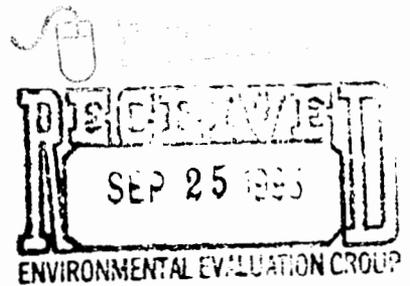




Department of Energy
Carlsbad Area Office
P. O. Box 3090
Carlsbad, New Mexico 88221
SEP 14 1995

COPY
WPP File

Ms. Ramona Trovato, Director
Office of Radiation and Indoor Air
U. S. Environmental Protection Agency
401 M Street, SW (MS #6101)
Washington, D.C. 20460

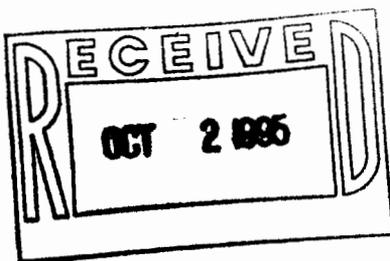


Dear Ms. Trovato:

The Department of Energy (DOE) is pleased to provide additional comments on the Proposed Rule 40 CFR Part 194, "Criteria for the Certification and Determination of the Waste Isolation Pilot Plant's Compliance with Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes" (60 FR 5766), dated January 30, 1995, as it applies to the Waste Isolation Pilot Plant (WIPP).

The enclosed comments do not represent a significant change to any of the DOE's positions contained in the first set of comments provided on May 5, 1995, and identified in your docket as IV-D-90. These additional comments, however, further clarify some of the Department's previous comments by providing further discussion, and also provide a better balanced picture of the WIPP program in light of comments you have received from others. This is particularly the case for peer review, human intrusion and drilling rates, and the performance of passive institutional controls. Our additional comments also contain specific notations on some individual sections of the proposed rule.

We are looking forward to the Environmental Protection Agency (EPA) finalizing the proposed rule and our having continuing regulatory interactions with your office. If you have any questions or would like to arrange a meeting between our staffs, please contact Michael H. McFadden of my staff at (505) 234-7486.



Sincerely,

George E. Dials
Manager

Enclosure



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950911



Ms. Ramona Trovato, Director

- 2 -

SEP 14 1995

cc w/enclosure:

T. Grumbly, Assistant Secretary for Environmental Management

R. Guimond, Principal Deputy Assistant Secretary

Air Docket - EPA

SEP 14 1995

DECISION BRIEF

40 CFR Part 194 Comments to be Submitted to the Environmental Protection Agency

Background

40 CFR Part 194 is a proposed Environmental Protection Agency (EPA) regulation, which when implemented, will provide criteria for certifying that the Waste Isolation Pilot Plant (WIPP) will meet environmental standards, as stated in 40 CFR 191, when acting as a repository for the disposal of transuranic (TRU) wastes. Definitive and constructive comments from the Department of Energy (DOE) were forwarded to the EPA on May 8, 1995. However an additional comment period was opened in August 1995 because of heavy public interest and the availability of the Department's Augmented Draft Compliance Certification Application.

As this regulation will build on the environmental radiation protection standards developed by 40 CFR Part 191, as enabled by the WIPP Land Withdrawal Act of 1992, it has a significant impact on allowing the WIPP to open on schedule and permit continued operations as now planned. The same review team as formed previously, was again convened to examine the proposed regulation, evaluate its technical validity, and organize another constructive response to the proposed rule.

These additional comments are provided for two reasons. First, the DOE wishes to clarify some of its previous comments by providing additional analyses. Second, the DOE is aware many comments by others do not focus on the proposed standards but dwell instead on the WIPP facility and the DOE's regulatory compliance and policy processes. While the DOE does not believe it is obligated to respond to these comments directly, it does wish to comment on the record to provide a balanced picture of the program and its intended performance.

Portions of the proposed rule critiqued in this second review round include:

- Inconsistencies with the original Part 191,
- Role of exploratory drilling rates,
- Passive institutional controls,
- Conditions of compliance (SEIS II, Phased Disposal),
- Quality assurance,
- Peer review,
- Waste characterization,
- Release limits,
- Performance assessments,
- Consideration of resources.

Issues

The proposed regulation (or rule) contains criteria and guidance that will have a profound impact on the ability to certify, open, and operationally monitor the WIPP for decades to come.

All 244 responses received by the EPA from the first round commentors in May 1995 were reviewed as applicable to the DOE's position and approach. The bulk of the submissions were opposed to the WIPP program.

A Review Team composed of representatives from the CAO, SNL, WID, WTAC and DOE-HQ developed comments in the general subject areas listed above.

The final set of comments, as attached, were further reviewed by the Review Team, the CAO Legal Counsel, EM-342, the Yucca Mountain Team, EM-412 and the General Counsel's Office. While all entities reviewed, commented and concurred (Yucca Mountain concurred without comment), the General Counsel's Office has not concurred. General Counsel felt that because no new issues were addressed in these comments, that some comments address issues raised by others in the first comment period, and these comments "rambled," they need not be submitted to the EPA. All other review groups concurred on form and content and felt it was important to enter these issues onto the record.

Options

1. Examine all current issues contained within the proposed rule and develop an appropriate technical response that can be submitted to the EPA by their September 15, 1995 deadline. This will supplement the DOE's May 1995 submission and presents the Department's latest effort to properly influence future regulatory actions.
2. Do not respond to the invitation to comment further on the proposed Part 194, despite the knowledge that various critical points require supplementation, and that others are taking advantage of this reopening period. The opportunity to follow up on our recent EPA NACEPT presentation made in early September would not be realized. The EPA would probably be disappointed with the DOE's lack of rule-building participation.

Recommendation

The CAO Office of Regulatory Compliance recommends the CAO Manager adopt Option 1 as the appropriate action. This should also prove to be the most rational method in maintaining our current technical posture consistent with the present WIPP Disposal Decision Plan.

9/13/95

**THE U.S. DEPARTMENT OF ENERGY'S
ADDITIONAL COMMENTS
ON
THE CRITERIA FOR THE CERTIFICATION AND DETERMINATION OF THE WASTE
ISOLATION PILOT PLANT'S COMPLIANCE WITH ENVIRONMENTAL STANDARDS
FOR THE MANAGEMENT AND DISPOSAL OF SPENT NUCLEAR FUEL, HIGH-
LEVEL AND TRANSURANIC RADIOACTIVE WASTES
40 CFR PART 194, PROPOSED**

1.0 INTRODUCTION

The Department of Energy (DOE) welcomes the opportunity to provide additional comments on the proposed criteria for the certification of the Waste Isolation Pilot Plant (WIPP) consistent with the final disposal standards in 40 CFR Part 191. These comments are provided for two reasons. First, the DOE wishes to further clarify some of its previous comments by providing additional analysis or discussion. Second, the DOE is aware that many comments provided to the Environmental Protection Agency (EPA) by others do not focus on the proposed standards but focus instead on the WIPP facility, the DOE's regulatory compliance process and DOE policy matters. While the DOE does not believe it is obligated to respond to these comments directly, the DOE does wish to comment on the record to provide a balanced picture of the WIPP Program and its intended performance. The attached comments do not represent a major change to any of the DOE's positions as stated in their comment package identified in the docket as IV-D-90.

2.0 GENERAL COMMENTS

The DOE has a single additional general comment on the proposed rule. This comment underscores the DOE's concern over the EPA's deviation from the technical bases used by the EPA in developing and promulgating the final disposal standards.

2.1 GENERAL COMMENT - CONSISTENCY WITH 40 CFR PART 191

STATEMENT OF CONCERN:

The DOE is concerned that the EPA has deviated from the technical bases and guidance in the disposal standards, particularly for the treatment of human intrusion. The DOE agrees, in general, that guidance can be changed by a regulatory agency to satisfy the permitting circumstances of a particular facility. However, in the case of Appendix C of 40 CFR Part 191, the DOE believes that the guidance is so closely related to the fundamental basis of the standard that the guidance can not change without 1) a corresponding analysis of how the new guidance alters the standard, and 2) justification for deviating from the standard.

9/7/95

Points which are related to this comment include:

1. Because of the importance of the guidance, the EPA intended that the implementing agencies not deviate from the Agency's fundamental approach without significant justification;
2. One important deviation involves the case of human intrusion drilling rates;
3. Another important aspect is the EPA's apparent reduction in confidence that passive controls will perform their intended purpose; and
4. The proposed rule appears to be inconsistent.

DISCUSSION:

It is the DOE's belief that an approach to compliance that is inconsistent with the approach used in developing the disposal standards results in a loss of correlation between implementing agency action and the desired outcome of reasonable expectation that human health will be protected far into the future.

Each inconsistency needs careful and systematic analysis to assure; 1) protection, and 2) reasonableness.

The following segments of italicized text are excerpts from the EPA rulemaking documents for 40 CFR Part 191. Some excerpts are underlined for emphasis. These excerpts focus on the treatment of human intrusion and clearly define the EPA's rationale in the 1985 rulemaking for 40 CFR Part 191. They are essential to understanding the Agency's intent for the application of 40 CFR Part 191. As the EPA itself noted in the summary for proposed 40 CFR Part 194:

the criteria . . . will be used by the Agency in ascertaining whether the WIPP disposal system complies with the disposal standards (Proposed Rule 40 CFR Part 194, 60 FR 5766).

1. **Although the EPA states its intention in the 40 CFR Part 191 supplemental information that the implementing agencies not deviate from the fundamental approach used by EPA in developing and issuing Part 191, the proposed Part 194 deviates significantly, particularly in the area of modeling human intrusion.**

As a basis for this statement, the DOE offers the following rationale. The Agency established that the greatest uncertainty in the prediction of long-term performance was that associated with inadvertent human intrusion. The following excerpt from the 1982 proposed disposal standards underscores the dilemma that human actions are far more difficult to predict than natural processes and that given the wrong set of assumptions about inadvertent human intrusion, the releases due to such intrusions will dominate, even for well-chosen repository

sites.

The Agency believes that the implementing agencies must determine compliance . . . by evaluating long-term predictions of disposal system performance . . . involving . . . [S]ubstantial uncertainties . . . The most speculative potential disruptions of a mined geologic repository are those associated with inadvertent human intrusion. According to our models, at well-chosen repository sites more of the projected risk from releases is due to possible human intrusions than from releases by geologic processes—if we make the very conservative assumption that passive institutional controls have no effect in deterring or limiting inadvertent human intrusion for more than 100 years after disposal. However, predicting human actions is much more uncertain than predicting natural events. In particular, we can only guess at the frequency of some actions (such as drilling for resources) (Proposed Rule, 40 CFR Part 191, 47 FR 58200).

As a means of mitigating the potential of overly conservative assumptions and procedures being used by an implementing agency in demonstrating compliance to the disposal standards, the EPA strongly recommended using the Agency's procedures as illustrated in the following excerpts from the proposed and final disposal standards:

The containment requirements in § 191.13 were derived with the assistance of our performance assessments of long-term repository performance. When these requirements are applied to a particular disposal system, some of the procedures we used in our assessments must be retained to insure that the intent of our containment requirements is met (emphasis added) (Proposed Rule, 40 CFR Part 191, 47 FR 58201).

The "guidance for implementation" included as Appendix B to the final rule . . . (now Appendix C) . . . describes certain analytical approaches and assumptions through which the Agency intends the various long-term numerical standards of Subpart B to be applied. This guidance is particularly important because there are no precedents for the implementation of such long-term environmental standards, which will require consideration of extensive analytical projections of disposal system performance (emphasis added) (Final Rule, 40 CFR Part 191, 50 FR 38069).

This supplement to the final rule . . . (i.e., Appendix C) . . . is based upon some of the analytical assumptions that the Agency made in developing the technical basis used for formulating the numerical disposal standards. These analytical assumptions incorporate information assembled as part of the technical basis used to develop the proposed rule . . . [t]he Agency believes it is important that the assumptions used by the implementing agencies are compatible with those used by EPA in developing this rule. Otherwise, implementation of the disposal standards may have effects quite different than those anticipated by EPA (emphasis added) (Final Rule, 40 CFR Part 191, 50 FR 38074).

