United States
Environmental Protection
Agency

Air and Radiation
(6602J)

EPA 402-R-96-001
January 1996

Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations

Response to Comments Document for 40 CFR Part 194

RESPONSE TO COMMENTS

40 CFR Part 194:

Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations

January 31, 1996

Office of Radiation and Indoor Air
U.S. Environmental Protection Agency
Washinton, D.C.

INTRODUCTION

The Waste Isolation Pilot Plant (WIPP) is a deep geologic repository proposed for the disposal of transuranic radioactive waste. The facility, operated by the Department of Energy (DOE), is subject to compliance with 40 CFR part 191, *Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes* (hereafter "radioactive waste disposal regulations" or "disposal regulations") promulgated by the U.S. Environmental Protection Agency (EPA). In 1992 Congress enacted the Waste Isolation Pilot Plant Land Withdrawal Act (WIPP LWA), which called for EPA to issue final radioactive waste disposal regulations, to issue criteria for determining whether the WIPP complies with the radioactive waste disposal regulations and for certifying whether the WIPP facility in fact complies with the disposal regulations. See generally WIPP LWA § 8, Pub. L. No. 102-579.

The radioactive waste disposal regulations establish general standards that apply to the disposal of spent nuclear fuel, high-level or transuranic radioactive wastes. The regulations require affected disposal systems to analyze their performance over 10,000 years and to predict releases of waste relative to specific containment requirements, to assess potential radiation doses received by individuals and through ground water, and to address assurance requirements intended to provide the confidence needed for long-term compliance with the containment requirements. Under section 8(d)(1) of the WIPP LWA, DOE must submit to EPA, and the Agency must approve, an application for certification of compliance before transuranic radioactive waste may be emplaced for disposal in the WIPP. If EPA certifies compliance, every five years following initial receipt of transuranic waste, section 8(f) of the WIPP LWA requires DOE to submit documentation for EPA to determine whether the WIPP facility continues to be in compliance with the disposal regulations. The compliance criteria, finalized in this rulemaking, to be codified at 40 CFR part 194, explain the basis on which the Agency will evaluate whether the DOE's WIPP facility complies and, if so, continues to comply with the disposal regulations of 40 CFR part 191. The WIPP LWA call for specific criteria, implementing the general disposal regulations at the WIPP facility.

Radioactive Waste Disposal Regulations: 40 CFR part 191

The EPA has the responsibility of promulgating the Federal environmental standards for spent nuclear fuel, high-level, and transuranic radioactive wastes. Standards for disposal were first promulgated in 1985 and judicial review was sought. The U.S. Court of Appeals for the First Circuit remanded 40 CFR part 191, subpart B to the Agency for further consideration. See NRDC v. EPA, 824 F.2d 1258 (1st Cir. 1987). The court found that the rationale for the individual protection requirements was insufficient and that the public was given inadequate notice of the groundwater protection requirements. However, the remand encompassed all aspects of Subpart B. Section 8 of the WIPP LWA reinstated the 1985 disposal standards, Subpart B, except those portions that were the subject of the judicial remand. Section 8 of the WIPP LWA also required the Agency to issue final disposal standards, to address the issues that were the subject of the remand. The Agency published the proposed amendments to 40 CFR part 191 in the *Federal Register* on February 10, 1993 (58 FR 7924). The EPA held

public hearings in New Mexico. See 58 FR 8028 (Feb. 11, 1993). The EPA extended the public comment period, in response to commenters at the public hearings. See 58 Fed. Reg. 15,320 (March 22, 1993). Final amendments were published in the *Federal Register* on December 20, 1993 (58 FR 66397).

WIPP Compliance Criteria: 40 CFR part 194

As noted, the WIPP LWA requires EPA to promulgate "Compliance Criteria" to implement the disposal regulations specifically for WIPP. See WIPP LWA § 8(c). Since the enactment of the WIPP LWA, EPA has been developing the criteria that will implement the 40 CFR part 191 disposal standards at the WIPP. The EPA has endeavored to provide substantial opportunity for public participation in the development of the compliance criteria. Some of the public outreach efforts are summarized below. In addition, EPA maintains a toll-free WIPP "hotline" to facilitate communications with the public.

The Agency published an Advance Notice of Proposed Rulemaking (ANPR) in the *Federal Register* on February 11, 1993 (58 FR 8029). The ANPR requested comment on seven specific issues, and the responses received were considered in EPA's deliberations on the proposed criteria. In January 1994, a preliminary draft of proposed criteria was sent to interested parties for comment. Among the parties who submitted comments were DOE, New Mexico Environmental Evaluation Group (EEG), the Nuclear Regulatory Commission (NRC), several offices of the State of New Mexico including the Attorney General's office, and citizens groups based in New Mexico. The comments informed the proposed compliance criteria.

The proposed WIPP compliance criteria were published in the *Federal Register* on January 30, 1995 (60 FR 5766). The EPA held a public meeting in February 1995 to discuss aspects of the proposed rule. The EPA held a public comment period of 90 days. In addition, public hearings were held in Carlsbad, Albuquerque, and Santa Fe, New Mexico in March 1995. See 60 FR 11060 (March 1, 1995) (notice of public hearings). In response to a written request that EPA extend the initial comment period by at least 30 days, the comment period was re-opened for an additional 45 days beginning in August 1995. See 60 FR 39131 (Aug. 1, 1995). On September 6-7, 1995, EPA held a public advisory committee meeting of the WIPP Review Committee National Advisory Council for Environmental Policy and Technology (NACEPT) in Albuquerque, New Mexico. See 60 FR 43470 (Aug. 21, 1995) (notice of meeting). The EPA elicited NACEPT's advice on the proposed criteria for passive institutional controls, release limits and peer review. Members of the public were invited to submit written statements to NACEPT and EPA provided opportunity for oral public comment to the Committee during the meeting.

The EPA was sued in two separate lawsuits for its failure to meet the WIPP LWA October 30, 1994 statutory deadline for the final compliance criteria. See New Mexico v. EPA, No. 95-1273 (D.C. Cir. filed May 26, 1995) & Southwest Research and Information Center v. EPA, No. 95-1285 (D.C. Cir. filed June 1, 1995). These two petitions asserted that EPA had

unreasonably delayed issuance of the final compliance criteria and requested the D.C. Circuit to issue an order requiring EPA to promulgate the final criteria by December 31, 1995.

The petitions, and subsequent requests for rehearing, were rejected by two separate panels of the D.C. Circuit. See New Mexico, No. 95-1273 (D.C. Cir. July 19, 1995) (Judges Silberman, Sentelle and Tatel) & Southwest Research and Information Center v. EPA, No. 95-1285 (D.C. Cir. Aug. 14, 1995) (Judges Wald, Ginsburg and Randolph). The court's orders reasoned that while EPA had not issued the final compliance criteria by the statutory deadline, the agency's delay was not so egregious to warrant a writ of mandamus, particularly in view of EPA's plans to reopen the public comment period (see 60 Fed. Reg. 39,131, Aug. 1, 1995) and issue final compliance criteria by February 1996. In light of the court orders, EPA has undertaken additional steps to expedite the rulemaking and ensure that it issues the final compliance criteria by February 1996.

Approximately 125 sets of written comments were submitted to EPA's Air Docket regarding the proposed WIPP compliance criteria. In addition, the Agency received oral testimony on the proposed rule from over two hundred speakers during public hearings. Comments received on the proposal were categorized according to the following topics, which correspond generally to sections of the proposed rule:

General comments and issues
Certification conditions and applications
Inspections
Quality assurance
Models and computer codes
Waste characterization
Future state assumptions
Expert judgment
Peer review
Application of release limits
Performance assessments
Human intrusion
Active institutional controls
Monitoring
Passive institutional controls
Engineered barriers
Consideration of presence of resources
Removal of waste
Individual and ground water protection
Public participation

While a section of this document is assigned to each topic, the document should be read comprehensively. Some comments presented overlapping issues -- for example, comments regarding mining could be relevant to the discussion of *Performance Assessments* or *Human Intrusion*, or some other section. Further, some comments contain several points and some

comments repeat points that are addressed elsewhere within a particular section or in a wholly different section. While in some instances EPA has cross-referenced related responses, it has not done so in every instance. Thus, the responses to comments set out in this document should not be read in isolation. Rather, the entire document should be considered as a whole, for it collectively reflects EPA's consideration of significant comments.

This document addresses comments received on the proposed regulations by summarizing the concerns expressed by commenters and presenting the Agency's response to the comments. All comments received during the initial comment period, during the re-opened comment period, and during the time between the two comment periods have been fully considered. The Agency has addressed all significant comments, both written and oral. Responding to comments was difficult in many cases because comments did not articulate specific concerns, did not suggest concrete alternatives, or did not substantiate the position advocated.

In addition to the comments received during or between the two public comment periods, EPA received written comments after the close of the re-opened public comment period. These comments have been placed in the late comments section of the rulemaking docket (Air Docket Number A-92-56, Category IV-G) and are similarly denoted herein. The EPA has endeavored to give the late comments full consideration, although not required to do so.

Some comments misunderstand EPA's charge in the WIPP compliance criteria rulemaking. As noted, section 8(a) of the WIPP LWA expressly reinstated the provisions of the general radioactive waste regulations adopted in 1985 except the specific aspects that were the subject of the remand in NRDC v. EPA, 824 F.2d 1258 (1st Cir. 1987). See 58 FR at 66399. Section 8(b) of the WIPP LWA called for EPA to issue, through rulemaking, provisions of the disposal regulations to address those specific aspects that were remanded. The rules were issued on December 20, 1993. See 58 FR 66398. Section 8(c) of the WIPP LWA calls for EPA, through a subsequent rulemaking proceeding, to issue criteria for determining the WIPP facility's compliance with the final disposal regulations and prescribed that this rulemaking occur by specific deadlines. This is the subject matter of the current rulemaking. Section 8(d) of the WIPP LWA calls for EPA, through rulemaking, to certify whether the WIPP facility in fact complies with the disposal regulations, on the basis of the specific compliance criteria issued for the WIPP.

Some public comments on the WIPP compliance criteria requested changes to the underlying disposal regulations themselves. Some comments address the technical underpinnings upon which the disposal regulations are premised. For example, one comment questioned the probabilistic basis for the containment requirements contained in 40 CFR part 191, and another comment questioned the dose-response calculus used in developing the individual protection requirements. The disposal regulations were adopted in 1985 after extensive technical analysis and notice-and-comment rulemaking. Those aspects of the disposal regulations that were not the specific subject of the judicial remand in NRDC v. EPA were reinstated by Congress. The EPA, in turn, conducted a specific rulemaking to address those provisions that were the subject of the remand. The EPA declines at this juncture to re-open the disposal regulations, and none of the comments provide a compelling basis for EPA to

question this judgment. The EPA instead is limiting this rulemaking, pursuant to section 8(c) of the WIPP LWA, to issuing criteria to implement the disposal regulations at the WIPP facility.

Many comments reflect a different conception or perhaps in some instances a misconception about EPA's responsibility in this rulemaking proceeding. As noted, in this rulemaking EPA is implementing general radioactive waste disposal regulations at the WIPP. The disposal regulations confer broad discretion on the implementing agency because of the "cutting edge" and "one-of-a-kind" judgments that must be made in regulating radioactive waste disposal activities. This is the first time criteria have been written to implement 40 CFR part 191 at a particular site.

The EPA received many comments recommending that EPA prescribe more detailed requirements in the compliance criteria. For example, EPA received comments suggesting that the compliance criteria dictate specific engineered barriers for the WIPP. At the same time, DOE, its contractors and its scientific labs were highly critical that EPA's compliance criteria contain too much specificity and unduly constrain DOE.

The EPA has acted well within its discretion in issuing the final compliance criteria for the WIPP. In this rulemaking, EPA has insisted on rigorous analysis and detailed information to ensure that EPA and the public can thoroughly evaluate whether the WIPP complies with the disposal regulations and to ensure that the underlying data and technical support used by DOE is of sound, reliable quality. At the same time, the compliance criteria attempt to avoid prescribing specific design choices or technical decisions so that EPA does not have the unintended effect of making the facility less safe and to allow the scientists and technical experts administering the WIPP the ability to make reasoned judgments. In addition, EPA believes strongly that it is DOE’s responsibility to design the facility, and EPA’s responsibility to evaluate the adequacy of that design. The compliance criteria rulemaking will be followed by DOE submittal of a compliance application and an EPA certification rulemaking to determine whether the WIPP facility complies with the disposal regulations. The certification rulemaking provides the forum for EPA to strictly scrutinize the WIPP facility in light of the final compliance criteria.

The EPA also received public comments raising issues outside the purview of EPA's authority in this rulemaking. For example, EPA received comments recommending that EPA modify the criteria to address concerns about transportation. The radioactive waste regulations being implemented in this rulemaking address disposal requirements and deliberately do not address transportation of radioactive waste. The WIPP LWA establishes separate requirements regarding transportation, and other issues, that directly apply to DOE.

The EPA also received comments directed at a draft guidance document, called the Compliance Application Guidance (CAG). The CAG does not establish compliance criteria but is intended to summarize and interpret the criteria issued in the final rule to provide guidance for the elements of a complete compliance application. The CAG is still being

developed and is expected to be issued some time after the final rule. This document does not address comments on the CAG that are unrelated to the compliance criteria.

Some commenters requested that comments submitted on previous parts of this rulemaking be considered (for example, comments on the ANPR). The Agency has done so to the extent possible, but has omitted from this document comments which were not relevant to the proposed version of the rule. In the interest of clarity and economy, some comments are paraphrased and some closely related comments are combined.

A staff-level review of the proposed rule was conducted by the Nuclear Regulatory Commission. While EPA has addressed these comments, they do not represent the views of the Commissioners, and EPA was informed that the Commissioners have declined to comment on the compliance criteria.

Each set of comments submitted to EPA is identified by a numeric/alphabetic code indicating its source. A list of the commenters and their identification is given in Appendix A. Copies of all comments submitted to EPA regarding the proposed rule can be found in Air Docket Number A-92-56 (Categories IV-D, IV-F, and IV-G). For more information on docket locations, refer to the *Federal Register* notice for the proposed or final rule. A list of acronyms and the terms they represent are in Appendix B.

Section 1: GENERAL COMMENTS AND ISSUES

Issue A: The EPA should assume a strong, independent regulatory posture and not be overly influenced by the Office of Management and Budget (OMB) and the Department of Energy (DOE). (SGNM-B, NMAG-A, NMAG-B, NMAG-F, SRIC-A, CCNS-A,A-01, A-07, A-17, A-23, A-25, A-26, A-27, A-29, A-30, A-32, A-33, A-36, A-39, A-40, A-41, A-42, A-43, A-44, A-46, A-47, A-48, A-51, A-53, A-54, A-55, A-60, A-65, A-66, A-67, S-09, S-12, S-25, S-27, S-28, S-36, S-40, S-41, S-51, S-52, S-55, S-56, S-57, S-58, S-64, S-65, IV-D-05, IV-D-08, IV-D-09, IV-D-12, IV-D-26, IV-D-27 [same as IV-D-86], IV-D-28, IV-D-29, IV-D-89, IV-D-91, IV-D-92, IV-D-96).

1. It is requested that the Agency publish its final regulation without OMB review. The inclusion of OMB review would be contrary to the intent of Pub. L. 102-579 and the applicable Executive Order, No. 12866. (NMAG-D)

2. EPA should not submit the final rule to review by the Office of Management and Budget (OMB). OMB review provides an additional, inappropriate opportunity for DOE to comment on the criteria. OMB review is prohibited by Executive Order 12866 since there is a statutory deadline for this rule, which makes it not practicable to schedule OMB review. (SRIC-G)

3. Any rulemaking regarding certification of the WIPP should be exempt from review by the Office of Management and Budget, or any other Federal agency. (SRIC-G)

Response to Issue 1.A:

President Clinton issued Executive Order (E.O.) 12,866 on September 30, 1993. Executive Order 12,866 provides for centralized review of regulations by the Office of Management and Budget's Office of Information and Regulatory Affairs (OMB/OIRA) to coordinate agency rulemaking within the executive branch of the United States government. See E.O. 12,866, § 6.

Section 6(b)(2)(B) of E.O. 12,866 generally provides for a 90 day review period by OMB. However, section 6(a)(3)(D) of E.O. 12,866 recognizes situations when an agency may be obligated by law to act more quickly than the 90 day review period allows:

> In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify [OMB] as soon as possible and, to the extent practicable, comply with subsections (a)(3)(B) and (C) of [section 6]. For those regulatory actions that are governed by a statutory or court-imposed deadline, the agency shall, to the extent practicable, schedule rulemaking proceedings so as to permit sufficient time for [OMB] to conduct its review.

The EPA was sued in two separate lawsuits for its failure to meet the WIPP LWA statutory deadline for the final compliance criteria. See New Mexico v. EPA, No. 95-1273 (D.C. Cir. filed May 26, 1995) & Southwest Research and Information Center v. EPA, No. 95-1285

(D.C. Cir. filed June 1, 1995). These two petitions asserted that EPA had unreasonably delayed issuance of the final compliance criteria and requested the D.C. Circuit to issue an order requiring EPA to promulgate the final criteria by December 31, 1995 and prohibiting OMB review under E.O. 12,866.

The petitions, and subsequent requests for rehearing, were rejected by two separate panels of the D.C. Circuit. See New Mexico, No. 95-1273 (D.C. Cir. July 19, 1995) (Judges Silberman, Sentelle and Tatel) & Southwest Research and Information Center v. EPA, No. 95-1285 (D.C. Cir. Aug. 14, 1995) (Judges Wald, Ginsburg and Randolph). The court's orders reasoned that while EPA had not issued the final compliance criteria by the statutory deadline, the agency's delay was not so egregious to warrant a writ of mandamus, particularly in view of EPA's plans to reopen the public comment period (see 60 Fed. Reg. 39,131, Aug. 1, 1995) and issue final compliance criteria by February 1996. While the court orders did not impose a deadline upon EPA or bar OMB review, OMB review was curtailed to facilitate EPA's ability to issue the final compliance criteria by February 1996.

The EPA considered the views of OMB and DOE during the inter-agency review provided under E.O. 12,866. However, the Administrator of EPA, exercising her independent judgment, determined the contents of the final compliance criteria, considering all public comments. Congress under the WIPP LWA delegated to the Administrator of EPA exclusive authority to issue the criteria. Further, EPA's final action is fully consistent with the rulemaking procedures at 5 U.S.C. § 553 and related principles of administrative law. Among other things, all aspects of the final compliance criteria are a logical outgrowth of the proposed criteria. Consistent with E.O. 12,866 EPA has placed in the WIPP compliance criteria rulemaking docket: the draft regulatory text provided at the outset of the OMB review process, information identifying the substantive revisions between the draft submitted and the Administrator's final action, and information identifying those revisions that were made during the OMB review process. The EPA has also placed summaries of inter-agency meetings in the rulemaking docket.

The EPA will not determine whether the WIPP facility complies with the final disposal regulations until DOE submits a complete and final application and EPA conducts a thorough review of that application in a public rulemaking conducted pursuant to 5 U.S.C. § 553. DOE plans to submit its final compliance application to EPA in the Fall of 1996. No decision has been made about the conduct of the interagency review process for this rulemaking. In all circumstances, the Administrator of EPA will exercise her expertise and independent judgment in determining whether the WIPP facility complies with the radioactive waste disposal regulations. Further, EPA is committed to a decision-making process that fully comports with the law and affords ample opportunity for public scrutiny.

Issue B: Compliance procedures must protect "whistleblowers." (CARD-B, A-60, S-17, S-40, IV-D-92)

Response to Issue 1.B:

The EPA is fulfilling a specific regulatory responsibility in issuing the compliance criteria for the WIPP. Section 8(c) of the WIPP LWA directs the Administrator of EPA to issue "criteria for the Administrator's certification of compliance with the final disposal regulations." The final disposal regulations at 40 CFR part 191, subparts B and C, establish specific standards that radioactive waste disposal systems must meet. The disposal regulations for which EPA is required to establish criteria do not include whistleblower provisions or other provisions related to employer-employee management for the operators of waste disposal facilities.

Further, DOE employees are given whistleblower protection under other provisions of federal law. The Whistleblower Protection Act (WPA) (see, e.g., Pub. L. Nos. 101-12 & 103-424) provides protection for Federal employees, former Federal employees, and applicants for Federal employment against job loss and recriminations because of whistleblowing activities. Under the WPA, it is a prohibited personnel practice for an agency to subject an employee to a personnel action if the action is threatened, proposed, taken, or not taken because of the employees whistleblowing activities. The WPA defines whistleblowing activities as any disclosure of information, including any disclosure to the Office of Special Counsel or the Office of Inspector General, that the employee reasonably believes is evidence of a violation of any law, rule, or regulation, or gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety. See 5 U.S.C. § 2302. The WPA applies to all Federal employees, including employees of DOE. Thus, protection for whistleblowers is directly provided under the WPA.

The final rule provides EPA authority to conduct inspections and audits to confirm reported conditions, activities, or information in compliance applications.

Issue C: Transportation problems associated with the WIPP have not been adequately addressed. (C-11, A-04, A-05, A-17, A-19, A-22, A-24, A-28, A-35, A-37, A-39, A-50, A-51, A-54, S-14, S-15, S-31, S-32, S-36, S-38, S-40, S-41, S-46, S-56, S-59, IV-D-96, IV-D-97).

Response to Issue 1.C:

As noted in response to Issue 1.B, in this rulemaking EPA is establishing criteria for determining compliance with EPA's radioactive waste disposal regulations at 40 CFR part 191, subparts B and C, in accordance with section 8(c) of the WIPP LWA. Section 16 of the WIPP LWA contains specific provisions related to transportation of radioactive waste to the WIPP. Section 16 of the WIPP LWA contains transportation requirements that directly apply to DOE. By contrast, transportation of waste to disposal systems is beyond the scope of EPA's disposal regulations being implemented at the WIPP in this rulemaking.

Issue D: The entire concept of WIPP is flawed. It should either be abandoned or delayed indefinitely until uncertainties can be resolved. Other solutions are possible, especially those that may become viable in the future. The Agency should obtain more information before finalizing the compliance criteria. (CARD-A, EEG-B, NMAG-B, SRIC-A, SRIC-F, A-04, A-05, A-06, A-09, A-17, A-18, A-19, A-20, A-21, A-22, A-23, A-25, A-26, A-28, A-29, A-32, A-35, A-36, A-37, A-38, A-39, A-43, A-49, A-51, A-52, A-53, A-54, A-55, A-57, A-58, A-60, A-63, A-64, A-69, A-70, S-08, S-17, S-21, S-23, S-26, S-28, S-30, S-31, S-33, S-34, S-35, S-36, S-42, S-43, S-45, S-46, S-48, S-50, S-54, S-55, S-56, S-58, S-59, S-60, S-61, S-63, S-64, S-65, S-66, IV-D-05, IV-D-07, IV-D-29, IV-D-44, IV-D-45, IV-D-95, IV-D-96, IV-D-97, IV-D-98, IV-G-5)

Response to Issue 1.D:

Congress authorized DOE to proceed with construction of the WIPP:

> The Secretary of Energy shall proceed with the Waste Isolation Pilot Plant construction project authorized to be carried out in the Delaware Basin of southeast New Mexico (project 77-13-f) in accordance with the authorization for such project as modified by this section. Notwithstanding any other provision of law, the Waste Isolation Pilot Plant is authorized as a defense activity of the Department of Energy, administered by the Assistant Secretary of Energy for Defense Programs, for the express purpose of providing a research and development facility to demonstrate the safe disposal of radioactive wastes resulting from the defense activities and programs of the United States exempted from regulation by the Nuclear Regulatory Commission.

See section 213(a) of the Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1980, Pub. L. No. 96-164.

Congress subsequently withdrew the WIPP site from the public domain and reserved the lands for DOE's use for the following WIPP activities:

> Such lands are reserved for the use of the Secretary [of DOE] for the construction, experimentation, operation, repair and maintenance, disposal, shutdown, monitoring, decommissioning, and other authorized activities associated with the purposes of WIPP as set forth in section 213 of the Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1980 and [the WIPP LWA].

See section 3 of the WIPP LWA, Pub. L. No. 102-579 (citation omitted).

At the same time that Congress withdrew the WIPP site from the public domain, Congress delegated to EPA certain regulatory responsibilities at the WIPP. See, e.g., sections 8 and 9 of the WIPP LWA. As noted, EPA's responsibility in the present rulemaking is to establish criteria for determining whether the WIPP facility will comply with EPA's general radioactive

waste disposal regulations. Congress also delegated to EPA the authority to certify, in a subsequent rulemaking, whether WIPP in fact complies with the disposal regulations. This subsequent certification rulemaking will be based upon the compliance criteria issued in this rulemaking and a compliance certification application to be submitted by DOE. Thus, Congress delegated to EPA the responsibility to determine whether WIPP will comply with disposal standards intended to protect the public from radioactive releases for 10,000 years. Congress also mandated that EPA fulfill these regulatory responsibilities within specific time frames. Section 8(c) of the WIPP LWA calls for EPA to issue final compliance criteria "[n]ot later than 2 years after the date of the enactment of this Act." Section 8(d) of the WIPP LWA calls for EPA to certify whether the WIPP facility in fact complies with the disposal regulations "[w]ithin 1 year of receipt of [DOE's compliance certification] application."

Congress did not delegate to EPA the authority to abandon or delay the WIPP because future technologies might evolve and eliminate the need for the WIPP. Congress did not delegate to EPA the authority to weigh the competing risks of leaving radioactive wastes stored above-ground at disperse sites or disposing of wastes in an underground repository. These considerations are outside the scope of this rulemaking.

The comment that EPA should obtain more information before finalizing the compliance criteria is vague. The EPA believes it has a sound basis for the compliance criteria established in this rulemaking. Invariably in complicated policy making there can always be "more information" obtained to guide decision making. However, Congress did not give EPA open-ended discretion in deciding how long to take in developing the compliance criteria. The EPA has endeavored to develop criteria based on sound information while also attempting to proceed in a manner consistent with the statutory deadlines.

Issue E: The proposed rule is costly, time-consuming, vague, and provides little increase in safety. (DOE-D, NMAG-A, NMAG-G, SNL-A, SGNM-A, SGNM-C, C-06, C-10, C-11, C-12, C-13, C-16, C-17, C-18, C-19, C-20, C-22, C-23, C-25, C-26, C-27, C-29, A-16, A-18, A-20, A-31, A-34, A-35, A-38 , A-44, A-53, S-20, S-47, S-51, S-62, IV-D-35, IV-D-51, IV-D-64 [same as IV-D-78], IV-D-76, IV-D-111 [same as IV-D-118])

Issue F: The compliance criteria should be strengthened. (CCNS-A, S-13, S-14, S-15, S-21, S-24, S-36, S-39, S-58, IV-D-97).

Issue G: The strategy of having DOE conduct studies in key areas and then recommending an approach for EPA's approval is sound and should be continued. (IV-D-100)

1. 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. (IV-D-111)

Response to Issues 1.E through 1.G:

In developing the final compliance criteria EPA has considered comments explaining particular areas where the proposed rule was believed to necessitate more specificity. In the final rule, the Agency has modified several sections from the proposal to clarify requirements for compliance application analysis and supporting documentation, including, for example, the criteria on waste characterization and monitoring. These issues are addressed in other sections of this document and in the preamble accompanying the final rule.

The comments criticizing the proposed rule as providing little increase in safety and needing strengthening are not specific. The EPA takes its regulatory oversight role at the WIPP very seriously. While EPA cannot speculate what safety would be provided at the WIPP in the absence of the disposal regulations, the application of the disposal regulations protect against harmful releases of radioactive waste occurring over the next 10,000 years. The EPA has adopted specific compliance criteria for the WIPP that are fully consistent with EPA's radioactive waste disposal regulations. The EPA's charge in this rulemaking is to develop compliance criteria.

In this rulemaking, EPA has insisted on rigorous analysis and detailed information to ensure that EPA and the public can thoroughly evaluate whether the WIPP complies with the disposal regulations and to ensure that the underlying data and technical support used by DOE is of sound, reliable quality. At the same time, EPA recognizes that EPA is the overseeing regulatory agency, and not the applicant seeking certification. Thus, the compliance criteria attempt to avoid prescribing specific design choices or technical decisions so that EPA does not have the unintended effect of making the facility less safe and to allow the scientists and technical experts administering the WIPP the ability to make reasoned judgments. The Agency believes strongly that it is DOE's responsibility to design the WIPP disposal system, and EPA's responsibility to evaluate the adequacy of that design. The compliance criteria rulemaking will be followed by DOE submittal of a compliance application and an EPA certification rulemaking to determine whether the WIPP facility complies with the disposal regulations. During the certification rulemaking, DOE's application must demonstrate, explain and justify that the WIPP facility complies with the disposal regulations. In the certification rulemaking proceeding, the issues will be particularized and concrete because EPA will be making a compliance judgment based on actual, detailed information.

