working Draft No. 7 (July 5, 1985) the language of the current Appendix C was introduced: "The Agency assumes that, as long as such passive institutional controls endure and are understood, they: (1) can be effective in deterring systematic or persistent exploitation of these disposal sites; and (2) can reduce the likelihood of inadvertent, intermittent human intrusion to a degree to be determined by the implementing agency." (at 23). The Agency explained: "Specific judgments about the chances and consequences of intrusion should be made by the implementing agencies when more information about particular disposal sites and passive control systems is available." (at 58). Similar language appeared in the final rule (50 Fed. Reg. at 38080). Again, the discussion of frequency of drilling cited the figure of 30 drillholes per square kilometer per 10,000 years, even considering passive institutional controls. Thus, it was the Agency's view, in drafting Part 191, that passive institutional controls will not reduce the rate of human intrusion to a "very small" number, that the effectiveness of such controls must be determined based on the specific site and control system in issue--and that the implementing agency must do that task.

The Agency's decision in 1985 to allow the "implementing agency" to determine the probabilistic contribution passed the issue to DOE as to WIPP. In 1992 the Agency became the "implementing agency" with regard to the compliance criteria and compliance determination at WIPP (see §191.12; "implementing agency"). Thus, if there can be a criterion to determine the

effectiveness of passive institutional controls, the Agency must set it forth in compliance criteria. The January 30, 1995 proposal does not contain any such criterion. Moreover, the 1995 BID, the Addendum, and the other materials accompanying the proposal do not suggest any methodology. DOE requests that the Agency "[p]rovide quantitative guidance for reducing the probability of human intrusion and define credit as a function of the effectiveness of passive institutional controls." (DOE Comments, at II-47). Sandia complains that "no guidance is provided as to what is required of the Department in order to obtain this credit and what basis would be used by the EPA to possibly reduce this credit." (SNL Comments, at 194.43). Our previous comments stated that any supposed method of projecting the effect of passive institutional controls on intrusion is inherently speculative and may involve nonconservative assumptions (see April 28, 1995 Comments, at 31-32). We respectfully suggest that no defensible method exists, and if one did exist, it has not been proposed for comment. The Agency has no choice but to drop the proposal for a credit for passive institutional controls.

§194.44: Engineered barriers

DOE's proposal (DOE Comments at II-48) would write the engineered barrier requirement out of 40 CFR Part 191. DOE suggests that it be required to adopt engineered barriers only "[t]o the extent necessary to provide a reasonable expectation that the containment requirements of 40 CFR 191.13 are met." Such a term wholly fails to consider the purpose of engineered barriers as a component of 40 CFR Part 191.

The Agency explained in adopting the rule that it did not intend to place all of its faith in a numerical demonstration of compliance: "While numerical standards are important to bring about appropriate selection and design of disposal systems, the Agency has long recognized that the numerical standards chosen for Subpart B, by themselves, do not provide either an adequate context for environmental protection or a sufficient basis to foster public confidence in the national program. There are too many uncertainties in projecting the behavior of natural and engineered components for many thousands of years--and too many opportunities for mistakes or poor judgments in such calculations--for the numerical requirements on overall system performance in Subpart B to be the sole basis to determine the acceptability of disposal systems for these very hazardous wastes. These uncertainties and potential errors in quantitative analysis could ultimately prevent the degree of protection sought by the Agency from being achieved. (Theoretically, it might be possible to develop adequate confidence in achieving this level of protection by choosing much more stringent numerical standards, but this could lead to substantial difficulties in implementation.) Therefore, the proposed standards also included qualitative assurance requirements chosen to ensure that cautious steps are taken to reduce the problems caused by

these uncertainties. The proposed rule emphasized that the assurance requirements were an essential complement to the quantitative containment requirements that were selected." (50 Fed. Reg. at 38079).

In contrast, DOE insists that the engineered barrier requirement has no purpose independent of the limitations on release of radioactivity, claiming that "if a reasonable expectation of compliance can be demonstrated using only a limited number of engineered barriers (or even one such barrier), the intent of 40 CFR Part 191 is satisfied." (DOE Comments, at II-48). Likewise, Sandia asserts that "all that is required is that there is a reasonable expectation that the selected engineered barrier(s), in conjunction with the natural barrier system, will maintain releases within the limits imposed in 40 CFR 191.13." (SNL Comments, at 194.44, p. 5). The Agency's own statements show that the assurance requirements are independently necessary. If the Agency, either in the compliance criteria or in the certification proceeding, concludes that a showing of compliance with the containment requirement means that the engineered barrier requirement has no further purpose, it will have forgotten the basic truth that probabilistic numerical projections cannot be the only reliance in confirming the safety of a disposal system.

DOE's position paper on the Disposal Room and Cuttings Models (March 28, 1995) gives an example of the uncertainties in projecting releases in an intrusion context and underscores the advantages of engineered alternatives:

"Of the three modes of release caused by high-pressure waste gas, stuck pipe and gas erosion would be most affected by increases in waste strength. This occurs because the drilling mud remains in the borehole and the pressure difference between the waste gas and borehole pressure is less than 7 MPa. With blowout the borehole pressure is considerably reduced (near atmospheric) and thus pressure differentials can be much greater (approaching 14 MPa).

"Aside from severely reducing gas generation in the waste, methods to reduce surface releases include reducing waste permeability and increasing waste strength. Restricting the compacted waste permeability to a narrow range above 10^{-16} m² would also reduce the effects of high pressure gas on waste transport to the surface." (at 81-82).

There is another related reason requiring engineered barriers. The containment requirement itself--even if satisfied--contains several assumptions which may well be nonconservative. One is the assumption of unchanged future states. It seems plainly unrealistic to assume that "the characteristics of the future [will] remain what they are today" (§194.25). The assumption may be necessary to spare risk assessment from speculation, but that does not mean it is true. Similarly, certain forms of human

intrusion may be excluded from consideration in the final certification, but they may occur nevertheless. Waste disposed in WIPP must contend with the real-world future, which may not be as safe as the stylized hypothetical that the Agency employs in granting certification. If the repository must encounter such events, waste may be kept from release, or releases may be limited, by the use of engineered barriers as part of the system design.

The Agency's preamble in 1985 states that one substitute for assurance requirements would be a revision of the containment requirement toward "much more stringent numerical standards." Thus, if the assurance requirements are written out of the rule, as DOE requests, the Agency would be required to reopen the issue of the release limits and to lower the permissible limits so that an equivalent level of protection is attained.

We repeat the point made in our previous comments: The Agency should obtain the results of the engineered barrier study promptly from DOE so that this issue will be addressed promptly rather than being further postponed (see Comments, April 28, 1995, at 33-34). We suggest that the study be submitted one year before the compliance certification application is submitted. At the same time the Agency should include in the compliance criteria quantitative release limits for engineered barriers. If the results of the study suggest some reason to do so, the limits may be reconsidered, but issuance of final compliance criteria should not be postponed.