Appendix C. . . of the rule describes the Agency's assumptions regarding performance assessments and uncertainties and should discourage overly restrictive or inappropriate implementation of the containment requirements (emphasis added) (Final Rule, 40 CFR Part 191, 50 FR 38077).

In addition, the EPA clearly stated that the performance assessment modeling performed by the EPA in establishing the rule was conservative. The EPA stated in the proposed disposal standards of 1982:

. . . [W]here information was uncertain, we made conservative assumptions that should tend to overestimate the long-term risks of disposal (Proposed Rule, 40 CFR Part 191, 47 FR 58196).

One area of concern to the DOE where the proposed certification criteria rule deviates from earlier guidance involves the assumptions surrounding human intrusion. Consequently, it is vital to recognize the important assumptions involving the frequency and types of human intrusions that were made by the EPA in establishing the containment requirements. The EPA assumed (and so states in both the 1982 proposed rule and 1985 and 1993 final rule):

[W]e can only guess at the frequency of some actions (such as drilling for resources). We considered setting separate containment requirements that would limit the radioactivity that could be released by any one likely human intrusion, in order to avoid having to estimate such frequencies. However, we did not do this because: (1) setting separate requirements for natural and human events would not place an upper limit on risk; and (2) setting separate requirements for individual intrusions in addition to the total combined requirements would not appreciably increase confidence that the overall requirements would be met unless we made the limits on individual intrusions unreasonably low (Proposed Rule, 40 CFR Part 191, 47 FR 58200).

. . . [t]hat the likelihood of such inadvertent and intermittent drilling need not be taken to be greater than 30 boreholes per square kilometer of repository area per 10,000 years for geologic repositories in proximity to sedimentary rock formations . . . Furthermore, the Agency assumes that the consequences of such inadvertent drilling need not be assumed to be more severe than: . . . release of 200 cubic meters of ground water pumped to the surface if that much water is readily available to be pumped; and . . . creation of a ground water flow path with a permeability typical of a borehole filled by the soil or gravel that would normally settle into an open hole over time-not the permeability of a carefully sealed borehole (Final Rule, 40 CFR Part 191, Appendix C).

The Agency believes that performance assessments should consider the possibilities of such intrusion, but that limits should be placed on the severity of the assumptions used to make the assessments. Appendix B (now Appendix C) . . . to the final rule describes

a set of parameters about the likelihood and consequences of inadvertent intrusion that the Agency assumed were the most pessimistic that would be reasonable in making performance assessments (emphasis added) (Final Rule, 40 CFR Part 191, 50 FR 38077).

In contrast to the guidance of the Agency above and the conservatism that is inherent in the EPA's approach in developing the final disposal standards, the preamble to the proposed certification criteria rule states:

. . . "[H]uman intrusion" includes those drilling events that reach the level of the waste in the disposal system or below. Such events would include, but would not be limited to, exploration for and development of oil and natural gas resources (Proposed Rule, 40 CFR Part 194, 60 FR 5774).

This is inconsistent with the earlier approach which specified that only inadvertent and intermittent *intrusions* be considered because these are the kinds of events which:

. . . may be usefully mitigated by repository design, site selection, or use of passive controls (Final Rule, 40 CFR Part 191, 50 FR 38089).

In the proposed certification criteria rule, the EPA is inconsistent with its earlier position, in which the Agency argued that it is **not** meaningful to address systematic or intentional intrusions because it is **impossible** to mitigate the effects of intrusions which are done intentionally, continuously or systematically, and with knowledge of the presence of the site.

In its proposed certification criteria rule, the EPA also explained that:

. . . [T]he Agency is limiting the consideration of human-initiated processes and events to drilling events because mining events were not included in EPA's analyses that supported the final rule of 40 CFR part 191 as promulgated in 1985 (Proposed Rule, 40 CFR Part 194, 60 FR 5774).

"Drilling events," as now defined by the EPA to include production or development wells, were also not included among the events considered by the EPA in the analysis it performed in support of the 1985 rule. As such, to be consistent with the earlier rulemaking, the EPA should also eliminate production or development wells from the analysis. In the 1985 rulemaking, the EPA stated that Appendix C:

. . . of the rule describes the Agency's assumptions regarding performance assessments and uncertainties and should discourage overly restrictive or inappropriate implementation of the containment requirements (Final Rule, 40 CFR Part 191, 50 FR 38077).

The application of drilling rates for all types of drilling is more restrictive than the application of drilling rates for exploratory drilling only. The reasoning for this inconsistency from the intent of the original rule is not explained by the EPA.

Related to the topic of human intrusion is the consideration of the effectiveness of passive institutional controls. As described in item 3 below, this is another area where the EPA has demonstrated inconsistency. Specifically, in the 1985 rulemaking the EPA expressed a high degree of confidence that passive institutional controls may be expected to perform their intended purpose. The language of proposed 40 CFR 194.43(c) deviates from this approach. The proposed certification criteria rule states that:

. . . [T]he EPA may be willing to consider contributions of passive controls in deterring human intrusion if a persuasive case can be made that the passive institutional controls can be expected to endure and act as a deterrent to potential intruders (Proposed Rule, 40 CFR Part 194, 60 FR 5779).

The DOE fully supports the inclusion of credit for passive controls in 40 CFR Part 194. Such credit is fully consistent with the intent of 40 CFR Part 191 rulemaking. However, it is suggested that the proposed 40 CFR 194.43(c) be revised to indicate that such credit will, as a minimum, be allowed consistent with the assumption used in developing 40 CFR Part 191.

These points are discussed in greater detail in the specific comments on 40 CFR 194.33 and 194.43 which follow.

2. It is reasonable to examine only exploratory drilling for resources.

The DOE believes that the only approach that is consistent with the original disposal standards is to consider only exploratory wells in the development of a reasonable human intrusion scenario. The EPA stated that it is reasonable to examine only the consequences of inadvertent and intermittent intrusion by exploratory drilling for resources. This is because these are the kinds of intrusions which:

. . . may be usefully mitigated by repository design, site selection, or use of passive controls (Final Rule, 40 CFR Part 191, 50 FR 38089).

The point the EPA made in the final disposal standards is that it is impossible to mitigate the effects of intrusions which are done intentionally, continuously or systematically. This point is reinforced by additional language in Appendix C of the regulation: The DOE . . . *can assume that passive institutional controls or the intruders' own exploratory procedures are adequate for the intruders to soon detect, or be warned of, the incompatibility of the area*

with their activities. It was clearly not EPA's intention in 1985 that the DOE assess the consequences of systematic or intentional intrusions.

3. The EPA is confident that passive institutional controls will perform their intended purpose to some degree.

In the proposed and final disposal standards, the EPA established that passive institutional controls had a valuable role in its performance assessment in support of the standards. Specifically, the EPA assumed that passive institutional controls will be effective in deterring systematic or persistent exploitation of the disposal site. This is demonstrated by the following language:

...because the Federal Government is committed to retaining control over these disposal sites in perpetuity, we expect that "passive" institutional measures should substantially reduce the chance of inadvertent human intrusion well beyond this period. Such passive controls will include permanent markers placed at the disposal site, public records or archives, Federal ownership or control of land use, and other methods of preserving knowledge about the disposal system (Proposed Rule, 40 CFR Part 191, 47 FR 58196).

In particular, the assumptions we made about the frequency of human intrusion were conservative because they ignored the substantial protection that passive institutional controls should offer. The performance assessments made for specific sites by the implementing agencies do not need to be as pessimistic with regard to human intrusion (emphasis added) . . . These passive controls should not be assumed to prevent all possibilities of inadvertent intrusion, because there is always a chance that the controls will be overlooked or misunderstood. However, such measures should be effective in deterring systematic or persistent exploitation of a disposal site. Furthermore, the chance of human intrusion should be very small as long as Federal Government retains passive control of disposal sites (Proposed Rule, 40 CFR Part 191, 47 FR 58201).

The EPA also assumed effectiveness for passive controls in deterring inadvertent intrusions for as long as passive controls endure and are understood:

The Agency also assumed that passive institutional controls should reduce the chance of inadvertent intrusion compared to the likelihood if no markers and records were in place . . . The parameters described in the "guidance for implementation" represent the most severe assumptions that the Agency believed were reasonable to use in its analyses to evaluate the feasibility of compliance with this rule . . . (emphasis added) (Final Rule, 40 CFR Part 191, 50 FR 38080).

Not allowing passive institutional controls to be taken into account to some degree when estimating the consequences of inadvertent human intrusion could lead to less protective geologic media being selected for repository sites. The Agency's analyses indicate that repositories in salt formations have particularly good capabilities to isolate the wastes from flowing ground water and, hence, the accessible environment. However, salt formations are also relatively easy to mine and are often associated with other types of resources. If performance assessments had to assume that future societies will have no way to ever recognize and limit the consequences of inadvertent intrusion (from solution mining of salt, for example), the scenarios that would have to be studied would be more likely to eliminate salt media from consideration than other rock types. Yet, this could rule out repositories that may provide the best isolation, compared to other alternatives, if less pessimistic assumptions about survival of knowledge were made (Final Rule, 40 CFR Part 191, 50 FR 38080).

...[m]ined geologic repositories planned for disposal of the materials covered by 40 CFR Part 191 are different from the disposal systems envisioned for any other types of waste. The types of inadvertent human activities that could lead to significant radiation exposures or releases of material from geologic repositories appear to call for much more intensive and organized effort than those which could cause problems at, for example, an unattended surface disposal site. It appears reasonable to assume that information regarding the disposal system is more likely to reach (and presumably deter) people undertaking such organized efforts than it is to inform individuals involved in mundane activities (Final Rule, 40 CFR Part 191, 50 FR 38080).

4. The proposed rule appears to be inconsistent.

The EPA stated in the proposed rule that it is disregarding Appendix C of Part 191 because:

... today's proposal is specific to the WIPP; the guidance, on the other hand, is generic (Proposed Rule, 40 CFR Part 194, 60 FR 5776).

The EPA also explained that it has established an acceptable range for the number of boreholes assumed to intercept the repository of:

... not less than 25 and not greater than 62.5 boreholes per square kilometer per 10,000 years (Proposed Rule, 40 CFR Part 194, 60 FR 5775).

On page 5775 of the *Federal Register* notice, the EPA states the following in regard to the development of these rates:

Using drilling data from the contiguous 48 states as a rough guide, the Agency estimated that a region of bedded salt would experience 25 to 62.5 boreholes per square kilometer per 10,000 years (Proposed Rule, 40 CFR Part 194, 60 FR 5775).

Although the EPA proposes to invalidate the guidance in Appendix C on the basis of its nonspecific nature, the Agency applies nonspecific information (i.e., rough estimates developed by EPA based on informed opinion) to establish intrusion rates that are labeled "WIPP specific."

RECOMMENDATIONS:

1. Guidance in the proposed standards which are inconsistent with the fundamental basis and requirements of 40 CFR Part 191 should be reconsidered. In those cases where the inconsistency results in abandonment of the assumptions used to develop the containment requirements of 40 CFR Part 191, a new basis is needed to demonstrate that the results are consistent with human health and environmental protection goals.
2. When establishing the frequency of inadvertent intrusions into the repository, 40 CFR Part 194 should address only intermittent exploratory drilling for resources; production or development drilling or mining should not be included.
3. Revise 40 CFR 194.43 to acknowledge that the assumptions used in the final disposal standards are valid. This includes the assumption that systematic and persistent exploitation is deterred and the assumption that inadvertent intrusion can be deterred for as long as markers are effective.
4. The EPA should examine the proposed rule for inconsistency with 40 CFR 191.

Several of these topics are described in greater detail in the more specific comments that follow.

3.0 SPECIFIC COMMENTS

3.1 SPECIFIC COMMENT REGARDING § 194.04 *CONDITIONS OF COMPLIANCE CERTIFICATION AND DETERMINATION*

STATEMENT OF CONCERN:

Recent questions have been raised over the process the DOE may use to expand the "envelope" of waste to be disposed in the WIPP.