Issue H: 40 CFR part 194 contradicts, amends, and exceeds 40 CFR part 191 and does not support its implementation. (DOE-D, WEC-A [same as WEC-B and WEC-C], WEC-D, EEG-A, EEG-B, NMAG-B, NMAG-F, NMAG-G, SNL-A, SNL-B, SNL-C, SGNM-A, CCNS-B [same as CCNS-C], C-06, C-11, C-13, C-14, C-15, C-17, C-18, C-22, C-28, C-29, A-11, A-13, A-31 A-45, A-56, IV-D-06, IV-D-35, IV-D-64)

1. The proposed 40 CFR part 194 has logical inconsistencies. Deviations from the fundamental rationale and technical bases, or from guidance derived from the fundamental rationale and technical bases of 40 CFR part 191 should be eliminated. Any apparent or intended deviations should be justified, and the Agency should demonstrate quantitatively that

the fundamental rationale, technical bases, and guidance of 40 CFR part 191 have not been abandoned. (SNL-D)

2. Guidance in the proposed standards which are inconsistent with the fundamental basis and requirements of 40 CFR part 191 should be reconsidered. A new basis is needed to demonstrate that the results are consistent with human health and environmental protection goals. (DOE-E)

3. 40 CFR part 194 exceeds the authority granted by the WIPP LWA and violates its provisions. (DOE-A [same as DOE-B and DOE-C], DOE-D, WEC-A, WEC-D, SNL-C, SRIC-B, SRIC-C, SGNM-B, C-13, C-14, C-15, C-17, C-23, A-11, A-45, A-56, IV-D-111)

Response to Issue 1.H:

The purpose of the rule is to establish criteria that implement the 40 CFR part 191 disposal regulations at the WIPP. The provisions of the final rule are consistent with the disposal regulations; for example, §194.31 of the final rule describes how release limits should be calculated at the WIPP, and §194.41 describes the requirements for DOE to implement and document the assurance requirement for active institutional controls. The EPA has exercised discretion in adopting WIPP-specific criteria from the more general disposal regulations and in addressing issues associated with EPA's role as the implementing regulatory agency for the WIPP. The disposal regulations at 40 CFR part 191 are crafted generally. The EPA has established requirements in the compliance criteria for the WIPP that are a necessary adjunct of EPA's role as the implementing regulatory agency. For example, the criteria relating to inspections and audits are entirely consistent with EPA's mandate to implement 40 CFR part 191 at the WIPP. The EPA has also elected in this rulemaking to bind itself to specific procedures in carrying out its compliance certification rulemaking. More specific comments on the relation of the compliance criteria to the 40 CFR part 191 disposal regulations are addressed in subsequent sections of this document.

Issue I: The rule should recognize the controlled area as a component of the disposal system.

1. The terms "disposal system" and "repository" should be clarified and made consistent with Part 191. (DOE-D, SNL-A, SNL-C)

2. The phraseology "away for the disposal system" and "toward the accessible environment" (40 CFR 194) effectively eliminates the consideration of the controlled area as a key natural barrier component of the disposal system. The Supplementary Information should be revised to specifically recognize the role of controlled area as a major component of the disposal system that is expected to become contaminated during the regulatory time frame. (SNL-A, SNL-B, SNL-C)

Response to Issue 1.I:

The comment correctly states that the term "disposal system" denotes the entire system of engineered and natural barriers. The natural barriers would include those geologic formations which lie within the controlled area. Thus, in the case of ground water, for example, the movement of radionuclides into underground sources of drinking waster (USDW) *within the controlled area* would not constitute endangerment of ground water. The disposal regulations of 40 CFR part 191 permit this in recognition of the fact that the natural barriers, which might contain potable ground water, nonetheless form a part of the system which isolates the radioactive waste from the accessible environment surrounding the WIPP. See, e.g., NRDC v. EPA, 824 F.2d 1258 (1st Cir. 1987). The disposal regulations define "accessible environment" to include the all of the lithosphere that is beyond the controlled area. See 40 CFR 191.12. This definition recognizes that the controlled area may act as a natural barrier and may be considered part of the disposal system.

The word "repository" does not appear in the regulatory language of the proposed or final 40 CFR part 194. The regulatory language uses the term "disposal system" when discussing the specific requirements. Occasionally, in the supplementary information which appears in the **Federal Register**, the Agency may refer to the WIPP as the "repository." This usage does not alter the requirement placed on releases to the accessible environment, or to individuals residing in or USDW's located in the accessible environment.

Issue J: Determination proceedings shouldn't be confused with certification and shouldn't be included in this rule. (DOE-D, WEC-D, NMAG-A, SNL-C, SRIC-B, SRIC-C, CCNS-B)

Response to Issue 1.J:

Section 8(c) of the WIPP LWA requires EPA to promulgate criteria for the Administrator's certification whether the WIPP facility will comply with the final disposal regulations (at 40 CFR part 191, subparts B and C). Section 8(f) of the WIPP LWA also requires EPA to periodically "determine whether or not the WIPP facility continues to be in compliance with the final disposal regulations" (so-called "determination proceedings"). Section 8(f) of the WIPP LWA calls for DOE to submit to EPA "documentation of continued compliance with the final disposal regulations" no later than five years after the initial receipt of transuranic waste for disposal at WIPP and every five years thereafter until the end of the decommissioning phase.

The final rules contain the criteria and procedures that EPA will use to certify whether the WIPP facility complies with the disposal regulations and to subsequently determine whether the WIPP facility continues to be in compliance with the disposal regulations. Because determining whether the facility continues to be in compliance is a logical and direct outgrowth of any initial compliance certification, EPA believes it is sensible and practical to establish the requirements and procedures that will govern recertification proceedings in this rule. As reflected in the final rules, EPA may not change the terms or conditions of a compliance certification through a recertification proceeding. Any subsequent modification or revocation to the compliance certification would require reopening the compliance

certification issued under section 8(d)(1) of the WIPP LWA and therefore is subject to the rulemaking procedures at 5 U.S.C. § 553 and judicial review. Provisions related to compliance re-certifications have been retained in the final rule. See also Section 2 of this document.

Issue K: The state and Federal laws for dumping need to be respected. (S-14)

Response to Issue 1.K:

As noted, section 8 of the WIPP LWA requires EPA to establish in this rulemaking the criteria that implement EPA's radioactive waste disposal regulations at the WIPP. This rulemaking does not implement other requirements under Federal and State law.

Section 9 of the WIPP LWA requires DOE to comply with all applicable Federal laws pertaining to public health and safety or the environment. Section 9 also provides for periodic, biennial oversight by EPA or the State, as appropriate, to determine whether DOE is in compliance with applicable laws, regulations and permit requirements. The DOE also has agreements with the State related to compliance with state laws.

The Land Disposal Restrictions of the Resource Conservation and Recovery Act (RCRA) are Federal requirements which apply to disposal of hazardous materials at the WIPP. These requirements are being addressed in another EPA regulatory proceeding. Determination of compliance with State laws on disposal of hazardous materials will be made by the State Agency reviewing DOE's RCRA permit application.

Issue L: Since WIPP is a major federal project significantly affecting the environment, DOE is required to complete an environmental impact statement (EIS) prior to making a decision. The rule should require that the application include a Supplemental EIS and record of decision (ROD) supporting the decisions implicit in the application, e.g., decisions as to current and proposed facilities at WIPP and at waste generating sites, and covering all generation, treatment, storage and disposal alternatives. (CARD-B, CCNS-B, NMAG-B, SRIC-C)

1. In §194.14 a subsection should be added to include the requirement that "supplemental environmental impact statement and record of decision reflecting the Department's decision to proceed as shown in the application after consideration of all applicable alternatives." (NMAG-D)

2. The regulatory compliance process already integrates NEPA-required activities such as the SEIS. 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. (DOE-E)

Response to Issue 1.L:

Neither the WIPP LWA nor the EPA radioactive disposal regulations provide that EPA must include in its compliance criteria a requirement that DOE perform a supplemental EIS or Record of Decision (ROD). Whether DOE is required to perform a supplemental EIS or ROD addressing the issues identified by the commenters is governed by the National Environmental Policy Act and is independent of EPA's rulemaking. The EPA will refer these comments to DOE for its consideration. Irrespective of any NEPA requirements, EPA's final compliance criteria require DOE to fully and thoroughly document the underlying basis for its compliance certification application.

Issue M: The rule should distinguish between remote-handled transuranic waste and contact-handled transuranic waste. (CCNS-B, A-13)

Response to Issue 1.M:

The WIPP LWA defined and set limits on the amount and concentration of remote-handled (RH) waste that can be disposed in the WIPP. See sections 2(12) and 7 of the WIPP LWA. Section 7 of the WIPP LWA establishes radiation dose rate (rem) and radioactivity (curie) limits for RH-waste allowed for emplacement at the WIPP. Transuranic waste that is not RH-waste is designated as contact-handled (CH). See section 2(3) of the WIPP LWA. In the final rule, the Agency has clarified that DOE must demonstrate that the waste inventory at the WIPP complies with the limitations on transuranic waste disposal established in the WIPP LWA. See §194.24(g) of the final rule; see also Section 6 of this document.

Issue N: In a proposed rulemaking, it is inappropriate for the EPA to imply inadequate information exists about a feature of the WIPP, when the Agency has not yet promulgated final implementation criteria and no application has been submitted. All such references should be deleted. (SNL-C)

Response to Issue 1.N:

The EPA agrees that it is inappropriate to pre-judge whether the WIPP facility will comply with the radioactive waste disposal regulations. No statements made in 40 CFR part 194 represent a decision on the ultimate suitability of the WIPP as a disposal system for transuranic radioactive waste. The Agency may make a binding decision only as part of the rulemaking for certification of compliance, conducted under section 8(d)(1) of the WIPP LWA. The Agency reserves final judgment on any matters relating to whether the WIPP facility will comply with the disposal regulations until the Agency conducts the rulemaking for certification of compliance pursuant to section 8(d)(1). However, the Agency does not believe it is inappropriate to engage in public discourse about issues related to the WIPP.

Issue O: The definition of "undisturbed performance" should be clarified.

1. The definition of undisturbed performance should be clarified as follows: "undisturbed performance means the predicted behavior of a disposal system, including characterization of the uncertainties in predicted behavior, if the disposal system is not disturbed by human intrusion, human activities, or the occurrence of unlikely natural events." (SNL-C)

2. EPA may wish to provide guidance, without applying a strict numerical limit, on the processes and events that are to be considered for evaluations of the "undisturbed performance" of the repository. (NRC)

3. It is appropriate that EPA define "unlikely natural events" and develop a list of probabilities for qualifying events specific for the WIPP. (SGNM-D)

Response to Issue 1.O:

The term "undisturbed performance" is defined in §191.12 as follows: "the predicted behavior of a disposal system, including consideration of the uncertainties in predicted behavior, if the disposal system is not disrupted by human intrusion or the occurrence of unlikely natural events." However, based on language used in the proposal, this definition could have been interpreted to mean that "undisturbed performance" should include consideration of the "human activities" described in proposed §194.33. It was not the Agency's intent to include consideration of "human activities" in analyses of "undisturbed performance." For clarity, the terms "human intrusion" and "human activity" used in the proposal have been replaced in the final rule by "deep drilling" and "shallow drilling," respectively. For more detail, see §194.33 of the final rule, and Section 12 of this document.

The disposal regulations require that compliance with the containment requirements be based on performance assessments of the cumulative releases of radionuclides from all "significant" processes and events that may affect the disposal system. See 40 CFR § 191.13(a)). Thus, the disposal regulations contemplate that some processes and events may be insignificant and excluded from consideration. The final rule provides a screening probability criteria to determine which processes and events are insignificant and may be excluded. The final rule provides that "[p]erformance assessments need not consider processes and events that have less than one chance in 10,000 of occurring over 10,000 years." See §194.32(d). This screening criteria is informed by the implementing guidance (Appendix C) which accompanied the disposal regulations. While the compliance criteria allow the exclusion of insignificant processes and events, the final compliance criteria mandate documentation explaining why any processes and events were not included performance assessment results. See § 194.32(e)(3). See Section 11 of this document for further discussion of this issue.

Unlikely natural events are those natural events which may be excluded from performance assessments, if it is demonstrated that their probability of occurring is less than the screening threshold. Any natural processes and events which, according to this criteria, must be included in performance assessment must be considered when analyzing the undisturbed

performance of the disposal system. As discussed above, undisturbed performance need not consider human intrusion into the disposal system. For further discussion of this issue as it relates to the Individual and Groundwater Requirements, see Section 19 of this document.

Issue P: Forthcoming guidance documents should not be used to direct or dictate experimental or other information gathering programs. (DOE-D, SNL-C)

Response to Issue 1.P:

The EPA plans to issue non-binding guidance on the elements of a "complete" compliance application that may summarize and interpret the criteria established in 40 CFR part 194. The guidance will not establish additional compliance criteria.

Issue Q: Although the recommendations may be presented to EPA after the official comment period for proposed compliance criteria closes, and EPA is not required to apply the National Academy of Sciences (NAS) findings to WIPP, staff recommends that EPA consider the NAS findings when developing the final rule. (NRC, IV-G-6)

Response to Issue 1.Q:

The comment refers to a National Academy of Sciences (NAS) review of the technical bases for standards applicable to a potential high-level radioactive waste disposal site at Yucca Mountain, Nevada. The report is titled "Technical Bases for Yucca Mountain Standards" and was issued in August 1995. The comment preceded issuance of the NAS report. The comments were not elaborated by the commenter after the report was issued. Thus, EPA has not received any specific comments in this rulemaking regarding the NAS report on Yucca Mountain.

The EPA reviewed the report in light of the general comment and concluded that the NAS recommendations do not militate revisions to the final WIPP compliance criteria. The 1992 Energy Policy Act excluded Yucca Mountain from EPA's general radioactive waste disposal regulations at 40 CFR part 191 and called upon EPA to develop separate standards for Yucca Mountain, to protect the public from radioactive materials at the Yucca Mountain site. The NAS report responds to specific questions presented by Congress in section 801 of the 1992 Energy Policy Act. Congress called for the NAS report to inform EPA's development of the separate standards for Yucca Mountain. Thus, the NAS report concerns a different site and, further, addresses development anew of standards for the proposed Yucca Mountain radioactive waste disposal facility. By contrast, in the 1992 WIPP LWA Congress charged EPA in the present rulemaking with implementing the 40 CFR part 191 radioactive waste disposal regulations at WIPP. The NAS report addresses approaches and assumptions addressed in 40 CFR part 191 and, for the reasons explained in the introduction and elsewhere in this document, EPA declines to revisit the policy and technical bases of 40 CFR part 191.

Issue R: The EPA should adopt the use of guidance in the following area of the compliance criteria: “Future state assumptions,” “Expert judgment,” “Consideration of

human-initiated processes and events." and "Consideration of protected individual." The EPA should use the compliance criteria in these sections to establish a broad framework of requirements, where supplementary guidance can provide an appropriate methodology for demonstrating compliance. The EPA should adopt a more flexible approach in developing performance measures appropriate for WIPP. (NRC, IV-D-94)

Response to Issue 1.R:

As noted in the introduction and in response to Issue 1.E, EPA has endeavored to balance flexibility and prescriptiveness in the final rule. The EPA believes the criteria in the areas identified by the commenter require documentation necessary to facilitate EPA and public review of the WIPP compliance certification application.

Issue S: The EPA must reissue the Compliance Application Guidance (CAG) as part of the rulemaking on the compliance criteria since this lies outside the rulemaking requirements of the WIPP Land Withdrawal Act. (SRIC-C)

1. The CAG contains numerous provisions which can only be interpreted as mandatory. (NMAG-C)

2. There is concern that the approach of issuing a separate CAG "as a supplement to the 40 CFR part 194 compliance criteria" but apparently without going through the rigorous rule-making process of 40 CFR part 194, may create confusion or be unlawful. (EEG-C, NMAG-B)

Issue T: The issuance of a separate guidance document is unnecessary. (DOE-D, SNL-C)

Response to Issues 1.S and 1.T:

The EPA intends to issue a non-binding guidance document, called the Compliance Application Guidance (CAG), after the final compliance criteria are issued. The document would summarize and interpret the final criteria to guide EPA's administrative determination about the completeness of the compliance certification application. As noted, EPA has established a screening for completeness as a predicate to EPA's compliance certification rulemaking.

The EPA has provided significant opportunity for public participation during the development of the guidance. The EPA circulated a preliminary draft, dated March 21, 1995, to interested parties for comment. In the Fall of 1995, a draft of the CAG was made available for public inspection, and a 60-day public comment period was provided. See 60 FR 53921-53922 (Oct. 18, 1995). A revised version of the guidance will reflect EPA's consideration of public comments and will be made consistent with the final compliance criteria. The EPA has revised and clarified the final compliance criteria and guidance, in light of concerns that the

draft guidance contains provisions which could be interpreted as establishing additional compliance criteria.

Issue U: A clarification of the scope of the rule is needed.

1. The requirements for actions pursuant to an excessive release of waste should apply to all stored materials, such as containers, engineered barriers et al. (IV-D-06)

2. Boundary conditions need to be established that can be met. (C-25)

Response to Issue 1.U:

The WIPP LWA calls for EPA to implement the radioactive waste disposal standards (40 CFR part 191, subparts B and C) at the WIPP in the present rulemaking. Thus, this rulemaking does not address releases from stored containers not disposed at the WIPP. However, the final compliance criteria do contain requirements that are a necessary adjunct of regulating disposal at the facility such as characterization of the stored waste to be emplaced in the repository and pre-closure monitoring to establish baseline conditions for assessing subsequent disposal system performance. Potential releases during the management and storage phase that are not relevant to the predicted long-term performance of the WIPP facility, are regulated under Subpart A of 40 CFR part 194. The EPA intends to issue guidance for the application of 40 CFR part 191, subpart A, to the WIPP, addressing the management and storage of radioactive waste at the WIPP prior to disposal. See also the response to Issue 2.K of this document.

Issue V: It is extremely important that uncertainties be reduced as much as possible. (S-16, S-55)

Response to Issue 1.V:

The Agency agrees with this statement, but also recognizes that not all information can be obtained with absolute certainty. In several instances, provisions of the disposal regulations expressly recognize that "there will inevitably be substantial uncertainties in projecting disposal system performance." See, e.g., §191.13(b). The EPA has attempted to mitigate uncertainty by including General Requirements in 40 CFR part 194. These requirements are intended to ensure that any compliance application is based on dependable and quality-assured data, that assumptions have undergone appropriate peer review, and that EPA has inspection authority to confirm disposal conditions and data [§§194.21-27]. The EPA's disposal regulations also include assurance requirements [§191.14, §§194.41-46] in recognition of the many uncertainties inherent in making long-term numerical predictions of performance.

Issue W: There are several terms that warrant a formal definition.

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

Response to Comment 1.W.1:

The compliance criteria also contain provisions applicable to modification, suspension, or revocation of any certification. The final rule has been clarified by stating that the criteria apply as well to "subsequent actions relating to the terms or conditions of certification of the Department of Energy's Waste Isolation Pilot Plant's compliance with the disposal regulations . . . . [see §194.1]."

2. The definition of "modification" should not have a reference to §8(f) of the WIPP LWA; in the definition of "revocation" and "suspension" the term "withdraw" should be replaced with "terminate." (NMAG-D)

3. Definitions of suspension, modification, and revocation need to be clarified. (SRIC-G)

Response to Comments 1.W.2 and 1.W.3:

Comments to EPA have indicated concern that the re-certification process, conducted without rulemaking, could be used to effect changes in the conditions incorporated in any certification. The Agency believes that re-certification is a process intended to assess compliance and confirm that the conditions of certification continue to be in effect. Thus, re-certification is a periodic review, but not a process to be used to change a certification in effect. Any significant departures from the conditions, activities, or evidence in the certification of compliance would necessitate a modification to any underlying certification issued pursuant to section 8(d)(1) of the WIPP LWA and therefore would be subject to the rulemaking procedures at 5 U.S.C. § 553 and judicial review. The definitions of modification, suspension, and revocation in the final rule have been revised to clarify that these actions apply to the certification under section 8(d)(1) of the WIPP LWA, if any, in effect at the WIPP.

As suggested by the comment, the definition of "revocation" in the final rule has been revised to mean "any action taken by the Administrator to terminate the certification under section 8(d)(1) of the WIPP LWA." The use of "terminate" is appropriate in this case because revocation is a permanent action that necessitates retrieval of the waste.

Suspension of a certification, on the other hand, is not meant to be permanent. A suspension can be issued at any time at the Administrator's discretion so as to promptly address any potential threat to public health. In such an instance, the Agency would not intend to immediately terminate any certification in effect, but rather would temporarily withdraw the

certification while the immediate threat was mitigated and any necessary remediation was planned or undertaken. The Agency could then determine whether modification or revocation was necessary, actions that require rulemaking because they re-open the underlying certification. Because suspension is an emergency action at the discretion of the Administrator and does not constitute a permanent action regarding a certification, the term "withdraw" is used rather than "terminate." See also the response to Issues 2.A, 2.B, and 2.D.

4. There is no technical basis for including definitions for exploratory and development well in the rule. (EEG-D)

Response to Comment 1.W.4:

The EPA agrees that there is no need to include definitions to differentiate between exploratory and developmental drill holes or wells. As discussed in the preamble to the final rule, and in Section 12 of this document, the Agency believes that both types of wells must be used when examining historical drill rates and establishing future drill rates for the purpose of performance assessments.

5. Add definitions for Performance Assessment, Safe Distance, Controlled Area. (SGNM-D)

Response to Comment 1.W.5:

As noted in §194.2, all terms in the compliance criteria have the same meaning as in 40 CFR part 191 unless otherwise noted in the criteria. The disposal regulations of 40 CFR part 191 include definitions of both *controlled area* and *performance assessment*. See §191.12. Therefore, it is unnecessary to define them in the compliance criteria. The term *safe distance* is not used in the final compliance criteria; a definition is not needed in the compliance criteria.

Issue X: The EPA should be more rigorous in its implementation of "reasonable expectation" language. It cannot just set hypotheses and models, frame the conditional risk analysis for the applicant, then claim without checking that the conditional means resulting from this analysis necessarily support "reasonable expectation" of human safety. (NMAG-E)

Response to Issue 1.X:

The EPA has not specified models to be used in performance assessments of the disposal system. The compliance criteria do specify some bounding assumptions, such as future state assumptions, in order to deal with inherent uncertainty. The results of DOE's analyses will be thoroughly reviewed by EPA through the compliance certification rulemaking process. The compliance criteria impose extensive documentation and analyses requirements on the compliance application so that EPA can scrutinize the underlying analysis. The Agency's evaluation will include rigorous comparison with the disposal standards, including the statistical requirements established for the results of performance assessments. In addition,

the final criteria implement the assurance requirements and contain supplementary requirements in 40 CFR part 194, subpart C, which ensure that any performance assessment and compliance application are based on sound, reliable information. The level of protection of human health is established by the disposal regulations of 40 CFR part 191. The compliance criteria are not intended to establish a new or more stringent level of protection, but are meant to implement the level of public protection embodied in the disposal regulations. The EPA believes that the final criteria are sufficiently rigorous. For further discussion of the results of performance assessments, see Section 11 of this document.

Section 2: CERTIFICATION CONDITIONS AND COMPLIANCE APPLICATIONS: SECTION 194.4 through SECTION 194.15

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

Issue B: Since the LWA dictates that determinations be done without rulemaking, any conditions imposed under §194.04(a) would not have the benefit of due process to ensure that they are reasonable. (WEC-D)

Response to Issues 2.A and 2.B:

At any point in time, there is only one certification in effect at the WIPP. The terms of certification, if it is granted, are established at the time of initial certification pursuant to section 8(d)(1) of the WIPP LWA, based on the compliance application submitted at that time. The terms of certification at the WIPP can be changed only through modification or revocation rulemakings, as described in §§194.64-65 of the final rule, which represent a decision to re-open the certification issued under section 8(d)(1). Re-certification (referred to as "determination in the proposed rule) pursuant to section 8(f) is a process intended to confirm (and document) that the conditions upon which certification is based continue to exist. Thus, re-certification is a periodic review, but is not a process to be used to change a certification in effect. If review of information submitted for re-certification, or provided at some other time, indicates that information, activities or conditions depart significantly from those upon which certification has been based, it will be necessary to modify or revoke the terms or conditions of certification or, in the interim, to temporarily suspend the certification. Any such modification or revocation would be re-opening the terms of the certification issued pursuant to section 8(d) and must therefore be conducted by rulemaking, as described in §194.65 and §194.66, and subject to judicial review. The definitions of modification, suspension, and revocation in the final rule clarify that these actions apply to the certification, if any, in effect at the WIPP, and are not affected by the re-certification review process.

The language in final §194.4(a) has been revised to clarify that conditions imposed by the Administrator apply to the underlying certification at the WIPP. Like other terms of the certification, such conditions may not be modified through the re-certification process. Any changes in the terms or conditions of certification must be accomplished through rulemaking, as described in §§194.64-65, and subject to judicial review. In the re-certification process DOE must document that the WIPP facility continues to be in compliance and the information on which certification is based continues to be valid, in order to obviate any need for modifying the certification.

The Agency notes that although re-certifications of compliance are prohibited, under provisions of the WIPP LWA, from undergoing a rulemaking process, EPA is committed to ensuring that any re-certification is conducted in an open forum. To that end, the final rule requires that there will be a public notice and opportunity for public comment regarding any potential decision on continued compliance, or re-certification [§194.64].

Issue C: Certification should include conditions with regard to: waste acceptance criteria; waste characterization; reporting of concerns about operations, monitoring, and scientific investigations; facility construction and maintenance; waste handling and related operations; closure activities. This should be added to §194.04(a). (NMAG-D, NMAG-G)

1. Any certification or re-certification must include specific conditions regarding waste acceptance criteria, waste characterization, volumes of waste allowed, facility construction and maintenance, monitoring, waste handling and repository operations, and closure activities. (SRIC-G)

Response to Issue 2.C:

Section 194.4 of the final rule defines general conditions, whether stated therein or not, which apply to any certification, and also allows the Administrator to include any other conditions deemed necessary to support a certification. According to the final rule, the Administrator may also modify, suspend, or revoke a certification if information becomes available that shows violations of the release limits or departs significantly from the information on which the certification was based. The EPA believes that the areas mentioned in the comments are already required, under various sections of the criteria [§194.4, §§194.21-27], to be addressed by compliance applications. The Agency would specify additional conditions in the event that the necessary confidence in the disposal system could be achieved by the implementation of additional measures, or if EPA determines that the WIPP will comply with the disposal regulations if certain terms of the application are changed. The compliance criteria provide the flexibility to add conditions that would address such situations, and the public will have ample opportunity to comment on the inclusion of any such conditions during the certification rulemaking proceeding.

Issue D: The process regarding modification, suspension, or revocation of certification should be clarified regarding the definition and basis for such actions and subsequent restoration of certification. (DOE-D, WEC-D, CARD-B, NMAG-B, NMAG-F, NMAG-G, SNL-A, SNL-B, SRIC-E, CCNS-B, A-11, A-16, A-41, A-45, IV-D-51, IV-D-76, IV-D-111)

Response to Issue 2.D:

The final rule authorizes EPA to modify, suspend, or revoke any certification. However, the definitions of modification, suspension and revocation have been revised from the proposal to clarify that these actions apply to the certification, if any, in effect at the WIPP, and are not affected by the re-certification review process. (See response to Issues 2.A and 2.B, above, and response to Comment 1.Y.2 for further discussion of the definitions.) Any modification or revocation of a certification must be done by formal rulemaking as specified in §§194.64-65 of the final rule.

The EPA has established some criteria that will govern whether modification or certification is required, but EPA declines to specify particular actions that may necessitate modification, revocation or suspension. The EPA has not done so because the Agency believes it would be a speculative and inexact undertaking in the absence of particular facts and circumstances. The Agency believes that decisions about the appropriate actions should be based upon the nature and gravity of a given scenario at the time it occurs. Any modification or revocation of a certification will be done by formal rulemaking explaining the basis for the decision, must provide opportunity for public comment on the decision, and will be subject to judicial review. Suspension may be initiated at the Administrator's discretion, in order to promptly reverse or mitigate a potential threat to public health. The Supplementary Information to the final rule includes a discussion of the criteria and general circumstances which might necessitate action to modify, suspend, or revoke a certification.

Issue E: 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. (DOE-E)

Response to Issue 2.E:

The compliance criteria requirements on modification of certification are consistent with the examples cited in many ways, but also differ from them for important reasons. The transportation certification requirements (10 CFR Part 71) of the Nuclear Regulatory Commission (NRC) are subject to the regulations for modification and revocation of all NRC licenses. These requirements are contained in 10 CFR Part 70. The conditions described in §70.61 as those which would necessitate a modification or revocation are consistent with EPA's requirements that DOE must report changes about the disposal system or other information in the compliance application upon which a certification was based.

Section 270.42 of the Resource Conservation and Recovery Act (RCRA) describes *Permit modifications at the request of the permittee*; it allows for different classes of RCRA-permit modifications, which have more or less rigorous requirements for reporting, review, and approval depending on the complexity of changes necessitating a modification [See §194.4.]. The classes of modifications are standardized and have been in effect for some time. The EPA's compliance criteria are similar to those of §270.42 in that they both require the facility operator to evaluate the complexity or magnitude of changes to the facility, report changes to the regulating Agency, and allow for public participation in the process. The criteria of 40 CFR part 194 are necessarily
different from those of RCRA because the RCRA regulations -- particularly the division of modifications into different classes of complexity -- can be based on extensive experience with numerous permitted facilities and the types of changes likely to occur. There is no

similar record for transuranic (or even high-level) radioactive waste facilities. Because it is thus not possible to
anticipate the situations which might necessitate modification of a certification, EPA believes it is not prudent to specify the circumstances that may or may not necessitate modification or revocation. The Agency also notes that, in RCRA's modification regulations, more rigorous review standards can be applied for changes that are especially complex, or for which "there is significant public concern about the proposed modification [§270.42(b)(6)(ii)(C)(1)-(2)]." Consistent with this approach, EPA believes that the level of public interest and concern regarding the WIPP dictates that, for the WIPP, EPA should retain authority to request information, require reporting of changes in the disposal system, and conduct modifications through public rulemaking.

Issue F: Section 194.4 must specify that the EPA can deny certification. (SRIC-G)

Response to Issue 2.F:

The authority granted to EPA in the WIPP LWA allows the Agency to deny certification if compliance cannot be demonstrated. Section 8(d) of the WIPP LWA calls for EPA to "certify, by rule pursuant to section 553 of title 5, United States Code, whether the WIPP facility will comply with the final disposal regulations." The final rule includes provisions for conducting certification through rulemaking. The final rule does not in any way assume a particular outcome to the certification process.