DOE comments, in response to the Agency's inquiry, that little is to be gained from adoption of quantified requirements for engineered barriers, along the lines of 10 CFR Part 60 (DOE Comments, at III-11). It is correct that the terms of §60.113(a)(ii)(B) apply specifically to the case of spent fuel and high-level waste. However, as stated above and in previous comments, a rule specifically for transuranic waste, defining release limits in disturbed and undisturbed circumstances, can be drafted and is essential to effective compliance criteria. See also EEG Comments, Appx. B.

Subpart D--Public Participation

§194.61: Advance notice of proposed rulemaking

§194.62: Notice of proposed rulemaking

§194.63: Notice of final rule.

§194.64: Documentation of continued compliance.

We have previously commented on the need to revise the public participation section (Comments, April 28, 1995, at 36-41). We now supply draft regulatory language to effectuate such revisions.

DRAFT REGULATORY LANGUAGE FOR SELECTED SECTIONS OF 40 CFR PART 194
NEW MEXICO ATTORNEY GENERAL'S OFFICE
(September 15, 1995)

§194.01: Purpose, scope, and applicability.

This Part specifies criteria for the certification or determination of compliance, under section 8(d) and section 8(f) of the WIPP LWA, with the disposal regulations at 40 CFR part 191, section 8(e) proceedings, and any proceedings involving the validity, effectiveness, modification, enforcement, suspension, or revocation of any decision under section 8(d) or section 8(f).

§194.02: Definitions.

* * *

Human activity means those drilling events that have as their objective a depth above the level of the repository.

Human intrusion means those drilling events that have as their objective a depth at the level of the repository or below.

* * *

Modification means action(s) taken by the Administrator that has the effect of altering the terms or conditions of the certification under section 8(d) of the WIPP LWA.

Population of CCDFs means all possible CCDFs that can be generated from sampling disposal system parameter values an infinite number of times, conditioned on specific probability distribution functions.

Population of estimates means all possible estimates that can be generated from sampling disposal system parameter values an infinite number of times, conditioned on specific probability distribution functions.

* * *

Revocation means any action taken by the Administrator to terminate indefinitely the effectiveness of certification under section 8(d) of the WIPP LWA or to terminate indefinitely the effectiveness of a determination under section 8(f) of the WIPP LWA.

* * *

Suspension means any action taken by the Administrator to terminate for any period that is not indefinite the effectiveness of certification under section 8(d) of the WIPP LWA or to terminate

for any period that is not indefinite the effectiveness of a determination under section 8(f) of the WIPP LWA.

§194.03: Communications.

(a) Except where otherwise specified in this part, all communications and reports concerning the criteria in this part, and any compliance application(s) shall be addressed to the Administrator or the Administrator's authorized representative.

(b) Any person may apply to the Administrator to be designated as a party to the rulemaking in connection with the compliance application before or after that application is filed. The Administrator shall admit any such person as a party to the rulemaking upon a showing that such person has an interest in the subject matter of the rulemaking and is prepared to comply with the procedures applicable to the rulemaking. The Department, the State of New Mexico ("State"), the National Academy of Sciences ("NAS"), and the Environmental Evaluation Group ("EEG") shall be deemed parties to the rulemaking.

(c) The Department and all other parties to the rulemaking shall mail a copy of all communications filed with the Administrator in connection with a rulemaking to all other parties to the rulemaking.

(d) The State, NAS, and EEG shall have free and timely access to data relating to health, safety, or environmental issues at WIPP. The Department shall provide the State and EEG with preliminary reports relating to health, safety, or environmental issues at WIPP and shall permit the State and EEG to attend meetings relating to health, safety, or environmental issues at WIPP with expert panels and peer review groups.

§194.04 Conditions of compliance certification and determination.

(a) Any certification or determination issued pursuant to the WIPP LWA may include such conditions as the Administrator finds to be necessary to support such certification or determination(s). Such certification or determination shall include conditions with regard to:

- (1) Waste acceptance criteria.
- (2) Waste characterization.
- (3) Reporting by the Department concerning operations, monitoring and scientific investigations.
- (4) Facility construction and maintenance.
- (5) Waste handling and related operations.

(6) Closure activities.

(b) Whether stated therein or not, the following shall be conditions in any certification or determination:

(1) The certification or determination shall be subject to modification, suspension, or revocation, by the Administrator. Any modification, suspension, or revocation shall be done by rule. If the Administrator revokes the certification, the Department shall retrieve any waste emplaced in the disposal system.

(2) Upon written request of the Administrator any time after the Administrator has issued a certification or determination of compliance, the Department shall submit information to enable the Administrator to determine whether the certification or determination should be modified, suspended, or revoked. Unless otherwise specified by the Administrator, the Department shall submit such information to the Administrator within 30 calendar days of receipt of the Administrator's request.

(3) Not later than six months after the Administrator has issued any certification or determination of compliance and at least every six months thereafter, the Department shall report to the Administrator, in writing, any changes in conditions or activities pertaining to the disposal system that depart from the application and that formed the basis of such certification or determination of compliance.

(4) Any time after the Administrator has issued a certification or determination of compliance, the Department shall report any changes in activities pertaining to the disposal system that depart significantly from the application that formed the basis of such certification or determination of compliance. A significant departure is any change which may affect the certification or determination of compliance under section 8(d) or 8(f). The Department shall inform the Administrator, in writing, prior to making a planned change. The Administrator will proceed, as described below, to rule whether the planned change invalidates the terms of the certification or determination. Any significant change must be approved by the Administrator prior to being made, and the Administrator will determine whether the change requires further action. Further action may include modification, suspension, or revocation of the compliance certification or determination.

(5) If the Department discovers that a condition pertaining to the disposal system differs significantly from that indicated in the application that formed the basis of the certification or determination of compliance, the difference must be reported, in writing, to the Administrator within 10 calendar days of its discovery. The Administrator will proceed, as described below, to rule whether the report requires further action. Further action

may include modification, suspension, or revocation of the compliance certification or determination.

(6) The Department shall report in writing to the Administrator any determination by it that releases of radioactive material have occurred or are reasonably expected to occur in excess of the amounts and probabilities specified in 40 CFR §§191.13, 191.15, or Subpart C. Such report shall be made within 24 hours of such determination, and upon making such determination the Department must immediately suspend emplacement of waste in the disposal system. Such report shall:

(i) identify the location of the release or prospective release;

(ii) identify the radionuclides released or expected to be released;

(iii) identify the time of the release or prospective release;

(iv) assess the hazard posed by the release or expected release; and

(v) contain any additional information requested by the Administrator or the Administrator's authorized representative.

(7) The Department shall report in writing to the Administrator any scientific or technical information which indicates that any of the data or assumptions upon which a certification or determination of compliance was made were erroneous in whole or in part. Such report shall be made within 30 days of the discovery of such error.

(8) The Department shall report in writing to the Administrator annually on the anniversary date of the certification, providing documentation of compliance with the terms and conditions of the certification.

(9) The Department may apply to the Administrator for a modification in the terms of the certification at any time.