DISCUSSION:

There are two issues inherent in the question of DOE initiated modifications to a certification. These two issues are 1) the legality of such an action, and 2) the process used to make such a modification. Regarding the first point, correspondence on record¹ between the legal offices

¹See Robert R. Nordhaus, General Counsel, US DOE to Doreen S. Feldman, Assistant General Counsel, General Accounting Office, September 19, 1994 and J. C. Nelson, General Counsel, US EPA to Doreen S. Feldman, Assistant General Counsel, General Accounting Office, November 1994.

of the DOE, EPA and General Accounting Office (GAO) appear to agree that there are no legal obstacles within the WIPP Land Withdrawal Act (LWA) to prevent the DOE from expanding the acceptable "envelope" of the waste at some time after an initial certification. Such flexibility is consistent with the original intent of Congress in Public Law 96-164 for WIPP to be a research and development facility for demonstrating disposal of TRU waste. While much of the argument focuses on the need for flexibility to accommodate the changing picture of waste generation practices, a more compelling argument is, simply, that there may be waste identified in the future for which WIPP is the best alternative for protection of public health and the environment. It does not seem reasonable that expedient decisions today should obviate sound decisions in the future. Furthermore, there is no need to seek legislative relief in this matter since Congress expects the DOE and the EPA to work to resolve such issues. It is only in the event of a failure of the agencies to arrive at a resolution that Congress should be asked to step in.

With regard to the second question, modifications to permits occur frequently and significant precedent exists for establishing workable and reasonable procedures. Two underlying principles, however, must be incorporated into a permit or certification modification process; 1) only the regulator can grant a modification, and 2) not all modifications are equal. The first principle drives the specification of authorities and schedules and the second drives the management of programmatic costs. Congress established the EPA's certification authority over WIPP in the LWA. Inherent in this certification authority is the EPA's power to modify any issued certification. In exercising this authority, however, the DOE believes that the EPA must provide sufficient flexibility in its regulatory program to avoid unnecessary impacts on the operation of the WIPP facility while issues and problems are being resolved. If the EPA is to implement this authority in a manner that is equitable to all involved parties it is necessary and requested that the proposed rule contain provisions addressing modification to accommodate phased certification at such point in time when new waste streams are generated, characterized, and subject to disposal.

RECOMMENDATION:

The EPA should consider the requirements for modifications that currently exist under other regulatory programs such as the Nuclear Regulatory Commission's (NRC's) transportation certification process (found in 10 CFR Part 71) and the EPA's Resource Conservation and Recovery Act (RCRA) program (found in 40 CFR Part 270.42). These requirements are well understood, have been implemented and interpreted over several years, and also provide a logical precedent. A modification of these rules to adapt them to radioactive waste disposal would prove beneficial to the rulemaking.

3.2 SPECIFIC COMMENT REGARDING § 194.14 CONTENT OF COMPLIANCE CERTIFICATION APPLICATION

STATEMENT OF CONCERN:

Issues have been raised regarding the DOE process for the National Environmental Policy Act

(NEPA) and its relationship with other regulatory compliance activities (e.g. the compliance certification process).

DISCUSSION:

The DOE's decision to use the WIPP for the disposal of transuranic waste was stated in the 1981 Record of Decision (ROD) associated with the WIPP Final Environmental Impact Statement (FEIS). The DOE is now engaged in other regulatory compliance demonstration activities that are designed to support a future decision to initiate the operation of the WIPP. One of these activities is the preparation of a Supplemental Environmental Impact Statement (SEIS) to support the disposal decision. The decision will be published in the SEIS II ROD.

Regulatory compliance processes like compliance certification are well integrated with the SEIS activity. The Council for Environmental Quality (CEQ) is clearly concerned about the potential for delay caused by the NEPA process. Title 49 CFR 1500.5, entitled "Reducing delay" emphasizes the provisions of 40 CFR 1502.25 as being one of 12 ways for agencies to reduce delay. 40 CFR 1502.25(a) states:

To the fullest extent possible, agencies shall prepare draft environmental impact statements concurrently with and integrated with environmental impact analyses and related surveys and studies required by . . . other environmental review laws and executive orders.

In the CEQ publication Forty Most Asked Questions Concerning CEQ's National Environmental Policy Act Regulations, 46 Fed. Reg. 18026 (March 23, 1981), the following question and answer appears:

9. *Applicant Who Needs Other Permits. To what extent must an agency inquire into whether an applicant for a federal permit, funding or other approval of a proposal will also need approval from another agency for the same proposal or some other related aspect of it?*

A. *Agencies must integrate the NEPA process into other planning at the earliest possible time to insure that planning and decisions reflect environmental values, to avoid delays later in the process, and to head off potential conflicts.*

RECOMMENDATION:

No provisions regarding the integration or sequencing of documents related to other regulatory compliance programs are needed or considered appropriate for the compliance certification criteria.

3.3 SPECIFIC COMMENTS REGARDING §194.22 QUALITY ASSURANCE

3.3.1 FIRST COMMENT

STATEMENT OF CONCERN:

The imposition of NQA-3 standards as proposed by the proposed certification criteria is no longer appropriate for the WIPP.

DISCUSSION:

Since submission of the previous comments, the DOE WIPP Project has learned that the DOE's Office of Civilian Radioactive Waste Management (OCRWM) is not required by the Nuclear Regulatory Commission (NRC) to meet the requirements of ASME's NQA-3². As noted in the letter, the NRC has not endorsed NQA-3 for use on the OCRWM project. In addition, the ASME's Subcommittee on Nuclear Waste Management considers the NQA-3 document as a guidance document.

The OCRWM Project has used portions of NQA-3 as guidance. The DOE WIPP Project meets most of the requirements of NQA-3. The following sections of NQA-3 are not appropriate for the WIPP Project.

Section II, Para. 3.3 - Peer Review: As discussed in the DOE comments on Section 194.27, peer review in accordance with NUREG 1297 is not appropriate for the DOE WIPP Project.

Section II, Paras. 17.1 and 17.2 - Sample and Reference Records: Samples should not be required to be controlled in accordance with the QA Records requirements of NQA-1. Since many of the samples are radioactive, additional health and safety concerns would arise if DOE had to collect two samples instead of one to meet duplicate storage requirements for records in NQA-1. The alternative would be to find a safe which would not only protect the public from radiation but also from fire for all radioactive samples. In addition, many of WIPP's samples have limited shelf lives and would be useless over time. Why would DOE expend time and money to protect these like QA Records? DOE already feels that Paragraph 8 of NQA-3 provides enough requirements for this Project to ensure that samples are adequately controlled.

RECOMMENDATION:

Delete the requirements in the proposed rule at 40 CFR 194.22(a)(1) that imposes Section II, para. 3.3 and Section II, para. 17.1 and 17.2 from NQA-3.

3.3.2 SECOND COMMENT**STATEMENT OF CONCERN:**

The data qualification criteria in the proposed standards are unnecessarily burdensome.

²See Donald G. Horton, Director, Office of Quality Assurance, U. S. Department of Energy to Dennis Brown, Quality Assurance Manager, U. S. Department of Energy, Carlsbad Area Office, August 16, 1995.

DISCUSSION:

DOE estimates that over 90% of the experimental data has already been collected to support compliance. The application of data quality indicators should not be retroactive since the testing is already complete.

RECOMMENDATION:

Delete the data qualification requirements in the proposed rule at 40 CFR 194.22(c).

3.4 SPECIFIC COMMENTS REGARDING §194.24 WASTE CHARACTERIZATION**STATEMENT OF CONCERN:**

One emphasis that appears often in comments to the EPA is on the amount of waste characterization needed to support the application. Many reviewers believe the current language in the proposed criteria does not require a sufficient amount of characterization prior to submittal of an application. In many cases, the comments reflect either a misunderstanding of the role of waste characterization in the regulatory process, or simply is the result of a lack of consistent use of terminology. The DOE would like to provide a concise statement of what it views is the role of waste characterization, along with a definition of the terminology as used in DOE documents.

DISCUSSION:

Within the context of compliance activities, "waste characterization" is any process that provides meaningful information about the chemical, physical, biological, radiological, or mechanical properties of a waste. Two classes of methods are used to characterize waste. These are 1) characterization through knowledge of the processes and materials that were used to generate the waste, and 2) characterization through sampling and analysis of a representative portion of the waste. The document that describes the strategy that is used to characterize waste is referred to as a waste analysis plan (WAP). Typically, the WAP is a document that is prepared by an applicant and reviewed by a regulator as part of a permitting process. Two of the major portions of a WAP are the selection of waste analysis parameters and the selection of sampling and analysis techniques to measure those parameters. Developing the list of parameters depends on the specific waste management activities at the facility being permitted. Developing the sampling and analysis strategy depends on the nature of the waste, the parameters being measured, the needed precision and accuracy, and the use of sanctioned techniques

The process for selecting the parameters for analysis is based on two factors. First, consideration is given to incompatibilities within the wastes. For example, waste that may be acidic is managed separately from wastes that are basic in order to avoid violent and dangerous reactions. In addition, incompatibilities between the waste and the characteristics of the waste management system need to be identified. The EPA has standardized techniques for making a determination of compatibility between the chemical components that may occur within the waste and the various portions of the waste management system. No significant

incompatibilities have been identified for the WIPP that would affect the long-term isolation of the waste. Waste compatibility is documented in the WIPP WAP submitted with the hazardous waste permit application (Chapter C of the WIPP Resource Conservation and Recovery Act Part B Permit Application, DOE/WIPP 91-005, Revision 5).

The second consideration for parameter selection is related to the design of the facility and the processes being used to manage the waste. In the case of the WIPP, the processes that are of interest over the long-term are those being modeled in the performance assessment as reasonably expected events and processes. They include such processes as compaction due to room closure, biological and chemical degradation, radiological degradation, and excavation due to drilling, erosion, and spalling. The identification of specific parameters is determined iteratively as the result of numerical studies in which various parameters are evaluated for importance to system performance. This study, which the DOE will have to conduct in order to select the appropriate parameters for waste analysis, is the same study specified in the proposed standards. While the DOE does not believe it is appropriate for the EPA to mandate specifics of the study within the criteria, the DOE does agree with the need for such a study. The DOE believes that the waste parameter study will disclose two aspects of the waste analysis program, namely, the parameter that must be measured and the accuracy and precision to which such measurements must be made. The selection of parameters will be based on those parameters that have the greatest effect on compliance. The precision and accuracy will be based on the significance of the possible range of parameter values with regard to compliance. For example, if some values of a parameter result in non-compliance and others result in compliance, precision and accuracy in measurements will be very important. On the other hand, if no known values of the parameter can lead to noncompliance, then precision and accuracy may not be important.

In selecting parameters for analysis, only general knowledge of the waste is needed. For example, if the processes used to describe the waste performance in the disposal system uses the mechanical strength of the waste as a parameter, then a general knowledge of the range of mechanical strengths of the various forms of waste is useful in order to conduct a meaningful evaluation of the importance of the parameter. Waste characterization is used to develop the range of parameters. Since only general knowledge is needed, characterization can be conducted generally. That means, knowledge of the waste based on previous characterization activities, the waste streams that generated the waste, and the materials used in the waste generation processes are generally sufficient to bound parameters for the purposes of evaluation and selection. The Waste Baseline Inventory Report is an example of a general characterization for such purposes. If, as in this example, the mechanical properties of the waste turn out to be important and the parameter is selected for analysis, then such selection is limited by the range of values considered in the parameter study.

The parameter study will result in identification of the important parameters and the acceptable values for those parameters. These then become targets for sampling and analysis. The parameters and ranges would apply to all waste forms, whether existing or to be generated in

the future. In essence the parameters become limits and bounds for the success of the disposal system over the long-term.

Conformance to these limits and bounds is demonstrated through the sampling and analysis program. This, too, is waste characterization. However, in this case, waste characterization is applied in a specific sense, in some cases to every container of waste. The sampling and analysis portion of the WAP specifies how often a representative sample is to be taken, the methodology to be used in taking the sample, and how it is to be analyzed. Sampling and analysis applied at this stage, generally as a condition of an operating permit, is often referred to as waste screening, waste verification, or waste fingerprinting. In all cases, the purpose is the same, to provide assurance that each drum placed in the disposal system can comply with the final disposal standards. Sampling and analysis occurs just prior to shipment, not prior to submittal of a permit application.