Issue G: The requirement to retrieve waste from the disposal system should be modified.

1. The requirement in the event of revocation that DOE "retrieve, to the extent practicable, any waste emplaced in the disposal system (40 CFR 194)" should be modified to include both risk and compliance with 40 CFR Part 191 Subparts B and C. (SNL-A)

2. Mandated removal or retrieval may be impractical and could pose occupational and public health risks. Any retrieval decision should be based on a performance assessment and a compliance assessment of waste already emplaced. (SNL-A)

3. A further condition of certification should be demonstration of retrieval capability. (CARD-B)
4. The requirement for retrieval should be removed. EPA should require a remedial plan that includes retrieval as an alternative in the event no other solution is possible and the waste emplaced poses a threat to human health and the environment. (IV-D-111)

5. To allow waste to remain at a site where certification has been revoked is unthinkable. Section 194.04(b)(1) should remain. (NMAG-D)

Response to Comments 2.G.1 through 2.G.5:

Permission for disposal of transuranic waste at the WIPP depends explicitly on a certification of compliance under the WIPP LWA. See section 7(b) of the WIPP LWA. If certification is revoked, then transuranic waste may not be disposed at the WIPP under the WIPP LWA. If, for example, the WIPP has been unable to consistently demonstrate long-term performance in accordance with the disposal regulations and is not reasonably expected to resume operation consistent with the disposal regulations, the Agency believes it may become reasonable to require retrieval of waste already emplaced in the WIPP. Therefore, EPA believes that a demonstration of feasibility of retrieval should be made before emplacement of waste begins. The Agency has declined to require a detailed plan because a plan written prior to emplacement is likely to be of little use in dealing with the specifics of a retrieval operation that could occur decades later. Any retrieval plan will have to be based on the situation and technologies that exist at the time of retrieval, should it become necessary.

The Agency agrees that situations could arise where the risks of retrieving the waste exceed the risks of leaving the waste in place and sealing the disposal system. Therefore, the final criteria state that, in the event of a revocation, waste shall be retrieved *to the extent practicable*. Practicability could be determined taking into account risks, a compliance assessment of the waste already in place, and other factors. In making a decision of whether to revoke the certification, EPA could determine that the waste emplaced up to that point in time does comply with 40 CFR part 191, but that additional waste would result in violation. In such a case, EPA could modify the certification to allow the waste emplaced to remain, but not to allow any further waste emplacement. Because it is not possible to predict the situations that might result in revocation of certification, EPA believes it is inappropriate to be more specific on the conditions that could make waste retrieval practicable. As noted, any revocation or modification decision would be subject to public rulemaking. The requirement for retrieval has been retained in the final rule. See also the response to Comment 20.G.6.

6. EPA and the State of New Mexico can invoke revocation and require implementation of retrieval plan procedures. (SGNM-D)

Response to Comment 2.G.6:

The purpose of the rule is to specify requirements for implementing the 40 CFR part 191 disposal regulations at the WIPP and to clarify compliance-related ambiguities which may exist. The EPA is the sole implementing agency at the WIPP for the disposal regulations and 40 CFR part 194. The State of New Mexico may have authority to require retrieval of waste under separate agreements, or under regulations such as the RCRA operating permit, which is implemented and enforced by the State. Such authority is separate from the compliance criteria and is independently enforced. It is unnecessary and inappropriate to re-iterate any such authority in the final criteria.

Issue H: Requirements to provide additional information must be reasonable and not overly detailed. EPA must have cause to ask for information and should require

submittal within "a reasonable time," rather than in 30 days. (DOE-D, WEC-D, SNL-D, IV-D-111)

Response to Issue 2.H:

The EPA has noted that it is not appropriate to specify at this juncture the particular actions that may necessitate a modification, suspension or revocation, because it is impossible to foresee all the situations which could precipitate such an action. For the same reason, the Agency believes it is unwise to limit the circumstances under which the Administrator could request additional information. Thus, EPA must retain broad authority to request information to learn about planned or unplanned changes to the disposal system, a significant departure from expected disposal system performance, a potential to exceed the release limits provided in §191.13, or any other information relevant to assessing the need for modification, suspension or revocation. While EPA intends to request information relevant to conditions of certification, such determinations of relevance will be at the discretion of the Administrator. The Agency believes that 30 days is a reasonable time for response by the DOE. Quick response time is important to ensure that, if necessary, the potential consequences can be mitigated early. If a situation arises where it is extremely difficult or impossible for DOE to obtain the requested information within 30 days, the Administrator has the flexibility to specify an alternative time frame for submittal of the information. The 30-day requirement was retained in the final rule.

Issue I: Paragraph 194.04(b)(3) in reference to changes of conditions in disposal system should be deleted. (WEC-D)

Response to Issue 2.I:

Section 194.4(b)(4) in the final rule (§194.4(b)(3) of the proposal) requires DOE to submit reports to EPA documenting any changes in the disposal system that depart from the information on which certification is based. The Agency strongly believes that any application for, or certification of, compliance must be based on the most current information. If a certification of compliance is issued for the WIPP, re-certification proceedings would take place only every five years, too long an interval to wait for information to be updated. Even if an application has demonstrated that the WIPP can comply with the disposal regulations, EPA is concerned that operation of the facility could result in changes which, while minor in and of themselves, collectively could have an impact on projected performance of the facility. The EPA does not consider the requirement to submit information on modified facility conditions or activities to be burdensome; the DOE should be documenting such changes in any case, and will be required only to submit a report on changes to EPA, and not to redo performance assessment calculations.

Issue J: "Likely" should be defined and "in excess of what is permitted by the disposal regulations" should be clarified. (NMAG-G)

Response to Issue 2.J:

In the proposed compliance criteria, EPA included the requirement that DOE notify EPA "[i]f the Department determines that a release of waste from the disposal system to the accessible environment in excess of what is permitted under the disposal regulations has occurred or is likely to occur . . . [60 FR 5784]." The comment requested clarification on terms used in the proposed rule. This section of the rule is intended to address a known or imminent release from the disposal system requiring immediate action; thus, it requires immediate notification of EPA, and suspension of waste emplacement activities. In order to limit confusion over interpretation of the term *likely*, the final rule states that waste emplacement must be suspended and EPA notified if releases have occurred or *are expected to* occur. The EPA has retained use of a qualitative descriptor because of the great difficulty in establishing a quantitative measure. Situations which do not require immediate action, but which indicate the potential for modifications or other action on a certification of compliance are addressed under §194.04(b)(3)(v), which also requires notification of the Administrator.

In response to this comment, the final rule was also changed to clarify that "in excess of what is permitted by the disposal regulations" means in excess of the radionuclide release limits established according to §191.13; the committed effective doses established under §191.15; or the concentrations of radionuclides and estimated doses due to radionuclides in underground sources of drinking water, established under 40 CFR part 191, Subpart C.

Issue K: Section 194.4(b)(6) should be eliminated in its entirety. Any releases from the repository while the Department is still emplacing waste at the site are covered by 40 CFR Part 191 Subpart A and should not be covered by 40 CFR Part 194. (EEG-A, EEG-C, SNL-A, IV-D-111)

1. The Agency needs to define "release" in §194.04(b)(6) to include only unintentional spills or releases to the environment. (WEC-D)

2. A provision regarding releases during operations should be incorporated. The DOE should be required to provide plans to assure rapid response and remedy of the more likely consequences of maximum hypothetical accidents. (NMAG-G, A-28, IV-D-06)

3. Compliance criteria should direct DOE to develop a contingency plan in the event that monitoring devices indicate a leak to the accessible environment. (CCNS-B)

Response to Issue 2.K:

The Agency has not applied the compliance criteria addressing waste disposal to the management of waste at the WIPP. The Agency intends issue guidance for compliance with 40 CFR part 191, Subpart A, that would address accidents occurring in the management operational phase.

Section 194.4(b)(3) of the final criteria [§194.4(b)(6) of the proposal] requires DOE to notify EPA and suspend emplacement of waste if a release of waste has occurred or is expected to occur which causes the containment, individual, or groundwater requirements to be exceeded. Permission for emplacement of transuranic waste at the WIPP depends explicitly on a certification of compliance, pursuant to section 7(b) of the WIPP LWA. If a certification is not in effect, then emplacement of waste at the WIPP is not allowed. Certification of compliance, in turn, is based on a demonstration that (among other provisions) predicted releases from the disposal system will not exceed the containment limits set forth in 40 CFR part 191.

If a release from the WIPP in excess of the disposal regulations has occurred or is expected, any certification of compliance could be jeopardized. In such a situation, it is necessary and reasonable that the Department stop emplacement of waste so the situation will not be worsened and so DOE can take immediate mitigating action. In addition, DOE must notify EPA of details of the release so that the Agency can determine if the release is related to factors involving the long-term containment of waste. Absent this provision of the criteria, any such releases would already have been required to be reported and evaluated during the re-certification process, since re-certification will be used to confirm that the information and conditions upon which certification is based continue the be valid.

If reported releases are determined to be related to the long-term containment of waste, action may be taken to modify, suspend, or revoke a certification. While an investigation is ongoing, it is reasonable that emplacement of waste should be suspended. If the release does not affect long-term containment, it will be covered by Subpart A of 40 CFR part 191 and will not affect certification. For these reasons, the requirements were retained in the final rule.

Issue L: Specify pre-application procedures, particularly with regard to draft applications.
(SGNM-A, NMAG-B, NMAG-F, SRIC-B, SRIC-C, SRIC-D, SRIC-F)

1. It is inappropriate for EPA to consider the DOE draft compliance certification application before the Agency has issued final compliance criteria. The draft application prejudices the compliance criteria rulemaking since it delineates DOE's views on the compliance criteria and allows DOE comment opportunities not available to others. The draft application should not be considered in formulating the rule. (SRIC-G)

Response to Issue 2.L:

The DOE submitted a draft compliance application (in two parts) to EPA's Office of Radiation and Indoor Air (ORIA) during the spring and summer of 1995. The EPA does not believe that the draft compliance certification application influenced the contents of the final compliance criteria. However, in response to concerns voiced by the public, the Agency decided to re-open the public comment period on the compliance criteria to provide an additional opportunity for public comments in light of DOE's draft compliance certification application, a copy of which was placed in the public dockets. The comment period on the

proposed criteria was therefore re-opened for 45 days ending September 15, 1995. [See 60 FR 39191-39132.]

As EPA has reiterated previously, EPA will not and may not make a compliance certification decision on the basis of the staff's review of a draft application. The comments provided by EPA staff to DOE are of a technical nature and do not represent a final decision of compliance. Any such compliance decisions are to be made by the Administrator of EPA only after EPA reviews a complete and final compliance application submitted by the Secretary of Energy.

Moreover, until final compliance criteria are issued, no benchmark exists against which to judge whether a draft application adequately demonstrate compliance. The EPA recognizes that the Agency cannot, by law, approve any part of the draft application. The staff's review is not intended to and plainly does not have any binding effect. Any decision about the sufficiency of a compliance application will be made by the Administrator only after the final compliance criteria are issued, a complete and final application is received from the Secretary of Energy and a public rulemaking proceeding is conducted pursuant to 5 U.S.C. § 553.

Issue M: Post-certification procedures should be clarified with regard to reporting requirements, violation assessment, mitigation, and reinstatement. (NMAG-B, NMAG-F, NMAG-G, A-11, A-16)

1. The DOE and EPA must be accountable. The public should be able to rely on the government for active, independent monitoring of WIPP. (IV-D-96)

2. The EPA must remain in charge of compliance. (A-1, IV-D-73)

3. It is important that the EPA strictly and rigorously regulates the DOE and not simply rubber stamp DOE decisions. (IV-D-28, IV-D-89)

Response to Issue 2.M:

If EPA certifies that the WIPP complies with the disposal regulations, ongoing confirmation will be needed to ensure that the disposal conditions remain consistent with information contained in the compliance application. The EPA intends to confirm disposal conditions in two ways -- first, by specifying several mechanisms to update the information in the application; and second, by exercising its inspection authority to confirm information and field conditions. The conditions of any certification require that DOE provide information on any planned or unplanned changes to the disposal system that depart from the application [§194.4(b)(3)]. The final rule also requires that DOE report annually any changes to the disposal system, and that a re-certification be conducted every five years after initial certification, if one is granted, to confirm that the conditions upon which any certification is based remain valid. In addition, EPA has retained in the final rule the criteria which allow the Agency to modify, suspend, or revoke a certification based on departures from information on which the certification was based [§194.4(b)(1)]. In response to concerns about EPA

oversight of the WIPP after certification (if one is granted), EPA revised the rule to allow for suspension of certification at the discretion of the Administrator rather than through rulemaking. This will allow the Administrator to immediately withdraw the effectiveness of a certification (for a limited period of time) and require DOE to temporarily cease emplacing waste, if such actions are deemed necessary to promptly address any potential threat to public health and to allow EPA time to evaluate whether a certification should be modified or revoked. Finally, the final rule contains inspection criteria [§194.21] which provide EPA with broad authority to conduct audits and inspections to assess the validity of information used to support a compliance application, and to ensure that activities and records described in an application are implemented as described. See responses to Comment 1.Y.2 and Issue 2.C for more information on modification, suspension, and revocation.

Issue N: The definition of certification application is unacceptable and must be changed. The Compliance Criteria must have different definitions for applications for certification and for determinations. (SRIC-C)

Response to Issue 2.N:

The WIPP LWA requires EPA to promulgate criteria for the Administrator's certification of compliance for WIPP with the final disposal regulations (40 CFR part 191). The WIPP LWA also requires EPA to make periodic determinations of continued compliance (re-certifications, referred to as "determinations" in the proposed rule). The comment did not suggest why it would be appropriate to make a distinction between applications for initial certification and for re-certification. The EPA recognizes that the determination of initial compliance and determinations of continued compliance are conducted differently. The decision regarding initial compliance is conducted by rule, and establishes the terms and conditions of certification of the WIPP. Re-certification, which is not subject to rulemaking, is a periodic review process intended to confirm (and document) that the conditions upon which certification is based continue to exist. Since it is intended to identify any changes in information, re-certification documentation must address the same issues considered in initial certification, regardless of the different processes and purposes of certification and re-certification. That is, documentation of either initial or continued compliance with the disposal regulations will be based on substantially similar information requirements, documentation requirements and format. Because of this similarity, and the desire for rulemaking to be as efficient as possible, the Agency believes that it is practical to address requirements for both initial certification and continued compliance (re-certification), and certification applications, in a single rule. The EPA has addressed specific instances where certification and re-certification processes differ (see, e.g., §194.14, §194.64).

Issue O: Rule should clarify whether "phased" applications for certification are allowed.

1. Recognize DOE's ability to submit subsequent applications seeking authorization for future operational changes. (DOE-D)

2. The requirement should clarify that there is a single certification application and a single EPA rulemaking to certify or not certify that the WIPP facility will comply with the disposal regulations. (SRIC-C)

3. It is suggested that EPA recognize the concept of "phased disposal" and the ability of the DOE to submit and seek subsequent approvals of different wastes, waste streams and operational parameters after the initial certification through the process of submitting additional applications. (IV-D-111)

4. "Phased disposal" is contrary to law and should not be authorized by regulation. The Agency should reject the request to receive authorization for "phased disposal." (NMAG-D)

5. It would be illegal to modify the application to include wastes that were not contained in the original application for disposal at WIPP. A separate rulemaking would need to be promulgated to consider groups of waste in phases. (NMAG-D)

6. The DOE must not be allowed, under re-certification proceedings, to emplace wastes in the WIPP that were previously prohibited. (SRIC-G)

7. The EPA must clarify that only a single certification proceeding is allowed. The DOE must not be allowed to conduct "phased disposal." (SRIC-G)

Response to Issue 2.O:

The rule does not contain any procedures to deal with a phased approval process. As the General Counsel of EPA stated in a letter to the General Accounting Office, "[this rule] would require reproposal of additions or amendments to the compliance criteria proposal before EPA could act on any partial application. . . . [Nov. 23, 1994]." EPA has not revised the rule to encompass phased approval. At any point in time, there is only one certification in effect at the WIPP. The terms of certification, if it is granted, are established at the time of initial certification, based on the compliance application submitted at that time. The terms of certification at the WIPP can be changed only through modification or revocation rulemakings, as described in §§194.64-65. The Agency believes that re-certification (referred to as "determination" in the proposed rule) is a process intended to confirm (and document) that the conditions upon which certification is based continue to exist. Thus, re-certification is a periodic review, but is not a process to be used to change a certification in effect. If an initial certification is granted, and information subsequently becomes available which differs significantly from the basis upon the certification was issued -- including changes relevant to long-term performance, or proposed disposal of waste not described in the application -- then EPA would undertake a modification, suspension, or revocation to the certification. Any modification or revocation will be done by rulemaking in accordance with section 8(d)(1) because EPA would be re-opening the initial certification. See also the response to Issue 2.A.

Issue P: Time period for certification decision needs to be clarified.

1. Acknowledge that decision on certification must be made within one year. (DOE-D, WEC-D)

2. It is reasonable to allow EPA the one-year period to act on a certification application after DOE has submitted a complete application. (NMAG-D)

3. It is reasonable that the statutory review period on an application not begin until the application is deemed complete. (SRIC-G)

Response to Comments 2.P.1 through 2.P.3:

Section 8(d)(1) of the WIPP LWA calls for EPA to certify whether the WIPP facility will comply with the disposal regulations within one year of receipt of DOE's compliance application. The concept of "completeness" is an administrative tool EPA is utilizing to screen a final compliance application received from DOE that because of incompleteness does not even warrant further EPA and public scrutiny. It would be highly unproductive for the public and EPA to devote substantial resources reviewing an application that lacks basic elements and information required by the compliance criteria. Inherent in the one year review period for a compliance application is the supposition that the application is complete and therefore warrants regulatory scrutiny. Thus, the one-year statutory review period commences when the Administrator determines that the compliance application is complete. If EPA determines a final compliance application "complete" then the compliance application will be subject to public notice-and-comment rulemaking procedures pursuant to 5 U.S.C. § 553 and as elaborated in the final compliance criteria.

4. Any changes made by DOE to a certification application should “re-start” the statutory review period to allow sufficient opportunity for public comment and EPA review. (SRIC-G)

Response to Comment 2.P.4:

The blanket rule that the statutory review period re-start any time DOE submits new information would be highly inefficient and discourage DOE from providing new information that, for example, may help clarify or elucidate the compliance application. The EPA declines to adopt this approach. Further, the rulemaking procedures required by Congress in the WIPP LWA place procedural constraints on the consideration of new information to ensure that there is adequate public notice and comment. As noted, EPA's review of a compliance application must be in accordance with 5 U.S.C. § 553, the Administrative Procedure Act. Underlying principles of administrative law require that the public be given "adequate notice" of agency action, and govern the circumstances when new information received after the close of the public comment period must be subject to additional public notice and comment.

Issue Q: Part 194 should clearly define completeness criteria, including extent of public participation in determination, and incorporation of study results. (DOE-D, WEC-D,

EEG-C, NMAG-B, NMAG-F, NMAG-G, SRIC-C, SRIC-D, SRIC-E, CCNS-B, C-14, A-29, A-35, A-38, A-41, S-17, S-21, S-28, S-29)

Response to Issue 2.Q:

The final compliance criteria establish the required contents of a compliance application. For example, §194.4 sets out specific information that a compliance application must include. Various other provisions of the compliance criteria establish detailed documentation and demonstration requirements for the compliance application. The EPA plans to summarize and interpret these requirements in a guidance document intended to guide EPA's assessment whether DOE's compliance application is "complete." The guidance document will not establish binding compliance criteria and therefore is not being included in this rulemaking. See also responses to Issue 1.T and Issue 20. F.

Issue R: It is critical that the EPA remains aware that the certification process is a regulatory-compliance driven process. The DOE should be required to submit only the information necessary to determine compliance with the stated regulatory requirements. (SNL-D)

Response to Issue 2.R:

The DOE is required to submit the information called for in the final compliance criteria, which reflects information EPA has determined is necessary to determine whether the WIPP facility will comply with the disposal regulations. Because EPA has the responsibility to evaluate a compliance application and issue or deny a certification of compliance, the compliance criteria provide that EPA may require additional information necessary to determine compliance [see, e.g., §194.4, §191.14].

Issue S: The following may be added to §194.12, "access to geographical information system/database to verify monitoring or experimental programs." (SGNM-D)

Response to Issue 2.S:

The compliance criteria allow sufficient access to information by EPA. Sections 194.12 and 194.13 of the final rule require that DOE submit copies of any accompanying materials and any referenced information related to compliance applications. In addition, §194.23(d) allows the Administrator to verify the results of computer simulations used to support any compliance application. Materials needed to perform such verifications are to be provided by the Department. The Agency also has discretion to request additional information in applications under §194.14(j). Further, the final rule provides inspection authority allowing EPA to conduct inspections and audits to verify monitoring programs, or the accuracy of information.

Issue T: A comprehensive table of references pertaining to the subject area should be provided (§194.13). (SGNM-D)

Response to Issue 2.T:

Section 194.13 of the final rule requires that DOE include, with certification applications, copies of any reference materials not generally available, in order to facilitate the Agency's review of any application.

Issue U: It is a concern that the wording used in this section (§194.14(j)) and the Supplementary Information would allow EPA to establish additional information requirements other than those covered in the proposed rule at some later time. (IV-D-111)

Response to Issue 2.U:

Any compliance application must include, at a minimum, basic information about the WIPP site and disposal system design, and must also address all the provisions of the compliance criteria; these needs are embodied in §194.14 of the final rule. In the face of uncertainty which remains about many aspects of the WIPP, EPA believes it is appropriate to allow flexibility to require additional information. Section 191.14(j) allows the Administrator to exercise discretion and request such additional information. The EPA believes this provision is necessary and prudent, and has retained it in the final rule.

Issue V: The requirements regarding the content of compliance applications is overly detailed and too prescriptive.

1. Let the burden of deciding the scope and depth of information to be included in the application rest with the applicant. The EPA should not pre-judge the importance of a particular area of information on the basis of preliminary information. (EEG-A)

2. The proposed rule includes overly prescriptive detail in some areas. (IV-D-76)

Response to Issue 2.V:

Any compliance application must include, at a minimum, basic information about the WIPP site and disposal system design, and must also address all the provisions of the compliance criteria; these requirements are embodied in §194.14 of the final rule. The documentation required in the compliance criteria is important to enable a rigorous, thorough assessment of whether the WIPP facility will comply with the disposal regulations.

Issue W: Additional specific information should be included in the compliance application, as described in Section 194.14.

1. A "waste characterization program" should be added to the WAC and "including a record of audits and surveillance and results of waste characterization studies." (SGNM-D)

2. Add the following to §194.14, "a topographic map showing the surface projection for the underground facility, the location of abandoned resource wells and WIPP wells, and location of current and proposed oil/gas exploration wells." (SGNM-D)

3. Add a visual representation of the penetrated horizons within the 16 section boundary to §194.14. (SGNM-D)

Response to Issue 2.W:

Many of the comments pertain to information which is already required to be submitted in an application because it relates to provisions elsewhere (Subpart C) of the compliance criteria. For example, the performance assessment provisions require an analysis of activities that occur in the vicinity of the disposal system prior to disposal and are expected to occur in the vicinity soon after disposal, including existing boreholes and the development of any existing leases that can be reasonably expected to be developed in the near future. See §194.32(c) and §194.14. The final rule requires the submittal of one or more topographic maps showing, among other things, the location of any active, inactive, and abandoned injection and withdrawal wells in the controlled area and in the vicinity of the disposal system (see §194.14(h)). As noted, any compliance application must include, at a minimum, basic information about the WIPP site and disposal system design, and must also address all the provisions of the compliance criteria; these requirements are embodied in §194.14 of the final rule.

Regarding waste characterization, the final rule requires that DOE document its waste characterization, and also implement a system of controls to confirm that waste is not emplaced in the disposal system if it does not comply with the limits on waste components established under §194.24. As provided in the final rule, EPA intends to use inspections and records reviews, such as audits, to verify compliance with the waste characterization requirements. For further discussion of waste characterization, see Section 6 of this document.

Issue X: Change §194.15(a)(4) to state "new waste characterization information." (SGNM-D)

Response to Issue 2.X:

Section 194.15(a)(5) of the final rule [§194.15(a)(4) in the proposal] requires DOE to submit updated documentation on "[a] description of any waste emplaced in the disposal system since the most recent certification or re-certification application. Such description shall consist of a description of the waste characteristics and waste components identified in §194.24 . . . ." The EPA does not believe that the language suggested in the comment would serve to further clarify or elaborate on this requirement.

Section 3: INSPECTIONS: SECTION 194.21

Issue A: The scope of the inspection requirements needs to be clarified.

1. This section is highly prescriptive and gives EPA inspection authority before an application has been submitted. (DOE-D, SNL-B, SNL-C)

2. This section (§194.21) should be revised to state that inspections will not begin until DOE submits its certification application and that the inspections will conform to all site requirements such as safety, personnel procedures and related activities. (IV-D-111)

3. EPA's authority to conduct sampling, analysis, or monitoring should apply continuously. (NMAG-B, IV-D-06)

Response to Comments 3.A.1 through 3.A.3:

The Agency must exercise a robust inspection program to guarantee that information, data, processes, and procedures documented by DOE in any compliance application are complete and correct. The EPA maintains its position, as stated in the preamble to the proposed rule, that "its inspection privileges [must] be broad enough to allow the Agency to inspect activities that may provide information used to support compliance application(s) and are deemed by the Administrator or the Administrator's authorized representative to be relevant to a compliance certification or determination [60 FR 5770]." For example, the Agency must be able to inspect and evaluate sources of data that are used in the performance assessment and data used in DOE's Waste Acceptance Criteria. The final rule provides that EPA shall be afforded access at any time to inspect any area of the WIPP, or any locations performing activities that provide information relevant to compliance applications.

Currently, it is not the intent of the Agency to perform formal inspections before submittal of a compliance application. However, in order to facilitate the evaluation of any application, the Agency may begin an informal inspection process before submittal of the initial compliance application. The preamble to the final rule clarifies that inspections will be used to verify the adequacy of information included in compliance applications.

Section 194.21(d) of the final rule states that the Administrator's authorized representatives will comply with applicable access control measures for security, radiological protection, and personal safety when performing inspections.

4. EPA does not have the authority of unannounced and unfettered access to a particular location that may have some remote connection to the WIPP facility. (WEC-D)

5. EPA's request to inspect operations directly affecting the WIPP is reasonable. (WEC-D)

6. The Agency's proposed authority to inspect the WIPP site and locations which generate compliance-related data should be retained. (NMAG-D, SRIC-G)

7. The requirement that shipments to WIPP must be inspected is redundant. (A-34, IV-D-11)

Response to Comments 3.A.4 through 3.A.7:

The rule does not grant EPA authority to inspect locations that have remote connections to the WIPP facility, nor does it require that DOE or EPA perform inspections of all waste shipments to the WIPP. The final rule does allow the Agency to inspect locations performing activities that provide information relevant to compliance applications. In addition to allowing EPA access to such sites, the final rule provides EPA with the right to monitor and measure aspects of the waste proposed for disposal in the disposal system. Locations for inspections could include, in addition to the WIPP disposal site, those sites at which waste characterization activities are conducted. Inspections, including, random, unannounced inspections of WIPP-related activates and records, will assist EPA in assuring the validity of information used to support compliance applications. The EPA must have access to such information, regardless of whether it is located at the WIPP or at generator or other sites. The provisions allowing EPA authority to inspect relevant sites has been retained in the final rule.

8. The EPA must consider the entire environment, not just the borders of the WIPP site. (C-03)

Response to Comment 3.A.8:

The EPA is concerned about the entire accessible environment outside the controlled area. For this reason, EPA's disposal regulations limit releases of radionuclides to the accessible environment, which includes all those areas, land, water, and air outside the controlled area containing the WIPP disposal system. In addition, 40 CFR part 191 limits radionuclide concentrations in any ground water that may be affected by the WIPP, and limits radiation doses to individuals on the surface of the earth. The Agency does not have the authority under the disposal regulations to regulate releases from sites associated with (but located apart from) the WIPP facility. Such releases may be regulated by State agencies or under the Resource Conservation and Recovery Act (RCRA), but do not fall within the purview of this rulemaking. However, EPA does believe it is important to understand what activities are being undertaken at these sites if these processes provide or affect information upon which a compliance application is based. Therefore, the final rule provides that EPA has the right to inspect any locations performing activities relevant to compliance applications, to which the Department has rights of access. This includes locations such as waste generator sites, which are outside the immediate borders of the WIPP site.

9. The rule should require EPA to conduct inspections. (NMAG-B)

Response to Comment 3.A.9:

The EPA is not required to bind itself to doing inspections. The EPA expects that it will conduct numerous inspections to verify the accuracy and adequacy of information contained in compliance applications. However, decisions on what and how to audit at facilities related

to the WIPP are within EPA's discretion as implementing agency for the disposal regulations at the WIPP. It is important that this discretion be retained so that inspections can be conducted commensurate with information needs. If a given site conducts few activities which provide information relevant to compliance applications, or if the information affects parameters unimportant to containment of waste in the WIPP, it would be illogical and not cost-effective for EPA to be required to perform inspections at that location. The final rule does not require EPA to conduct inspections.

Issue B: The nature of sampling and analysis for inspections needs to be clarified.