(10) Upon receipt of a report under subsection (3), (4), (5), (6), (7), or (8) or an application under subsection (9) the Administrator shall give notice thereof in the Federal Register and publish an Advance Notice of Proposed Rulemaking and shall proceed to determine, based upon the record of prior certification and determination and the information contained in the report or application, whether the outstanding certification should be confirmed, modified, suspended, or revoked. The procedures of Subpart D (relating to public rulemaking) shall be employed.

§194.11 Completeness and accuracy of compliance applications.

Information provided to the Administrator in support of the compliance application shall be complete and accurate. The Administrator's evaluation for certification under section 8(d)(1)(B) of the WIPP LWA and evaluation for determination under section 8(f)(2) of the WIPP LWA shall not begin until the Administrator has notified the Secretary, in writing, that a complete application in accordance with this part has been received. The Administrator's determination of completeness shall be made after a period of public comment on the application submitted by the Department and any supplements and modifications thereto, as provided in section 194.61 hereof.

§194.14: Content of compliance certification application.

The application for certification of compliance with the disposal regulations shall include:

(a) A description of the disposal system and those features that may affect disposal system performance. The description of the disposal system shall include the following information:

(1) The location of the disposal system and the controlled area;

(2) A description of the geology, geophysics, hydrogeology, hydrology, and geochemistry of the disposal system and its vicinity and how these conditions are expected to change and interact over the regulatory time frame;

(3) The presence and characteristics of potential pathways for transport of waste from the disposal system to the accessible environment, including but not necessarily limited to solution features, breccia pipes, and other potentially permeable features including but not necessarily limited to interbeds; and

(4) The projected geophysical, hydrologic and geochemical conditions of the disposal system due to the presence of waste, including but not limited to the effects of production of heat or gases from the waste.

(b) A description of the design of the disposal system, including:

(1) Information relative to materials of construction (including, but not necessarily limited to, geologic media, structural materials, engineered barriers, general arrangement, and approximate dimensions); and

(2) Codes and standards that have been applied to the design and construction of the disposal system.

(c) Results of assessments conducted pursuant to the disposal regulations.

(d) A description of input parameters associated with assessments conducted pursuant to the disposal regulations and the basis for selecting those input parameters.

(e) Evidence that disposal of waste in the disposal system meets the requirements of §191.14.

(f) A description of any waste acceptance criteria and actions taken to assure adherence to such criteria. Data supplied shall include the results of the characterization of all existing waste in accordance with the methods proposed for characterization of all waste.

(g) A description of background radiation in air, soil, and water in the vicinity of the disposal system and the procedures employed to determine such.

(h) One or more topographic map(s) of the vicinity of the disposal system. Contours must be shown on the map. The contour interval must be sufficient to clearly show the pattern of surface water flow in the vicinity of the disposal system. The map(s) shall clearly show the following:

- (1) Scale and date;
- (2) Floodplain area;
- (3) Surface waters including intermittent streams;
- (4) Surrounding land uses, i.e., residential, commercial, industrial, agricultural, recreational;
- (5) A wind rose, i.e., wind speeds and directions;
- (6) Orientation of the map, i.e., north arrow;
- (7) Boundaries of the controlled area;
- (8) Location of the proposed active and passive institutional controls;
- (9) Location of any active, inactive, and abandoned injection and withdrawal wells in the controlled area and in the vicinity of the disposal system; and
- (10) Location of proposed monitoring stations or wells.

(i) A description of past and current climatologic and meteorologic conditions in the vicinity of the disposal system and

how these conditions are expected to change and interact over the regulatory time frame.

(j) A supplemental environmental impact statement and record of decision reflecting the Department's decision to proceed as shown in the application after consideration of all applicable alternatives.

(k) Any other information required elsewhere in this part or determined by the Administrator or the Administrator's authorized representative to be necessary for a decision whether to certify or determine compliance. The Agency shall publish notice of any supplementation of the application and shall give the public an opportunity to comment on the new matter in accordance with §194.61.

§194.21: Inspections.

(a) The Administrator or the Administrator's authorized representative(s) shall be afforded unfettered and unannounced access to inspect any area of the WIPP and other locations performing activities which may provide information to support any existing or prospective compliance application(s) to which locations the Department has rights of access. Such right shall continue for as long as any certification of compliance is in effect.

(b) The Agency shall conduct periodic inspections to verify data presented by the applicant in support of an application for certification of compliance and in reports pursuant to this part and shall periodically conduct audits and inspections of waste characterization and other activities relevant to operational compliance.

(c) Records kept by the Department relating to a certification or determination of compliance or to an existing or prospective application for certification or determination of compliance shall be made available to the Administrator or the Administrator's authorized representative within 30 calendar days of a request from the Administrator or the Administrator's authorized representative.

(d) Representatives of the State, NAS, EEG, or any other party to the rulemaking shall be afforded access on reasonable notice, not to exceed one week, to inspect any area of the WIPP and any locations performing activities which may provide information to support any existing or prospective compliance application(s) to which locations the Department has rights of access. Such right shall continue for as long as any certification of compliance is in effect. The Agency shall enforce the right to access by administrative order on application by a party entitled thereto.

(e) Records kept by the Department relating to a certification or determination of compliance or to an existing or prospective application for certification or determination of compliance shall be made available to the State, NAS, EEG, or any other party to the rulemaking within 30 calendar days of a request from a representative of such a party. The Agency shall enforce the right of access by administrative order on application by a party entitled thereto.

(f) (1) The Department shall, upon request by the Administrator or the Administrator's authorized representative, provide rent-free office space at the WIPP site for the exclusive use of the Administrator's authorized inspection personnel. The office space shall be convenient and have full access to the disposal system.

(2) The Department shall afford the inspection personnel of the Administrator, the State, NAS, EEG, or any other party to the rulemaking access, equivalent to access provided Department employees, following proper identification and compliance with applicable access control measures for security, radiological protection and personal safety.

(g) Representatives of the Administrator, the State, NAS, EEG, or any other party to the rulemaking shall be allowed to obtain samples, including split samples, and to monitor any aspects of the disposal system or the waste proposed for disposal in the disposal system.

§194.22 Quality assurance.

(a) (1) The Department shall implement a quality assurance program that meets the requirements of ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda (part 2.7) to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c)).

(2) The application for certification of compliance shall include information which demonstrates that the quality assurance program implemented under paragraph (a) (1) of this section has been established and executed for:

(i) Waste characterization activities and assumptions;

(ii) Environmental monitoring, monitoring the performance of the disposal system, sampling, and analysis activities;

(iii) Field measurements of geological factors, ground water, meteorology, and topography;

(iv) Computations, codes, models and methods used to demonstrate compliance with the disposal regulations;

(v) Expert judgment elicitation used to support applications for certification or determination of compliance;

(vi) Design of the disposal system and actions taken to ensure compliance with design specifications;

(vii) The collection of data and information used to support compliance application(s); and

(viii) Other systems, structures, components, and activities important to the containment of waste in the disposal system.