RECOMMENDATION:

The DOE recommends that the waste characterization requirements be made more general in order to allow the DOE to develop a WAP for compliance to the disposal standards. The specifics of the waste parameter study should be left to the DOE instead of codified in the rule.

3.5 SPECIFIC COMMENTS REGARDING §194.27 PEER REVIEW

STATEMENT OF CONCERN:

DOE still does not agree that peer review is necessary to "validate" the entire WIPP program. The DOE has a Quality Assurance (QA) program which meets the requirements of ASME NQA-1. This program also meets the standards proposed by the Agency. The DOE QA program requires that technical work be performed and managed in accordance with written procedures, and that the adequacy of the work be independently assessed. Various levels of technical review and oversight are accomplished to assure the DOE that the adequacy of information meets or exceeds all compliance and/or performance requirements. This information includes assumptions, calculations, methods, alternate interpretations, analyses, state-of-the-art testing, acceptance criteria, scientific protocol, and conclusions. Any permit or certification applicant utilizes technical scientific reviews, as needed, to treat uncertainty with the intent of verifying that the information in its regulatory submittal is true and accurate to the best of his knowledge.

DISCUSSION:

The Environmental Protection Agency (EPA) stated that peer review was widely used to validate technical data, processes, and assumptions. The DOE polled nuclear QA experts in the nuclear waste management community and determined that peer review (in accordance with NUREG 1297 requirements) is rarely used as a means of validating technical information, including technical processes and data. Nuclear industry NQA-1 based QA programs have always required independent technical review or verification of design (including computer software) and testing activities. These reviews have been performed by personnel who have

technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter) to a degree at least equivalent to that needed for the original work.

DOE will conduct Independent Reviews in order to increase confidence in the results of activities when the adequacy cannot otherwise be established through testing, alternate calculations, or reference to previously established standards and practices. In addition, the Environmental Evaluation Group (EEG) and the National Academy of Sciences have been providing independent review of important technical activities at WIPP since 1979.

The Agency has proposed six activities requiring peer review:

- (1) **Evaluation of Engineered Barriers - This work is being conducted under the existing DOE NQA-1 QA program. A NUREG 1297 review would be redundant.**
- (2) **Processes and Events That May Affect the Disposal System - All DOE work affecting the disposal system is being conducted under the existing DOE QA program. Historical information used to support WIPP is also subject to the requirements of the DOE QA program. Again, for the reasons cited above, peer review would be redundant.**
- (3) **Quality Assurance Programs and Plans - The Agency has already proposed that DOE meet an established nuclear industry QA standard (NQA-1). DOE and contractor QA programs and plans have been developed and are reviewed against the requirements from NQA-1. The DOE does not think it is appropriate to peer review an accepted industry standard which the Agency has already proposed that DOE meet.**
- (4) **Models and Computer Codes - Computer codes are developed and reviewed in accordance with the proposed NQA-2, Part 2.7 which is also an accepted nuclear industry standard. Again, the DOE does not wish to peer review NQA-2, Part 2.7. Models are reviewed as part of the established DOE QA program.**
- (5) **Data used to Support Models and Computer Codes - The Agency and the EEG have publicly supported the DOE approach to qualifying existing data in EPA sponsored meetings in Washington, D.C. in January and February of 1995. In light of this, the DOE does not think it is appropriate to peer review all data collected to support compliance. Formal Independent Review is being used to qualify some of the data.**
- (6) **Waste Characterization - This work is being conducted under the existing DOE QA program. Once more, for the reasons previously indicated, peer review**

would be redundant.

The DOE does recognize that certain areas need a more rigorous technical review than NQA-1 requires. For certain critical activities, the DOE uses an Independent Review process. As an example, certain activities at SNL supporting performance assessment will be subject to an Independent Review.

The Independent Reviews at SNL will be initially focused on the integration of existing data (experimental) with data currently being acquired (i.e., data acquired under a qualified QA program) and with other forms of data required by performance assessment. These reviews will start with and build upon the findings of the Independent Review Teams' conclusions (from the Qualification of Existing Data process) with respect to the development, collection, and analysis of experimental data, to establish the quality of all data, and determine its value for the intended use in the compliance process. The Independent Review groups will review assumptions, methods, and interpretations in the PA process.

The recent System Prioritization Method study (SPM-2) formed the basis for the DOE prioritization of ongoing experimental work. The objective of the SPM-2 process was to focus DOE project resources on those parameters which appeared to be best suited for supporting an ultimate demonstration of compliance. A list of critical and important parameters had previously been generated by using sensitivity analysis techniques. The sensitivity analysis was derived from performance assessment "snapshot" calculations. The SPM-2 added the parameter of colloid transport in the Culebra to this list. The SPM-2 process confirmed that six parameters account for approximately 98% of the uncertainty in the calculations. This strongly suggests that these parameters should receive the primary emphasis and highest rigor of technical review. The six parameters are physical transport of radionuclides in the Culebra, rock mechanics, seals, cuttings, actinide source term, and chemical and colloid retardation in the Culebra.

These data supported by a data package may form all or part of the basis for a parameter distribution function (PDF) for a specific model(s) used in the compliance calculations. As is likely, the total set of parameters for a particular model (computer code) may include a few or several data sets, some from experiments and some from other sources. Further, it is often the case that an experiment is small in scale relative to the size of the repository-scale physical model represented by the numerical model. For this reason, it is frequently necessary to consider the scale-up of experimental values to "match" the size of the actual process or situation. The development of the PDF is completed after scale-up activities are performed. This process involves professional judgment and quite often, the integration of data from more than one source. Because the process just described is complex, it necessarily involves judgment, and it frequently incorporates information from a variety of sources, and it is a candidate for review, in particular for data and information associated with the high priority, high sensitivity parameters.

Independent Reviews at the SNL will be performed to review data and information needed for the compliance calculations that address the six parameters of high priority and sensitivity. In addition to the experimental data, data and information from the non-experimental sources will be integrated into the Independent Review process to the degree that they support a particular computer code or group of codes that address each priority issue. The Independent Reviews at the SNL build upon the Independent Review Team process now being used as part of qualification of existing data processes for the review of individual data packages. The product of those reviews is a Statement of Condition (SOC) for each data package. That is, the SOC contains an independent assessment of the adequacy of the scientific protocol for the tests or experiments and an assessment of the adequacy of the associated test or experiment records to meet the QA requirements of the NQA series.

The SNL Independent Reviews will be performed by a technical group which is typically comprised of three to five members. The actual size of the groups will vary depending on the extent of differing viewpoints, degree of uncertainties, type of technical areas involved, and the complexity. Every attempt will be made to select group members who are independent of the DOE WIPP Project. These experts will be well recognized in the scientific community in their technical areas of expertise.

Independent Reviews will cover issues such as:

- (A) Have the right data been collected?
- (B) Have large uncertainties in predictions been adequately studied?
- (C) Have adequate methods been used to collect and analyze these data?
- (D) Have alternate methods for data collection and analysis been sufficiently considered?
- (E) Has good scientific protocol been used?
- (F) Are the data adequate for its intended use?

The SNL Independent Reviews will be formally planned, performed, and documented in accordance with an approved SNL procedure. At the conclusion of the review, dissenting viewpoints will be clearly identified in the reports.

These Independent Reviews at SNL are an example of how DOE intends to implement its QA program for more complex technical issues. For those reasons, the DOE does not consider that a NUREG 1297 Peer Review is appropriate for use at the WIPP.

RECOMMENDATION:

The EPA should delete the peer review requirements from the proposed rule.

3.6 SPECIFIC COMMENTS REGARDING §194.31 APPLICATION OF RELEASE LIMITS

STATEMENT OF CONCERN:

The EPA has proposed that the expected curie activity existing 100 years after disposal be used when calculating applicable release limits under Appendix A of 40 CFR Part 191 (60 CFR 5788). This proposed regulation significantly conflicts with the basis used for developing 40 CFR Part 191. In effect, the proposed requirement creates an unwarranted regulatory burden and penalizes the WIPP through the imposition of additional conservatism that was not intended when 40 CFR Part 191 was promulgated. The DOE made this comment earlier and now has further information to indicate that additional conservatism is not needed.

DISCUSSION:

The containment requirements in 40 CFR 191.13(a), and the associated release limits in Appendix A, specifically apply to radionuclides with half-lives greater than 20 years. However, the rationale for the proposed approach states that the 100-year delay is intended to allow a "long enough period of time for most of the radioactive material with short half-lives to decay to low levels," a question that has already been resolved during the promulgation of 40 CFR Part 191.

The Agency is proposing this approach because EPA believes that 100 years represents a long enough period of time for most of the radioactive material with short half-lives to decay to low levels. The remaining activity after the 100-year period will largely be the result of radioactivity from waste with long half-lives. Such waste may pose the most danger to human health and the environment and, therefore, should be the focus of attention (60 FR 5774).

The Supplementary Information to the proposed Part 194 implies that a correction is needed in the manner of estimating the release limits, "because the curie content of the waste inventory will vary over time due to natural ingrowth and decay of radionuclides." If the manner of calculating the release limits is in doubt, the appropriate action is a modification of the requirements in Table 1 of Appendix A to 40 CFR Part 191. This should be accomplished in a manner that assures that the natural variation over time of the curie content will be equitably regulated for all radioactive wastes governed by 40 CFR Part 191. The statement that "most of the radioactive material with short half-lives" should "decay to low levels," directly contradicts what is specified by Table 1, which is part of the containment requirements of 40 CFR 191.13(a).

The proposed approach is also inconsistent with the spent-fuel equivalency rationale developed to allow derivation of a single set of release limits. The waste unit determines the release limits for a specific repository. The EPA based the waste unit derivation on a philosophy of equivalence between the various types of waste regulated under 40 CFR Part 191. The following is quoted from a draft report prepared for the EPA, Risk Assessments of Spent Fuel, Transuranic, and High-Level Radioactive Wastes in Mined Repositories, Technical Support Document, by S. Cohen & Associates, Inc., January 20, 1993 (RAE-9231\1-3), page 2-23.

In the version of 40 CFR 191 promulgated in 1985, Note 1(c) specified that the Table 1 release limits applied to each 100 million curies of beta/gamma-emitters with half-lives between 20 and 100 years; Note 1(d) stated that the limits applied to each 1 million curies of beta/gamma-emitters with half-lives greater than 100 years; and Note 1(e) stated that they applied to each 1 million curies of transuranic wastes containing alpha-emitters with half-lives over 20 years. The EPA did not provide a detailed explanation of the basis for these quantities. The preamble to the proposed 40 CFR Part 191 published in 1982 stated that the 1 million-curie quantity specified in Note 1(e) for TRU waste was chosen 'so that the standards would require radioactivity from either high-level or transuranic wastes to be isolated with about the same degree of effectiveness' [U.S. Environmental Protection Agency, Preamble to Proposed 40 CFR Part 191, 47 FR 58200, December 29, 1982.] Furthermore, the Draft EIS stated that the reference values of 1 million curies of TRU waste and 1,000 MTHM of spent fuel 'were selected so that about the same fraction of transuranic radionuclides would be retained for either high-level or transuranic wastes' (emphasis added) (US EPA, 'Draft Environmental Impact Statement for 40 CFR 191: Environmental Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes,' EPA-520/1-82-025, December 1982, p. 116). These estimates had been made based on looking at the number of TRU curies in 10 year old spent fuel and rounding to the nearest arithmetic order of magnitude.

The proposed 40 CFR 194.31 requirement would cause the TRU curie content of the WIPP wastes to be as much as 150 years into the decay cycle at the time the release limits are to be calculated (for wastes stored 25 years before emplacement and emplaced during the first year of disposal operations). The TRU curie content of WIPP wastes would no longer bear any similarity to the TRU curie content of 10-year-old spent fuel. The change in the age and associated activity of the waste from that of the initial inventory upon leaving the waste stream to that of the remaining radionuclides 100 years after sealing the repository destroys any equivalence with spent fuel or high-level waste in the calculation of the waste unit. This is a significant departure from the basis for derivation of the release limits and effectively imposes new release limits on the WIPP.