1. It is not clear how and for what purpose EPA will institute a parallel sampling and analysis program at the WIPP site. If EPA plans to conduct an independent sampling and analysis program, it is strongly recommended that a pilot program be conducted prior to full implementation to identify and quantify all of the "bugs" that are sure to arise. (IV-D-100)

Response to Comment 3.B.1:

The Agency is not proposing a parallel sampling program. The Agency will sample data it believes are needed to verify information used to support any compliance application. The Agency intends to develop and test any sampling plans before they are implemented to ensure that procedures are readily understandable and useable. The final rule retains the criteria allowing EPA to obtain samples and monitor aspects of the disposal system.

2. A feasibility requirement should be added to allow the Administrator to obtain samples, splits, or monitor disposal system aspects (reference to 194.21(b)). (WEC-D)

Response to Comment 3.B.2:

As with any sampling or monitoring program, the Agency intends to evaluate the feasibility of implementation and the value of the information to be obtained. As noted in §194.21(d) of the final rule, EPA will comply with applicable access control measures for security, radiological protection and personal safety as it implements inspection plans. However, the Agency believes that, in order to make an objective decision regarding compliance, EPA must be allowed full access to conduct inspections at sites providing information relevant to compliance applications. The final rule does not limit EPA's authority as suggested by the comment.

Issue C: EPA needs to coordinate inspections with other organizations.

1. EPA should provide notice of and coordinate DOE site inspections with the New Mexico Environment Department. (SGNM-A)

2. EEG, State, NAS, and specified members of the public should have same rights as EPA. Areas of disagreement between DOE and its reviews should be included in appendices of the rule. (NMAG-G, CCNS-B)

3. EPA should provide comments or copies of its comments on inspections and/or the written inspection reports under 194.21. (CCNS-A)

4. The State of New Mexico and other parties should be afforded access to the WIPP and related facilities on reasonable notice. (SRIC-G)

5. The State, NAS, EEG, and other parties should have access to DOE records, similar to access codified in NRC regulations. (NMAG-B)

Response to Issue 3.C:

Throughout its regulatory processes EPA has taken special steps to provide the public with information pertaining to the WIPP. The Agency values public participation and input and intends to place inspection reports or other relevant information in the docket for public examination. At the same time, EPA will be performing many activities in implementing the compliance criteria. Neither the WIPP LWA or 40 CFR part 191 require EPA to specify in the WIPP compliance criteria that inspection reports be made publicly available. The EPA thinks it more appropriate to address this and other similar implementation issues in policy statements and in how the Agency elects to exercise its discretion in implementing the compliance criteria, considering the circumstances that arise during the implementation phase. It is not possible or reasonable to codify in the rule all commitments and procedures for information exchange among EPA, DOE and the public.

Regarding rights to inspect DOE records and facilities, EPA notes that any outside party could always request that EPA gather specific information, or audit specific aspects of a process. The Agency would evaluate any such requests and could conduct inspections on that basis if appropriate. Further, specified parties are entitled access to information pursuant to Section 17 of the WIPP LWA, which reflects an explicit congressional judgment about access to information. Section 17 directly established specific duties on DOE, independent of EPA's compliance criteria. The EPA believes it is inappropriate to specify in this rule that specific parties have exceptional access to information generated or recorded by DOE. It would also be inappropriate to assign inspection rights to parties that have no regulatory authority at the WIPP because of the particular importance in maintaining control of access to a site with radioactive wastes and because Congress solely charged EPA with regulatory oversight. The EPA recognizes that there may be benefits to coordinating inspections with other entities that have regulatory authority over the WIPP (such as the State) and that might conduct inspections with similar goals; the Agency will coordinate with such parties as appropriate.

Issue D: EPA is exceeding its authority (references to 40 CFR part 191 and the AEA).

1. Part 191 does not set standards or requirements for site inspections, office space, or sampling. (C-28)

2. Neither LWA nor Part 191 provide a regulatory basis for a "formalized" pre-certification inspection process. (DOE-D, SNL-B)

Response to Comments 3.D.1 and 3.D.2:

The WIPP LWA and 40 CFR part 191 establish EPA as the Agency with authority to implement 40 CFR part 191 for the WIPP. The General Requirements of Subpart C -- including those for inspections -- ensure that an application for certification will be based on sound information and that EPA has the right to confirm the accuracy of such information. The Agency must be provided access to confirm the adequacy of information in a compliance application prior to certification in order to make an objective decision regarding certification. Such requirements are entirely consistent with EPA's mandate to implement 40 CFR part 191 at the WIPP. In fact, effective and active oversight (including inspections and sampling) is a necessary adjunct of EPA's responsibilities as implementing Agency. Therefore, providing for inspections to assure quality, completeness, and adequacy is appropriate. See also the response to Issues 1.H and 1.I.

3. This subsection should clearly state that it will be used as a criterion to evaluate whether a reasonable expectation of compliance with 40 CFR 191.13, 191.15, and 191.24 exists. (DOE-D, SNL-C)

Response to Comment 3.D.3:

A " reasonable expectation" of compliance with the disposal standards is established by the entire body of evidence supplied in a compliance application. The general requirements of the compliance criteria, including those for inspections, are intended to ensure that any compliance application is based on dependable and verifiable information. As components of the final compliance criteria, the inspection requirements are enforceable. Any application must demonstrate that the requirements of §194.21 have been fulfilled specifically, and cannot meet the requirements of this section by stating that other compensating factors establish a reasonable expectation of compliance. The DOE must independently establish compliance with the final rule, regardless of what actions EPA undertakes to establish or verify the adequacy of information used in compliance applications. Therefore, EPA believes it is inappropriate to include the suggested language in the final rule.

4. For non-mixed TRU waste, under the AEA exclusion in 40 CFR Part 261, the EPA would be exceeding its authority as granted by the Atomic Energy Act of 1954. (IV-D-11)

Response to Comment 3.D.4:

The WIPP LWA and 40 CFR part 191 specifically authorize EPA to regulate TRU waste, including non-mixed TRU waste. Hazardous wastes are regulated by EPA as authorized by the Resource Conservation and Recovery Act (RCRA). The RCRA regulations apply only to materials categorized as solid waste. However, this does not include "special nuclear material," such as TRU wastes (See 40 CFR 261.4 and the Atomic Energy Act (AEA) of 1954, Section 11(a)). Thus, the comment correctly states that non-mixed TRU wastes cannot be regulated by EPA under its RCRA authority. They may, however, be regulated by EPA under the authority of the AEA, and thus under 40 CFR part 191. In addition, as noted above, EPA was specifically authorized to implement the TRU waste disposal regulations at the WIPP. Therefore, EPA is not exceeding its authority to regulate non-mixed TRU waste.

Section 4: QUALITY ASSURANCE: SECTION 194.22

Issue A: The scope and nature of the quality assurance criteria need to be clarified.

1. The focus should be on quality control measures not on long term monitoring. (SNL-B, IV-D-40)

2. Quality assurance standards should take priority over inspections both at WIPP and at the generator and storage sites. (A-13)

Response to Comments 4.A.1 and 4.A.2:

Quality assurance is an ongoing process intended to ensure that information contained in any compliance application is reliable. Inspections serve a different purpose, allowing EPA to confirm descriptions of field conditions and activities, as well as review documentation of procedures. Monitoring serves a third purpose, to detect detrimental deviations from expected performance of the disposal system. The EPA believes that quality assurance, inspections and monitoring are all important requirements that must be met. The Agency will enforce all these requirements to ensure that any application is based on reliable and verifiable information, and EPA believes that it is inappropriate to prioritize these activities in the rule.

3. The definition of Quality Assurance should not include quality control because such a definition confuses the two processes. The definition should be revised by separating Quality Assurance and Quality Control. (SNL-C)

Response to Comment 4.A.3:

Section 194.22 of the final rule demonstrates that EPA intends to emphasize quality assurance (which includes quality control) as it affects data, systems, structures, components and activities important to containment of waste in the disposal system. The EPA believes that the definition of quality assurance provided in the final rule [at §194.2] is consistent with the use of this term in the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) standards, which are incorporated by reference in the final rule. In addition, the definition provided in the rule emphasizes that EPA intends for quality assurance to be a planned and systematic exercise which applies not only to experimental results, but also to the methods used for conducting processes, activities and experiments which produce data or are important to containment of waste in the disposal system. For these reasons, the definition in the final rule retains the reference to quality control.

4. The QA requirements are not geared to the unique circumstances of the formal expert judgment elicitation process, which produces information rather than data. (SNL-C)

Response to Comment 4.A.4:

The EPA notes that it has addressed expert elicitation elsewhere in the rule at §194.26, which imposes constraints on the use and conduct of expert judgment. In addition, the final rule requires that the procedures for implementation the expert elicitation, if employed, shall be shown to have been under conditions of quality control, as would any other process subject to the requirements of a quality assurance program. In other words, while the product of expert elicitation is different than data, EPA requires the process to be conducted in a quality-controlled manner. The final rule clarifies that the criteria on quality assurance apply to the procedures for implementation of expert judgment elicitation. See also the response to Comment 4.A.3.

Issue B: EPA needs to incorporate flexibility into its requirements.

1. DOE should be permitted to utilize a QA graded approach where appropriate. (DOE-D, WEC-D)

2. Incorporate flexibility indicated in Supplementary Information into rule itself. (DOE-D)

Response to Issue 4.B:

The EPA believes that flexibility exists within the main requirements of the ASME Nuclear Quality Assurance (NQA) series to address the graded approach issue. The ASME NQA-1 standard (Basic Requirements) states that the "program shall provide control over activities affecting quality to an extent consistent with their importance [II.02.00:01p04]." The EPA will evaluate DOE's use of this flexibility upon receipt of the certification application; however, EPA has expressed concern to DOE that such flexibility be applied consistently and not be delegated away from the overall program management level in such a way that it could be applied arbitrarily. The EPA also believes that the citation of the ASME NQA standards incorporates all supplementary requirements, and that no further citation is necessary. The final rule clarifies that compliance applications shall provide, to the extent practicable, information that describes how all data are qualified for their use in the demonstration of compliance [§194.22(d)]; this statement allows flexibility in qualifying data which may not relate to critical parameters in performance assessments.

Issue C: EPA should use specific standards for quality assurance (re: NQA series).

1. EPA must insist on the most stringent QA requirements for all aspects of WIPP. It is encouraged that EPA use NRC QA requirements to modify some of the draft criteria. (SRIC-E)

2. The proposed rule cites NQA-1, NQA-2, and NQA-3; these standards have been updated since the rule was published. Since NQA-1 is cited and invoked in all sections of NQA-3, NQA-1 need not be cited. (IV-D-36)

3. Adopt requirements similar to NRC's 10 CFR Part 50, Appendix B. (NMAG-G)

4. The selection of NQA-1, NQA-2, and NQA-3 are the appropriate QA programs for the WIPP. (DOE-D, SNL-C)

5. Since NQA-3 was developed for high level waste disposal, it is questionable as to its applicability. More appropriate would be "applicable portions for NQA-1, appropriately supplemented." (IV-D-36)

Response to Comments 4.C.1 through 4.C.5:

Neither the WIPP LWA nor the disposal regulations at 40 CFR part 191 expressly address the issue of quality assurance; thus, they do not impose specific quality assurance requirements which must be implemented in the compliance criteria. The EPA established the quality assurance requirements in 40 CFR part 194 to ensure that compliance applications are based on sound, quality-assured data and processes. It is not necessary to include the "most stringent" standards available in order to meet this goal. The EPA anticipates that the certification application will contain site characterization data, site evaluation data, facility design and construction data, waste characterization data, and other information that is used in computer models to demonstrate compliance for the WIPP, which is a nuclear facility. Given this, the most appropriate standard is the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) series which is incorporated in the final rule. The EPA believes that the quality assurance standards selected for inclusion in the final rule are reasonable and appropriate because they represent a nationally accepted standard, developed under a consensus process (including representatives of regulatory agencies), and designed to apply specifically to nuclear facilities. Furthermore, the standards incorporated in the final rule address all major processes and activities associated with the WIPP which EPA requires to be quality controlled. Other standards were considered and rejected because they did not meet the goals for the quality assurance program at the WIPP. For example, EPA's internal QAMS manual does not constitute a nationally-accepted consensus standard. The American National Standards Institute (ANSI) E4-1994 Standard is a consensus standard designed for national use. However, it was developed to be applied broadly to environmental technologies and data; its application a nuclear facility could be questionable in view of the stated scope of that standard.

The decision was made to select the 1989 and 1990 versions of the ASME NQA standards because, taken together, they address all major processes and activities associated with the WIPP which EPA requires to be quality controlled; they are sufficiently rigorous; and they include adequate implementation guidance. In addition, the NQA versions cited were effective at the approximate midpoint of the time period during which data for the WIPP was being collected; their use imposes less of a retroactive penalty on DOE than other standards considered (including more recent editions of NQA standards), allowing for consideration of reliable, quality "old data" while still providing rigorous standards.

The EPA has examined the Nuclear Regulatory Commission's (NRC) quality assurance requirements in its disposal regulations at 10 CFR part 50. The EPA agrees that the approach to quality assurance embodied in NRC's requirements is reasonable and viable. Staff at NRC reviewed the QA requirements in the proposed rule, and concluded that they are substantially similar to the NRC Appendix B approach. The final rule reflects a definition of QA that is consistent with 10 CFR part 50, Appendix B, and incorporates standards by reference which are consistent with the Appendix B criteria. However, EPA does not believe that it would be appropriate to incorporate 10 CFR part 50 requirements in the final rule since NRC's requirements were developed to apply specifically to licensees for nuclear power plants. The ASME NQA standards, as a consensus industry standard, are designed to cover a broader range of activities, including those expected to be conducted regarding the WIPP. Finally, EPA notes that NRC's Appendix B requirements do not address QA of software or QA of technical data, whereas these issues are addressed by the NQA standards, in Part 2.7 of NQA-2, and in NQA-3, respectively. Therefore, EPA believes that the requirements of NQA-1 are substantially similar to 10 CFR part 50, Appendix B; and that the ASME NQA standards taken as a whole address a broader range of issues and are more comprehensive than NRC's requirements.

6. There are inconsistencies between the NQA standards and the EPA Quality Indicator requirements found in 40 CFR 194.22. The applicability needs to be clarified and the QAMS requirement should be deleted or include as an alternative. (IV-D-111)

7. Section 194.5 should read "reference ASME NQA-1 for design, inspection and test control and EPA QAMS-005/80 for environmental and other monitoring data." (SGNM-D)

8. The adoption of NQA-1 is acceptable, but there are inconsistencies between NQA-1 and the EPA's QAMS-005/80; the quality indicators are from QAMS-005/80, not NQA-1. (SNL-C)

9. Differences between NQA-1 and QAMS-005/80 should be addressed and rectified. (SNL-C)

10. This section is inconsistent with EPA's practices. (SNL-C)

Response to Comment 4.C.6 through 4.C.10:

The EPA believes that the appropriate quality assurance standards applicable to the WIPP are the ASME NQA series, relevant parts of which have been incorporated by reference into the rule. No other quality assurance standards are incorporated by reference into the rule. The document referred to in several comments, EPA's Quality Assurance Management Staff (QAMS) document number 005/80 (now obsolete), was Agency guidance applicable only to internal EPA operations for all measurements and processes conducted by EPA. For that reason, it was not included in the proposed rule, and has not been incorporated into the final rule. Because it is not part of the rule, and does not apply to the WIPP, there is no need to resolve inconsistencies between the QAMS and the NQA standards.

Several comments suggest that the list of quality indicators is inconsistent with the NQA standards incorporated in the rule. This list of data quality indicators is based on EPA's assessment of what is necessary to assure reliable data. The EPA believes the characteristics cited are fully consistent with the intent and requirements of the NQA standards. The terms data validation and data verification have been removed from the list at §194.22(c) of the final rule to avoid confusion. In their places, EPA has specified a list of data quality characteristics which must be considered and documented in a compliance application. The final rule includes definitions of these quality characteristics, in order to clarify the Agency's intent, and to lessen confusion in interpreting these terms. The EPA believes that the data quality characteristics included in the final rule are reasonable and sufficient to provide assurance that data has been rigorously qualified for its use in any demonstration of compliance.

11. 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. (DOE-E)

Response to Comment 4.C.11:

The comment requested that the final rule exclude Section 17.1 of ASME NQA-3 ("Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories"). Section 17.1 of that standard requires that geotechnical samples and other material samples be considered and treated as quality assurance records. This classification would then subject such samples to several burdensome requirements, such as a need for dual storage or fireproof storage. The EPA agrees that the level of control associated with considering physical samples as quality assurance records would be excessive. The Agency believes that the requirements in Section 13 of NQA-3 for handling, storage and shipping of samples are sufficiently rigorous and will ensure adequate protection and control of such samples. Therefore, Section 17.1 of ASME NQA-3 is excluded from incorporation by reference in the final rule, at sections §194.5 and §194.22.

Section 17.2 of NQA-3 applies to retrieval of reference records -- documents and samples referenced by final reports -- from the quality assurance records system. As noted above, EPA has excluded geotechnical samples from the definition of quality assurance records (by excluding Section 17.1 of NQA-3 from incorporation by reference). Therefore, the Agency does not believe that geotechnical samples are subject to the requirements of Section 17.2, since they are not required to be treated as quality assurance records. The Agency does believe it is necessary that documents referenced by final reports should be readily retrievable for review. The EPA interprets the requirements of Section 17.2 to mean that documents must be retrievable from the QA records system; samples should be retrievable from the applicable storage, in conformance with the requirements of Section 13 of the ASME NQA-3 standard. For these reasons, Section 17.2 of NQA-3 has not been excluded from the QA requirements of the final rule.

The Agency does not believe it is necessary or appropriate to delete the quality assurance requirements in Section 3.3 of NQA-3 which describe the application of peer review as part of

a quality assurance program. The scope of peer review requirements was narrowed in §194.27 of the final rule in response to concerns that such requirements were redundant with quality assurance requirements in the rule. The EPA agreed that it would be unnecessary and burdensome to require peer review of processes, data, or quality assurance procedures which had already been qualified by other established means, such as those in a standard quality assurance program. However, as specified in the ASME NQA standards which have been incorporated by reference into the final rule, EPA does believe that peer review can play a reasonable and necessary part in quality assurance, where the soundness of information or procedures cannot be assured otherwise. For these reasons, Section 3.3 of NQA-3 has not been excluded from the quality assurance requirements of the final rule.

Issue D: The EPA is exceeding its authority from 40 CFR part 191 and the WIPP LWA.

1. EPA does not have the authority to require the implementation of certain QA programs; under the WIPP LWA it is limited to developing criteria for certifying compliance with those disposal regulations. (WEC-D, C-28)

2. This section should clearly state that it is intended as a criterion to evaluate whether a reasonable expectation of compliance with 40 CFR 191.13, 40 CFR 191.15, and 40 CFR 191.24 exists. (SNL-B, SNL-C)

3. This subsection should clearly state that it will be used as a criterion to evaluate whether a reasonable expectation of compliance with 40 CFR 191.13, 191.15, and 191.24 exists. (SNL-C)

4. The rule should simply state the documentation EPA would like the applicant to provide in describing the DOE's engineering and operational approach. (WEC-A)

Response to Comments 4.D.1 through 4.D.4:

Several comments questioned EPA's authority to require conformance to specific quality assurance requirements or the past precedent for doing so. Also, a number of comments stated that EPA should clarify that its quality assurance requirements are to be used to evaluate whether a reasonable expectation of compliance with 40 CFR part 191 has been provided in a certification application. As to the issue of precedent, EPA has had no past precedent in the certification of a nuclear waste disposal facility as required by the Land Withdrawal Act, and notes that the Nuclear Regulatory Commission, which has such a precedent, has laid down explicit quality assurance requirements at 10 CFR Part 60, and a standard at 10 CFR Part 50, Appendix B. In its role as certifying Agency, EPA believes that confidence in the quality of data and processes used by the applicant to demonstrate compliance with all of the 40 CFR part 191 requirements is of the utmost importance, in the eyes of both the regulator and the public. The requirement for an adequately implemented quality assurance program conforming to an nationally accepted quality assurance standards package is essential to obtain this confidence. Indeed, with a compliance demonstration of a site as complex as the WIPP, it is all that more important to ensure the quality assurance and

quality control of all data and processes in the evaluation of the application. See also the response to Comment 4.C.1, for further discussion of the basis for selecting NQA standards. Any application must demonstrate that the requirements of §194.22 have been fulfilled specifically. For these reasons, the language regarding "reasonable expectation of compliance" was not incorporated in the final rule.

5. The completeness and quality of data used in the WIPP PA can be assured only if the Agency requires DOE to supply data quality control information and makes provision for orderly review both by the Agency and by the public of the data and the conclusions claimed to be drawn from it. (NMAG-D)

Response to Comment 4.D.5:

Section 194.22 of the final rule requires that any compliance application submitted by DOE shall include information which demonstrates that a quality assurance program conforming to the requirements of paragraph 194.22(a) has been established and executed for specific activities and data important to the containment of waste in the disposal system. Compliance applications must also document that "old data" have been qualified in an appropriate manner. Finally, applications must include information which describes how all data used to support the compliance application have been assessed for quality characteristics. As noted, all such information is required to be included in compliance applications, which will be examined by EPA in determining whether the WIPP complies with the disposal regulations. Any application will be placed in the dockets and will be available for public inspection and comment (see §194.61 and §194.64 of the final rule). The EPA will verify appropriate execution of quality assurance programs through inspections, record reviews and record keeping requirements, as stated in §194.22 of the final rule. The Agency believes these requirements are reasonable to assure the completeness and quality of data used in support of compliance applications.

Issue E: Clarification of data validation, data quality indicators, and data verification is necessary.

1. The language in Section 194.22(c) should be modified so that the application of data quality objectives is not retroactive. (DOE-D, SNL-C)

2. Reproducibility means that for every sample that is part of certification package, DOE must demonstrate that the sample has been analyzed at more than one laboratory. (DOE-D)

3. Applicability of EPA data quality indicators needs to be clarified. (DOE-D)

4. Data verification will be impossible in many cases because there has not been a requirement to collect duplicate data sets for many WIPP experiments. (DOE-D)

5. Data comparability and data verification are technically impossible to apply to existing ("old") WIPP data. (SNL-C)

6. The requirement (§194.22(c)) to provide information establishing compliance with certain quality indicators should be retained. (NMAG-D)

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

Response to Comments 4.E.1 through 4.E.7:

The EPA believes the data quality characteristics cited in the final rule are fully consistent with the intent and requirements of the NQA standards. The final rule specifies a list of data quality characteristics which must be considered and documented in a compliance application. The final rule includes definitions of these quality characteristics, in order to clarify the Agency's intent, and to lessen confusion in interpreting these terms. The EPA believes that the data quality characteristics included in the final rule are reasonable and sufficient to provide assurance that data has been qualified for its use in any demonstration of compliance.

Any application must provide, to the extent practicable, information which describes how all data have been assessed for data characteristics, including data accuracy, precision, representativeness, completeness, and comparability. The Agency is requiring the demonstration of these data quality indicators in order to ensure that the type, quantity, and quality of data used in WIPP decision-making processes will be appropriate for the use of the data in any demonstration of compliance. Further, the EPA believes that these indicators will help the DOE improve the effectiveness, efficiency, and defensibility of decisions made in a resource-effective manner. To clarify the Agency's expectations, the final rule includes definitions of these terms (accuracy, precision, etc.). The rigor of the analysis may differ according to the intended use of the data, as indicated by §194.22(d) and the NQA standards. The EPA recognizes that the evaluation of some data quality characteristics is difficult to apply to "old data" or to apply over a 10,000-year regulatory time frame. Thus, EPA has stated in the final rule that such documentation of these characteristics must be provided to the extent practicable, and has also clarified that all data must be qualified with a rigor that is commensurate with the intended use of the data in any compliance demonstration.

8. Data validation is not applicable to most WIPP data because of the 10,000-year period of regulatory concern. (SNL-C)

9. "Validation" is difficult and cannot be done by observational data over two or three years. Language should be added that allows validation "including extrapolation to the relevant time period and circumstances." (NMAG-G)

10. The following should be added to §194.22(c)(1-8), "Quality indicators should include: (6) Data Validation and (7) Data Verification." (SGNM-D)

Response to Comments 4.E.8 through 4.E.10:

The EPA notes that DOE must address the issue of data quality indicators directly as required in the NQA standards incorporated in the rule (see Section 3 and Supplement 3SW1 of NQA-3). The terms data validation and data verification have been removed from the list at §194.22(c) of the final rule to avoid confusion. In their places, EPA has specified a list of data quality characteristics which must be considered and documented in a compliance application. The final rule includes definitions of these quality characteristics, in order to clarify the Agency's intent, and to lessen confusion in interpreting these terms. The EPA believes that the data quality characteristics included in the final rule are reasonable and sufficient to provide assurance that data has been rigorously qualified for its use in any demonstration of compliance. Further, EPA believes that the list of data quality characteristics is fully consistent with the intent and requirements of the NQA standards incorporated in the final rule.

Regarding data validation in particular, EPA considers data validation a quality assurance measure which is applied to all field or laboratory data as they are collected, for the purpose of assessing overall quality of the data, screening outliers, etc. As discussed in several comments, validation of the predictions of a model could be complicated by the 10,000-year time frame, although EPA expects model and software validation to be conducted to the extent practicable for the WIPP, consistent with the requirement of the NQA package cited at §194.22, and with the criteria for models and codes at §194.23. For further discussion of the data quality indicators, see response to Comment 4.E.1.

Issue F: There is a need to incorporate a flexible approach regarding QA of "old" data.

1. A flexible approach on QA for "old data" is the only reasonable route. The objective is to use good data and not discard good data because of a technicality. (IV-D-51)

2. Flexibility in the approach regarding the QA of "old" data is appropriate and necessary. (DOE-D, IV-D-76, IV-D-100)

3. Retrofitting old data to the new process will add time and money without additional safety. (C-24)

4. The qualification of information collected prior to implementation of the quality assurance program is an overly burdensome requirement. (WEC-D)

5. Subsection 194.22(b) should state that other alternative methods to be considered by the Administrator include, but are not limited to, publications, confirmation by additional experimentation, confirmation by the original investigator, and assurance by a peer review panel. (SNL-C)

6. Endorse NQA-3 Supplement 3 SW-1, which addresses controls for qualification of data of indeterminant quality. (DOE-D)

7. The requirements fail to state what criteria will be applied in assessing the qualifications of data gathered before the institution of a quality assurance program. (NMAG-B)

8. Application of the proposed regulation to existing data that have already been developed is technically not feasible, and should not be required. (SNL-C)

9. All old data should be subjected to rigorous review process, including independent peer review. (CARD-B, A-09)

10. The regulation does not show how requiring applicants to spend additional money to reconfigure data that have already been computed and reported will enhance the safety of WIPP. (A-34)

11. The draft criteria adequately address the topic of data obtained before quality assurance was adopted, and use of expert judgment. (EEG-C)

12. A flexible approach for acceptance and inclusion of "old data" is justified. (SGNM-D)

13. Retain the flexible approach to data qualification, with specific reference to "flexibility" in the text of 40 CFR part 194.22(b). Similarly, revise 40 CFR part 194.22(b) to state that only data used to support a certification application is subject to qualification. (SNL-D)

14. The Agency should articulate criteria for its approval of quality assurance programs for "old data." (NMAG-D)

15. There is a need for approved and documented procedures for the use of old data. Other issues related to "old data" quality include independence of reviewers, necessary tests to be met by data which are deemed qualified, QA requirements, etc. (NMAG-D)

16. Revise 40 CFR part 194.22(c) to eliminate any implication of retroactivity, and to add applicability statements as previously recommended. (SNL-D)

17. Criteria need to be developed for an alternative method for a quality assurance program. (NMAG-D)

Response to Issue 4.F:

The EPA believes that it is of utmost importance to have confidence in the quality of data which are used in the WIPP compliance demonstration. The Agency is aware that such data have been collected over a twenty-year period under a variety of quality assurance program approaches which have been implemented to varying degrees. The EPA agrees that it is important to be balanced in order to avoid establishing retroactive standards that would exclude existing data that is reliable and of sound quality. In the interest of maintaining a balanced approach, the final rule allows alternative methodologies to be used in qualifying old

data, but also requires that application of such methodologies must be approved by the Administrator.

Several comments requested that the final rule specify criteria or alternative methodologies for qualifying data collected prior to the implementation of a quality assurance program meeting the requirements of the NQA standards incorporated by reference in the final rule. In the interest of providing a balanced approach, while ensuring confidence in all data used in support of a compliance application, EPA has identified four alternative approaches which may be acceptable to qualify existing data. Since there is little previous experience in qualifying such data, the final rule also requires approval by the Administrator for the use of alternative methodologies for WIPP-related data. The four approaches which EPA may allow are:

- Establishing that data were collected under a quality assurance program which was substantially equivalent in scope and implementation to that required to be implemented by the final rule -- namely, the ASME NQA standards which are incorporated by reference. This is the most desirable approach since it directly establishes confidence in the body of data to be qualified, based on the existence of an implemented quality assurance program.
- Use of peer review, consistent with NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories." Conformance to the guidelines established by NUREG-1297 will ensure that the process is conducted using qualified and independent peers, employs a formal process with clear objectives, and is adequately documented. The purpose of the peer review would be to evaluate the overall adequacy of work which generated the data under examination, and to establish whether the planning and implementation of such work provide adequate confidence that the data are suitable for their use in any compliance demonstration.
- Use of corroborating data. This would involve a formal comparison of the data to be qualified with all other bodies of data from similar work which have been published in scientific journals; and a systematic assessment of the confidence that can be afforded the body of data to be qualified, due to agreement with similar work. Factors which need to be addressed for this approach to be viable include consideration of all similar studies, and a means for assessing the quality of published studies.
- Use of confirmatory testing. Data from studies of indeterminate quality could, under some circumstance, be partially re-measured under adequate quality assurance. It would be necessary to determine the confidence attained by re-measurement, by using a statistically significant number of data points.