(b) The application for certification of compliance shall include information which demonstrates that data and information collected prior to implementation of the quality assurance program under paragraph (a) of this section has been qualified in accordance with:

(1) a quality assurance program equivalent in scope and implementation of ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda (part 2.7) to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c)); or

(2) an alternative method approved by the Administrator for use at the WIPP under the following criteria:

(i) Such method shall include the consideration of records concerning existing data, including the work plan, any procurements, test methods and procedures, qualifications and training records of participants, construction records, records of equipment used, calibration records, records of sample descriptions and handling, records describing data acquisition systems, records of data gathered, reports about the work, correspondence, and records of any verifications and assessments.

(ii) Such method shall include:

(A) Initial review of data and supporting materials by quality assurance staff which is independent from management direction.

(B) Such initial review shall determine whether the existing records show compliance with a quality assurance program described in subsection (b)(1) of this section.

(C) Data not satisfying the initial review may be qualified through corroboration by existing or newly generated data, provided that such corroborative data directly support the data in issue and that the corroborative data satisfy the quality assurance requirements of this section.

(D) Data not satisfying the initial review may be qualified by peer review only as to questions which are not subject to checking through testing, alternate calculation, or reference to previously established standards or practices. Peer review cannot be used to support conclusions based on inadequate or limited data. Peer review shall conform to the requirements of NUREG-1297 (see §194.05(1)) and shall be fully documented as to issues examined and conclusions.

(c) The application for certification of compliance shall provide information which addresses how the following quality indicators for the collection of data and information used to support the compliance application have been and will continue to be achieved:

(1) Data accuracy, i.e., the degree to which data agree with an accepted reference or true value;

(2) Data precision, i.e., a measure of the mutual agreement between comparable data gathered or developed under similar conditions expressed in terms of a standard deviation;

(3) Data representativeness, i.e., the degree to which data accurately and precisely represent a characteristic of a population, a parameter, a variations at a sampling point, or environmental conditions;

(4) Data completeness, i.e., a measure of the amount of valid data obtained compared to the amount that was expected;

(5) Data comparability, i.e., a measure of the confidence with which one data set can be compared to another;

(6) Data reproducibility, i.e., a measure of the variability among measurements of the same sample at different laboratories;

(7) Data validation, i.e., a systematic process for reviewing a body of data against a set of criteria to provide assurance that the data are adequate for their intended use; and

(8) Data verification, i.e., a systematic process for reviewing a body of data generated by one source against a body of data generated by another source.

(d) The Administrator will verify appropriate execution of quality assurance programs through inspections which include surveillances, audits, and management systems reviews.

§194.23: Models and codes.

(a) As used herein, a "conceptual model" is a description of a system or part of the environment, a "mathematical model" is a translation of the conceptual description into mathematical relationships, a "numerical model" is a representation of a process or system using a sequence of arithmetic operations, and a "computational model" is the computer-applicable instructions which carry out calculations in accordance with a numerical model.

(b) The compliance application shall include:

(1) A complete listing and description of each model used directly or indirectly in support of the application. The description shall be sufficiently complete to permit technical review of the purpose of modeling, the modeling approach, method of analysis, and the assumptions underlying such analysis. The application shall include descriptions of models of the following:

(i) Regional geology

(ii) Stratigraphy of:

(A) Bell Canyon Formation

(B) Capitan Limestone

(C) Castile Formation

(D) Salado Formation

(E) Rustler-Salado contact zone

(F) Rustler Formation

(G) Dewey Lake Formation

(H) Dockum Group

(iii) Present climate

(iv) Climate variability

(v) Surface water

(vi) Water table

(vii) Regional water balance

(viii) Groundwater flow above Salado Formation

(ix) Radionuclide retardation in rock bodies above the Salado Formation

(x) The Salado Formation at the repository horizon, including hydrologic parameters and excavation effects

(xi) Repository design

(xii) Seal design

(xiii) Waste inventory

(xiv) Waste containers and backfill

(xv) Radioactive ingrowth and decay

(xvi) Radionuclide dissolution and colloid formation

(xvii) Disposal room closure, gas generation, brine flow, and room-waste interactions

(xviii) Human intrusion methods, practices, and regional history

(xix) Direct releases of radioactivity by human intrusion

(xx) Castile Formation brine reservoirs

(c) The application shall contain a complete listing of conceptual models considered but not used in support of such application, a description of such models, and an explanation of the reasons why such models were not used to support such application.

(d) The application shall contain a scientific and technical justification for each model used directly or indirectly in support of the application, including:

(1) the data, judgments, or assumptions underlying the model, demonstrating the accuracy or conservatism thereof.

(2) a showing that a high degree of agreement exists between the conceptual model and measured data.

(3) a showing that the provisions of this part as to expert judgment elicitation and peer review have been complied with.

(4) a showing that the model is valid for the time period and circumstances to which it is applied.

(5) a showing as to each conceptual model that the inferences underlying it are justified, that it accounts for all available data, and that it accounts for all processes believed to apply.

(6) a showing that conceptual models accurately or conservatively represent the disposal system;

(7) a showing that mathematical models incorporate equations and boundary conditions which reasonably represent the conceptual models;

(8) a showing that numerical models provide numerical schemes which enable the mathematical models to obtain stable solutions;

(9) a showing that computer models accurately implement the numerical models; i.e., codes are free of coding errors and produce stable and accurate solutions; and

(10) a showing that models, computer codes, and observed and measured data used to confirm models and computer codes have undergone peer review according to §194.27.

(e) Models and computer codes used to support the application for certification of compliance shall be fully and clearly documented in a manner that complies with the requirements of ASME NQA-2a-1990 addenda (part 2.7) to ASME NQA-2-1989 edition.

(f) The application shall contain a complete description and justification of performance assessment methodology, indicating the theoretical bases for the methodology and demonstrating the accuracy or conservatism thereof, including:

(1) Scenario selection and development;

(2) Determination of scenario probabilities;

(3) Determination of scenario consequences, including:

(i) methods of uncertainty analysis;

(ii) selection of variable parameters;

(iii) determination of ranges and distributions of variable parameters;

(iv) methods for accounting for covariance;

(v) sample generation and number of samples;

(vi) propagation of samples through analysis;

(vii) construction of complementary cumulative distribution functions;

(viii) selection of one or more complementary cumulative distribution functions to demonstrate compliance.

(ix) Software coding, user's manuals, programmer's manuals, and any necessary licenses.

(g) Models and codes used to support the compliance application shall be fully and clearly documented in a manner compatible with NUREG 0856 "Final Technical Position on Documentation of Computer Codes for High Level Waste Management."

(h) Documentation shall include:

(1) A description of the theoretical background of each model, the method of analysis or assessment, scenario construction, and data collection procedures;

(2) Detailed descriptions of the structure of each computer code and complete listings of the source codes;

(3) Users' manuals which include general descriptions of the models, discussions of the limits of applicability of each model, detailed instructions for running the computer codes, including hardware and software requirements, input and output formats with detailed explanations of each input and output variable and parameter, listing of input and output files from a sample computer run, and reports on code verification, benchmarking, validation and quality assurance procedures;

(4) Programmers' manuals; and

(5) Necessary licenses.