In addition, the requirement clearly penalizes the WIPP, because the dominant radionuclide (approximately 80% of the 1994 projected inventory), Pu-238, has a half life of 87.7 years, so that it is reduced 69% in 150 years of post waste-stream decay. The second most abundant radionuclide (14% of the 1994 projected inventory), Am-241, has a half life of only 432 years, so that it is reduced 21% in 150 years of decay. Thus, the waste unit is reduced by 65% and the release limits are reduced by almost a factor of three, if all waste is 150 years old at the time of the calculation. (These are rough estimates, because they begin with the 1994 projected inventory for stored wastes as well as to-be-generated wastes, not with an inventory assayed at the waste-stream exit.) The 100-year post-disposal requirement results in almost a

factor of three change in the location of the calculated CCDF, shifting the CCDF to the right with respect to the 40 CFR 191.13(a) limits. Although the shift in the relative position of the CCDF for a specific performance assessment may be only a factor of three, this relative position already reflects all other conservatisms built into Part 191 and proposed in Part 194, so that the factor of three is multiplicative. Multiplying this conservatism by the additional conservatism associated with the proposed 100-year release limit is inappropriate and contradicts the basis for 40 CFR 191.13(a).

The characterization of the source term used in deriving the release limits for 40 CFR Part 191 was examined (US EPA, 1977, Technical Support of Standards for High-Level Radioactive Waste Management, Volume A Source Term Characterization, Arthur D. Little, Inc., EPA 520/4-79-007A). The following information from that source-term characterization, including three figures which are attached, supports the DOE's recommendation.

Source term numbers for TRU isotopes in the low-specific-activity general process trash generated from materials handling during reprocessing and mixed-oxide fuel fabrication operations may be characterized as approximately one-tenth the value of the TRU content of high-level waste. "In addition, the low-specific-activity TRU waste is in much less concentrated form than the TRU content of high-level waste. Furthermore, the potential radiotoxicity from these low-specific-activity TRU wastes is significantly less than 10% of that for high-level TRU wastes because, per unit weight, the latter have a much higher content of transplutonium elements. About 94% of the high-level waste TRU component is transplutonium waste" (US EPA, 1977, p.11). "The low-specific-activity TRU waste, which includes general process trash generated from materials handling during reprocessing and mixed-oxide fuel fabrication, results in source terms significantly lower (by an order of magnitude) than the TRU content of HLW" (US EPA, 1977, p.14). Indeed, the UDI² for total trash TRU waste per metric ton of spent fuel never exceeds the UDI for the natural uranium ore used to make the fuel (US EPA, 1977, p. 84).

The decay time from discharge for fission products, actinides and daughters, and natural uranium ore for spent fuel from the PWR fuel cycle without reprocessing is shown on Figure A-6, from US EPA, 1977. Fission products clearly dominate for the first 200 years, and initially exceed the UDI of actinides by more than two orders of magnitude. Actinides decay to the UDI of natural ore in 10,000 years. More detail on the composition of the curves in

² "For the purpose of this report, the untreated dilution index has been derived by a method generally used to compare the biological potency of different mixtures of radionuclides." "Untreated dilution indices are presented in order to gain an understanding of the relative radiotoxicity of waste isotopes (normalized to a metric ton of fuel)." The untreated dilution index (UDI) is defined as the volumetric quantity of water, or air, required to dilute a quantity of radionuclides to the concentration specified under the Standards for Protection Against Radiation in non-occupational exposure, published in 10 CFR 20, Appendix B. The UDI gives a gross indication of the comparative risks of radionuclides, were these nuclides actually released to the environment. The UDI does not consider waste disposal methods (packaging or geologic isolation), or their resultant environmental pathways to man. Radiotoxicity is defined as the base-10 logarithm of the untreated dilution index (US EPA, 1977, glossary). The UDI of the uranium ore used to make the fuel is 10^6 m³ water/MTHM. The activity resulting from reprocessing or burial of a given amount of fuel was compared with the activity originally present in the ore used to manufacture that amount of fuel (US EPA, 1977, p. 30).

Figure A-6 is shown in the following two figures. The decay time from discharge for fission products and for natural uranium ore for the spent fuel from the PWR fuel cycle without reprocessing is shown on Figure A-7. After 10 years, Sr^{90} dominates, and decays to the UDI of natural ore in 200 years. The decay time from discharge for actinides and daughters and for natural uranium ore for the spent fuel from the PWR fuel cycle without reprocessing is shown on Figure A-8. Only three actinides ever exceed the UDI of the ore; these are curium, plutonium, and americium. Curium falls below the UDI of the ore after 20 years. Americium ingrowth (as a daughter product) raises its UDI above that of the natural ore during the first year, and it dominates the actinide activity from about the 30th year to the 2,000th year. Plutonium dominates for the first 30 years, exceeds the UDI of the ore by less than a factor of two after the 300th year, and falls below the UDI of the ore at about 4,000 years.

These curves show that release limits based on the health effects of HLW, as compared to the natural ore, significantly penalize a repository containing no HLW, such as a repository for TRU waste derived primarily from general process trash. The fact that ingrowth americium cannot be included in the calculation of the waste unit for a TRU repository (Pu^{241} has a half-life of 14y, while its daughter, Am^{241} has a half-life of 432 y), but must be accounted for in the release calculation, builds conservatism into the release limits. Similarly, uranium cannot be included in the waste unit, but must be accounted for in releases. Both are included in the waste unit for spent fuel or HLW repositories.

The basis for the release limits in Appendix A of 40 CFR Part 191 clearly recognizes the activity and radiotoxicity of TRU wastes from the time they are generated, but is derived for the high-specific-activity TRU in HLW, not for the low-specific-activity TRU in process trash. Thus the derivation (inadvertently) penalizes TRU-contaminated process trash to account for the early-time dominance of fission products in HLW. The equivalence factor established for the TRU waste unit already recognizes the characteristics and decay patterns of the actinides. Therefore, no changes that increase the conservatism in the manner of calculating the release limits (i.e., in calculating the waste unit used to calculate the release limits) are warranted. The manner in which the EPA equated HLW and TRU wastes in a single set of release limits in 40 CFR Part 191 is already significantly more conservative for TRU wastes than for HLW.

Klett (Klett, R. D., 1991, Proposed Extensions of United States Fundamental and Derived Standards for High-Level and Transuranic Radioactive Waste Disposal, SAND91-0211, Sandia National Laboratories, Albuquerque, New Mexico.) plotted the Annual Risk Potential in health effects/year versus time (see Figures 4 and 5 from Klett, 1991 which are attached). These plots demonstrate that the risk potential from TRU waste is consistently at least an

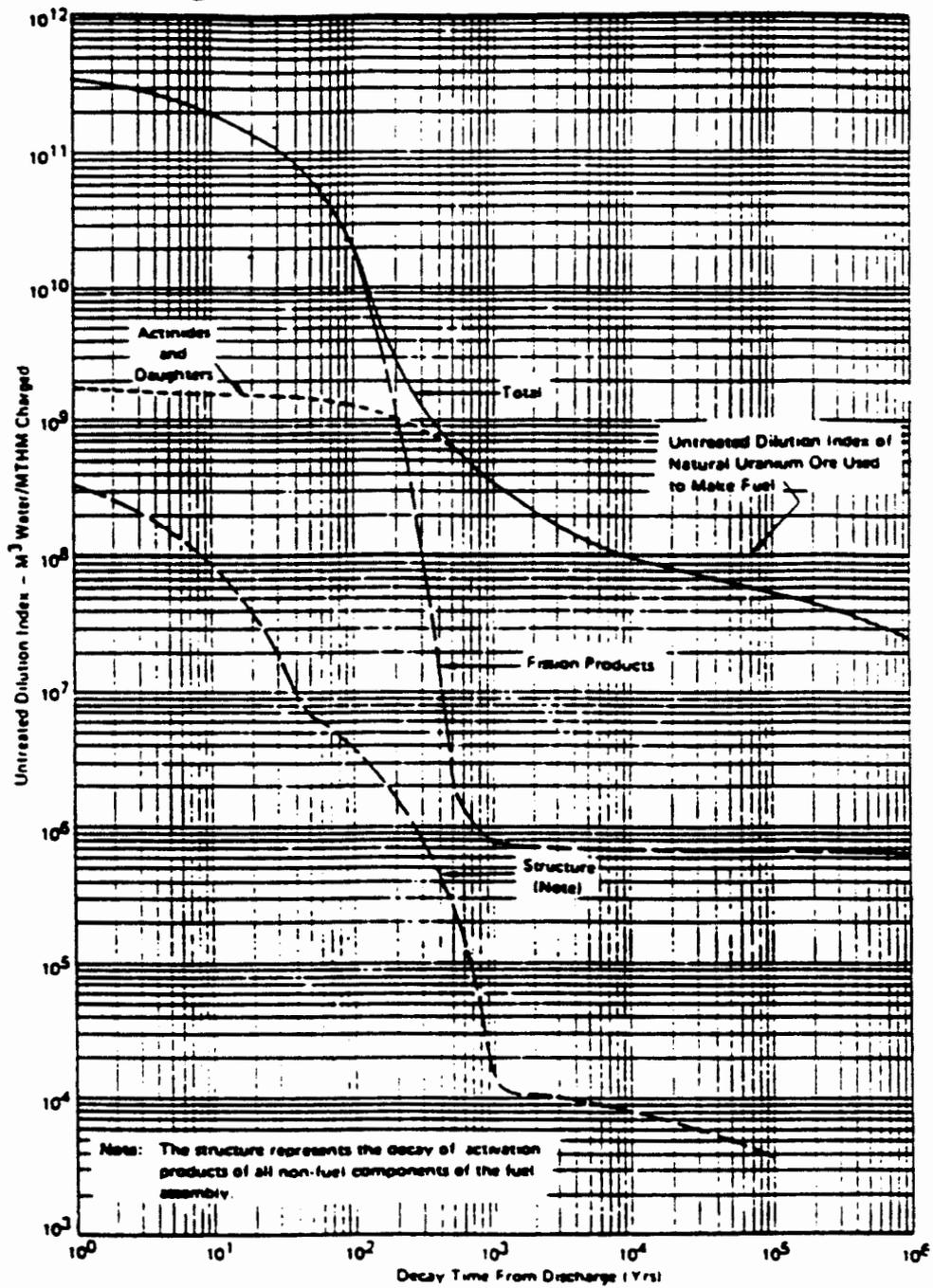


Figure A-6. PWR throwaway cycle (case 1) - untreated dilution index (all sources).
 Source: US EPA, 1977, *Technical Support of Standards for High-Level Radioactive Waste Management, Volume A, Source Term Characterization*, Arthur D. Little, Inc., EPA 520/4-79-007A.