These four alternative approaches to data qualification are informed by guidance in NUREG-1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories." However, there is currently no implementation guidance available to use these approaches to develop viable methodologies for data qualification. Hence, the final rule requires approval by the Administrator of any alternative methodology employing one or more of these approaches.

The underlying important principle which emerges from quality assurance requirements in the final rule is that all data used in the compliance demonstration need to be assessed to be adequate to meet the quality needs of their intended use. Paragraph 194.22(b) of the final rule explicitly applies to data and information collected prior to the implementation of a quality assurance program that meets the requirements of the NQA standards cited. In response to public comments, the final rule specifies four approaches that may be acceptable for use to qualify data collected prior to implementation of a quality assurance program as noted. Application of these approaches to develop methodologies and apply them to WIPP-related data must be approved the Administrator.

Issue G: The following should be added to §194.22(a)(2)(ii), "indefinite environmental monitoring" and "continuous drilling fluid monitoring for radioactive elements for oil and gas drilling within a projected distance from WIPP." (SGNM-D)

Response to Issue 4.G:

The final rule requires that the quality assurance program must be implemented for "environmental monitoring, monitoring of the performance of the disposal system, and sampling and analysis activities;" see §194.22(a)(2)(ii). Paragraph 194.22(a)(2)(viii) also requires implementation of a quality assurance program for "[o]ther systems, structures, components, and activities important to the containment of waste in the disposal system." Thus, drilling activities by the Department, if they provide data used to support a demonstration of compliance, would be subject to quality assurance requirements. It is not necessary to include such actions specifically since they are covered by the provisions mentioned above. Drilling by parties other than the Department would be subject to drilling regulations under the State of New Mexico and/or the U.S. Department of the Interior (Bureau of Land Management), and would not be bound by the QA requirements of this rule since their activities are not in support of a compliance demonstration. Drilling regulations for resource exploration are separate from this rule, and are enforced by regulatory agencies other than EPA. It would be unnecessary and inappropriate to implement them in the compliance criteria.

Issue H: Quality Assurance Plans should also include "Data from Laboratory Measurements." (SGNM-D)

Response to Issue 4.H:

The final rule requires that any quality assurance program be executed and implemented for "[t]he collection of data and information used to support compliance application(s) [§194.22(a)(2)(vii)]." Laboratory data and measurements relied upon or required in compliance applications are included in this category, and thus are subject to the quality assurance requirements of this section.

Section 5: MODELS AND COMPUTER CODES: SECTION 194.23

Issue A: There are differences between the standards in 40 CFR part 191 and 40 CFR part 194.

1. Part 191 does not set standards or requirements for independent or other computer modeling, thus 194 is irrelevant. (C-28)

Response to Comment 5.A.1:

Performance assessments must provide a reasonable expectation that the WIPP will meet the containment requirements of §191.13. The basis of the demonstration of compliance with the containment requirements is performance assessment, accomplished in part through the use of computer modeling. Section 194.34 of the final rule establishes statistical requirements on the results of performance assessments; those requirements speak to the issue of "reasonable expectation." The EPA believes that a reasonable expectation of compliance is also based on confidence that the information and methods used to conduct performance assessments are valid and reliable. Thus, although there is no explicit requirement for computer models in the disposal standards, the computer and model requirements are relevant and are within EPA's authority to implement 40 CFR Part 191 at the WIPP.

2. If this subsection (194.23) is to be used in the Agency determination of reasonable expectation compliance for 40 CFR part 191 sections 13, 15, and 21, then the subsection should so state. (SNL-B, SNL-C)

Response to Comment 5.A.2:

Any application must demonstrate that the requirements of §194.23 have been fulfilled specifically, and can not meet the requirements of this section by stating that other compensating factors establish a reasonable expectation of compliance. Therefore, EPA believes it is inappropriate to include the suggested language in the final rule.

3. The differences between the compliance demonstration requirements of 40 CFR 191.13, 191.15, and 191.24 are not reflected in the rule. (SNL-C)

Response to Comment 5.A.3:

The rule does separately address the compliance demonstration requirements of the containment, individual, and ground water requirements. Statistical requirements regarding the results of performance assessments (for the containment requirements) and compliance assessments (for the individual and groundwater requirements) are articulated separately in the final rule at §194.34 and §194.55, respectively. Other provisions of the rule are not differentiated because they apply to demonstrations of compliance for all the requirements. For example, data contained in compliance applications are subject to the quality assurance requirements of §194.22 regardless of whether the data are used in performance assessment

for containment requirements of §191.13, or for a compliance assessment pertaining to the individual protection requirements of §191.15.

Issue B: There is a need for flexibility and criteria for the models and computer codes.

1. EPA should not be telling DOE what codes or theories it can or have to use for its analysis. (IV-D-06)

Response to Comment 5.B.1:

The compliance criteria do not dictate to DOE what specific codes or theories it must use in its analysis. The DOE may select the models and codes for performance assessments, but must substantiate and justify the codes and theories that are used for EPA's review in the certification rulemaking. Section 194.23 of the final rule establishes basic criteria which models and codes must fulfill (e.g., that conceptual models and scenarios reasonably represent possible future states of the disposal system, and that computer models accurately implement numerical models), and specifies the minimum documentation of models needed to allow EPA to evaluate whether the choice and implementation of models and codes in compliance applications is adequate.

2. EPA should provide assurances that a graded approach to documentation applies to WIPP codes. (CARD-B)

Response to Comment 5.B.2:

It is expected that all codes used to model the performance of WIPP will have appropriate documentation. Large, complex codes would be expected to have documentation that explains the entire code, while smaller codes would require the same type of information, but the amount of documentation would likely be less. That is, the level of quality assurance required is the same for all codes, but the amount of documentation needed to fulfill quality assurance requirements, as required in ASME NQA-2, Part 2.7 (incorporated by reference in the final rule), is commensurate with the complexity and number of functions for which the code is used. In its review of DOE's application for certification, EPA will examine documentation of codes. The final rule does specify minimum information which must be included in compliance applications for all codes; any compliance application must include detailed descriptions of the structure of computer codes and complete listings of the source code, as well as a description of how computer codes incorporate the effects of correlation of parameters. Such information is reasonable and necessary to provide EPA adequate information to evaluate computer codes. The Agency intends to conduct detailed reviews of the computer codes used in performance and compliance assessments, since it is the results of computer codes themselves that will be compared to the numerical requirements found at section 13 of 40 CFR part 191.

3. EPA must have requirements that account for possible lack of sufficient data support for inferences, failure to account for all available data, and failure to account for all processes believed to apply. (NMAG-B)

4. Conceptual models must be based on experimental data and mathematical expressions which account for the relevant factors in the conceptual models. (NMAG-F)

Response to Comments 5.B.3 and 5.B.4:

Since the final rule requires that models (including information on natural processes expected to occur at the WIPP) and data need to be documented and substantiated, EPA believes that the rule addresses these concerns. Compliance applications must provide information on and descriptions of models and computer codes which will permit the Agency to conduct a review of the modeling approach, theoretical bases, and the methodology employed in developing the list of processes and events used to support the compliance application. Section 194.23 specifies the types of information which must be included in compliance applications for conceptual models, mathematical models, numerical models, and computer codes. The EPA will review the application to determine if it is complete and appropriately accounts for data and processes.

The Agency does recognize the importance of conceptual models, and their incorporated assumptions, in accounting for processes expected to occur at the WIPP and for available site characterization information. Examination of alternate conceptual models can help EPA evaluate the soundness of the process by which the final conceptual models of disposal system behavior were developed and also provide insight into the effect that changing certain assumptions might have on the predicted behavior of the disposal system. Therefore, the final rule requires that DOE describe plausible, alternative conceptual models seriously considered but not used to support compliance applications, and an explanation of the reason(s) why such model(s) was not deemed to accurately portray performance of the disposal system. In addition, compliance applications must include documentation that conceptual models and scenarios reasonably represent possible future states of the disposal system; such documentation would include a discussion of the theoretical basis and the relationship of modeling assumptions to experimental data which supports or contradicts such assumptions. Finally, conceptual models selected and developed by DOE for use in compliance applications are subject to the peer review requirements of the final rule [§194.27]. See also the response to Issue 5.I.

5. The EPA should avoid those situations where it independently models the design or performance of the WIPP where this modeling does not represent the manner in which DOE proposes to operate the facility. (IV-D-100)

Response to Comment 5.B.5:

It is incumbent upon DOE to provide the models of the repository. The EPA does not intend to conduct a separate performance assessment, but the Agency may use other models, as

appropriate, to verify DOE's performance assessment. When the Agency uses other models to verify DOE's models, the modeling will be suitable to the disposal system. The DOE will be expected to provide the pertinent information in compliance application documentation so that EPA can appropriately model the performance of the repository.

6. To determine which models are appropriate EPA must review DOE's plan to identify the scenarios requiring consideration, and on that basis determine the conceptual models required. (NMAG-F)

Response to Comment 5.B.6:

The final rule requires that DOE describe and justify the selection both of conceptual models and of processes and events determined to be within the scope of performance assessment. [See §194.23 and §194.32.] The EPA will review the information provided in the application to determine if all valid scenarios have been considered and if the models are appropriate. See also the response to Comment 5.B.3.

7. EPA should not rely on a single set of conceptual models when evaluating compliance with the numerical limits (i.e., containment requirements, individual protection requirements, and ground water protection requirements) of Part 191, unless all plausible alternatives can be definitely ruled out. It is recommended that EPA consider results from alternate conceptual models when making its decision. It is also recommended that EPA not allow a range of competing alternate conceptual models to be combined in performance assessment calculations. (NRC)

Response to Comment 5.B.7:

The issue of conceptual models is important to the Agency. The EPA is requiring the applicant to include information on plausible alternative conceptual models seriously considered but not used to support compliance applications. The DOE must also explain the reasons why such plausible models were not deemed to accurately portray performance of the disposal system. It is EPA's intent, from this information on alternative models, to review the appropriateness of the final model used. The compliance criteria do not require multiple conceptual models to be compared directly based on their impact on performance assessment results; the Agency believes that this approach might lead to selection of the least conservative model, rather than selection of a realistic or accurate model. Rather, DOE must document in its compliance application that the conceptual models implemented in PA reasonably represent possible future states of the disposal system.

The EPA will not be restricted in its review of the WIPP modeling. Examining results from alternative conceptual models is one possible evaluation method. Because the containment requirements consider human intrusion while the individual and ground water protection requirements do not, it will be necessary for DOE to use various conceptual models. This information should be apparent in the application. As noted above, the DOE must provide

documentation of the models so that the Agency can determine if they are selected and used appropriately.

Issue C: The track record of DOE in dealing with a successful radioactive waste disposal site should be factored into EPA's probabilistic models. (S-07)

Response to Issue 5.C:

The Agency will review the documentation provided in DOE's compliance application to determine whether DOE is in compliance with the disposal regulations at 40 CFR part 191. The Agency recognizes that uncertainty cannot be fully eliminated from performance assessment. Therefore, performance assessments and compliance are required to account for uncertainty in calculations, and EPA has required that compliance with numerical limits be demonstrated to within specific statistical confidence limits. In addition, assurance requirements were included in the disposal regulations to complement the numerical containment requirements and add confidence in the long-term performance of the disposal system.

Issue D: Additional peer review of models and computer codes is unnecessary and cumbersome. (DOE-D, SNL-C)

Response to Issue 5.D:

The Agency believes that in order for computer models to perform their function with acceptable accuracy, they must be based upon appropriate conceptual, mathematical, and numerical models. Peer review is an accepted method to achieve this goal, and is customary throughout industry for computer codes and models. Section 194.27 of the final rule, Peer review, requires that conceptual models selected and developed by the DOE for use in compliance applications must be peer reviewed. Other levels of models and computer codes may undergo peer review, but peer review is not required. While only conceptual models are required, a priori, to undergo peer review, all levels of computer codes and models must be described and documented, pursuant to the requirements of §194.23. The Agency believes peer review of conceptual models is important because they embody the most basic models and assumptions upon which performance assessments and compliance assessments are based. Models which already have undergone peer review will not be required to do so again.

Issue E: EPA must adequately address climate change in all its predictive models and assumptions. (A-43, A-48)

Response to Issue 5.E:

Climate change is required to be incorporated into the disposal system modeling. The issue of climate change is specifically addressed under §194.25, Future states assumptions. The DOE must incorporate climate change into the appropriate models, and EPA will review the models to ensure that it has been adequately incorporated. There are multiple ways in which climate

change can be incorporated into the modeling, and DOE must justify the approach ultimately used in the application. At a minimum, DOE shall consider the effects of increased precipitation (as compared to present conditions) on the disposal system [see §194.25].

Issue F: It would be difficult to verify model results and observed data.

1. It may not be feasible to provide information used to verify the results of the computer simulation in 30 days; use a reasonable period of time. (WEC-D)

Response to Comment 5.F.1:

It is necessary to require DOE to promptly provide information for verifying computer simulations in order for EPA to make a certification decision in a timely manner. If the computer codes, data files, and hardware are documented properly, EPA believes that the 30-day request time is adequate and reasonable.

2. Demonstrating agreement between model results and observed data is impossible given the regulatory time frame. (SNL-C)

3. It is not possible to demonstrate agreement between data and model results because the 10,000-year period of performance is far beyond any reasonable data collection period. (DOE-D, C-12)

4. EPA should require agreement between model results and measured and observed data. (SGNM-A, IV-D-06)

5. While it can be helpful if there is information demonstrating agreement between modeled and measured results, voluntary submission of such data should be encouraged but not required. (IV-D-51)

6. The EPA should not limit its ability to assess the performance of the models and/or codes by using an arbitrary approach; that is, whether models should be used to reproduce the data faithfully or conservatively. (IV-D-100)

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

8. The Agency should retain the requirement that a high degree of agreement exist between the model and measured data. (NMAG-D)

Response to Comments 5.F.2 through 5.F.8:

The ability to verify model results depends on the process being modeled. For some short-term processes for which data have been collected, such as with room closure and gas generation models, it is possible to compare the models with measured data for an appropriate time period represented by the data. In such instances, EPA expects that such information would be used document whether conceptual models reasonably represent possible future states of the disposal system; such justification is required by the final rule. The rule does not state, nor does EPA expect, that agreement between model results and observed data can be demonstrated for 10,000 years. While it is impossible to demonstrate agreement between data and model results for long-term processes over a 10,000-year time frame, the use of peer review of data and models, computer code quality assurance procedures, benchmarking and other measures can contribute to increased confidence that the disposal system will perform within expected limits. The use of peer review and quality assurance are addressed in other sections of the rule. Section 194.23 requires that, at a minimum, compliance applications provide appropriate documentation of models and codes supporting their selection and implementation.

Issue G: With current technology, computers should be able to account for the curie load in a real-time sense. (S-53)

Response to Issue 5.G:

The EPA agrees that the decay of radionuclides is an integral part of the performance assessment calculations that can be readily incorporated into models. In estimating potential releases from the disposal system, the performance assessment codes will need to incorporate radionuclide decay for each radionuclide and the subsequent activities to determine compliance with the containment requirements and the individual and ground water protection requirements. In its evaluation of DOE's codes, EPA will examine whether the decay has been appropriately incorporated.

Issue H: The requirement for covariance is inappropriate.

1. Covariance is not an appropriate consideration for the rule. (DOE-D, SNL-C, A-45, IV-D-51)

2. It is not unreasonable to ask DOE to make covariance calculations. (SGNM-A, SGNM-B)

3. The subsection on covariance should be deleted because of its questionable technical basis. (SNL-C)

4. It is suggested that EPA not impose a blanket requirement for a covariance study on DOE but use the technique as a part of the regulatory process where valid results would be expected. (IV-D-100)

5. It is essential to deal with correlations among variable parameters. (NMAG-E)

6. DOE should be required to account for covariance in its computer models. (SRIC-G)

7. EPA should retain its requirements for the treatment of covariance. (NRC)

Response to Issue 5.H:

The intent of the rule is for the correlations of dependent sampled parameters (i.e., parameters using distributions) to be considered in the computer codes and models. Thus not all input parameters are subject to the covariance requirement; for input parameters which are not sampled, or which can be demonstrated to be independent of other variables, DOE need not account for correlation. The EPA believes that treating all variables as independent would be an unrealistic assumption, and could introduce significant error in the results of compliance assessments. The final rule requires that compliance applications include documentation of how models and computer codes incorporate the effects of parameter correlation. In cases where neglecting correlation between variables is not expected to significantly affect the results of modeling, the final rule would not require models to include covariance, but the compliance application would be required to explain the technical basis for the determination that results will not be affected by the exclusion of correlation between parameters.

Issue I: The request for rejected models is excessive.

1. The request for listing of conceptual models is too open-ended. (DOE-D, SNL-C)

2. The DOE should not be required to defend what it did not do. Models not used should be documented only to the extent that they reasonably represent the disposal system. (DOE-D, SNL-B, SNL-C)

3. The EPA's request for rejected models is not related to health and safety. (A-45)

4. It would be counterproductive and a grave error to require DOE to identify and describe all models considered. (IV-D-51)

5. The provisions to provide a complete listing and description of all models and codes considered are inappropriate. (DOE-A, WEC-D)

6. It would seem prudent to focus on the adequacy of the codes and models used in the performance assessment to show compliance rather than to dilute valuable resources on material unrelated to compliance assessment codes. (IV-D-100)

7. The requirement for the applicant to show all conceptual models considered and how and why a particular model was chosen is a very important and wise requirement. (EEG-C)

8. The question of conceptual model uncertainty is so important and otherwise neglected that the requirement should be retained. (NMAG-D)

9. DOE must be required to submit a complete listing of conceptual models considered but not used in support of an application. (SRIC-G)

10. The proposed 40 CFR part 194.23(a)(2) creates an extra burden and unnecessary documentation for the applicant to follow. (IV-D-65)

11. The requirement as stated appears to be unnecessary and any direct benefit to the certification process is not clear. Since the disposal standards are performance standards and not technical standards this approach should be deemed adequate and reasonable. (IV-D-111)

12. It is unreasonable and unnecessary for EPA to require that DOE defend information, such as rejected conceptual models, that is not included in compliance applications. (DOE-A)

13. It is recommended that EPA should require that only a range of *plausible or credible* alternatives be explored and considered in detail by the applicant. (NRC)

Response to Comments 5.I.1 through 5.I.13:

Public comments have stated that the proposed rule was unreasonably burdensome in requiring a listing and description of all conceptual models that were considered but not used to support compliance applications. In the proposed rule, the Agency had required submission of this complete listing of alternate conceptual models in order to evaluate the soundness of the process by which the final conceptual models of disposal system behavior were developed and also to provide insight into the effect that changing certain assumptions might have on the predicted behavior of the disposal system. The Agency recognizes, however, that the development of conceptual models may begin in the early stages of repository development, before a complete site characterization has been achieved and in-depth experimental programs have been performed. As a result, some conceptual models considered may have been preliminary in nature and, in light of later information, be found not to provide accurate portrayals of disposal system performance. Further, some conceptual models could have been reviewed initially but screened out quickly because they contained assumptions that were clearly incompatible with conditions known to exist at the WIPP. The Agency believes that a review of these preliminary conceptual models will provide little insight into the technical adequacy of the final performance assessments, the development of which will presumably be based on more thoroughly developed and accurate conceptual models.

However, in the different case of plausible conceptual models -- even those which may ultimately be replaced -- the Agency does believe that a review can provide beneficial insight into the adequacy of the performance assessment that is contained in the compliance application. Models which are seriously considered but ultimately not used may contain different assumptions from those contained in the final conceptual models used in

performance assessments. For example, there are multiple, plausible conceptual models for ground water flow in the Culebra Dolomite. The Agency believes that by reviewing alternate conceptual models, the Agency can better understand the effect of model choice on the results of long term predictions. The EPA believes that it is especially important to examine the impact of different assumptions in conceptual models regarding the processes and events that can have an effect on the disposal system. Hence, the final rule requires that compliance applications include description of plausible, alternate conceptual models seriously considered but not used to support the compliance application, and requires that an explanation be provided of why these alternate conceptual models were deemed not to accurately portray disposal system performance. The EPA does not expect that DOE should provide the same level of documentation for rejected models as it does for models that are used to support compliance applications. For the models not used, the application should list (identify) these models and provide enough information so that the Agency can understand the modeling approach, method of analysis and the assumptions underlying these analyses. The final rule also requires that conceptual models selected and developed by DOE for use in compliance applications must undergo peer review according to the requirements of §194.27. For further information, see also the response to Comments 5.B.3 and 5.B.4.

14. Additional modeling over and above the models which have already been created and those which might be included with the application would be totally useless and would only propagate uncertainty. (IV-D-111)

Response to Comment 5.I.14:

The EPA is not requiring modeling in addition to what is included in performance assessments and compliance assessments. The Agency is requiring that DOE justify the selection of conceptual models and include descriptions of plausible conceptual models seriously considered but not selected for use. The Agency believes justification of the choice of conceptual models is especially important because they embody the most basic models and assumptions upon which performance assessments and compliance assessments are based. For the models not used, the application should describe these models and provide enough information so that the Agency can understand the modeling approach, method of analysis and the assumptions underlying these analyses. The final rule does not, however, require that DOE perform additional modeling using these alternate models. See also the response to Comment 5.B.7.

Issue J: EPA needs to determine the factors used to select appropriate computer models and codes.

1. EPA should specify which models need to be included in application ("model" is a very broad term). Also, a description of each model should be required (specifically for numerical, computational, conceptual, and mathematical). Further, the consideration of alternative models should be described and justification provided for the rejection of any models. (NMAG-G)

2. The application should include detailed scientific and technical justification for each model used directly or indirectly in support of the application. (NMAG-D)

Response to Comments 5.J.1 and 5.J.2:

The compliance criteria do not specify the models to be used for performance or compliance assessments. Rather, the application must describe the models that have been used. Plausible, alternative conceptual models seriously considered but rejected must be discussed, although the information necessary for rejected models is not as intensive as the requirements for the models and codes actually used for compliance applications. The final compliance criteria require that DOE document that conceptual models and scenarios reasonably represent possible future states of the disposal system; that mathematical models incorporate equations and boundary conditions which reasonably represent the mathematical formulation of the conceptual models; that numerical models provide numerical schemes which enable the mathematical models to obtain stable solutions, and that computer models accurately implement the numerical models [§194.23(a)(3)]. In addition, computer codes must be documented in accordance with the requirements of ASME NQA-2a-1990, Part 2.7, incorporated by reference, and the requirements of §194.23(c) of the final rule. The EPA believes that documentation in this manner should provide the information needed by the Agency to evaluate the accuracy and adequacy of models and codes used in compliance applications. See also the response to Comments 5.I.1 through 5.I.13.

3. EPA should not limit itself as to the factors it will use to assess the appropriateness of computer codes and models. (IV-D-06)

Response to Comment 5.J.3:

The Agency has not limited itself on the factors used to assess whether computer codes and models are used appropriately in compliance applications. The final rule does establish what documentation is required for conceptual, mathematical, numerical, and computer models in a compliance application. [See §194.23(a)(3) of the final rule, and the response to Comment 5.J.1 of this document.] The documentation requirements establish the minimum justification needed for models and codes. For example, conceptual models and scenarios must reasonably represent possible future states of the disposal system. The EPA is also requiring that detailed descriptions be provided for all models and codes, including theoretical background, discussion of the limits of applicability, and reports on quality assurance procedures applied. Such information will allow EPA to evaluate many aspects of models and codes to determine if they have been selected and applied appropriately. Finally, as specified in the final rule, EPA may verify the results of computer simulations by performing independent simulations.

4. EPA should provide an explanation of how it will evaluate what constitutes a computer model's reasonable representation of the WIPP facility. (WEC-D)

Response to Comment 5.J.4:

A computer model's representation of the facility depends largely on the conceptual model which forms the basis of the computer model. If a conceptual model is appropriate, then the measures of a computer model's adequacy are objective and functional, if the appropriate quality assurance has been performed on the code. That is, the computer model's adequacy depends primarily on whether the implemented computer code is free of coding errors. The decision on whether a conceptual model reasonably represents the disposal system can be difficult. Because such decisions are complicated and can be subjective, EPA has placed additional requirements on conceptual models. The DOE must submit information on rejected models, and the selection and development of conceptual models by DOE is subject to peer review, pursuant to §194.27 of the final rule. See the response to Comment 5.I.1 of this document for further discussion of conceptual models.

Issue K: Participants in the rulemaking must have access to all computer models and the authority to request additional CCDFs.

1. The final rule must ensure that participants can require DOE to produce additional CCDFs that use other data and assumptions provided by the person making such a request. (SRIC-E)

2. Participants in the certification rulemaking should be able to have access to all models, computer codes, and information necessary to generate their own CCDFs, or range of CCDFs. (SRIC-E, CCNS-B)

Response to Issue 5.K:

The final rule requires that DOE must provide EPA access to all materials or information required to verify the results of computer simulations [§194.23(d)]. The rule requires that numerous CCDFs be generated, and the Agency will have the capability to produce CCDFs as it believes necessary during the review of the application. The EPA considered that some members of the public could have an interest in performing additional simulations. However, given the number and complexity of tools required to perform such simulations, EPA determined that it would be an undue burden if DOE were required to make such material available to the public. The Department is required to provide extensive documentation on the computer models and codes used in any compliance application. This documentation includes computer codes and detailed descriptions of the computer codes. In addition, compliance applications must include detailed instructions for executing computer codes used in performance assessment calculations. The Agency plans to place copies of any application and such supporting documents in the docket for examination by the public. The EPA believes that such documentation will provide adequate information to allow the public to comment on the adequacy of DOE's models. Further, EPA notes that the public may comment to EPA during the certification rulemaking that a particular simulation should be performed.

Issue L: There is no "best" model, only "appropriate" and "inappropriate" ones. (DOE-D)

Response to Issue 5.L:

The Agency agrees with this comment. While having the "best" model is the ideal situation, this is usually impossible, and models that satisfy the rule's requirements and satisfactorily model the physical situation are acceptable. Any references to "best models" have been eliminated in the final rule and preamble.

Issue M: The rule should list each parameter in the application for which a model is to be provided. (NMAG-D)

Response to Issue 5.M:

The DOE must submit documentation on all conceptual, mathematical, numerical, and computer models used in a compliance application. General descriptions of each model must be provided in compliance applications, including detailed explanations of each input and output parameter. Required documentation also includes detailed descriptions of data collection procedures, sources of data, data reduction and analysis, and code input parameter development. Finally, DOE must account for the effects of correlation between dependent parameters. The EPA believes such documentation will adequately indicate what processes and parameters are included in models.

Issue N: The following should be added to §194.23, "Models and codes used to support the compliance application shall be fully and clearly documented in a manner compatible with NUREG 0856 'Final Technical Position on Documentation of Computer Codes for High Level Waste Management.'" (NMAG-D)

Response to Issue 5.N:

The EPA has considered such a requirement and determined that the intent, scope and implementation of NUREG-0856 is substantially similar to the requirements of NQA-2a-1990 addenda, part 2.7 to NQA-2-1989 edition, in terms of documentation requirements (such as a description of mathematical models and numerical methods). The specific documentation requirements articulated in the final rule, combined with requirements incorporated by reference in the NQA standards, address areas included in the NUREG. The NQA standards incorporated by reference into the final rule are a nationally accepted standard, developed through a consensus process (including participation by regulatory agencies), and designed to address the specific needs of a nuclear facility. (See Section 4 of this document for further discussion of the selection of quality assurance standards incorporated into the final rule.) The EPA believes that the requirements of the ASME NQA standards taken as a whole address a broader range of issues and are more comprehensive than NRC's requirements. The EPA does not believe that incorporation of the NUREG would provide additional information or assurance that models and codes have been appropriately selected and implemented.

Issue O: A method is lacking for verification of computer modeling which analyzes risk and probability of occurrence for natural hazards/events and anthropogenic processes and hazards. (SGNM-D)

Response to Issue 5.O:

Any computer models used to conduct such analyses must be documented to the same degree as all other models used in support of compliance applications. Several other sections of the rule also contain requirements relevant to the features and processes considered in performance assessments and compliance assessments. For example, paragraph §194.32(e)(3) of the final rule requires the Department to justify why any processes and events were not included in performance assessments. The preamble to the final rule clarifies EPA's approach to evaluating the likelihood of processes and events. In addition, §194.27 requires that peer review be conducted of all conceptual models selected and developed by DOE for use in compliance applications. The probability of occurrence of some events may be subject to peer review under this requirement, since the selection and evaluation of scenarios are central to the formulation of conceptual models. Further, estimation of the probability of occurrence is subject to the quality assurance and expert judgment requirements of the final rule, as applicable (see §194.22 and §194.26). The EPA believes that the above criteria are adequate to ensure that DOE objectively evaluates the probability of events.

Issue P: EPA should adopt a definition for "conceptual model" similar to that used by Bonano, where the conceptual model describes the physical and/or chemical processes taking place, the variables that relate to these processes, including boundary conditions and the spatial and temporal scales of the assumed processes (Bonano, 1988) or similar to that used by Tsang (Tsang, 1991), where a site specific conceptual model consists of three main components: structure, processes, and boundary and initial conditions. (NRC)

Response to Issue 5.P:

The comment refers to multiple definitions for the use of conceptual models, suggesting that alternative definitions of conceptual model are acceptable. While EPA has declined in the final rule to define the term conceptual model, usage of the term in the final rule is compatible with definitions described in the comment. Conceptual models provide a broad overview of the disposal system, including processes which may occur during the regulatory time frame at the WIPP, and may incorporate some simplifying assumptions regarding behavior of the system. In the final rule, EPA has required that compliance applications document conceptual models, with an emphasis on the justification of why selected models are appropriate for the disposal system. Documentation of conceptual models of necessity should discuss site characteristics -- including the processes active on the site, the scale at which they operate and existing initial conditions (e.g., groundwater flow) -- similiar to those discussed by Tsang. In addition, the data collected as part of the site characterization effort should be used by DOE in establishing initial conditions for the disposal system. Rather than specifically defining terms such as conceptual model or mathematical model, EPA has instead chosen in the final rule to

specify what information must be provided on models used. The information required to be included in compliance applications by §194.23 is intended to provide EPA with an understanding of the entire progression from conceptual models to computer models and codes which are implemented in performance assessments. Although EPA has not defined conceptual model as requested in the comment, the final rule does require documentation of the factors described in the comment.