(i) The Administrator or the Administrator's authorized representative may verify the results of computer simulations used to support the compliance application or preliminary performance assessments or to carry out alternative simulations by performing independent simulations. All data files, source codes, executable versions of computer software for each model, anything else needed to permit the Administrator or the Administrator's authorized representative to perform independent simulations, and access to any necessary hardware to perform such simulations shall be provided upon the request of the Administrator or the Administrator's authorized representative.

(j) Representatives of the State, NAS, EEG, or any other party to the rulemaking may verify the results of computer simulations used to support the compliance application or preliminary performances assessments or to carry out alternative simulations by performing independent simulations. All data files, source codes, executable versions of computer software for each model, anything else needed to permit such person or entity to perform independent simulations, and access to any necessary hardware to perform such simulations shall be provided upon the request of such person or entity.

§194.24: Waste characterization.

(a) The compliance application shall include a detailed chemical, radiological, and physical characterization of waste proposed for disposal in the disposal system. Such waste characterization shall be used in assessing compliance with 40 CFR Part 191.

(b) Characterization data shall include the following:

(1) Waste characteristics to which a compliance demonstration is sensitive, as established in a study. The Department shall submit such study one year before submission of its compliance determination application. Such study shall examine sensitivity of compliance with the disposal regulations to alternative assumptions as to the waste acceptance criteria applicable to sensitive characteristics. The following waste characteristics shall be considered sensitive:

(i) Species and curie quantity for each radionuclide at time of emplacement;

(ii) Solubility (mobile actinide concentration) of each radionuclide species under disposal system conditions (as projected by the applicable model);

(iii) Waste pH and Eh under disposal system conditions;

(iv) Waste form;

(v) Free liquid content and initial liquid saturation;

(vi) Pyrophoric or explosive materials;

(vii) Any other characteristics to which a compliance demonstration is sensitive, including, but not necessarily limited to, those affecting the solubilization of radionuclides, formation of colloidal suspensions containing radionuclides, production of gas from the waste, nuclear criticality, and generation of heat in the disposal system.

(2) Such study shall examine reasonably available alternative combinations of waste acceptance characteristics as to sensitive parameters.

(3) Such study shall examine reasonably available alternative waste acceptance characteristics limitations on the entire waste inventory or on subcategories of the inventory, such as the contents of each container, room, or panel.

(4) Such study shall examine reasonably available alternative waste acceptance characteristics stated either as proportions of

the relevant quantity of waste or as absolute limits on the waste inventory in a relevant part of the repository.

(5) Such study shall account for uncertainty as to compliance with the waste acceptance criteria in issue.

(6) The compliance application shall demonstrate that the disposal system will comply with the disposal regulations, assuming the waste inventory has any possible combination of waste characteristics permitted by the waste acceptance criteria proposed by the applicant. In addition, the compliance application shall demonstrate whether compliance is achieved with reasonably available alternative combinations of waste acceptance criteria.

(7) The compliance application shall contain a waste characterization method based upon physical sampling and statistical analysis that will establish that the relevant characteristics of the waste so characterized corresponds to the characteristics assumed in demonstrating compliance.

(8) The compliance application shall demonstrate using such method that waste in existence at the time of the application in fact corresponds in the range and distribution of each sensitive parameter to the range and distribution assumed in demonstrating compliance.

(9) The compliance application shall contain a plan to apply such waste characterization method to waste not in existence at the time of the application(s) so to establish that such waste corresponds in the range and distribution of each sensitive parameter to the range and distribution assumed in demonstrating compliance.

(10) The compliance application shall contain a demonstration based upon physical sampling and statistical analysis that waste in existence at the time of the application meets the current Waste Acceptance Criteria.

(11) The compliance application shall contain a plan based upon physical sampling and statistical analysis to apply the appropriate Waste Acceptance Criteria to waste not in existence at the time of the application so to establish that such waste meets such Waste Acceptance Criteria.

(c) Waste may only be emplaced in the disposal system if the characteristics of such waste comply with the limits approved by the Agency in its certification of compliance with the disposal regulations.

(d) The compliance application shall provide information which demonstrates that a system of controls which includes but is not necessarily limited to measurements, sampling, chain of custody

records and other record-keeping is and will continue to be implemented to assure that only waste containers whose contents comply with the limits approved by the Agency in its certification of compliance are emplaced in the disposal system. The compliance application shall identify and describe such controls and the uncertainty associated with them.

(e) The Administrator will use audits and inspections to verify compliance with the requirements of this part. All records generated in an audit or inspection shall be placed in the public docket of the compliance certification rulemaking.

(f) Application of the plans referred to in sections (b) (6) and (b) (10) hereof shall be demonstrated in reports pursuant to §194.04(b) (8), which are subject to approval by the Administrator in a public rulemaking.

§194.25: Future state assumptions.

(a) Unless otherwise specified in this part or in the disposal regulations, certifications or determinations of compliance with the disposal regulations shall assume that characteristics of the future remain what they are today: Provided, that such characteristics are not related to geologic, hydrologic, or climatic conditions; or to institutional controls.

(b) The Department has the burden of demonstrating the current state as to each point of fact asserted as the basis for a future state assumption. Proof shall take the form of systematically gathered and documented data. Variable parameters shall have a defensible range and distribution, and fixed parameters shall have a value that reflects an invariable current practice or is demonstrably conservative.

(c) In considering the effects of climatic conditions on the disposal system, certifications and determinations of compliance with the disposal regulations shall consider the effects of increased and decreased precipitation and evaporation on the disposal system over the regulatory time frame.

§194.26: Expert judgment.

(a) Expert judgment, by an individual expert or panel of experts, may be used to support the application for certification of compliance by providing estimates or conclusions as to the range and distribution of variable parameters, the probability of occurrence of future events, the validity of extrapolating long-term behavior based upon short-term data, the validity and reliability of models, the validity of simplification of natural

phenomena, the reliability of sampling methods, the adequacy of laboratory analyses to project field behavior, the validity of interpolating based upon experimental data points, the validity of adjustments to experimental data, and other judgments explicitly or implicitly contained in a compliance application: Provided, that expert judgment does not substitute for information that reasonably could be obtained through data collection or experimentation.

(b) The application for certification of compliance shall clearly identify any expert judgments used to support the application, shall describe the process of eliciting expert judgment, and shall document the results of expert judgment elicitation processes and the reasoning supporting those results. Documentation shall be provided of the questions presented for elicitation of expert judgment, background information provided to experts, interviews used to elicit judgments from experts, deliberations among and interactions among experts, and the conclusions reached by the experts.

(c) A formal elicitation of expert judgment shall incorporate the following elements:

(1) A clear statement of the issue to be addressed.

(2) A record of the reasoning leading to a specific central value or probability distribution function and the result of that reasoning. In estimating probabilities experts must decompose issues into a decision or event tree, assign fractile values to different levels of the variable in question, and explain and justify their judgments.