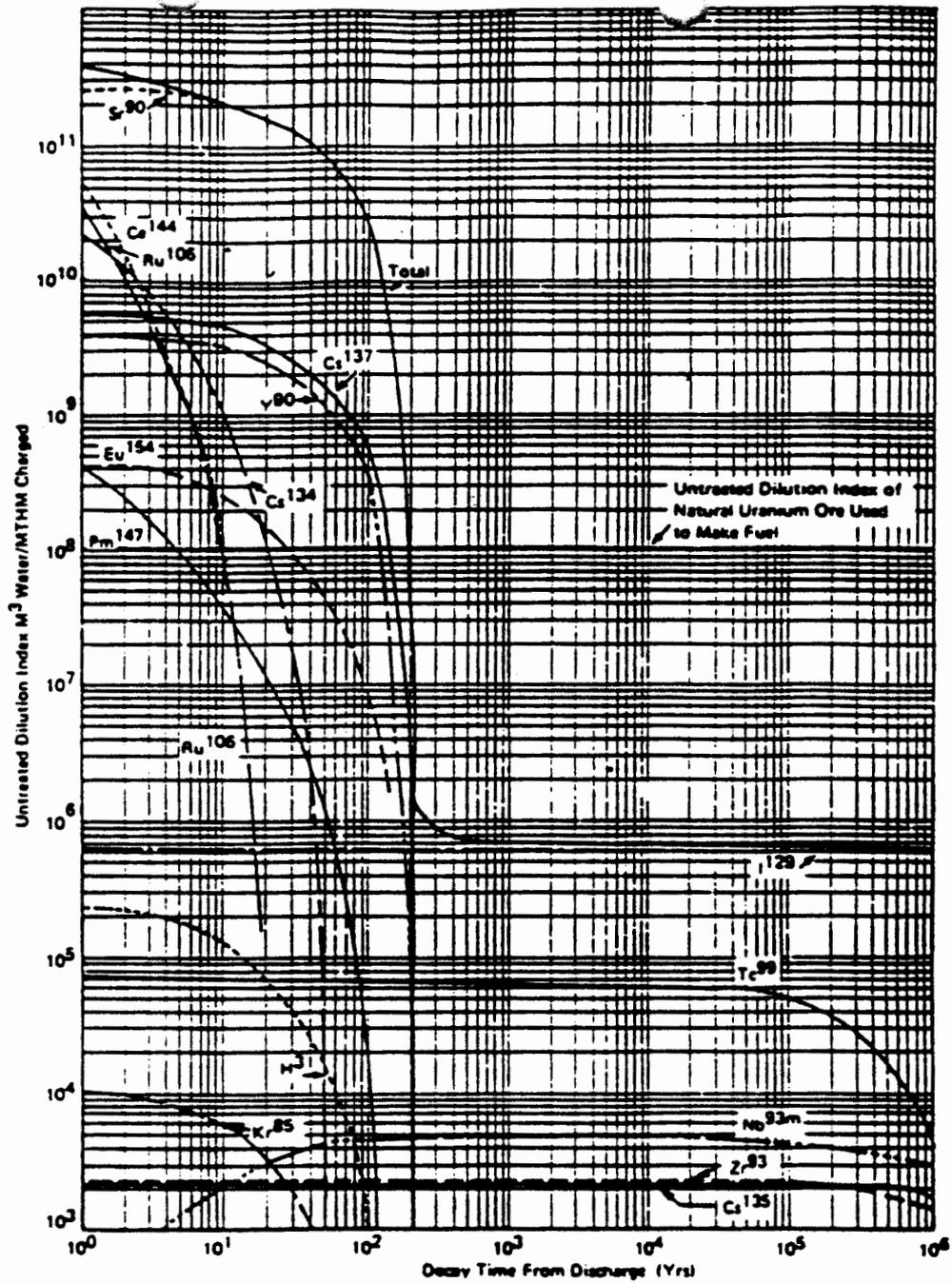


Figure A-7. PWR throwaway cycle (case 1) - untreated dilution index - fission products. Source: US EPA, 1977, *Technical Support of Standards for High-Level Radioactive Waste Management, Volume A, Source Term Characterization*, Arthur D. Little, Inc., EPA 520/4-79-007A.

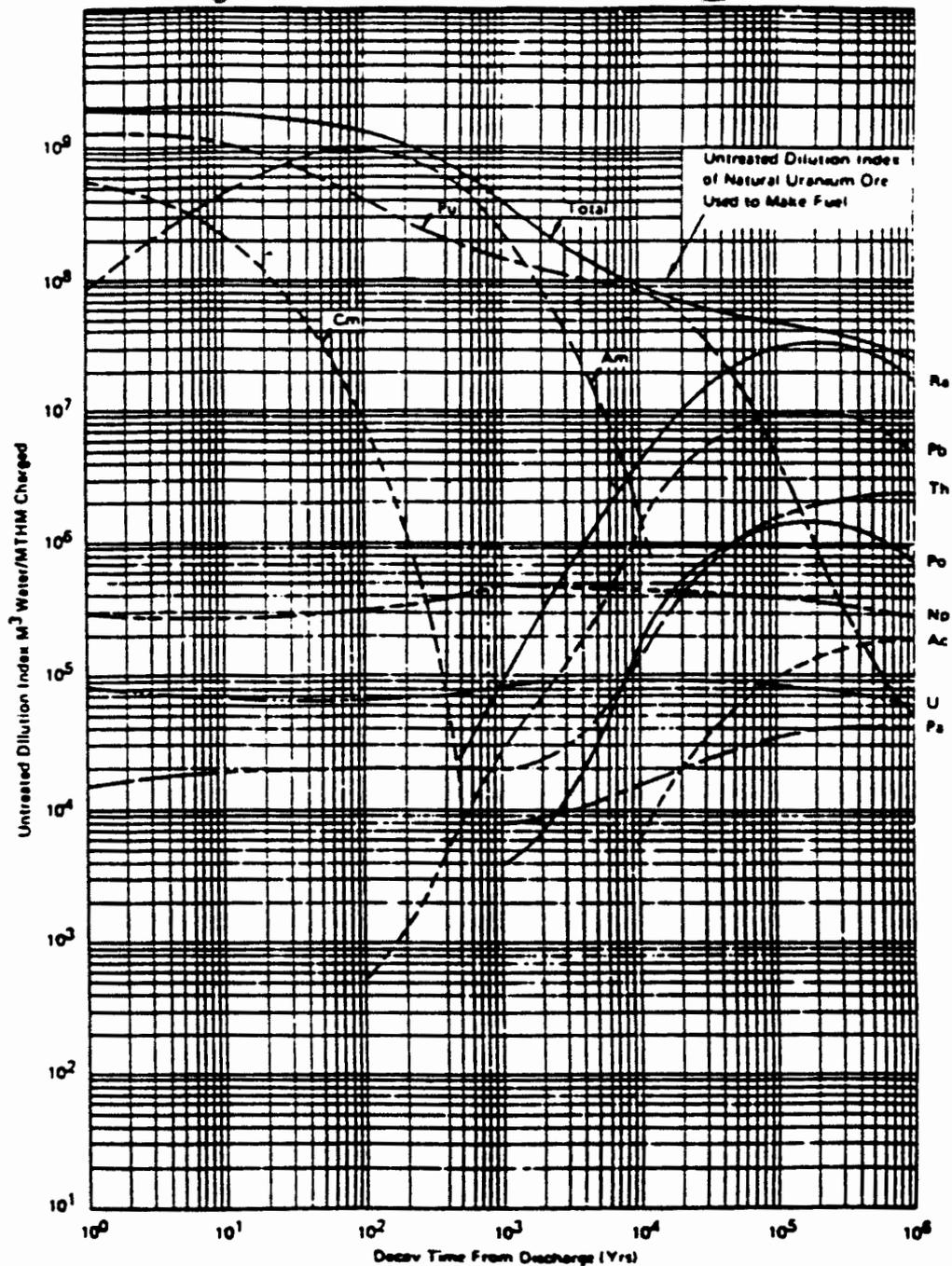


Figure A-8. PWR throwaway cycle (case 1) - untreated dilution index - actinides and daughters. Source: US EPA, 1977, *Technical Support of Standards for High-Level Radioactive Waste Management, Volume A, Source Term Characterization*, Arthur D. Little, Inc., EPA 520/4-79-007A.

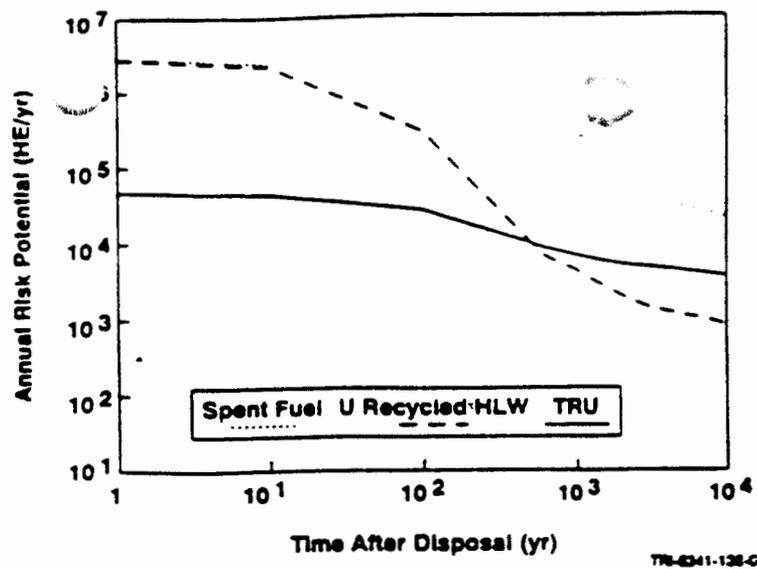


Figure 4. Risk potentials for 1,000 MTHM spent fuel and U recycled HLW, and 10^6 Ci TRU radioactive waste, based on EPA release to surface waters. Source: Klett, 1991, *Proposed Extensions of United States Fundamental and Derived Standards for High-Level and Transuranic Radioactive Waste Disposal*, SAND91-0211.

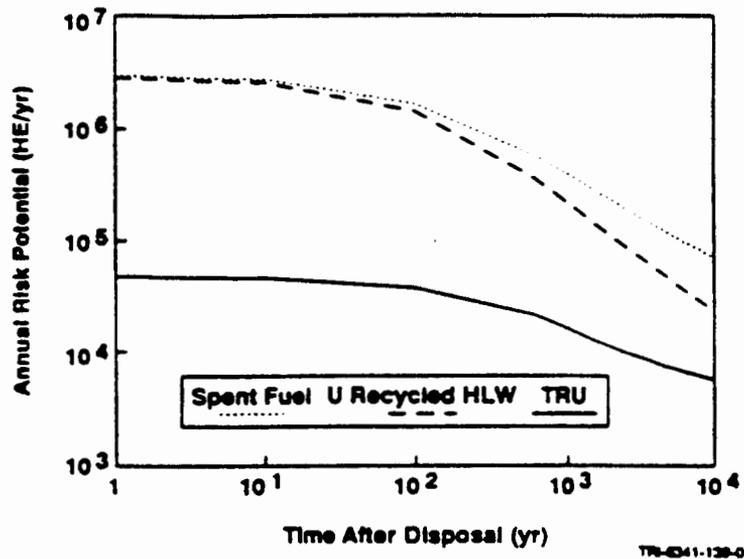


Figure 5. Time averaged risk potentials for 1,000 MTHM of spent fuel and U recycled HLW, and 10^6 Ci TRU radioactive waste, based on EPA release to surface waters. Source: Klett, 1991, *Proposed Extensions of United States Fundamental and Derived Standards for High-Level and Transuranic Radioactive Waste Disposal*, SAND91-0211.

order of magnitude less than that for spent fuel, and that the time averaged risk potential is consistently less than that for either spent fuel or HLW. These plots also demonstrate that the existing release limits are more stringent for TRU waste repositories than for spent fuel or HLW repositories. Therefore, any additional conservatism in the calculation of the waste unit is inappropriate.

The DOE is proposing that the waste-unit curie content be determined by assay prior to shipment of the waste. For newly generated waste, the waste-unit curie content assay will be consistent with the derivation of Part 191, which established zero time as the time of the generation of the waste. For old waste, this measurement will incorporate the decay that occurred during storage; the curie content at the time of generation will not be back-calculated. Assays of both old-waste and new-waste inventories can be adequately accounted for in the Performance Assessment (PA).

RECOMMENDATION:

The DOE recommends that the waste unit be based on the curie content determined at the time of assay to be performed prior to shipment to the WIPP.

3.7 SPECIFIC COMMENTS REGARDING § 194.32 SCOPE OF PERFORMANCE ASSESSMENTS

3.7.1 FIRST COMMENT

STATEMENT OF CONCERN:

Others have suggested that low probability of occurrence should not be used to eliminate events, processes or scenarios from evaluation and that numerical criteria should be established for screening based on consequence arguments.

DISCUSSION:

The DOE uses both low probability and low consequence as screening tools to screen features, events or processes from evaluation. The DOE agrees with the position stated in the Supplementary Information to the 1985 version of 40 CFR Part 191 that ". . . the Agency [EPA] believes there is no benefit to public health or the environment from trying to regulate the consequences of such very unlikely events." (50 FR 38071). If events and processes cannot be screened out on the basis of low probability, events such as meteorite impacts and volcanic eruptions are given levels of credibility that their likelihoods of occurrence do not merit. Consequently, such considerations are not justified from a cost/benefit perspective.

In addition, the release limits in the Containment Requirements are probabilistic, so consequences that have low probabilities of occurrence are not relevant to compliance assessment.