Section 6: WASTE CHARACTERIZATION: SECTION 194.24

Issue A: An exact characterization of the wastes prior to disposal is necessary.

1. The DOE application must be based on detailed information about the specific waste being disposed. (CARD-A, A-08, A-12, A-18, A-46, A-60, S-3)

2. An exact characterization of the waste must be developed. (SGNM-C, S-53)

3. DOE's application should disclose detailed information about the specific wastes to be disposed. (S-37, IV-D-06, IV-D-13, IV-D-14, IV-D-15, IV-D-16, IV-D-17, IV-D-18, IV-D-19, IV-D-20, IV-D-21, IV-D-22, IV-D-23, IV-D-24, IV-D-25, IV-D-30, IV-D-31, IV-D-32, IV-D-33, IV-D-34, IV-D-35, IV-D-37, IV-D-38, IV-D-42, IV-D-46, IV-D-47, IV-D-48, IV-D-52, IV-D-53, IV-D-54, IV-D-55, IV-D-56, IV-D-57, IV-D-58, IV-D-59, IV-D-60, IV-D-61, IV-D-62, IV-D-63, IV-D-66, IV-D-67, IV-D-68, IV-D-69, IV-D-70, IV-D-71, IV-D-72, IV-D-74, IV-D-75, IV-D-79, IV-D-80, IV-D-83, IV-D-87, IV-D-88, IV-D-99)

4. It must be specifically stated in the criteria that the DOE must provide detailed information about the specific wastes to be disposed of at WIPP. (IV-D-43)

5. It's fundamental to compliance that DOE give a complete and accurate inventory of all waste characteristics important to the facility's ability to contain radioactivity. (CARD-B, S-40)

6. The criteria for waste characterization must require specific information on the waste DOE wants to dispose of in the WIPP. (S-11, S-14, S-37)

7. All the waste needs to specifically characterized as it exists now, not as it existed when it was placed in the canisters. (S-12)

8. The final rule must require actual physical waste characterization. (SRIC-G)

Response to Comments 6.A.1 through 6.A.8:

The EPA revised the language from the proposed compliance criteria so that the final rule clarifies the Agency's requirements on this issue. The rule requires DOE to describe the chemical, radiological and physical composition of currently existing and, to the extent practicable, of to-be-generated waste proposed for disposal in the disposal system. The descriptions must include a list of waste components and their approximate quantities in the waste. This list may be based upon process knowledge, current non-destructive examination/assay, or other information or methods. Use of process knowledge to quantify waste components in waste must conform with the quality assurance requirements found in §194.22 of the final rule; collection of other data and information regarding waste characterization are also subject to the quality assurance requirements of the final rule, pursuant to paragraph §194.22(a)(2)(i). The EPA believes that it is essential for DOE to begin

its identification of waste characteristics and waste components which significantly influence the containment of waste in the disposal system based on a comprehensive and detailed list which includes the materials present in the waste from all generator sites. Once the significant components are identified, the final rule requires that DOE limit, control and quantify these components. Once limits have been established for waste components which significantly influence containment of waste in the disposal system, DOE must implement a system of controls to ensure that waste is emplaced in the disposal system only if the emplaced components of such waste will not cause the limits on waste components to be violated (see §194.24(c)(4) and §194.24(e)). Furthermore, paragraph §194.24(f) of the final rule requires that waste emplacement in the disposal system must conform to the assumed loading conditions, if any, used in performance assessments and in compliance assessments.

9. Contents of barrels containing waste must be identified before they are emplaced. (A-68, S-17, S-21, S-40)

10. Waste characterization needs to be more intensely considered. (S-16, S-23, A-27, IV-D-07, IV-D-26)

11. Adequate characterization of all waste coming to WIPP is essential to a determination of compliance with the disposal regulations. (SRIC-A, SRIC-C, SRIC-E)

12. In reference to a “system of controls” to enforce the ranges applicable to waste characteristics and categories, the Agency should require that the system be applied to existing waste, and the results supplied. (NMAG-D)

13. All waste bound for WIPP must be characterized, not simply studied. (C-03, A-29, A-43, A-48, IV-D-03)

14. Compliance criteria must insist that DOE not only include the results of its "study of the effects of waste characteristics on the containment of the waste in the disposal system," but also state what impacts the results of this study have on WIPP's ability to meet 40 CFR part 191 requirements. (SRIC-C, CCNS-B)

Response to Comments 6.A.9 through 6.A.14:

The waste characterization requirements have been revised from the proposal to clarify that DOE must actually characterize waste proposed for disposal in the disposal system. The purpose of the waste characterization analysis required pursuant to §194.24(b) of the final rule is to ensure that all waste characteristics and waste components which influence containment of waste have been systematically identified and evaluated; the evaluation is based on effects of components and characteristics on the containment of waste in the disposal system (and therefore, on the ability of the disposal system to demonstrate compliance with the disposal regulations). The required analysis thus identifies which waste components must be quantified during waste characterization activities. Physical sampling or other methods of waste characterization (such as use of process knowledge) must then be used to ensure that

significant waste components are controlled. Compliance applications must document why any waste characteristics and waste components are not considered -- that is, why they are not expected to significantly influence the containment of waste in the disposal system. Once important components have been identified, the Department must establish upper or lower limits, as appropriate, on such components. Section 194.24 in the final rule clarifies that DOE is required to provide information which shows that a system of controls is implemented which will assure that waste containers are allowed to be emplaced in the disposal system only if their components fall within limits established for the compliance demonstration. This system of controls is required to be applied to all waste actually emplaced in the disposal system, regardless of whether such waste is currently existing, or is yet to be generated. Thus, each container of waste (or group of containers, depending on the important level of scale) to be shipped to the WIPP must be characterized as to all waste parameters which are significant to compliance with the disposal regulations. In addition, DOE is obligated by other regulatory requirements to characterize each container of waste for components important to transportation and to compliance with the Resource Conservation and Recovery Act.

Although EPA is not requiring that each drum of waste be characterized for every one of its components quantitatively, the rule contains requirements for the identification and characterization of all waste components which significantly influence containment of waste in the disposal system. The rule requires that DOE describe the components of waste (both existing and to-be-generated), based on reliable information. Both waste characterization sampling data and the use of process knowledge for quantifying waste components are subject to the quality assurance requirements of the final rule. The EPA is concerned that radiation exposures to workers performing waste characterization should be limited as much as possible without compromising the quality of waste characterization data; see response to Issue 6.L for further discussion of this issue.

15. Future generated wastes should be fully characterized by an independent agency (not the DOE). (A-48)

Response to Comment 6.A.15:

The EPA is requiring that DOE's compliance application provide assurance, through a documented and implemented system of controls, that only those containers of waste (whether generated in the past or the future) whose contents fall within the limits of waste characteristics and components used to demonstrate compliance will be emplaced in the disposal system. This means that all containers of waste, whether existing or to-be-generated, must meet the same characterization requirements. As to the comment for independent characterization, EPA believes that its independent oversight though inspections and audits of DOE waste characterization will be sufficient. The EPA has revised the final rule language to clarify that future-generated waste must conform to the same characterization requirements as currently stored waste.

Issue B: Waste characterization should occur at the current waste site.

1. It is essential that all waste be characterized that is to be transported and placed in the WIPP. (IV-D-12, IV-D-28, IV-D-92)

2. Characterization and the application should be done at each waste site so that actual physical data is basis for application. (SRIC-C, A-08, S-03)

3. EPA should establish a regulatory requirement mandating facilities storing WIPP destined waste to submit the desired information, as part of this application for characterization and disposal, rather than using the WIPP LWA as a mechanism to establish the right of access for otherwise non-regulated activities. (IV-D-11)

Response to Comments 6.B.1 through 6.B.3:

Section 194.24 requires that the Department describe the chemical, physical and radiological composition of the waste using currently available site data, including process knowledge. In this sense, current characterization data is expected to be the basis of the application. However, since the waste components for current and to-be-generated waste which are important to compliance with the disposal standard have not been identified, EPA is requiring that they be identified by a comprehensive process, that they be limited for purposes of estimating the inventory, and that they be confirmed through actual waste characterization before waste is emplaced at the WIPP. The logistics of this characterization are left to the Department, as waste generator and facility operator. This information must be provided as part of any compliance application, and will therefore be subject to public review during a certification rulemaking. The EPA will verify compliance with all characterization requirements through periodic audits and inspections; this inspection authority extends to sites which generate waste proposed for disposal at the WIPP.

It is DOE's responsibility to demonstrate compliance of the WIPP. The EPA believes that a single comprehensive DOE application, which must conform with waste characterization requirements for all waste proposed for disposal from any generator site, is appropriate.

4. Perhaps a "chain-of-custody" and other administrative controls that would bar the introduction of additional materials into a waste stream should be enacted, to ensure that the waste originally destined for the WIPP is the waste actually disposed there. (IV-D-11)

Response to Comment 6.B.4:

Paragraphs 194.24(c)(3)-(5) and §194.24(e) of the final rule address this concern. These provisions require that waste may be emplaced in the disposal system only if the components of the waste fall within the limits under which compliance can be demonstrated. In addition, DOE must establish and document controls to ensure that any waste approved for disposal meets the limits. The EPA plans to verify compliance with these requirements through audits and inspections [§194.24(f)]. The EPA clarified these requirements in the final rule.

Issue C: There is a need for the establishment of clearly defined criteria for waste characterization.

1. The proposed rule includes extensive criteria for waste characterization, and does not specify any particular method for characterizing the waste. It would be overly prescriptive and inefficient to detail methods in the rule. (WEC-B)

2. The objectives of the rule (§194.24) need to define waste characterization processes and a waste characterization plan. (NMAG-D)

Response to Comments 6.C.1 and 6.C.2:

The final rule requires the Department to identify and describe the method(s) used to determine and to limit important waste characteristics and components. Further, §194.24(c)(5) requires that measurements and other controls used to characterize and limit waste components be conducted in conformance with quality assurance requirements of §194.22. This assures an appropriate level of rigor to characterization without being overly prescriptive.

The Agency leaves the choice of characterization method(s) to the Department to allow flexibility for selecting the method appropriate for the waste stream in question. Ultimately, as part of its certification determination, the Agency will determine if the chosen methods are adequate and provide the level of detail necessary to confirm the conditions under which compliance is demonstrated through performance assessment.

3. EPA should clarify what it means by the statement "the DOE shall be required to substantiate such characterization." (IV-D-11)

Response to Comment 6.C.3:

The final rule has been changed to amplify this point: "[Any compliance application shall] [p]rovide information which demonstrates that the use of process knowledge to quantify components in waste for disposal conforms with the quality assurance requirements found in §194.22 [See §194.24(c)(3).]." The use of process knowledge for quantitative purposes must be quality controlled in accordance with requirements of the ASME standards cited under §194.22, in order to substantiate that the data quality obtained by the use of process knowledge meets or exceeds that required by the intended use of the data to confirm the waste conditions assumed in the demonstration of compliance. If the Department chooses to use records of past processes to meet pertinent waste characterization requirements, then the records need to be substantiated by characterizing waste containers to verify the records of a particular waste stream. In addition, the system of controls must be used to confirm that waste emplaced in the system does not violate the limits established for waste components.

4. Guidance should be provided describing categorization methods which are acceptable and which are not acceptable and the bases for acceptance or rejection of such methods. (IV-D-65)

Response to Comment 6.C.4:

Upon reassessment of the waste categorization requirement of the proposed rule, EPA has determined that little is gained by the imposition of a requirement to group wastes into categories, provided that all significant waste components are identified and controlled. Therefore, in the final rule, EPA deleted the requirement to group wastes into categories. The final rule does require identification of waste characteristics and waste components which significantly influence containment of waste in the disposal system.

5. Application should list procedures and processes that will be followed for characterization, characteristics of waste that will be allowed into WIPP, and how it was concluded that WIPP can contain such waste for 10,000 years. (CARD-B)

Response to Comment 6.C.5:

Section 194.24 requires that all necessary steps be taken to identify and limit significant waste components. Compliance must be demonstrated by the performance assessment, based on the inventory and the waste limits established in the compliance application, in accordance with §194.24(c). Finally, controls are required to be in place to assure that no waste component limit is exceeded. The final rule clarifies the steps that must be taken to appropriately characterize waste for compliance with 40 CFR part 191 and the compliance criteria.

6. Applicant needs firm guidance regarding waste characterization requirements. (SGNM-A)

Response to Comment 6.C.6:

Section 194.24 requires the Department to take all necessary steps to derive and implement essential waste characterization requirements important to compliance with the containment requirements of 40 CFR part 191. The language in the final rule for §194.24 was modified from the proposal to clarify EPA's expectations of waste characterization and spells out in reasonable detail DOE’s responsibilities.

7. DOE has too much flexibility in the amount of characterization required of it. (A-41)

8. The compliance application should contain more specific provisions on the waste characterization method and the waste in existence at the time of the application meets the current Waste Acceptance Criteria. (NMAG-D)

Response to Comments 6.C.7 and 6.C.8:

Neither the WIPP LWA nor 191 prescribe specific waste characterization requirements to be implemented by the compliance criteria, and EPA has broad discretion in establishing these requirements. The EPA has specified requirements for DOE regarding the particular steps it must follow to characterize waste proposed for disposal, and to verify that waste characterization requirements are met for actual waste emplaced. The EPA is requiring DOE to set total inventory (including all present and to-be-generated waste) limits on each waste component identified as significant; to demonstrate compliance with the disposal regulations for this inventory; and to demonstrate the existence of a system of controls to confirm that no limit is exceeded in actual disposal operations, subject to inspection. The EPA has required that DOE substantiate the identification of those characteristics and components which are important, and that such an assessment provide substantiation for any decisions not to consider any waste characteristic. This approach is believed to be neither too flexible nor too prescriptive.

9. EPA waste characterization requirements should be clearer and stronger. (A-41)

Response to Comment 6.C.9:

The comment did not suggest any specific requirements or revisions that EPA should implement. It is important to understand that EPA has formulated its waste characterization requirements on the basis of its assessment of current areas of uncertainty in DOE's transuranic waste characterization program and current uncertainties in what waste parameters are or may be significant to containment of waste in the disposal system and thus to the disposal regulations at 40 CFR part 191. From site visits it is evident to EPA that currently stored TRU waste contains a wide diversity of materials, some of which may have the potential to cause waste-disposal system interactions and therefore could affect the performance of the disposal system. Moreover, there is considerable uncertainty in the large volume of waste to be generated in the future, and DOE has been unable to provide EPA with any current plans for generating this waste, adding to this uncertainty. Faced with this and other uncertainties, EPA is requiring the following: Rather than adding prohibitive cost and worker radiation exposure by requiring full characterization by physical sampling of all drums of waste (which would eliminate uncertainty but produce substantial risk to human health), EPA is requiring DOE to identify, limit and confirm through quantification, all waste components which can affect containment. The significant components must be identified through an assessment of all waste components, characteristics of all currently stored waste, and anticipated characteristics of waste to be generated in the future. The DOE must substantiate all decisions to exclude waste characteristics which are deemed to be insignificant. The EPA is also requiring DOE to submit evidence which demonstrates that only waste whose contents lie within limits used to demonstrate compliance are allowed to be disposed of at the WIPP. In doing so, DOE must take into account the uncertainty of the characterization method used, showing, that at the upper end of measurement uncertainty bands, the waste still lies within the limits. In this way, EPA provides DOE the flexibility to address the challenges of diverse waste characterization, but requires that all steps in this

process which may affect the demonstration of compliance are considered and addressed. The EPA believes this is an appropriate balance between flexibility and prescriptiveness. The final rule clarifies the requirements for appropriate waste characterization.

10. The rule should state that regular reports on compliance with waste characterization requirements shall be made by DOE, that they shall operate, when submitted, to reopen the certification rulemaking, and that the Agency must approve or disapprove the report. (NMAG-D)

Response to Comment 6.C.10:

The Department must implement and maintain documentation on a system of controls to track the amount of waste entering the disposal system and to confirm that waste is emplaced in the disposal system only if it conforms to the limits on components established in §194.24(c). Waste may not be emplaced at the WIPP unless it meets the description of waste proposed for disposal at the facility. The EPA intends to confirm the adequacy of waste characterization activities, both at the WIPP and at other applicable sites, through audits and inspections [§194.24(f)]. If it is determined that conditions exist that differ significantly from those upon which a certification of compliance is based, the Agency has the authority to suspend, modify, or revoke a certification. Changes in waste characterization activities, like other changes to the disposal system, may be required to be reported under the requirements of §194.4, which also requires submission of regular reports that document changes in activities. In addition, information on the waste emplaced in the WIPP must be part of any certification application. The EPA does not believe that requiring approval or dis-approval of such reports would enhance public safety to a greater degree than the Agency's ability to modify, suspend or revoke certification, or not re-certify.

Issue D: The future state of the waste needs to be addressed.

1. EPA needs to clarify whether there are different requirements for existing and to-be-generated wastes. For example, in requiring detailed characterization, does that mean actual examination of the waste? If so, it cannot be applied to future waste. Also, EPA needs to clarify how "any other characteristics which could affect the transport of radionuclides" are to be identified. Further, "statistically valid" is confusing. (NMAG-G)

2. The compliance criteria must address those "future" wastes much more completely than is done in the draft criteria. (SRIC-E)

Response to Comments 6.D.1 and 6.D.2:

The final rule has been modified from the proposal in order to clarify the implementation of the waste characterization requirements. The language questioned in comment 6.D.1 above has been eliminated in the final rule. Instead, the final rule clarifies that DOE must identify, limit, and control waste components which influence containment of waste in the disposal system, and thus are directly relevant to the performance of the disposal system relative to the disposal regulations. The results of DOE's analysis of waste characteristics and components, required under §194.24(b), must be documented in any compliance application, as well as documentation that a system of controls has been implemented at the WIPP to ensure that waste emplaced in the disposal system conforms to the limits established for significant waste components. Thus, these analyses and associated waste characterization activities will be subject to public scrutiny in the compliance certification rulemaking.

In the interest of consistency, EPA is not requiring separate or different characterization of existing or future generated waste. The EPA's approach is to require DOE to identify and limit all components of the waste which influence containment of waste in the disposal system, regardless of whether the wastes are currently existing or to-be-generated. In addition, EPA is requiring DOE to implement a system of controls to assure that no limiting value is exceeded in actual waste to be emplaced (again, irrespective of when the waste was generated). In this way, EPA expects to be provided with assurance that important waste properties have been identified and will be controlled adequately to remain within the boundaries used to in performance assessments. The EPA modified the language from the proposed compliance criteria so the final rule clarifies that DOE must account for the characteristics of future wastes planned for disposal at the WIPP when setting acceptance limits and conducting performance assessments to demonstrate compliance. See also responses to Comments 6.A.9, 6.C.3, and 6.C.9.

3. Compliance criteria must state that all future waste will meet finalized WIPP WAC and undergo the same waste characterization analysis that is required for the current waste inventory. (CCNS-B)

Response to Comment 6.D.3:

There is no difference in characterization requirements or controls between current and future waste. The EPA has revised the language for the final rule to clarify that future-generated waste must conform to the same characterization requirements as waste currently being stored. The DOE's compliance application is required to demonstrate that containers of waste (whether generated in the past or the future) will be emplaced in the WIPP only if their contents fall within the waste characteristic and component limits used to demonstrate compliance.

4. EPA should be more concerned with the final waste form to be disposed of in the WIPP, and less concerned about the current characteristics and the storage operations at facilities storing waste destined for the WIPP. (IV-D-11)

Response to Comment 6.D.4:

The EPA is requiring the Department to describe all waste proposed for disposal, and to assess and limit and control all significant waste characteristics and components of waste proposed for disposal in WIPP. Thus, if waste form significantly influences the containment of waste in the disposal system, it must be so limited and controlled. In such a case, the final waste form must reflect the limits in the application, and DOE must demonstrate a system of controls to confirm that this is the case.

5. Not only is activity level important the mobility of the radionuclides is also important. Some radionuclides tend to attach more readily to clay or other negatively charged particle, while others are more mobile, and have less of a tendency to attach to clays. Therefore, mobility of the radionuclides in the environment should also be considered. (IV-D-11)

Response to Comment 6.D.5:

The final rule has been clarified to require the Department to assess the impact of all waste characteristics influencing containment of wastes including the assessment of those waste components which can affect solubility or formation of colloids. Compliance applications may also include waste loading schemes (which may aggravate or mitigate the effects of factor such as mobility of radionuclides); however, the final rule requires DOE to demonstrate that actual waste emplacement at the WIPP conforms to assumed waste loading conditions, if any, used in performance assessments and compliance assessments. The DOE must comprehensively address and control all significant factors which affect solubilization and mobilization of radionuclides towards the accessible environment.

Issue E: The use of the range of values must be clarified.

1. The ranges for waste characteristics do not present criteria that can be assimilated. (DOE-A)

2. The waste characterization study does not explain how the study will give rise to values, range of values, and maximum amounts of waste categories. The regulation should explain how such a study will be designed. (NMAG-D)

Response to Comments 6.E.1 and 6.E.2:

Some comments suggested that the limits on waste characteristics or components should be expressed as a range and distribution of sensitive waste parameters, and that they may be difficult to assimilate into waste acceptance criteria. The DOE is not precluded from fulfilling the requirements of this section by expressing ranges and distributions of sensitive parameters. However, the requirement is intended to result in a set of limiting values or ranges of values which are to be applied at the inventory scale, room scale (if needed), and container scale to define and limit the inventory proposed for disposal to that which can be shown to support compliance with the disposal regulations through performance assessment.

This set of limits or ranges of values could be called an "envelope" of important waste characteristics and components.

Moreover, EPA is requiring DOE to implement a system of controls to limit the waste which is actually emplaced in WIPP to that which lies within the envelope of limiting values. The DOE must confirm that the actual waste inventory emplaced at WIPP conforms to the important properties of the estimated inventory used to model the demonstration of compliance and submitted with the certification application. The final rule language was modified from the proposal to define waste characteristics and waste components, and to clarify the approach of determining important waste characteristics and components, and establishing limits on them.

3. The range of values for each waste characteristic must not be lowered, but should be realistic and conservative. (C-03)

Response to Comment 6.E.3:

In addition to those of §194.23, the principal requirements that the total inventory planned for disposal at the WIPP must meet are compliance with the requirements of §194.34 and §194.55 and compliance with the WIPP LWA waste limits pursuant to §194.24(g). The DOE must confirm that waste emplaced in the disposal system conforms to the limiting values or range of values established for each important waste characteristic or component. This has been clarified in the final rule. This, coupled with the requirement for a system of controls which confirms that the actual waste inventory emplaced at WIPP does not exceed any of the limits, assures that compliance, if demonstrated, will be maintained. Compliance applications may establish broad waste acceptance envelopes, but must demonstrate that the disposal system complies with the disposal regulations under the stated assumptions. The requirements provide an incentive for compliance applications to establish realistic limits on the components of waste proposed for disposal, since such waste must be shown to conform to such limits before it can be emplaced in the WIPP.

4. Will the range of values as discussed in the preamble be the means by which the DOE can account for decay of radionuclides and the potential for the decay of organics? If so, a discussion should be incorporated as one of the criteria. (IV-D-11)

Response to Comment 6.E.4:

The final rule requires that DOE conduct an analysis to identify waste characteristics and waste components which influence containment of waste in the disposal system. The results of this analysis must be used to establish limits on waste components, and DOE must implement and document a system of controls to ensure that waste actually emplaced in the disposal system conforms to the limits established for signficant components. The activity (in curies) of waste is an example of a waste component for which limits must be established. The decay of radionuclides is not a waste characteristic or component, but rather would be accounted for in the models used in performance assessment. Documentation of models and

computer codes, as required in §194.25 of the final rule, would include descriptions of the methods used to account for decay of radionuclides. For further discussion of radionuclide decay, see Section 5 (Models and Computer Codes) and Section 10 (Application of Release Limits) of this document. See also the responses to Comments 6.E.1 and 6.E.3.

Issue F: Characterizing wastes is not reasonable and the requirements are burdensome and imprudent.

1. The requirement for action interferes with the systematic design approach and have not been shown to be worthwhile. (DOE-D, WEC-A)

2. These requirements would increase the cost of waste characterization and potentially reduce safety and increase the risk associated with the characterization activity. (WEC-A, SNL-C, C-13, C-13, C-15, C-23, C-25)

3. The waste characterization processes delineated in the proposed rule are, in many ways, too prescriptive. (DOE-A, IV-D-76)

4. Characterizing waste is unrealistic due to potential changes in waste generation. (C-25)

5. Waste need be characterized only to the extent needed to demonstrate compliance as modeled by performance assessment. (DOE-D, SNL-A)

6. The approach taken by EPA is too-open ended and would result in a characterization effort that would exceed that needed to demonstrate compliance with 40 CFR part 191. These activities may require a degree of characterization that jeopardizes existing regulations that protect occupational and public health and safety. (SNL-A, SNL-C)

7. Waste characterization should be limited to characterization sufficient to demonstrate compliance with 40 CFR 191.13, 191.15, and 191.24, as modeled by performance assessment. (SNL-C)

Response to Comments 6.F.1 through 6.F.7:

The EPA's requirements were formulated to require DOE to identify and control, by measurements or other means of quantification (such as use of process knowledge), those waste characteristics which significantly influence the containment of radionuclides in the disposal system. Flexibility has been afforded DOE to scope and provide the necessary information through analysis and documentation (process knowledge, for example), provided that the results are acceptably rigorous. The results of an analysis of waste characteristics and components will be used to establish criteria for waste acceptance, based on which characteristics and components of waste are expected to significantly influence containment of waste in the disposal system.

The EPA agrees with the philosophy, in the interest of cost-effective expenditures and limiting worker radiation exposures, of not prescribing detailed physical sampling requirements. However, the transuranic waste currently stored at DOE facilities is highly heterogeneous and is known to contain a wide variety of materials, chemicals, etc. which have potential to influence the containment of radionuclides in the disposal system. Based upon DOE documentation to date, it is not clear whether all waste characteristics and components which are significant to total disposal system performance have been identified, or that adequate consideration has been given in decisions to disregard other characteristics or components deemed less important. For this reason, EPA has required that DOE substantiate the identification of those characteristics and components which are significant (sometimes called sensitive parameters in the language of performance assessment), and that such an assessment provide substantiation for any decisions not to consider any waste characteristic or component. Further, EPA is requiring that all significant waste components be limited (if necessary to demonstrate compliance), and quantified before disposal to confirm that no limits are exceeded.

Waste characteristics affect the long-term behavior of the WIPP in a number of ways; solubility, gas generation, shear strength, and other characteristics have been shown in previous performance assessments to be critical parameters. There are a large number of waste characteristics; some of these, such as activity of radionuclides in the waste, are important; others, such as color of the waste are unimportant, to compliance. The EPA must ensure that the information it receives in any compliance application provides sufficient detail on the waste characteristics that affect containment. Without this assurance, DOE simply can not show a reasonable expectation of compliance. The function of prescribing to DOE what waste characterization is needed is completely within EPA's discretion in implementing the disposal standards. The EPA believes that the approach in the final rule balances flexibility with prescriptiveness to assure that waste characterization is rigorous and reliable for those waste parameters important to containment of waste in the disposal system.

8. This subsection should clearly state that it will be used as a criterion to evaluate whether a reasonable expectation of compliance with 40 CFR 191.13, 191.15, and 191.24 exists. (SNL-A, SNL-C)

Response to Comment 6.F.8:

Meeting the requirements for waste characterization ensures that any compliance application is based on dependable and verifiable information. The waste characterization requirement is derived from the need to demonstrate a reasonable expectation of compliance with the disposal regulations. Any application must demonstrate that the requirements of §194.24 have been fulfilled specifically, and cannot meet the requirements of this section by stating that other compensating factors establish a reasonable expectation of compliance. Therefore, EPA believes it is inappropriate to include the suggested language in the final rule.

9. There is a question whether the cost of characterizing waste to such a great degree will offset benefits gained. (A-13)

Response to Comment 6.F.9:

The Agency shares the concern for occupational exposure to the workers who are involved in characterizing the waste, but believes it is also inappropriate to jeopardize future generations from potential releases to the accessible environment because this generation failed to study and characterize the waste that could significantly impact the total performance of the repository.

The Economic Impact Assessment indicates that the level of characterization required by the rule does not appear to increase cost over the costs already anticipated for meeting other regulations. The EPA has modified the language in the final rule from the proposed rule to clarify that waste characterization should focus on those parameters that may significantly influence the containment of waste in the disposal system. The Agency believes this strategy is both prudent and cost-effective. See response to Comment 6.F.1 for more information.

10. The requirements for action related to waste characterization have not been shown to be worthwhile. (C-29)

Response to Comment 6.F.10:

The Agency is requiring the Department to identify and assess the impact of significant waste characteristics and components on performance. Until this is done in an adequate fashion, considerable uncertainty exists as to what waste characterization should take place. The final rule also requires that DOE establish limits for significant waste components and implement a system of controls to confirm that the characteristics of the inventory emplaced at the WIPP (if a certification is granted) conform to estimates of the inventory used to demonstrate compliance. The required actions increase confidence that the repository will contain the actual waste as demonstrated by modeling. Moreover, this goal is to be obtained by performing the characterization actions necessary to provide adequate assurance, making this approach highly cost effective.