(3) Where a probability distribution is generated, the record shall reflect the alternative hypotheses and the probabilities assigned to them, the distribution model chosen for the variable in issue and the reasoning supporting such choice, and the probability distribution chosen for the variable and the reasoning supporting such choice.

(4) Where the elicitation involves multiple experts, the record shall reflect that all experts (i) agree on the substance of the question, (ii) consider and account for all available data, (iii) and articulate the relationship between the data and their judgment as to the probability of the various models. Different opinions shall be aggregated by a process whereby the experts meet and interact to (iv) discuss the data, (v) explain their models, (vi) discuss the probability of each model, (vii) assess such probabilities, and (viii) generate a composite probability distribution.

(5) The application for certification of compliance shall demonstrate that the following guidelines have been applied to any selection of individuals used to render expert judgments:

(i) Each expert shall have recognized and verifiable technical credentials in the technical area he or she has been selected to cover. The technical qualifications of each expert, and hence of the expert group as a whole, should relate to the importance of the subject matter to be reviewed;

(ii) Individuals shall not be selected who are members of the team of investigators requesting the judgment or the team of investigators who will use the judgment (such teams being deemed to include any employees of the Department or any contractor of the Department which has requested or will use the judgment);

(iii) Individuals shall not be selected who maintain, at any organizational level, a supervisory role or who are supervised by (directly or indirectly) those who will utilize the judgment;

(iv) At least five individuals shall be used in any expert elicitation process;

(v) At least two-thirds of the experts involved in an elicitation shall be persons who are not employed, directly or indirectly by the Department (including persons whose professional work receives significant support from the Department);

(vi) When assembling an expert panel, individuals shall be selected such that collectively they represent a diversity of scientific and technical viewpoints, including all areas of expertise directly required to address the question or issue presented; and

(vii) Individuals shall not be selected who maintain a personal or economic interest in the results of the elicitation.

(d) The results of any expert judgment processes shall be peer-reviewed according to §194.27 of this part. The report of the proceedings and findings of peer review processes shall be filed with the application.

(e) The elicitation process shall include an opportunity for presentation to the expert(s) of the scientific and technical views of groups and individuals other than those affiliated with the Department.

§194.27 Peer review.

(a) The application for certification of compliance shall include information which demonstrates that peer review has been conducted to evaluate the adequacy of:

- (1) experimental design;
- (2) data collection methodology;

(3) technical studies, such as studies of engineered barriers, waste characterization requirements, seals, drilling methods, institutional controls, monitoring requirements, resource site consideration, waste removal plans, and similar studies;

(4) scientific basis for scenario selection and construction;

(5) scientific basis for conceptual models;

(6) use of experimental data in constructing conceptual models; and

(7) conservatism of assumptions.

(b) Peer review processes used in certifying or determining compliance with the disposal regulations shall be conducted in a manner which is compatible with NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories."

§194.33: Consideration of human-initiated processes and events.

(a) The following process shall be used in assessing the likelihood and consequences of human-initiated processes and events, and the results of such process shall be documented in the application for certification of compliance. Performance assessments need not consider intentional intrusion into the disposal system. Intentional intrusion is intrusion by persons to whom the content of information contained in passive institutional controls has fully and effectively been communicated:

(1) The record of human activity in the Delaware Basin over the past 50 years shall be examined. The Delaware Basin is defined as that area of the surface and subsurface which includes the central basin and the land underlain by the Capitan Reef. A separate examination of each type of human activity shall be conducted.

(2) In assessing the likelihood of human-initiated processes and events that may affect the disposal system, performance assessment shall assume the rate of occurrence over the regulatory time frame for each type of human activity (per square kilometer per year) in the controlled area and the Delaware Basin is equal to the average rate of human activity (per square kilometer per year) for each type of human activity in the Delaware Basin over the past 50 years.

(3) In assessing the consequences of human-initiated processes and events, performance assessments shall assume that human activity in the controlled area and the Delaware Basin occurs at random intervals in time and space throughout the regulatory time frame, provided, however, that the frequency of subsequent drilling intrusions shall be adjusted pursuant to subsection (c)

hereof. The consequences of each human activity in the controlled area and the Delaware Basin shall be calculated; however, performance assessments shall take into account the cumulative consequences of all human activities in the controlled area and the Delaware Basin.

(4) In assessing the consequences of human-initiated processes and events, performance assessments shall assume that the future characteristics of those processes and events, including but not limited to the types and amounts of drilling fluids, and borehole depths, diameters, and seals will remain consistent with current practice in the Delaware Basin.

(b) In assessing the consequences of human-initiated processes and events, performance assessments shall assume that:

(1) Boreholes will be sealed at the rate boreholes have been sealed over the past 50 years in the Delaware Basin; and

(2) Natural processes will degrade or otherwise affect the permeability of boreholes over the regulatory time frame.

(c) In examining human-initiated processes and events, such processes and events shall be assumed initially to occur at random intervals in time and space. The probability of second and subsequent such events shall be adjusted upwards from the random value to reflect the success of the initial intrusion, the adjustment to be based upon the average rate of subsequent intrusions following successful first intrusions of the same type with the Delaware Basin in the 50 years next preceding the application.

§194.34: Results of performance assessments

(a) (1) The results of performance assessments shall be assembled into "complementary cumulative distribution functions" (CCDF's) that represent the probability of exceeding various levels of cumulative release caused by all significant processes and events.

(2) Probability distribution functions shall be developed for all uncertain disposal system parameter values which may be material to any decision or evaluation under Part 191 or this Part. Probability distribution functions for parameters which describe waste, engineered components, or geologic characteristics must be based on data specific to the site or the materials in question. The number of values in the data set supporting any probability distribution function must be at least five. The shape (e.g., normal, lognormal) and numerical parameters (e.g., minimum, maximum, median, percentile points, mean, standard deviation) used to construct the distribution must be supported by data specific to the waste or the site or the materials in question.

(3) Computational techniques which draw random samples from across all of the probability distributions developed under paragraph (a)(2) of this section shall be used in generating CCDF's. This provision shall not preclude use of stratified or Latin hypercube sampling; however, covariance and other correlations among sampled variables must be accounted for in the sampling method chosen.

(b) The number of CCDF's generated must be large enough such that the maximum CCDF generated exceeds the 99th percentile of the population with at least a 0.95 probability.

(c) The application for certification of compliance shall display the full range of CCDF's generated.

(d) The application for certification of compliance shall provide information which demonstrates that there is at least a 95% level of statistical confidence that the mean of the population of CCDF's meets the requirements of section 13(a) of 40 CFR Part 191.

(e) The application for certification of compliance shall also demonstrate that there is at least a 95% level of statistical confidence that the mean of the population of CCDF's exceeds the 90th fractile of the population of CCDF's at each relevant point.