Based on Appendix C guidance to the Standard, certain processes and events that may occur and affect the disposal system can be excluded from PA analyses. The guidance for the use of consequence in the screening of processes and events from performance assessments is based on "a reasonable expectation that the remaining probability distribution of cumulative releases would not be significantly changed by such omissions" (50 FR 38088). This wording indicates that the implementing agency must explain or demonstrate why exclusion of a process or event on the basis of low or no consequence would not significantly affect the CCDF. The EPA retains the right to accept or reject the explanation or demonstration.

RECOMMENDATION:

The DOE recommends that low probability of occurrence and consequence, as defined in Appendix C to Part 191 and used as one of the bases for the Standards in Appendix A, retained as screening criteria for processes, events, and scenarios.

3.7.2 SECOND COMMENT

STATEMENT OF CONCERN:

Recent discussion in the technical community have suggested that the 10,000 year limit in the disposal standards is not sufficient to adequately mitigate the hazards associated with the long-lived waste. The DOE wishes to provide input to the EPA on this topic.

DISCUSSION:

The DOE agrees with the philosophy set forth in the Supplementary Information for 40 CFR Part 191 that:

There was no intention to indicate that times beyond 10,000 years were unimportant, but the Agency felt that a disposal system capable of meeting the proposed containment requirements for 10,000 years would continue to protect people and the environment well beyond 10,000 years. (Final Rule, 40 CFR Part 191, 50 FR 38076)

DOE supports the EPA position:

. . . that 10,000 years was chosen, in part, because compliance with quantitative standard for a substantially longer period would have entailed considerably more uncertain calculations. (Final Rule, 40 CFR Part 191, 50 FR 38076)

Furthermore, the DOE shares the EPA concern that:

Those commenters who argued for longer periods did not suggest effective ways that might compensate for the substantially greater uncertainties inherent in longer projections of disposal system performance. (Final Rule, 40 CFR Part 191, 50 FR 38076).

The source term for time periods beyond 10,000 years would be lower than that of the uranium ore, i.e., health effects would drop below the basis used to derive 40 CFR Part 191 (see Figure A-6 in the comment on Section 194.31). The 10,000 period has been well established in both the ORIA's rulemaking and in rulemaking by the EPA's Office of Solid Waste as a reasonable period for the prediction of the isolation capabilities of a disposal system. Further, it must be noted that the performance measure in 40 CFR Part 191 was developed on a 10,000 year basis.

With regard to natural processes that could disrupt the waste disposal system, a review of the Final Environmental Impact Statement (FEIS) and the Geological Characterization Report reveals that no problems are anticipated as indicated in the following:

- The waste at WIPP is expected be isolated from circulating groundwater for over 2 million years,
- Erosion will not expose the waste within the required 10,000 year period of regulatory concern,
- Seismic activity nearby poses no threat to the long-term integrity,
- There are no known post-Permian faults in the area,
- There is no evidence of recent igneous activity. A nearby dike, which is the only indication of igneous activity in the Delaware Basin, is 35 million years old,
- Geothermal gradient is normal.

RECOMMENDATION:

The time period of regulatory concern for the Containment Requirements should be retained at 10,000 years, consistent with 40 CFR Part 191.

3.8 SPECIFIC COMMENTS REGARDING § 194.33 CONSIDERATION OF HUMAN-INITIATED PROCESSES AND EVENTS

STATEMENT OF CONCERN:

The determination of the proper way to treat human-initiated events and processes is one of the more contentious topics contained within the proposed standards. This is because such considerations can range over a broad spectrum of assumptions. For example, based on testimony given during public hearings and comments of the proposed 40 CFR Part 194, the recommended number of drill holes that are to be modeled to penetrate the repository in 10,000 years varies from one to over 3000 depending on the assumptions used in determining drilling rates and in the credit taken for markers and monuments that are used to warn drillers.

Resolving this and related issues requires a systematic approach and a logical use of available data to assure consistency with the bases used by the EPA in formulating the final disposal standards in 40 CFR Part 191.

The following discussion describes the approach that the DOE is using to resolve these issues for the final compliance certification application. This information is provided to the EPA to assure that this logic is documented in the 40 CFR Part 194 rulemaking docket. Additional detail will be provided in the final application after all data collection and verification activities are completed and appropriate performance assessment calculations performed.

DISCUSSION:

1. Drilling Rate—A review of public comments on the issue of drilling rates shows nearly unanimous agreement on one topic, that the EPA used only exploratory holes in its technical basis for developing the standards. There is significant diversity of opinion, though as to whether or not this is the correct assumption for the WIPP. The DOE believes that exploration of an area and the development of any resources found by that exploration activity require fundamentally different assumptions. The DOE believes that in developing the final disposal standards, the EPA has correctly limited the considerations about human intrusion to exploratory drilling. This is because such drilling is independent of the drilling (or mining) that would accompany resource development.

It is the geologic characteristics of a region, including its structure, that draws a driller to a particular area for exploration. On the other hand, the extent to which subsequent drilling occurs (development drilling) specifically depends on the nature of the resource that is discovered. For example, a driller may venture into the Delaware Basin because he knows that sedimentary basins often have resources associated with them. Once he confirms that favorable characteristics for resource accumulation are present, specific targets for specific resources are sought. Liquid resources, like oil and gas, are sought in "traps" defined by local geological relationships. These regional or localized features are drilled in a manner that is significantly different than the basin-wide exploration activities. Consequently, it is inconsistent with EPA's assumptions to mix exploration drilling with development drilling in any context, and particularly in the context of determining the rate of inadvertent human intrusion. It is this mixing of drilling activities that has resulted in the extremely high intrusion rates for the Delaware Basin.

As pointed out previously, the EPA has stated:

. . . that the most productive consideration of inadvertent intrusion concerns those realistic possibilities that may be usefully mitigated by repository design, site selection, or use of passive controls (Final Rule, 40 CFR Part 191, Appendix C, 50 FR 38089).

Furthermore, the EPA concluded that:

. . . inadvertent and intermittent intrusion by exploratory drilling for resources . . . can be the most severe intrusion scenario assumed by the implementing agencies (Final Rule, 40 CFR Part 191, 50 FR 38089).

Also, the EPA stated as guidance that:

. . . the implementing agencies can assume that passive institutional controls or the intruders' own exploratory procedures are adequate for the intruders to soon detect, or be warned of, the incompatibility of the area with their activities (Final Rule, 40 CFR Part 191, 50 FR 38089).

Finally, the disposal standard allows the implementing agency to "assume" that systematic development is deterred:

. . . the Agency assumed that society in general will retain knowledge about these wastes and that future societies should be able to deter systematic or persistent exploitation of a disposal site (Final Rule, 40 CFR Part 191, 50 FR 38080).

Therefore, inclusion of developmental drilling when calculating the frequency of human intrusion is not consistent with this earlier EPA position.

2. Delaware Basin Definition—Closely related to the determination of the drilling rates is the definition of the "geologic structure" that will attract future societies to explore the area looking for resources. Since resources are typically tied to "geological features", the implication is that the area needs to be defined differently for different resources. For example, the oil and gas industry looks at the Delaware Basin as being structurally distinct from surrounding production areas. They use the inner edge of the Capitan Reef in defining the boundary of the Delaware Basin. To the south, the basin margin is not clearly defined but is typically taken to be the northern opening of the Hovey Channel. This area encompasses nearly 23,100 square kilometers. A preliminary estimate shows nearly 13,000 exploration and development drill holes over an 80-year period. A determination of how many of these are classed as exploratory is being conducted at this time. Based on all indications from the various drilling data bases being evaluated, the DOE believes that the final rate, however, will be less than the minimum established by the proposed certification criteria rule.

RECOMMENDATION:

The EPA should clearly define the use of exploratory wells in the development of intrusion rates to be consistent with the technical basis for the final disposal standards. In addition, the criteria should retain its use of the Delaware Basin consistent with the discussion above as the area of interest.

3.9 SPECIFIC COMMENTS REGARDING § 194.43 PASSIVE INSTITUTIONAL CONTROLS

3.9.1 FIRST COMMENT

STATEMENT OF CONCERN:

Others have suggested that credit should not be allowed for potential effectiveness of passive controls as a deterrent to potential inadvertent human intrusions. Conversely, the EPA's Supplementary Information in the proposed 40 CFR Part 194 states that:

The Agency may (emphasis added) be willing to consider such contributions if a persuasive case can be made that the passive institutional controls can be expected to endure and act as a deterrent to potential intruders. (Proposed Criteria, 40 CFR Part 194, 60 FR 5779).

DISCUSSION:

The EPA's Supplementary Information published with the 1985 promulgation of 40 CFR Part 191 states their assumption that passive institutional controls can be effective in deterring inadvertent human intrusion:

The Agency also assumed that passive institutional controls should reduce the chance of inadvertent intrusion compared to the likelihood if no markers and records were in place. (Final Rule, 40 CFR 191, 50 FR 38080)

The EPA has stated the implications of not undertaking Performance Assessments consistent with these assumptions:

Not allowing passive institutional controls to be taken into account to some degree when estimating the consequences of inadvertent human intrusion could lead to less protective geologic media being selected for repository sites (emphasis added). The Agency's analyses indicate that repositories in salt formations have particularly good capabilities to isolate the wastes from flowing ground water and, hence, the accessible environment. However, salt formations are also relatively easy to mine and are often associated with other types of resources. If performance assessments had to assume that future societies will have no way to ever recognize and limit the consequences of inadvertent intrusion (from solution mining of salt, for example), the scenarios that would have to be studied would be more likely to eliminate salt media from consideration than other rock types. Yet, this could rule out repositories that may provide the best isolation, compared to other alternatives, if less pessimistic assumptions about survival of knowledge were made (50 FR 38080);

and

The implementing agencies are responsible for selecting the specific information to be used in these and other aspects of performance assessments to determine compliance with 40 CFR Part 191. However, the Agency believes it is important that the assumptions used by the implementing agencies are compatible with those used by EPA in developing this rule. Otherwise, implementation of the disposal standards may have effects quite different than those anticipated by EPA (emphasis added) (50 FR 38074).

RECOMMENDATION:

The EPA should continue to allow credit for the planned implementation of passive institutional controls. If defensible credit for the effectiveness of passive controls is not allowed, the resulting analysis will be inconsistent with the conceptual basis of 40 CFR Part 191. It is recommended that 40 CFR 194.43 be revised to acknowledge that the assumptions used in the final disposal standards are valid. This includes the assumption that systematic and persistent exploitation are deterred and that inadvertent intrusion be deterred for as long as markers are effective. In addition, 40 CFR 194.43(c) should be revised as follows:

The Administrator shall allow such credit, or a smaller credit, to be taken in the Department demonstrates, consistent with a reasonable expectation, that such credit is justified because the passive institutional controls can be expected to endure and be understood by potential intruders for the period of time postulated.

3.9.2 SECOND COMMENT

STATEMENT OF CONCERN:

Neither the Supplementary Information nor the proposed rule tells how credit for passive institutional controls is to be taken.

RECOMMENDATION:

Add the following text to the Supplementary Information:

The Agency will allow credit to be taken for the design and planned implementation of each type of passive institutional control. The amount of credit allowed, in terms of the percentage reduction in the calculated drilling rate and the time such reduction applies, will be consistent with the design proposed. Designs need not be planned for effectiveness over the entire 10,000-year period of regulatory concern in order to provide a credit but they must be consistent with the Agency's requirements that they be the most permanent practicable.

Performance assessment calculations must be undertaken and a compliance certification application submitted to the Agency well in advance of the actual need for the implementation of passive institutional controls. The Agency will allow credit to be taken in performance

assessment calculations for the effectiveness of passive institutional controls based on a reasonable expectation, prior to the preparation of final plans or the actual implementation of the controls.

Create new subsections under 40 CFR Part 194.43 (b):

(i) The descriptions of the proposed passive institutional controls shall be contained in a detailed reference design, consistent with EPA guidance that the passive institutional controls be "practicable" (40 CFR Part 191.14(c)). Given the long period of time between development of the reference design and the implementation of the passive institutional controls, the reference design may be modified with concurrence by the EPA Administrator.

(ii) The expected effectiveness of the proposed passive institutional controls as a function of time is to be established by the Department. Information supporting the credit proposed will be included in the compliance certification application. A passive institutional control is considered to be effective if there is a reasonable expectation that its messages will endure and be understood.