11. These requirements are premature and in the the final analysis are likely to be unnecessary. (WEC-A)

Response to Comment 6.F.11:

The disposal regulations require that DOE provide a reasonable expectation of meeting the containment requirements of 40 CFR part 191. All processes which may affect the containment requirements need to be considered. In the case of the WIPP, certain waste/disposal system interactions between the diverse types of waste materials in TRU waste and the conditions associated with bedded salt need to be considered in order to assess whether the containment requirements of the disposal regulations can be met. It is therefore necessary for EPA to require waste characterization to the extent needed to identify waste characteristics significant to the containment of waste and to require that these characteristics be quantified and controlled in the overall inventory.

12. The DOE should not be required to study the performance effects of characteristics that will not be represented in the WIPP inventory. DOE only needs to confirm that the wastes comply with applicable transportation criteria. (SNL-C)

Response to Comment 6.F.12:

The EPA is requiring the Department to identify, limit and control the waste characteristics that significantly influence the containment of waste in the repository. The EPA does not require characterization of the waste components that are not in the inventory. The transportation regulations do not consider the long-term containment of disposed waste in a geologic repository. Hence, compliance with the waste characterization requirements for transportation does not assure that waste has been adequately characterized to show compliance with 40 CFR part 191.

13. The waste characteristics requirements are unnecessarily burdensome, and would have the effect of excluding the more hazardous components of nuclear waste from WIPP. The effect of such regulation is to subject people near the defense related facilities to potential hazards from shallow ground water and air contamination, while delaying disposal of waste in salt that has been recognized as providing the most substantial barriers to such contamination. (IV-D-40, IV-D-64)

Response to Comment 6.F.13:

The requirements of §194.24 do not specify any restrictions on transuranic waste which would exclude the most hazardous components from disposal at WIPP unless the presence of such components would prevent compliance with the disposal regulations at 40 CFR part 191 or are otherwise inconsistent with the waste limits in the WIPP LWA. Even in such a case, DOE would have the option to treat such waste instead of excluding it, provided that compliance could be demonstrated and the WIPP LWA limits met. The WIPP Land Withdrawal Act imposes limitations on waste which can be disposed of at the WIPP; for example, any waste which meets the definition of High Level Waste may not be emplaced at the WIPP. The compliance criteria cannot and do not negate such requirements of the WIPP LWA.

With regard to the near-term delays which may occur as a result of the need to meet waste characterization provisions of §194.24, EPA has taken care to afford DOE flexibility in development and implementation of 40 CFR Part 191-based waste characterization requirements. However, the Agency feels that it is essential that the Department fully assess the potential for waste/disposal system interactions which can affect the ability of the disposal system to contain radionuclides for the 10,000 year regulatory period. Since the Department is required by RCRA and the provisions of the Atomic Energy Act to manage currently stored transuranic waste in a manner which is protective of human health and the environment, the Agency believes that any additional time in this vital area, which is necessary to provide reasonable assurance of compliance with the disposal regulations, will not result in increased risk.

14. The rule should be re-written as follows: DOE should identify the characteristics which are important through performance assessments. When they have been identified, DOE should develop waste characterization parameters which will ensure that the inventory will have the required characteristics to support demonstrations of compliance. Existing waste must be shown to meet the criteria through examination and statistical analysis. As to the future waste, DOE must show that the waste characterization parameters will be satisfied or the waste will not go to WIPP. (NMAG-G)

Response to Comment 6.F.14:

The EPA appreciates the straightforward and concise manner in which this commenter has formulated the waste characterization requirements, and has tried to clarify the entire content of waste characterization in §194.24 of the final rule. There are a number of simplifications in the commenter's approach which, if adopted literally, would have the effect of being overly prescriptive. For example, the performance assessment (PA) is not the only methodology which can or should be used to identify significant waste characteristics; logical screening and bounding arguments, assessment through sidebar calculations, and use of ancillary models and codes (for example, the actinide source term model) could be used as well as PA codes. Moreover, EPA considers it important that DOE begin its assessment from a detailed list of waste components in the waste, as opposed to a performance assessment model which already incorporates or excludes a number of assumptions and conceptual models involving waste properties. The final rule language generally conforms with the approach recommended in the comment.

15. It is recommended that the waste characterization requirements be made more general in order to allow the DOE to develop a waste acceptance plan 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. (DOE-E)

Response to Comment 6.F.15:

While EPA has specified the steps to be taken in order to establish important waste characteristics and components, EPA has not dictated that limits be established for specific characteristics or components. The final rule does include a list of waste characteristics and a list of waste components which must be included in any studies to determine which characteristics and components are significant to containment of waste. These lists have been derived from past performance assessments, which indicated that the parameters in question were critical to containment of waste. Given this, EPA believes it is reasonable to require that the characteristics be studied to determine if they are still considered important to containment. The Agency believes this approach is not overly prescriptive.

16. It would be desirable to initiate a more aggressive program to prepare, characterize, and certify transuranic waste containers for disposal at WIPP, but this idea, would be difficult to

be accepted by management without some assurance that WIPP will open in FY '98 as planned. (IV-D-111)

Response to Comment 6.F.16:

The purpose of waste characterization criteria is to ensure that all characteristics that are significant to containment of waste are considered, and that DOE confirm that no waste is emplaced in the system that falls outside the component limits under which compliance was demonstrated (assuming compliance was demonstrated). The EPA's regulatory role at the WIPP is not to ensure its operation by an given date, but rather to issue these compliance criteria and then certify whether or not the WIPP complies with the disposal standards. A reasonable expectation of compliance cannot be demonstrated if waste characterization is inadequate, especially since predicted releases in performance assessments depend heavily on the characteristics of waste. The requirements of the final rule provide an incentive for DOE to aggresively pursue and accomplish rigorous waste characterization, since information resulting from waste characterization efforts must be included in any compliance application.

Issue G: Worst case analysis may not be appropriate since it is difficult to know what the worst case is, given the complexity of the system. Instead, EPA should call for a range and distribution of sensitive parameters. (NMAG-G)

Response Issue 6.G:

The final rule requires that DOE establish limits (either upper or lower limits, as appropriate) on all waste components determined to be significant to containment of waste. The DOE must then demonstrate that, for the total inventory of waste proposed for disposal in the disposal system, WIPP complies with the containment, individual, and ground-water requirements for the upper or lower limits for each waste component, and for the plausible combination of upper and lower limits that would result in the greatest estimated releases. Combinations of upper and lower limits are not required to be considered if it can be shown that a given combination is not plausible due to the nature of waste proposed for emplacement at the WIPP; any such exclusions must be documented and justified in compliance applications. The EPA believes this approach is reasonable because, once a waste "envelope" is established, it is possible that all the waste emplaced in the WIPP could meet the limits for each component. This analysis is not considered a "worst case" because the waste envelope establishes acceptance criteria which are real, rather than hypothetical, limits. In addition, although compliance must meet the worst plausible combination of established limits on waste components, other aspects of the performance assessment are still allowed to operated probabilistically, and are not held constant in "worst case" scenarios.

Issue H: EPA is exceeding its authority. The proposed rule sets a new standard for waste characterization.

1. The proposed rule sets a standard, and not a criterion to an existing standard. (IV-D-40)

2. If EPA deems that study on waste characterization is necessary to comply with 40 CFR part 191 then such a requirement should be contained in that regulation. (WEC-D)

3. 40 CFR part 191 does not mention waste characterization, so Part 194 should not. (C-28)

4. Confirmation of the absence of waste characteristics is outside the scope of Subparts B and C and should not be included with this regulation. (SNL-C)

5. EPA should examine the extent to which the proposed regulations require a substantial increase in waste characterization from 40 CFR part 191. (C-13, C-15)

Response to Issue 6.H:

A specific waste characterization requirement is not in 40 CFR part 191. However, in order to demonstrate compliance with the Containment requirements of 40 CFR part 191, it is essential to evaluate how actual waste characteristics will impact the containment of radionuclides for the long-term performance of the repository. In addition, the WIPP LWA established certain limits on waste which may be emplaced in the WIPP, and waste characterization activities must be undertaken to demonstrate that waste emplace in the WIPP conforms to these limits.

The intent of the disposal regulations is that the implementing agency provide a reasonable expectation of meeting the containment requirements of Part 191. All processes which may affect the containment requirements need to be considered. In the case of the WIPP, certain waste/disposal system interactions between the diverse types of waste materials in TRU waste and the conditions associated with bedded salt need to be considered in order to assess whether the containment requirements of 40 CFR part 191 can be met. It is therefore necessary for EPA to require waste characterization to the extent needed to identify waste characteristics significantly influencing the containment of waste and to require that these characteristics be quantified and controlled in the overall inventory.

Issue I: EPA should impose a liquids prohibition on waste to be disposed of in the WIPP. Of course, the ability to seek a waiver should also be incorporated into this prohibition. Waivers could be performance based. (IV-D-11)

Response to Issue 6.I:

Current transportation regulations, with which DOE must comply in order to transport waste to the WIPP, impose a restriction on free liquids in the waste. The disposal regulations of 40 CFR part 191 impose no explicit liquids restrictions for geologic disposal, but include containment requirements. In the final compliance criteria, EPA is requiring DOE to assess the impact of all waste components, and explicitly water and other liquids in the waste, on the disposal system performance, and to limit all significant waste components to values for which compliance with the containment requirements can be assured. 40 CFR Part 268, enforced separately from the compliance criteria, imposes additional requirements connected

with obtaining a "No Migration Variance" which require an assessment of hazardous substances, including hazardous liquids. The EPA will evaluate DOE's assessments for radioactive wastes in this area upon receipt of its certification application for the WIPP. It is unknown at this time whether these assessments will result in more stringent performance-based limits on free liquids in waste than those currently required for transport, but if this is the case, then DOE must adhere to them.

Issue J: The waste characterization study should contain criteria and be submitted to EPA before the compliance application is allowed to be submitted.

1. Any study of waste characteristics should be submitted at least one year prior to application submission. (SRIC-C, SRIC-G)

2. The rule should contain specific characterization requirement that you find necessary to support the performance assessment. The rule should require that existing waste be characterized before the application is submitted. (NMAG-A)

3. The question of waste characterization is so complex that it is suggested that the Agency require the study to be completed one year before the compliance certification application is submitted. (NMAG-D)

4. DOE should complete its study of waste characterization needs before the compliance criteria are made final, and the Agency should use the study to draft characterization requirements. Existing waste should be characterized before the application is submitted. (NMAG-B)

Response to Issue 6.J:

Neither the WIPP LWA nor the disposal regulations being implemented call for EPA to require DOE to complete an analysis of waste characterization before EPA may finalize compliance criteria, or to characterize existing waste before a compliance application is submitted. Rather, the waste characterization requirements are derived from the overall containment, ground-water protection and dose-limiting requirements of 40 CFR part 191. The EPA believes that waste characterization is a critical component of any compliance application, and has developed criteria to ensure that extensive and dependable waste characterization is conducted in preparing a compliance application. As part of the final rule, DOE is required to characterize all existing waste and all to-be-generated waste and to document this characterization as part of the compliance application. The final rule also provides for verification of these properties through a system of controls to ensure that waste is emplaced in the disposal system only if it will not cause the established limits on waste components (pursuant to §194.24(c) of the final rule) to be violated. The EPA believes this is a reasonable approach, that waste characterization form the basis of the compliance application. The DOE is bound to adhere to the limits established, which form the basis upon which compliance is demonstrated, if indeed compliance is demonstrated. Any significant departure from the limits which form the basis of certification, if granted, would require

modification of the certification. The DOE must verify that the limits established in the compliance application are met by any waste emplaced in the disposal system; because much of the waste is still to-be-generated, the characterization assumptions must be specifically confirmed. The EPA also has authority to inspect any waste characterization activities to confirm that conditions or activities described in compliance applications remain valid.

The EPA is requiring the Department to set total inventory (including all present and future waste) limits on each waste component identified as significant to containment of waste in the disposal system, to demonstrate compliance with the disposal regulations for this inventory, and to demonstrate the existence of a system of controls to confirm that no limit is exceeded in actual disposal operations, subject to inspection. This places an upper bound on the many sources of uncertainty which the comment has touched upon, rather than bounding only part of it.

The EPA's approach in §194.24 is to require that the Department take the essential steps to meet all waste characterization requirements and controls necessary to assure that compliance with the disposal regulations is demonstrated. The assumed properties of the waste used in the compliance demonstration must be confirmed through quantification. The EPA will determine during its review of the certification application whether the assessment, limitation and plans for confirmatory quantification of significant waste components are adequate. In addition, EPA will verify the adequacy of application materials, and the plans and performance of waste characterization activities through inspections and audits.

With regard to requiring that existing waste be characterized before the application is submitted, EPA believes that considerable delay and expense might be incurred with little gain by this requirement. Since the majority of waste has not yet been generated, such a requirement would do little to reduce the overall uncertainty in the inventory used to demonstrate compliance. However, this uncertainty is addressed through EPA's requirement that DOE confirm waste components before waste is emplaced. Moreover, requiring characterization before the application submission does not assure that characterization is adequate. The EPA believes it is more appropriate to evaluate waste characterization information (and any uncertainty regarding characterization) within the context of the overall compliance determination. By evaluating the overall approach to identification, limitation and confirmation of waste components which are important to meeting the containment, individual and ground-water protection requirements of 40 CFR part 191, EPA can be assured that the waste characterization approach is adequate. For these reasons EPA has chosen not to require that existing waste be characterized before the application, but instead chooses to require that a comprehensive waste characterization approach be submitted as part of compliance applications.

Issue K: The utility of process knowledge must be clearly stated.

1. EPA should place equal weight on "process knowledge." (IV-D-11)

2. Process knowledge is so rife with guesswork, assumptions, and relies so heavily on unreliable documentation that it should be disallowed as a characterization procedure. (CARD-B)

3. DOE must be required to discuss clearly and precisely the uncertainties associated with process knowledge in each case where it is used. (SGNM-C, A-35)

Response to Issue 6.K:

One comment states that EPA should give greater importance to the use of process knowledge for characterization of waste, and several other comments state that process knowledge is inherently unreliable and should not be allowed to be used. In the interest of reducing cost and radiation worker exposure, EPA is willing to consider the use of process knowledge, but is requiring DOE in the final rule to provide information which confirms that the use of process knowledge conforms to the quality assurance requirements described under §194.22. The EPA is currently observing DOE's initiative to develop guidance for all of the waste generator sites on the use of and substantiation of process knowledge, and will be observing DOE activities aimed at verifying the documentation and other substantiation in the near future. By familiarizing itself with the kinds of process knowledge to be used and the reliability of such knowledge, EPA can share current concerns and be in a position at the time of the application to evaluate whether DOE's use of process knowledge is substantiated sufficiently for its intended purpose in the demonstration of compliance.

Issue L: More attention should be given to occupational exposure related to waste characterization.

1. The tradeoff between accurate waste characterization and occupational exposure should be explicitly recognized and ALARA specifically referenced. (DOE-D, A-45)

2. Visual examination of the waste entails great occupational risk and prohibitive cost. (SNL-C)

3. It should be recognized that the handling of radioactive wastes for the purposes of waste characterization will subject people to doses of ionizing radiation. Such waste handling activities constitute a hazard. This hazard must be evaluated in light of the information gained in determining compliance with 40 CFR part 191. (IV-D-40)

4. For purposes of personnel safety, EPA should accept process knowledge and non-invasive evaluations as waste characterization methods in lieu of physical sampling and analysis. (IV-D-111)

Response to Issue 6.L:

The EPA too is concerned about limiting worker radiation exposures. However, the transuranic waste currently stored at DOE facilities is highly heterogeneous and is known to

contain a wide variety of materials, chemicals, etc. which have potential to influence the containment of radionuclides in the disposal system. Based upon DOE documentation to date, it is not clear whether all waste characteristics and components which are significant to total disposal system performance have been identified, or that adequate consideration has been given in decisions to disregard other characteristics or components deemed less important. For this reason, EPA has required that DOE substantiate the identification of those characteristics and components which are significant (sometimes called sensitive parameters in the language of performance assessment), and that such an assessment provide substantiation for any decisions not to consider any waste characteristic. Further, EPA is requiring that all significant waste components be limited and quantified before disposal to confirm that no limits are exceeded.

The EPA believes that such an approach balances flexibility with prescription to assure that waste characterization is rigorous and reliable for those waste parameters important to containment of waste in the disposal system. The Agency shares the concern for occupational exposure to the workers who are involved in characterizing the waste, but believes it is also inappropriate to jeopardize future generations from potential releases to the accessible environment because this generation failed to study and characterize the waste that could significantly impact the total performance of the repository. The EPA's requirements were formulated to require DOE to identify and control, by measurements or other means of quantification (such as use of process knowledge), those waste characteristics which are significant to the containment of radionuclides in the disposal system, as identified by study. Flexibility has been afforded DOE to scope and provide the necessary information through study and documentation (process knowledge, for example), provided that the results are acceptably rigorous. The results of an analysis of waste characteristics and components will be used to establish criteria for waste acceptance, based on which characteristics and components of waste are expected to significantly influence containment of waste in the disposal system.

As to the ALARA principle, DOE is responsible for implementing radiation protection measures with its work force, and is explicitly obligated through its Orders to address ALARA; this is not an EPA regulatory function. The EPA has tried to afford sufficient flexibility to DOE to carry on an effective ALARA program for its workers while also addressing the important issue of protection of the public and the environment through demonstration of compliance with EPA disposal regulations.

Issue M: EPA should issue guidance on four alternatives to the use of visual examination: 1) non-destructive assay methods, 2) process knowledge, 3) statistical analyses, and 4) acceptable error bands or uncertainty ranges. (SNL-C)

Response to Issue 6.M:

At this juncture, EPA is not requiring the use of any specific characterization method and hence does not intend to issue guidance on specific characterization methodologies. The EPA is willing to consider the application of a variety of waste characterization methodologies, and

is expecting DOE to demonstrate that any such methodology is capable of producing data which are adequately qualified to support their intended purpose (i.e., confirmation that waste characteristics or components used in the performance assessment or otherwise deemed significant do not exceed limiting values used to demonstrate compliance). Section 194.24 has been clarified in the final rule to require that DOE submit information with its application to confirm that the use of process knowledge and waste characterization measurements conforms with the quality assurance requirements of §194.22. In addition, paragraph 194.22(d) has been added to the final rule requiring DOE to provide information which demonstrates how all data (including waste characterization data) are qualified for their intended use.

Section 7: FUTURE STATE ASSUMPTIONS: SECTION 194.25

Issue A: There is difficulty in predicting climatic conditions.

1. There is concern as to whether or not future hydrological factors have been sufficiently considered. If the climate does warm, then the salt structures may destabilize. (C-25, A-55, IV-D-73)

2. If reliable models of climate change cannot be created, the WIPP should not be opened. (IV-D-91)

3. The issue of climate change is crucial since it is wetter than anticipated. (S-12)

4. There is no adequate means for predicting the performance of WIPP under climatic conditions of increasing moisture. (CARD-B)

5. The effects of climate change must be fully considered. (NMAG-D, SRIC-G)

Response to Issue 7.A:

The application for certification of compliance will have to show that climate change has been adequately considered. There is evidence to indicate that past climate in the vicinity of the WIPP has been both wetter and drier than the present climate. Using the past as a guide we can assume that the climate at WIPP will have future periods that are wetter and drier than they are today. From paleontological information it is possible to make reasonable estimates of the magnitude of climate change, even if the timing of the climate change events are not precise. The main effect of climate change is precipitation and the subsequent recharge to aquifers in the vicinity of the disposal system. The potential effects of more or less recharge, such as increased hydraulic heads in the aquifers and possible dissolutioning, can and must be modeled. The final rule (at §194.25) requires DOE to consider the effects of potential future climatic conditions on the disposal system, and to document, to the extent practicable, the effects of potential changes to future climate cycles of increased precipitation as compared to present conditions.

Issue B: EPA should limit consideration of climatic effects to those that may directly affect disposal system performance (i.e., ground water recharge). (DOE-D, SNL-C)

Response to Issue 7.B:

The EPA does not expect the Department to analyze effects of climatic conditions or events that are not relevant to repository performance; performance assessments do not need to consider natural processes and events that do not affect the disposal system during the regulatory time frame (see §194.32(a)). However, the final rule does not explicitly limit the climatic conditions which must be considered for the WIPP. The final rule does specifically require that DOE document the effects of potential changes to future climate cycles of

increased precipitation as compared to present conditions. Recharge to aquifers in the vicinity of the WIPP is a potential effect of increased precipitation, but is not the only effect that should be analyzed. Other potential effects could include dissolution, or deterioration of shaft seals. The final rule does not limit consideration of climatic changes to aquifer recharge, or to direct effects on the disposal system. If natural processes such as climatic change are not included in performance assessments, DOE must document why such a process, event, or sequence was not included, pursuant to paragraph §194.32(e)(3) of the final rule. The EPA would expect such documentation to include a technical rationale describing why the process is not expected to affect the disposal system during the regulatory time frame.

Issue C: More investigation is needed into the karst formations at WIPP.

1. A large karst formation is moving toward WIPP and would likely intrude the WIPP site. The possibility needs to be analyzed. (S-17, S-23)

2. The karst formation results in irregular water flows and thus it is difficult to measure how quickly the water in the aquifer under the WIPP site flows into the Pecos River. (S-30)

3. The brine and karst features throughout the site are inappropriate. (C-03)

4. We do not understand why EPA and DOE are not more concerned about the very real dangers that the karst represents. (CARD-A, A-60, S-40)

Response to Issue 7.C:

An analysis by EPA's Office of Solid Waste in 1990 indicated that in an undisturbed scenario, brine pools would not be problematic to the performance of the WIPP [55 FR 47714]. In addition, EPA examined karst formations at the site in response to a commenter who invited EPA to the site to discuss this issue. Upon investigating the WIPP site, EPA found no evidence of active karst features in the WIPP Land Withdrawal Area. On the basis of this investigation and further discussion, EPA concluded that karst is not now an issue at the WIPP, and is unlikely to become one for many thousands of years, if ever [55 FR 47714].

Nevertheless, DOE must consider geologic features such as karst formations, when conducting performance assessment. As geologic features exempted from the general future states requirements (see §194.25(a)), the effects of brine pockets and karst formations may be included in performance and compliance assessments if they are found to affect the disposal system during the regulatory time frame. The disposal regulations at 40 CFR Part 191 require that a performance assessment be used in determining if a facility meets the containment requirements (i.e., evaluation of the disturbed performance of the repository). The development of a performance assessment for a facility requires an analysis of the following three elements: 1.) identification of processes and events that might affect the disposal system; 2.) examination of the effects of these processes and events; and 3.) estimation of the cumulative releases of radionuclides, considering the associated uncertainties, caused by all significant processes and events. Similarly, the analysis required for the compliance

assessment also considers potential processes, events or sequences that may occur over the regulatory time frame for the undisturbed performance of the repository. The final rule specifies that compliance applications must consider, to the extent practicable, the effects of potential changes to geologic conditions, including dissolution, near surface geomorphic features and processes, and related subsidence in the geologic units of the disposal system (§194.25(b)(2)). Additionally, compliance applications must consider natural processes that may affect the disposal system during the regulatory time frame, and must document why any such processes are excluded from performance assessments (§194.32). The Agency believes that performance and compliance assessments are the vehicles to be used when considering the types of site specific concerns articulated in comments, and believes that the requirements of the final rule regarding scope of performance assessments and future state assumptions ensure that the effects of geologic features such as karst will be adequately considered.

Issue D: The use of present conditions for future state assumptions needs to be re-evaluated.

1. To reduce uncertainty in compliance assessment, EPA should specify certain "future states" assumptions. DOE cannot assume any "future states" that would result in less protection of human health and the environment than "current states." (SRIC-F)

Response to Comment 7.D.1:

The EPA agrees with the commenter's goal of reducing the uncertainty in modeling, and to that end, EPA proposed to specify certain assumptions about the future to be used in long-term modeling. For example, the final rule states that compliance assessment analyses should assume that characteristics of the future remain the same as today (unless otherwise specified); consideration of climate changes must include the effects of increased precipitation; and with respect to human technology and behavior, present conditions should be used as default values. As discussed in the preamble to the final rule, EPA has found no acceptable methodology to predict the future state of society, science, languages or other characteristics of future mankind. Therefore, to limit speculation and further uncertainty, the Agency has retained the proposed approach towards future states. Present conditions at least have the advantage of providing ascertainable and verifiable values. The EPA believes that this approach will minimize the possibility of developing assumptions about the future that result in less protection to human health and the environment than the current states will allow.

2. The assumption that future characteristics of the future remain what they are today is more appropriately included in 40 CFR part 191. (WEC-D)

3. EPA should not specify future states assumptions to the modeler (DOE). (IV-D-06)

Response to Comments 7.D.2 and 7.D.3:

The EPA believes that including the criteria for future states assumptions is completely within the Agency's authority to implement 40 CFR part 194, subparts B and C, for the WIPP. The general requirements of the compliance criteria, including those for future states assumptions, support a reasonable expectation of compliance because they ensure that any compliance application is based on dependable and verifiable information. Demonstrating compliance with the disposal regulations involves the use of computer models, based on conceptual models, which project, over an extended period of time, the transport of radionuclides from the disposal system to the accessible environment, and resultant radiation doses to individuals and radionuclide concentrations in ground water. Because of the long-term nature of these evaluations, uncertainty of values may be very large for many parameters important to the analysis. The Agency believes that the future states assumptions approach in the final rule will enable compliance assessment to focus on more predictable and more significant features of disposal system performance.

4. EPA should re-evaluate its proposal to employ present conditions as default values for future states. (A-41)

5. EPA's deduction that it has no better approach on future state assumptions is troubling. (A-41)

6. It is arbitrary and nonconservative to assume that the future will resemble the present for 10,000 years. (NMAG-G, A-44)

7. The approach taken in dealing with Future States is balanced and appropriate and is the only way this difficult issue can be addressed. (EEG-A, EEG-B, SNL-A, IV-D-76, IV-D-100)

8. Characteristics of the future should be assumed to remain what they are today, except those related to geologic, hydrologic, or climatic conditions. This criterion should require that the positive and negative aspects of the constant future state be assumed rigorously in the performance assessment calculations. (EEG-C)

Response to Comments 7.D.4 through 7.D.8:

The Agency solicited comments specifically on its approach to future states assumptions with the hope to gather ideas on this subject. After careful evaluation of comments received, the Agency found that commenters did not provide any technically defensible or methodical new approaches for the Agency's consideration. Given the state-of-the-art on this subject, the Agency believes that it is reasonable to retain the proposed approach. The Agency continues to believe that there is no reasonable way to predict what changes will take place in the future of mankind over the 10,000-year regulatory time frame. The use of present conditions at least has the advantage of providing ascertainable and verifiable values. Any predictions of future conditions of mankind and society would be speculative, and fixing such values for the purpose of performance assessments would be arbitrary. The EPA does not believe that the

future state assumptions in the final rule are necessarily non-conservative; DOE must fix all relevant values and rigorously consider their impact -- both positive and negative -- in performance assessment calculations. Where established scientific methods can make plausible predictions regarding future states (i.e., for geologic, hydrogeologic, and climatic conditions), the final rule requires that DOE analyze the potential evolution of these processes over the 10,000-year regulatory time frame.

9. One of the criteria EPA should use in evaluating WIPP is the amount of future nuclear waste that will need to be disposed of at the WIPP. (IV-D-50)

Response to Comment 7.D.9:

The Agency considers to-be-generated waste that is proposed for disposal in the WIPP at §194.24, Waste characterization. The Agency believes that characteristics of the wastes should be determined, to the extent practicable, based on parameters that are both measurable and verifiable. The amount of waste should be able to be estimated based on sampling and analysis, process knowledge, or a combination; a documented and supportable estimate must be established since the information will be used to determine the release limits under §191.13. Estimates of to-be generated waste will have to be documented in order to be included in the application. See Section 6 of this document for further discussion of waste characterization requirements in the final rule.

10. Existing intrusions must become part of the undisturbed case: their presence must be assumed in all calculations. (NMAG-B)

Response to Comment 7.D.10:

The Agency agrees with the comment. The consideration of undisturbed performance requires an analysis of the predicted behavior of the disposal system, including consideration of the uncertainties in the predictive behavior, if the disposal system is not disrupted by human intrusion or the occurrence of unlikely natural events. Given the current activities in the Delaware Basin, where the WIPP site is located, consideration of the existing intrusions should be considered as part of the undisturbed case, consistent with the inclusion of all other conditions of the site at the time the application is prepared. The EPA considers existing drill holes and other artifacts of past intrusions to be part of the site description (the natural and present state of the site) which underlies analysis of undisturbed scenarios. It is reasonable to assess the undisturbed performance of WIPP to fully consider the realities of the site-specific conditions. Section 194.32, Scope of performance assessments, has been revised in the final rule to explicitly require that DOE document and analyze the effects on the disposal system of existing boreholes and other activities.

11. It is not known at what rate Rustler Creep and the Nash Draw advance towards WIPP; these characteristics must be studied and addressed. (C-03)

Response to Comment 7.D.11:

The Agency agrees with the comment. The movement of those formations towards the WIPP is a natural geologic process that should be considered as part of the analysis of both performance and compliance assessments. Section 194.54, Scope of compliance assessments, requires that potential processes, events or sequences of processes and events that may affect the disposal system during the regulatory time frame should be identified and considered. In a similar fashion, §194.32, Scope of performance assessments, requires that both natural and human-initiated processes and events that may affect the disposal system be considered. In addition, the future state assumptions of the final rule (§194.25) require evaluation of changes in the long-term geologic, hydrologic, or climatic conditions of the system and its vicinity. Therefore, the criteria in 40 CFR part 194 require the evaluation of natural processes that may affect the performance of the disposal system.