(f) The application for certification of compliance shall also demonstrate that the assumptions underlying the performance assessment as to health effects of radiation exposure, exposure pathways, and release models are conservative. Such demonstration shall establish that, when such assumptions are replaced by probabilistic statements of reasonable alternative hypotheses, and probabilistic analyses of such hypotheses are conducted, the curve which represents the mean of the population of CCDF's with at least a 95% level of statistical confidence shows compliance and is not moved to a lower fractile of the CCDF family.

§194.41: Active institutional controls.

(a) The application for certification of compliance shall include detailed descriptions of proposed active institutional controls, the controls' location, and the period of time the controls are proposed to remain active.

(b) The application for certification of compliance shall include specific financial and contractual commitments made to support the operation of the active institutional controls.

(c) Assumptions pertaining to active institutional controls and their effectiveness in terms of preventing or reducing radionuclide releases shall be supported by such descriptions and commitments.

(d) Assessments to determine compliance with the disposal regulations shall not consider any contributions from active institutional controls for more than 100 years after disposal.

§194.43 Passive institutional controls.

(a) The application for certification of compliance shall include detailed descriptions of the measures that will be employed to preserve knowledge about the location, design, and contents of the disposal system. At a minimum, such measures shall include:

(1) Identification of the controlled area by markers that have been designed, fabricated, and emplaced to be as permanent as practicable;

(2) Placement of records in the archives and land record systems of local, State, and Federal governments, and international archives, that are likely to be consulted by individuals in search of unexploited resources. Such records shall identify:

(i) The location of the controlled area and the disposal system;

(ii) The design of the disposal system;

(iii) The nature and hazard of the waste;

(iv) Geologic, geochemical, hydrologic, and other site data pertinent to the containment of waste in the disposal system; and

(v) The results of tests, experiments, and other analyses relating to backfill of excavated areas, shaft sealing, waste interaction with the disposal system, and other tests, experiments, or analyses pertinent to the containment of waste in the disposal system.

(b) The application for certification of compliance shall include detailed descriptions of the proposed passive institutional controls and the period of time those controls are expected to endure and be understood.

(c) The application for certification of compliance shall include specific financial and contractual commitments made to support the implementation of the plans as to passive institutional controls

§194.44 Engineered barriers.

(a) Disposal systems shall incorporate engineered barriers designed to prevent or substantially delay the movement of water or radionuclides toward the accessible environment.

(b) For contact-handled transuranic waste, such barriers shall maintain the integrity of the disposal room in both disturbed and undisturbed conditions, such that no more than one part in 100,000 per year of the radionuclide inventory of such room, as calculated pursuant to §194.31, shall be released from the room.

(c) For remote-handled transuranic waste, such barriers shall maintain the integrity of the container in both disturbed and undisturbed conditions, such that no more than one part in 100,000 per year of the radionuclide inventory of such container, as calculated pursuant to §194.31, shall be released from the container.

(d) In selecting engineered barriers for the disposal system, the Department shall evaluate the benefit and detriment of engineered barrier alternatives including but not limited to such engineered barriers as cementation, shredding, supercompaction, incineration, vitrification, improved waste canisters, grout and bentonite backfill, melting of metals, alternative configurations of waste placements in the disposal system, and alternative disposal system dimensions. The results of this evaluation shall be submitted to the Agency at least one year before the submission of the application for certification of compliance and shall be used to justify the selection or rejection of all engineered barriers evaluated.

(e) In conducting the evaluation of engineered barrier alternatives, the following shall be considered:

(1) the ability of the engineered barrier to prevent or substantially delay the movement of water or waste toward the accessible environment;

(2) the impact on worker exposure to radiation both during and after incorporation of engineered barriers;

(3) the increased ease or difficulty of removing the waste from the disposal system;

(4) the increased or reduced risk of transporting the waste to the disposal system;

(5) the increased or reduced uncertainty in compliance assessment;

(6) the increased or reduced public confidence in the performance of the disposal system;

(7) the increased or reduced total system costs;

(8) the impact, if any, on other waste disposal programs from the incorporation of engineered barriers (e.g., the extent to which

the incorporation of engineered barriers affects the volume of waste);

(9) the effects on mitigating the consequences of human-initiated processes and events. In such analysis the Department should not be restricted by assumptions as to characteristics of the future or of human-initiated processes and events.

(f) If, after consideration of one or more of the factors in paragraph (e) of this section, the Department concludes that an engineered barrier shall be rejected without evaluating the remaining factors in paragraph (e) of this section, then any application for certification of compliance shall provide a justification for this rejection explaining why the evaluation of the remaining factors would not alter the conclusion.

(g) In considering the benefit and detriment of incorporation of engineered barriers, the benefit and detriment of engineered barriers for existing (as of 1994) waste already packaged, existing waste not yet packaged, existing waste in need of re-packaging, and to-be-generated waste shall be considered separately and described.

(h) The evaluation shall consider engineered barriers alone and in combination.

(i) In considering the benefit and detriment of alternative disposal system dimensions, the benefit and detriment of alternative dimensions for parts of the disposal system now constructed (as of 1994) as well as parts to be constructed (after 1994) shall be considered.

§194.45 Consideration of the presence of resources.

The application for certification of compliance shall include information that demonstrates that the favorable characteristics of the disposal system compensate for the presence of resources in the vicinity of the disposal system and the likelihood of future human-initiated processes and events as a result of the presence of those resources. Such demonstration shall compare the disposal system with alternative systems which would be located at sites which contain no resources and shall show that the likelihood of releases in violation of the disposal standards is lower at the WIPP site than at such other sites.

§194.61: Advance notice of proposed rulemaking.

(a) Upon receipt of the application for certification of compliance, the Agency will publish in the Federal Register an Advance Notice of Proposed Rulemaking, announcing that the application for certification of compliance has been received, soliciting comment on such application, and announcing the Agency's

intent to conduct a rulemaking to certify whether the WIPP facility will comply with the disposal regulations.

(b) A copy of the application for certification of compliance will be made available for inspection in Agency dockets.

(c) The notice will provide a public comment period of at least 120 days addressed to the question whether the application is complete, as required by this part and the disposal regulations.

(d) After the public comment period the Agency shall issue one or more notices to the Department, either indicating that the application is deemed complete or identifying additional information required to complete the application and specifying a date by which such information should be supplied.

(e) Upon receipt of the Department's response to a notice pursuant to subsection (d) identifying information to be supplied, the Agency will publish in the Federal Register an Advance Notice of Proposed Rulemaking, announcing that additional information in support of the application for certification of compliance has been received, soliciting comment on such information, and announcing a further comment period of at least 120 days addressed to the question whether the application is complete, as required by this part and the disposal regulations.

(f) After the public comment period pursuant to subsection (e) the Agency shall issue a notice pursuant to subsection (d), indicating either that the application is deemed complete or that additional information is required to complete the application, and if additional information is required shall proceed pursuant to subsection (e).

(g) If at any time the Department submits additional information in support of its application, the Agency shall publish notice of such receipt and shall solicit comment on such additional information and shall provide a public comment period of at least 120 days.