(iii) The proposed passive institutional controls need not be implemented (e.g., markers constructed) prior to incorporating credit for the controls in performance assessment calculations.

(iv) The Administrator will review the reference design, expected efficacy, and the supporting information. If the Administrator modifies or rejects the credit proposed, the Agency will provide a justification and indicate the information that will be necessary for approval of credit.

Rewrite the second sentence 40 CFR Part 194.43 (c) as follows:

The Administrator shall allow such credit, or a smaller credit, to be taken if the Department demonstrates, consistent with a reasonable expectation, that such credit is justified because the passive institutional controls can be expected to endure and be understood by potential intruders for the period of time postulated.

3.9.3 THIRD COMMENT

STATEMENT OF CONCERN:

The statement in the Supplementary Information that:

The Agency may be willing to consider such contributions if a persuasive case can be made that the passive institutional controls can be expected to endure and act as a deterrent (emphasis added) to potential intruders (60 FR 5779).

and the language at proposed 40 CFR Part 194.43(c) stating that:

The Administrator shall allow such credit, or a smaller credit, to be taken if the Department demonstrates that such credit is justified because the passive institutional controls can be expected to endure, be understood, and act as a deterrent (emphasis added) to potential intruders throughout the regulatory time frame (60 FR 5789).

is not clear in that the concept of deterrence is inconsistent with the intent of 40 CFR Part 191, as stated in 40 CFR Part 191, Appendix C that:

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 (Final Rule, 40 CFR Part 191, Appendix C).

DISCUSSION:

The EPA should clarify the usage of the term "act as a deterrent" because the implication is that if a message endures and is understood, but potential intruders do not change their intended course of action, the passive institutional control has not been effective. The EPA's language in 40 CFR Part 191 states repeatedly that the concern with human intrusion is for **inadvertent human intrusion (emphasis added)**. If a message is communicated and understood, whether the potential intruder changes course of action or not, the passive institutional control has been effective. The passive institutional control has been effective because any intrusion would no longer be inadvertent, but would be intentional. The responsibility for intentional, informed intrusion rests with the intruder.

The EPA's language elsewhere in the proposed rule correctly limits the discussion to effective communication by stating "Any 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 (emphasis added)" (60 FR 5789 [§ 194.43(b)]).

RECOMMENDATION:

Rewrite the second sentence 40 CFR Part 194.43 (c) as follows:

The Administrator shall allow such credit, or a smaller credit, to be taken if the Department demonstrates, consistent with a reasonable expectation, that such credit is justified because the passive institutional controls can be expected to endure and be understood by potential intruders for the period of time postulated.

3.9.4 FOURTH COMMENT

STATEMENT OF CONCERN:

The EPA's language in the proposed 40 CFR Part 194.43(c) states that "The Administrator shall allow such credit, or a smaller credit, to be taken if the Department demonstrates that such credit is justified because the passive institutional controls can be expected to endure, be understood, and act as a deterrent to potential intruders throughout the regulatory time frame (emphasis added)."

DISCUSSION:

This text suggests that only those passive institutional controls expected to deter inadvertent human intrusion for the entire 10,000-year period of regulatory concern can be considered for providing a credit. This is inconsistent with the text in the Supplementary Information and in the proposed 40 CFR Part 194.43(b) which require a certification application to include "the period of time those controls are expected to endure and be understood."

EPA's language requiring passive institutional controls states that:

Disposal sites shall be designated by the most permanent markers, records, and other passive institutional controls practicable (emphasis added) to indicate the dangers of the wastes and their location (50 FR 38086, 40 CFR 191.14(c)).

The extent and design of the passive institutional controls that are necessary is based on the requirements that they be "practicable". Likewise, the assumptions that the Agency has made about the effectiveness of passive institutional controls are compatible with the requirement that the controls be "practicable".

RECOMMENDATION:

Rewrite the second sentence 40 CFR Part 194.43 (c) as follows:

The Administrator shall allow such credit, or a smaller credit, to be taken if the Department demonstrates, consistent with a reasonable expectation, that such credit is justified because the passive institutional controls can be expected to endure and be understood by potential intruders for the period of time postulated.

3.9.5 FIFTH COMMENT

STATEMENT OF CONCERN:

Text in the proposed rule states the Administrator shall allow credit for passive institutional controls if "the Department demonstrates that such credit is justified" (60 FR 5789).

DISCUSSION:

There may be confusion as to the extent of the demonstration required to take credit for

passive institutional controls. The "reasonable expectation" concept from 40 CFR Part 191 must be included here. Credit for passive institutional controls would be incorporated into the calculations to determine compliance with the containment requirements. Text in the Supplementary Information published with the 1985 promulgation of 40 CFR Part 191 states that: "...a paragraph has been added . . . to emphasize that unequivocal proof of compliance is neither expected nor required because of the substantial uncertainties inherent in such long-term projections. Instead, the appropriate test is a reasonable expectation of compliance based upon practically obtainable information and analysis" (50 FR 38076). In addition, the evidence provided should be consistent with the EPA's instructions: "However, assessing the ways and the reasons that people might explore underground in the future--and evaluating the effectiveness of passive controls to deter such exploration near a repository--will entail informed judgment and speculation. It will not be possible to develop a 'correct' estimate of the probability of such intrusion" (50 FR 38077).

The EPA has further stated that the use of expert judgment in the performance assessment predictions is appropriate and necessary: "In making these various predictions, it will be appropriate for the implementing agencies to make use of rather complex computational models, analytical theories, and prevalent expert judgment relevant to the numerical predictions. Substantial uncertainties are likely to be encountered in making these predictions. In fact, sole reliance on these numerical predictions to determine compliance may not be appropriate: the implementing agencies may choose to supplement such predictions with qualitative judgments as well" (50 FR 38088).

RECOMMENDATION:

Rewrite the second sentence 40 CFR Part 194.43 (c) as follows:

The Administrator shall allow such credit, or a smaller credit, to be taken if the Department demonstrates, consistent with a reasonable expectation, that such credit is justified because the passive institutional controls can be expected to endure and be understood by potential intruders for the period of time postulated.

3.10 SPECIFIC COMMENTS REGARDING §194.45 CONSIDERATION OF RESOURCES

STATEMENT OF CONCERN:

A recent minerals report that was commissioned by the DOE and authored by the New Mexico Bureau of Mines and Mineral Resources (NMBMMR) has been tied to compliance to this portion of the proposed rules. The DOE wishes to put the report into the proper perspective.

DISCUSSION:

Numerous comments have been made over the past decade regarding the presence of minerals at the WIPP. WIPP project detractors state that because one of the assurance requirements of 40 CFR Part 191 discourages the use of sites that may be rich in minerals, the WIPP is in

"violation" of the standards. Obviously, such statements do not convey the entire picture since the standard (at 40 CFR 191.14(e)) actually allows such sites if the favorable characteristics of the site can be shown to compensate for any increased risk due to resources. However, since the determination of risk of inadvertent intrusion is defined by regional activity, it is not apparent that the presence or absence of minerals at the WIPP site is even relevant. Furthermore, the inclusion of the resource provisions as an assurance requirement means that containment will have to be demonstrated independent of the presence or absence of resources. The recent publication of a minerals re-evaluation by the NMBMMR has been characterized by some as evidence that the risk to WIPP is greater than originally envisioned. This is a mischaracterization of the study. The study was performed simply because the regulations being satisfied by the DOE require the use of current information. The DOE judged, based on the oil and gas activity and the changes in market conditions for minerals that these older data were no longer sufficient to satisfy the requirements for current data. Consequently, a re-evaluation was performed. The original conclusions drawn from the mineral studies done in the 1970's have not changed. These original studies were conducted for three reasons. First, it was necessary to understand the nature and scope of minerals development in order to identify an intact block of salt for the repository. This was done successfully with the identification of the WIPP site as it exists today. The minerals re-evaluation has not changed this. Second, the extent of minerals development in the area was required to assess the risk that such development might pose to the repository. This consideration was included in the Final Environmental Impact Statement and will be part of the Performance Assessment for compliance to the disposal standards. The minerals re-evaluation has not resulted in any change in the assumptions for the process for inclusion of the risks in the Performance Assessment. Finally, the decision making process mandated by federal standards in the National Environmental Policy Act (NEPA) requires the evaluation of the impacts of the denial of resources in the decision making process. The extent of this consideration is documented in the FEIS, Table 9-14. The currently denied quantities in the updated report are significantly less than those that were used as the basis for the NEPA decision in 1980. Consequently, this decision would not change based on the re-evaluation. In summary, the minerals re-evaluation report allows the DOE to comply with regulations that require the submittal of current information. It does not invalidate or otherwise change any of the bases used previously in decision making. It has had no impact on the approach to modeling long-term compliance of the disposal system.

RECOMMENDATION:

The EPA should keep the resources report in the proper perspective during deliberations over the significance of the resources in the vicinity of the WIPP.

4.0 REVISIONS TO PREVIOUSLY SUBMITTED COMMENTS

4.1 REVISION TO COMMENT #6 IN PART I OF THE DOE'S SUBMITTAL (DOCKET ITEM IV-D-90)

REASON FOR REVISION:

DOE would like to clarify that the NQA-1 graded approach that it uses to implement its QA program is related to items and activities which are important to nuclear safety and waste isolation. The previous comment (COMMENT #6 in the earlier submittal) should have included the words "nuclear" and "waste isolation". This revised comment is repeated in total as follows (revision is in the DISCUSSION section and is underlined):

6. REQUEST FOR COMMENT ON PAGE 60 FR 5770, col. a

Relevant Text from the Supplementary Information

(Text beginning on page 60 FR 5770, col. b)

The ASME NQA-1-1989 edition sets forth requirements for the "establishment and execution of quality assurance programs for the siting, design, construction, operation, and decommissioning of nuclear facilities."

The NQA-2(a)-1990 addenda (part 2.7) to ASME NQA-2-1989 edition standard is directed toward establishing requirements for "the development, procurement, maintenance, and use of computer software, as applied to the design, construction, operation, modification, repair, and maintenance of nuclear facilities." More specifically, it applies to computer software "used to produce or manipulate data which is used directly in the design, analysis, and operation of structures, systems, and components."

*The NQA-3-1989 edition standard sets forth quality assurance requirements for "the collection of scientific and technical information for site characterization of high-level nuclear waste repositories." The requirements apply to "activities which could affect the quality of scientific and technical information collected as part of the site characterization phase of high-level nuclear waste repositories * * * [which include] as a minimum: (a) Readiness reviews; (b) peer reviews; (c) data and sample management; (d) data collection and analysis; (e) coring; (f) sampling; (g) in situ testing; and (h) scientific investigations."*

EPA is proposing criteria which require submission of information which demonstrates that QA programs have been established and executed for aspects of the WIPP disposal system important to the containment of waste in the disposal system. QA programs must address elements such as models used to support applications for certification of compliance, waste characterization, monitoring, field measurements, design of the disposal system (and actions taken to ensure compliance with design specification), use of expert judgment, and other factors important to the containment of radionuclides in the disposal system. EPA solicits comment on the appropriateness of the items listed above and on any other items which should be specifically included in such a list.

DOE Comment

The DOE generally agrees with the approach that the EPA has described. Because NQA allows the implementing agency to use a graded approach to QA, the levels of documentation may not be the same for all the items in all the categories that the EPA lists. The graded approach emphasizes aspects of the disposal system that are important to nuclear safety and waste isolation. The DOE has successfully used the graded approach at the WIPP and at other facilities as a means to assure the quality of data collection programs, operational programs, and construction programs are matched to the safety significance of the activity being performed.

**4.2 REVISION TO COMMENT ON 194.22(b) CONTAINED IN PART II-18
and 19 OF THE DOE'S SUBMITTAL (DOCKET ITEM IV-D-90)**

REASON FOR REVISION:

Clarification of a previously submitted comment.

DOE Comment

The DOE would like to clarify its previously cited recommended action. Qualification of data is discussed specifically in paragraph 9 of Supplement 3 SW-1. Our reference to Supplement 3 SW-1 should have specifically stated paragraph 9 of this Supplement.