(h) After the Agency deems the application complete, it shall publish in the Federal Register an Advance Notice of Proposed Rulemaking, announcing that it is undertaking to consider the sufficiency of the application to demonstrate compliance with the disposal standards, soliciting comment on such application, and identifying particular questions on which it requests comment. Such notice will provide a public comment period of at least 120 days.

(i) A public hearing shall be held concerning the application if a written request for a hearing is received within 30 calendar days of the date of publication of the notice under subsection (h).

Written requests shall be directed to the Administrator or the Administrator's authorized representative.

(j) The public hearing shall be held in New Mexico. At such hearing comment shall be received from the public. Comment by qualified experts shall be received without restrictions as to time or page limitation. At the hearing, in addition, persons knowledgeable in the contents of the application shall be made available by the Department to answer questions on the record. The staff of the Agency shall address questions to the persons appearing on behalf of the application, who shall respond. Parties to the rulemaking may also address questions to the persons appearing on behalf of the application, who shall respond. Members of the public may also, subject to reasonable limits as to time, address questions to the persons appearing on behalf of the application, who shall respond.

(k) After the hearing the Agency shall allow at least 60 days for the public to comment, addressing issues raised at the public hearing.

(l) Any comments received on the notices provided pursuant to this section will be made available for inspection in the dockets established under section 65 of this part.

(m) Any comments received on the notices will be provided to the Department, and the Department may submit written responses to the comments within 120 days of receipt.

(n) Comment periods shall be extended to compensate for any delays by the Department or the Agency in making available any document relevant to the rulemaking requested by any member of the public or party to the rulemaking.

(o) The procedures set forth in this section shall apply to any request to modify the terms or conditions of certification and any other decisions to be made by rulemaking, such as approval of reports pursuant to §194.04(b) concerning operations, suspension or revocation of certification, or any other decision calling into question issues decided in the certification proceeding.

§194.62: Notice of proposed rulemaking.

(a) Upon completion of review of the application for certification of compliance, the Administrator will publish a Notice of Proposed Rulemaking in the Federal Register announcing the Administrator's proposed decision on whether the WIPP facility will comply with the disposal regulations and soliciting comment on the proposal.

(b) The proposed decision will not be subject to review outside the Agency by any other body of the Executive branch before its publication.

(c) The notice will provide a public comment period of at least 120 days.

(d) The notice will announce the opportunity for public hearings in New Mexico and provide information on the timing and location of such hearings and procedures for registering to testify.

(e) The public hearing shall be held in New Mexico. At such hearing comment shall be received from the public. Comment by qualified experts shall be received without restrictions as to time or page limitation. At the hearing, in addition, persons knowledgeable in the contents of the application shall be made available by the Department to answer questions on the record. The staff of the Agency shall address questions to the persons appearing on behalf of the application, who shall respond. Parties to the rulemaking may also address questions to the persons appearing on behalf of the application, who shall respond. Members of the public may, subject to reasonable limits as to time, also address questions to the persons appearing on behalf of the application, who shall respond.

(f) After the hearing the Agency shall allow at least 60 days for the public to comment, addressing issues raised in the public hearing.

(g) Any comments received on the notices provided pursuant to this section will be made available for inspection in the dockets established under section 65 of this part.

(h) Any comments received on the notices will be provided to the Department, and the Department may submit written responses to the comments within 120 days of receipt.

(i) Comment periods shall be extended to compensate for any delays by the Department or the Agency in making available documents relevant to the rulemaking requested by any member of the public or party to the rulemaking.

(j) The procedures set forth in this section shall apply to any request to modify the terms and conditions of certification and any other decision to be made by rulemaking, such as approval of reports pursuant to §194.04(b) concerning operations, suspension or revocation of certification, or any other decision calling into question issues decided in the certification proceeding.

§194.63: Notice of final rule.

(a) The Administrator will publish a Notice of Final Rule in the Federal Register announcing the Administrator's decision on certifying whether the WIPP facility will comply with the disposal regulations. Such decision shall state the Administrator's findings of fact, conclusions, and the rationale supporting his decision. All conditions of certification shall be published in the decision. The decision shall state that it constitutes the Administrator's certification pursuant to §8(d)(1)(b) of the WIPP LWA and shall identify the date when it shall be deemed made for purposes of judicial review pursuant to §18 of the WIPP LWA.

(b) The final decision will not be subject to review outside the Agency by any other body of the Executive branch before its publication.

(c) A document summarizing major comments and issues arising from comments received on the Notice of Proposed Rulemaking as well as the Administrator's response to such comments and issues will be prepared and will be made available for inspection in the dockets established under section 65 of this part.

(d) The procedures set forth in this section shall apply to any request to modify the terms or conditions of certification and any other decisions to be made by rulemaking, such as approval of reports pursuant to §194.04(b) concerning operations, suspension or revocation of certification, or any other decision calling into question issues decided in the certification proceeding.

§194.64: Documentation of continued compliance.

(a) Upon receipt of documentation of continued compliance with the disposal regulations pursuant to section 8(f) of the WIPP LWA, the Administrator will publish a notice in the Federal Register announcing that such documentation has been received, soliciting comment on such documentation, and announcing the Administrator's intent to determine whether the WIPP facility continues to be in compliance with the disposal regulations.

(b) Copies of documentation of continued compliance received by the Administrator will be made available for inspection in the dockets established under section 65 of this part.

(c) The notice will provide a public comment period of at least 120 days.

(d) The notice will announce the opportunity for public hearings in new Mexico and provide information on the timing and location of such hearings and procedures for registering to testify.

(e) The public hearing shall be held in New Mexico. At such hearing comment shall be received from the public. Comment by

qualified experts shall be received without restrictions as to time or page limitation. At the hearing, in addition, persons knowledgeable in the contents of the documentation shall be made available by the Department to answer questions on the record. The staff of the Agency shall address questions to the persons appearing on behalf of the documentation, who shall respond. Members of the public may, subject to reasonable limits as to time, also address questions to the persons appearing on behalf of the documentation, who shall respond.

(f) After the hearing the Agency shall allow at least 60 days for the public to comment, addressing issues raised in the public hearing.

(g) Any comments received on the notices pursuant to this section will be made available for inspection in the dockets established under section 65 of this part.

(h) Any comments received on the notices will be provided to the Department, and the Department may submit written responses to the comments within 120 days of receipt.

(i) Comment periods shall be extended to compensate for any delays by the Department or the Agency in making available documents relevant to the determination requested by any member of the public.

(j) Upon completion of a review of documentation of continued compliance with the disposal regulations, the Administrator will publish a notice in the Federal Register announcing the Administrator's decision determining whether the WIPP facility continues to be in compliance with the disposal regulations. Such decision shall state the Administrator's findings of fact, conclusions, and the rationale supporting his decision. The decision shall state that it constitutes the Administrator's determination of continued compliance pursuant to §8(f)(2) of the WIPP LWA.

(k) The Administrator's decision will not be subject to review outside the Agency by any other body of the Executive branch before its publication.