12. Significant geologic changes are not likely within the time frame of interest. (IV-D-51)

Response to Comment 7.D.12:

In the proposed rule, the Agency stated that the future state assumption of constant conditions would not apply when dealing with the long-term geologic, hydrologic, or climatologic conditions of the system and its vicinity. Future state assumptions, unless otherwise specified (e.g., deep and shallow drilling in §194.33), apply to parameters or values that may vary or change in significant and unforeseeable ways over the lengthy time frame that will be analyzed for compliance.

Section 194.54, Scope of compliance assessments, requires that potential processes, events or sequences of processes and events that may occur over the regulatory time frame should be identified and considered. In a similar fashion, §194.32, Scope of performance assessments, requires that both natural and human-initiated processes and events that may affect the disposal system over the regulatory time frame be considered. In the course of performing such analysis the Department needs to calculate the probability of the particular event or processes happening during the regulatory time frame. If no significant geologic events would take place during the regulatory time frame, then those processes or events may be excluded from performance assessments; however, compliance applications must document and justify why such processes were not considered in the analysis (i.e., why they were determined not to affect the disposal system over the regulatory time frame).

13. Future states assumptions cannot be applied to institutional controls. (NMAG-D)

Response to Comment 7.D.13:

Future states assumptions do not apply to passive institutional controls. The final rule states that conditions will be assumed to be the same as the present unless otherwise specified in the rule. The final rule also clarifies that such assumptions apply in performance assessments and in compliance assessments; they are not to be applied to assurance requirements. The design

of passive institutional controls, both markers and records, must be designed so that they are as permanent as possible, taking into account, to the extent possible, potential collapses in institutional, societal, or linguistic structures. The final rule requires that DOE document the period of time passive controls are expected to endure and be understood [§194.44]. Compliance with the assurance requirement for passive controls will be evaluated based in part on the depth of the analysis and the scope of potential societal changes which are accounted for in the design of passive controls.

Issue E: The scope of the requirements needs to be clarified.

1. The wording in this section should be amended to state definitively that EPA intends for the DOE to focus attention and resources on investigating the more predictable aspects of the disposal system. (SNL-C)

Response to Comment 7.E.1:

The Agency agrees that spending resources on trying to assess parameters or values that may vary or change in significant and unforeseeable ways over the lengthy regulatory time frame is not an efficient way to allocate scarce resources and will not be of measurable value to the demonstration of compliance. The Agency believes that the future state approach in the final rule has the advantage of providing readily ascertainable and verifiable values. The EPA does not believe it is necessary or appropriate to state in the rule the goal of the assumptions; EPA's expectation for implementation of the future state assumptions is clearly stated.

2. This subsection should clearly state that it will be used as a criterion to evaluate whether a reasonable expectation of compliance with 40 CFR 191.13, 191.15, and 191.24 exists. (SNL-B, SNL-C)

Response to Comment 7.E.2:

The purpose of the future state assumptions is to avoid unverifiable and unbounded speculation about possible future states of society, and to help focus compliance assessments on the more predictable and more significant features of disposal system performance, instead of examining exceedingly speculative developments over the 10,000-year regulatory time frame. Demonstrating compliance with 40 CFR part 191 B and C involves the use of computer models which project, over an extended period of time, the transport of radionuclides from the disposal system to the accessible environment and resulting radiation doses to individual members of the public. Given the long-term nature of these evaluations and the fact that many of the parameters or values may change in significant and unforeseeable ways, the Agency decided to specify certain assumptions about the future for use in long-term modeling. The Agency believes that this approach has the advantage of providing readily ascertainable and verifiable values; and allows the Department to focus its resources for data gathering in a more efficient way. The requirements for future state assumptions establish assumptions to be used in compliance assessments and performance assessments; they are not used to analyze whether a reasonable expectation of compliance has

been achieved in the results. Any compliance application must demonstrate that the requirements of §194.25 must be specifically fulfilled.

3. It is recommended that EPA establish a clear framework for the treatment of indirect anthropogenic effects (related to geologic, hydrologic or climatic conditions) on repository performance. EPA should clearly state that these effects are not to be included in assessing the "undisturbed performance" of the repository. (NRC)

Response to Comment 7.E.3

The EPA does not intend or expect that DOE will consider indirect anthropogenic effects on repository performance, since this would be an exceedingly speculative undertaking. As stated in the preamble to the final rule, the Agency believes that established scientific methods exist for making plausible predictions regarding the future states of geologic, hydrogeologic, and climatic conditions. However, the Agency has not identified an acceptable methodology to make reliable predictions about characteristics of future mankind. The final rule therefore specifies that such characteristics should be assumed to remain as they are today (unless otherwise specified in the rule). Analysis of geologic, hydrogeologic, and climatic conditions should include the evolution of these natural processes over the regulatory time frame. Indirect anthropogenic effects -- for example, effects on living patterns due to increased precipitation -- should not be included in analysis of future states, since such assumptions pertain to the future state of society and mankind.

4. It is unclear how the future state assumptions are to be used for the consideration of protected individual. It is recommended that EPA develop a framework that integrates the treatment of characteristics used in the compliance demonstrations, including those for the development of a reference biosphere and an exposure scenario. This framework would be best developed as a guidance document, which would provide the necessary flexibility to make the compliance criteria implementable. (NRC)

Response to Comment 7.E.4:

The general requirements of the subpart C of the final rule apply both to performance assessments (used to predict releases of radionuclides from the disposal system) and to compliance assessments (used to predict radiation doses to individuals). Thus, compliance assessments should assume (in conformance with §194.25 of the final rule, that the characteristics of the future remain what they are today, provided that such characteristics are not related to hydrogeologic, geologic, or climatic conditions. As stated in the disposal regulation at 40 CFR part 191, compliance assessments need not consider human intrusion or unlikely natural events. The EPA believes that the requirements for future states assumptions in the final rule is appropriately applied to the individual and groundwater requirements of the disposal regulations. Establishment of a reference biosphere or exposure scenario would require unbounded speculation regarding future states of society; as previously discussed, EPA does not believe that such speculation is productive. The final rule clarifies that, for the purposes of calculating radiation doses to individuals, compliance assessments shall assume

that the individual resides at the single geographic point on the surface of the accessible environment where that individual would be expected to receive the highest dose from radionuclide releases from the disposal system (§194.51). For further discussion of future states assumptions, see response to Comment 7.D.4; for further information on the individual and groundwater requirements of the final rule, see Section 19 of this document.

Issue F: The provisions should be changed so that they do not come into conflict with existing regulations and so that their application is made clear. (NMAG-C)

Response to Issue 7.F:

The final rule states that characteristics of the future should be assumed to remain what they are at the time a compliance application is prepared, *except* for geologic, hydrogeologic, and climatic conditions, and *unless* otherwise specified in the compliance criteria or the disposal regulations. The final rule also states that the future state assumptions of §194.25 apply to performance assessments and compliance assessments conducted pursuant to the provisions of this part to demonstrate compliance with §191.13, §191.13, and part 191, subpart C. The Agency believes this clearly establishes how future states assumptions are to be applied and implemented. The EPA is not aware of any other radioactive waste disposal regulations which apply to the WIPP, and with which the final rule might conflict regarding future states assumptions. In addition, EPA notes that the compliance criteria and disposal regulations are apart and separate from RCRA or state regulations. The basis of compliance for these other rules differs significantly from that of the disposal regulations since they apply to operational activities, have different regulatory time frames, or are not based on performance assessments. Therefore, it is reasonable and necessary that different assumptions and approaches be applied for each regulation.

Issue G: To the extent that the characteristics of future drilling, mining, or other land or resource use are governed by regulation and oversight, the Agency cannot assume that such regulation and oversight are effective more than 100 years into the future. (NMAG-C)

Response to Issue 7.G:

The final rule states that characteristics of the future should be assumed to remain what they are at the time a compliance application is prepared, *except* for geologic, hydrogeologic, and climatic conditions, and *unless* otherwise specified in the compliance criteria or the disposal regulations. The final rule clarifies that the future state assumptions of §194.25 apply only to compliance assessments and to performance assessments; they are not applicable to assurance requirements. Moreover, elsewhere in the rule, at §194.41, EPA specifies that performance assessments may not consider any contributions from active institutional controls for more than 100 years after disposal. Such controls would include land access restrictions at the WIPP. In addition, the assumed frequency of drilling activities is established in §194.33, and is independent of any analysis of whether drilling regulations will continue to exist in the future.

Issue H: This text of §195.25(a) should be changed to state, "Unless otherwise specified in this part or in other disposal regulations, certifications or determinations of compliance with the disposal regulations shall assume geologic, hydrologic, and climatic conditions evolve with time, and all other systems remain as they are today." (IV-D-111 [same as IV-D-118])

Response to Issue 7.H:

The final rule requires the same approach at that indicated in the comment. The EPA does not believe that the specific wording suggested will provide clarification or information beyond the language used in the final rule.

Issue I: The following should be added to §194.25, "The Department has the burden of demonstrating the current state as to each point of fact asserted as the basis for a future state assumption." (NMAG-D, SRIC-G)

Response to Issue 7.I:

As noted in §194.11 of the final rule, information provided in support of any compliance application shall be complete and accurate. Thus, assumptions about future states must be supported with appropriate information, and information sources will be referenced.

Section 8: EXPERT JUDGMENT: SECTION 194.26

Issue A: The necessary use of expert judgment is limited.

1. Section 194.26 establishes sufficient process and documentation requirements to be able to evaluate the quality of the process. (SNL-C)

2. This section places unworkable restrictions on the selection of experts. (SNL-C, IV-D-06)

3. The proposed wording in the rule is too narrow in that it inappropriately limits necessary use of judgment when data are not available. (SNL-B, DOE-D)

4. If expert elicitation is used, it should not remain unclear whether the result will be objectionable for bias. (NMAG-D)

5. The final rule should provide for excluding certain persons from expert elicitation on the grounds of presumed bias. (SRIC-G)

Response to Issue 8.A:

The Agency has placed certain requirements on the membership of expert panels to avoid the creation of a panel that has a conflict of interest that might prejudice its judgment on scientific matters related to the WIPP. In the proposed rule, a restriction was included that would require an expert panel to consist at least two-thirds of persons not employed directly by the DOE or its contractors. In the event that this requirement cannot be satisfied due to the unavailability of a sufficient number of non-DOE experts *and* this circumstance can be documented, then only one-half of the expert panel need to be non-DOE or DOE contractor.

The final rule modified the restriction placed on the number of expert panelists who must not be employed directly or indirectly by DOE. The section still requires that two-thirds of the experts be non-DOE or DOE contractor; however, in the event that a sufficient number of such experts cannot be found, then only one-third of the experts must not be employed directly by the DOE or its contractors. Previously, the requirement had stated that at lease *one-half* of the experts must be non-DOE, regardless of availability. The Agency modified this requirement in recognition of the DOE's pervasive work in the field of nuclear waste disposal. The Agency reasoned that it would not be beneficial to reduce the technical qualifications of an expert panel in order that the panel remain totally independent of the Department of Energy.

The restriction on the composition of expert panels applies specifically to those persons who work for DOE, whether directly, by contract (such as the national laboratories) or, indirectly, by research grants. However, those persons who are funded by DOE research grants but who are not conducting a program of research related to WIPP, would not be subject to the exclusions applied to DOE and DOE supported persons. Therefore, when assessing whether

an expert panel's membership is in excess of the requirement that two-thirds not be employed by the DOE, directly or indirectly, such individuals would not be counted.

The selection of the individual participants on the expert panel is also subject to certain restrictions designed to minimize bias. The final rule prohibits the selection of participants who will be requesting or using the elicited results of the expert judgment process. Additionally, the final rule prohibits persons who supervise or are supervised by a member of the expert panel from participating in the process as a panel member. The restrictions that apply to the composition of the entire expert panel also will indirectly minimize the bias of the individual participants, as noted above.

With respect to restricting the use of expert judgment in the place of experimental data, the Department may substitute expert judgment for the gathering of measured data,*provided* that the Department can justify that expert judgment does not substitute for information that could reasonably be obtained through experimental data collection.

Issue B: EPA is appropriately and reasonably requesting the use of expert judgment.

1. The EPA is correct in allowing the use of expert judgment in those cases where it is not possible to generate the necessary information through test or analysis. (IV-D-100)

2. The section on expert panels is interesting and well stated. (S-53)

3. The proposed arrangements for expert judgement are reasonable and adequate. The protection against intimidated input is particularly important. (IV-D-51)

4. DOE should justify any decisions to treat critical variable distributions through expert opinion rather than through experiments or measurement where feasible. (NMAG-E)

Response to Issue 8.B:

The Agency has developed the section of the final rule on expert judgment with the goal of eliminating any bias that might improperly tilt the results of performance assessments, compliance assessments and any other activity conducted as part of the compliance application. Objective means of developing the compliance application are always preferred. However,
the Agency recognizes that, because there is ultimately a limit on DOE's resources, DOE must weigh practical considerations that expert judgment does not substitute for information that could reasonably be obtained through experimental data collection. While the Agency agrees that actual measurements are preferable to the use of expert judgment, DOE may substitute expert judgment for the gathering of measured data *provided* that the Department can justify this on the basis of limitations of time and resources. Nonetheless, all distributions of uncertain variables will be subject to random sampling across the full range of values during the numerical calculations of the performance and compliance assessments, unless an alternate, more conservative method can be justified.

Issue C: Expert judgment is a poor alternative to scientific data. EPA should apply a rigorous standard in determining where DOE use of expert judgment is appropriate and warranted. (SGNM-D, CCNS-B)

Response to Issue 8.C:

The criteria for compliance, 40 CFR part 194 permit the use of expert judgment to produce data as a substitute for laboratory and field measurements. The Agency agrees that actual measurements are preferable to the use of expert judgment, but recognizes that practical considerations must be weighed in assembling the application for certification. Accordingly, the Department may substitute expert judgment for the gathering of measured data,*provided* that the Department can justify this on the basis of limitations of time and resources.

The Agency has required that two-thirds of an expert panel shall consist of non-DOE or non-DOE funded personnel. With this requirement, and the additional restrictions and documentation requirements, the EPA believes that the likelihood of biased input will be greatly lessened.

Issue D: The definition of expert judgment needs to be clarified.

1. There is concern related to the restrictive definition of expert judgment present in the proposed rule. (DOE-A)

2. There is no definition for "expert" or "expert judgment" in the proposed rule. A definition should be added for these two terms. (SNL-C)

3. EPA's statement that expert judgment “be limited to those situations where data is not reasonably attainable (60 FR 5773)” is too narrow and should be expanded. (SNL-C)

4. This [expert judgment] subsection should refer to “formally elicited expert judgment”, rather than “expert judgment.” A formal approach has considerable advantages over an informal approach. (DOE-D, SNL-C)

5. The expert judgment rule cannot be limited to formal elicitation. (NMAG-D)

Response Comments 8.D.1 through 8.D.5:

The Agency has not defined the term “expert judgment” explicitly. One should note, however, that the requirements of this section apply to expert judgment used in cases in which data are not reasonably obtainable through data collection or experimentation. The EPA is also requiring that any compliance certification application clearly identify all instances in which such judgment is used along with the names and professional affiliations of all experts involved. The term “expert judgment,” as referred to in these statements, denotes any instances in which these methods are used to generate data. The requirements in 40 CFR

part 194 would apply to any such case in which the collection of data is foregone in exchange for expert judgment.

The rule applies to expert judgment that is conducted by one individual or a panel of experts. The Agency is requiring that all instances of expert judgment, including all those which substitute for actual field and laboratory measurements, be conducted subject to the restrictions and exclusions specified in 40 CFR part 194.

The Agency recognizes the commenter's concern that informal expert judgment might be used in place of formal elicitation, for example, when determining the probability distributions of uncertain parameters. However, section 34 of the final rule requires that the probability distributions of all parameters be documented and described in the final application. Such documentation and description must be adequate to support the numerical results of the performance assessments and compliance assessments, and will be subject to the Agency's final decision on the issuance of a certification.

6. It should not be assumed that restrictions on expert judgment only apply when estimates are to be made for values which DOE has identified as model parameters. (NMAG-C)

7. The expert judgment provisions should remain which allow such judgments to be used only when information could not be obtained through data collection or experimentation, and which call for a structured process of elicitation. The rule should list which parameters are subject to expert judgment. (NMAG-D)

8. Expert judgement should not be allowed to substitute for information that is reasonable obtainable through data collection or experimentation. (SRIC-G)

Response to Comments 8.D.6 through 8.D.8:

The requirements on expert judgment apply equally to estimates of parameter values as to more subjective judgments such as what might be the effect of passive institutional controls, or to any other question that is the subject of an expert panel’s deliberation. The final rule does place the additional restriction on quantitative expert judgment, beyond those applied to non-quantitative judgment, such that expert judgment may not be used in the place of reasonably obtainable data. Nonetheless, all other requirements would still be in force for non-quantitative expert judgment.

With respect to listing which parameters DOE may derive by expert judgment, the Agency believes that any decision on the specific treatment of parameters might quickly be over-turned by the results of new experiment or studies. Hence, the Agency has declined to provide such an instruction in the final rule. The Agency will look to the results of sensitivity and uncertainty analyses which are included in the compliance application in order to determine the relative importance of the different parameters.

Issue E: Clarification is needed for the definition of expert judgment and professional judgment.

1. There is no distinction between the use of professional judgment and the expert elicitation process. (DOE-D)

2. EPA should distinguish between expert judgement applied to critical performance assessment components and professional judgement applied throughout the scientific investigation. The EPA must also distinguish between expert judgement and peer review. (WEC-D)

3. A distinction must be made between day-to-day use of professional judgment in scientific decisions and a formal expert judgment elicitation process. (SNL-C)

4. It is recommended that EPA clearly and explicitly distinguish between "expert judgment" and the formal process of "expert elicitation." It is also recommended that EPA specify, through regulatory guidance, the types of information that must be acquired through formal expert elicitation and those which may be obtained through less formal mass. (NRC)

Response to Issue 8.E:

The applicability of the section on expert judgment does not extend to an investigator's judgment, unless that investigator's judgment provides a substitute for actual field or laboratory measurements. Expert judgment and peer review are two separate activities, subject to the exclusions and restrictions of different sections of the rule. Peer Review (§194.27) is applied to completed studies and activities as a means of providing validation, while Expert Judgment (§194.26) is conducted when such studies or activities cannot reasonably be performed.

Issue F: References to 40 CFR part 191 warrant clarification.

1. This subsection should be amended to state that authorization for the use of expert judgment in implementing 40 CFR part 191 is granted by Appendix C of 40 CFR part 191. (SNL-C)

2. This subsection should clearly state that it will be used as a criterion to evaluate whether a reasonable expectation of compliance with 40 CFR 191.13, 191.15, and 191.24 exists. (SNL-C)

Response to Issue 8.F:

The Agency has the authority to require a demonstration that the radioactive waste disposal regulations found at 40 CFR part 191, subparts B and C, have been met, in the form of an application for certification. See 106 Stat. 4777, Sec. 8(d). The final rule does allow expert

judgment to be used to support analyses that are conducted to show the disposal system's compliance with these disposal regulations.

The Agency does not believe that any one section of an application for certification should be used as the basis for an assessment of "reasonable expectation." Instead, the entire record placed before EPA will form the basis for this assessment. Any compliance application must comply with the requirements of §194.26 specifically.

Issue G: Guidance is needed for selecting the participants in the expert panels.

1. Specifying the number of experts for an elicitation is not an appropriate part of specifying certification criteria. The requirement that a minimum of five individuals be used should be made more flexible such that no minimum requirement is included. (SNL-B)

2. The restriction on including DOE employees and contractors in an elicitation should be lifted and these individuals should be allowed to serve in an elicitation provided he or she is not employed on any aspect of WIPP and that he/she demonstrates an absence of conflict of interest. (DOE-D, SNL-C)

3. Suggests that 2/3 of experts should be non-DOE. EPA should clarify what relationships are prohibited. (NMAG-G)

4. This subsection inappropriately requires specific panel composition and constraints on membership. (DOE-D)

5. No group or individual should be provided an automatic right of presentation, irrespective of experience and relevance. (C-28)

6. EPA should issue guidance to ensure that all expert panels have a uniform number of members and to ensure that all expert panels be required to estimate probability in a single, consistent and uniform manner. (SGNM-A)

7. The proposed regulation has the effect of eliminating professionals who have the greatest experience in repository work from providing expert judgement. The Agency itself provides independent judgement of the WIPP, and the requirement on expert judgement needs to be eliminated. (IV-D-40)

8. The manner in which the EPA suggests the experts is flawed and should be replaced with a more reasonable basis that relies on the technical qualifications of the expert rather than their employment history. (IV-D-100)

9. It is suggested that the text be either deleted or changed to state, "Any individual employed by the Department or one of the Department's contractors may serve as an expert." Prudent use of experts would help to resolve conflict of interest issues. (IV-D-111)

10. Formal guidelines are needed for the selection of individuals used to render expert judgment. (NMAG-D)

11. Concerning the specific issue of the selection of experts for purposed of expert judgment elicitation, such persons should be required to meet a test of recognition by their peers in the scientific community to demonstrate scientific competence in the field. (NMAG-E)

12. This section should also include a provision for elicitation of State representatives with adequate credentials to expert panels. (SGNM-D)

Response to Issue 8.G:

The Agency has required that a minimum of five persons form an expert panel so that the elicited results are representative of diverse viewpoint. The Agency believes that this will result in a more informed and objective process. However, an expert elicitation that is subject to this section could be conducted with fewer than five individuals in the event that there is a lack or unavailability of potential experts, provided that a rationale is stated. Section 194.26 of the final rule states this restriction:

> At least five individuals shall be used in any expert elicitation process: Unless there is a lack or unavailability of experts and a documented rational is provided that explains why fewer than five individuals were selected.

The Agency agrees that any expert panel member should be free from conflict of interest. Accordingly, the Agency has promulgated the requirement that two-thirds not be employed by the DOE, directly or indirectly. The rule does not extend this restriction to those persons who receive funding from the Department in those instances in which such funding is for activities not related to the WIPP. Provided that the two-thirds requirement is met, expert panels may include persons employed by the State of New Mexico or any other organization, provided that their expertise can be demonstrated to be adequate for the elicitation that is to be conducted. The final rule requires that compliance applications demonstrate this expertise, and the Agency's judgment on the adequacy of this demonstration will be used in making the decision on the issuance of a certification.

The Agency does not intend to sacrifice technical qualification for the sake of an expert panel's independence from the DOE. The Agency recognizes the pervasiveness of the DOE's work in the field of nuclear waste disposal. The final rule, 40 CFR part 194, requires that two-thirds of the experts be non-DOE or DOE contractor; however, in the event that a sufficient number of such experts cannot be found, then at least one-third of the experts must not be employed directly by the DOE or its contractors. The Agency believes that this latter requirement does allow for the prudent selection of experts while providing a sufficient level of assurance that the outcome of the elicitation will not be biased.

Issue H: Guidance is needed for the analysis of elicited values.

1. The supplementary information contains a misapprehension about expert judgment: information elicited from experts cannot be "meaningfully averaged" without knowledgeable weighting unless the elicited values are very close together. Portions of the supplementary section that refer to this concept should be deleted. (SNL-C)

2. Elicitations from experts cannot be melded unless they are essentially in agreement to begin with. In the event of divergent views, all must be reported and taken into consideration. (A-45)

3. The section does not define the processes to be used in eliciting expert judgements and specifically overlooks the issue of combining judgments of multiple experts. (NMAG-B)

4. When DOE seeks expert opinion using incomplete data, arbitrary limits are set of particular factors and inaccurate estimates to come up with information are used which may be of critical importance in determining whether WIPP will be safe. (S-11)

5. Supplemental Information is incorrect in discussion of “averaging” of elicited values. (DOE-D)

6. Judgment should not be elicited collectively by panels; instead, individuals should be required to independently express their views based on their expertise. The opinions should explain all the decisions that lead up to them (by use of decision tree). (NMAG-G)

7. Panelists should be required to assign fractile probabilities values to high, low, and intermediate levels of the variable in question; in other words, the exercise should focus on the creation of a probability distribution function which may be incorporated into a PA. (NMAG-G)

8. It is imperative that all expert groups conform to identical restrictions in membership number and utilize a single methodology for deriving quality probabilities. (SGNM-A)

9. The rule must be revised to specify methods to resolve differences among members of the expert panel. (NMAG-D)

10. Concerning the aggregation of expert opinions of multiple experts, the process must include methods to reduce the range of disagreement. To aggregate different opinions, it is preferable to employ an interactive process. (NMAG-E)

11. It is important that there is currently no standard procedure for the aggregation of expert opinions, and that this exercise will remain subjective in nature. The key to success is to focus on the probabilities of the models and assumptions as opposed to weighting the experts. (NMAG-E)

12. There should be an interactive process wherein the experts discuss the data, explain their models, discuss the probability of each of the models, assess such probabilities, and generate

a composite distribution. Criteria are needed to establish formal elicitation of expert judgment. (NMAG-D)

13. Concerning elicitation of expert opinion on parameter values, the process must include the elements of (a) clarity of question, (b) identification of desired central value-probably the mean- and (c) the description of the thought process leading to the estimate. (NMAG-E)

14. Concerning elicitation of expert opinions as to distributions of variable parameters, the process must include (a) construction of a probability distribution for a set of possible hypotheses, (b) identification of the appropriate distribution model for an identified model variable, and (c) given such model, identification of the distribution for the value of the variable. (NMAG-E)

15. It is recommended that Sandia identify variables whose distributions are critical for the results, to justify their decision to treat them through expert opinions, to better justify their findings by describing exactly how they have encoded and aggregated expert opinions, or to redo the encoding and aggregation of these judgments if it concluded that some of the variables have not been properly treated. (NMAG-E)

Response to Issue 8.H:

The Agency has not required that any one specific process of expert judgment be used. The Agency believes that a more productive application of expert judgment will take place if the process of elicitation matches the needs of each individual instance. The method of combining the elicited judgments of the individual experts is also initially left to the Department. Documentation and a justification for the method employed must be included in the application for certification and will be evaluated by the Agency when the final decision on whether to issue a certification is made. Other requirements of the final rule might also apply to these results once they have been incorporated into other parts of the compliance application, for example the performance assessment.

Issue I: The following should be added to §194.26, "The results of any expert judgment processes shall be peer-reviewed according to §194.27 of this part. The report of the proceedings and findings of peer review processes shall be filed with the application. (NMAG-D)

Response to Issue 8.I:

To the extent that peer review is the professional judgment of a group of individuals, peer review is in fact similar to an expert judgment. Typically, the knowledge gained from a peer review derives its legitimacy from the familiarity that peer reviewers already have from performing similar studies, analyses or experiments. Peer reviewers can then evaluate the adequacy of a study or activity by comparison to these established norms or more generally, to scientific principles. Expert judgment is not the equivalent of a laboratory experiment or study; it does not objectively derive factual results by using conventional practices.

Submitting the inherently judgmental results of an expert elicitation to another group of experts, such as a peer review group, would, effectively, be to repeat the elicitation. It is the Agency's view that this would not add significant value to the results of the initial expert elicitation.

Issue J: Third parties must have an opportunity to present their views to expert panels.

1. The rule should require that groups and individuals with relevant expertise be afforded an opportunity to present scientific and technical reviews to an expert elicitation panel. (IV-D-111)

2. DOE should not restrict third parties to present information to the expert panel. (NMAG-D)

3. Third parties should be allowed to provide information to any expert panel. (SRIC-G)

Response to Issue 8.J:

The final rule requires that DOE must solicit the views of the public, to be presented to the expert panel members, and requires that DOE provide documentation which demonstrates that this has occurred in the compliance application. The Agency believes that this requirement will insure that the experts receive a broader spectrum of background information when such information is presented to them at the start of the elicitation process.

Section 9: PEER REVIEW: SECTION 194.27

Issue A: Compliance criteria must more clearly require independent peer review of all documentation. (CCNS-B)

1. Peer review should be required for any part of the compliance demonstration that is not subject to checking by a technical review. This may include experimental design, data collection methodology, technical studies, scientific basis for scenario selection and construction, scientific basis for conceptual models, use of experimental data in constructing conceptual models, and conservatism of assumptions. (NMAG-D)

Response to Issue 9.A:

The Agency sought the advice of the WIPP Review Committee of the National Advisory Council for Environmental Policy and Technology (NACEPT) in September, 1995 regarding which activities should be required to be peer reviewed. During this meeting, members of the public provided formal presentations and oral comments to the committee. See 60 Fed. Reg. 43470-43471 (Aug. 21, 1995). The Committee suggested that peer review of quality assurance programs would be unnecessary, since, by requiring DOE to adhere to a program that meets the requirements of three sets of ASME's standards, today's action would already be sufficient to control the quality assurance process. The Agency agrees with both the Committee and with similar public comment and has eliminated the requirement for peer review of quality assurance programs and plans. The Committee also suggested that conceptual models should be peer reviewed to help ensure that such models represent the physical reality of the disposal system's long-term performance. The Agency agrees with this advice and therefore retains the proposed rule's requirement that peer review be performed of conceptual models.

In the final rule, the Agency also requires peer review of conceptual models and of the engineered barrier study and waste characterization analyses, the latter of which would include studies by DOE of waste components and waste characteristics. Peer review of these two activities is necessitated because of their central importance to the performance of the disposal system. The Agency recognizes that peer review of all activities related to the WIPP is neither practical nor sufficiently beneficial. In many instances, particularly with respect to data, the Agency believes that formal peer review would be redundant with quality assurance programs and has therefore deleted the proposed rule's requirement that data used to support models and computer codes be peer reviewed.

In areas and activities for which peer review is not required, formal peer review can be partially supplanted by the results of other reviews which are currently ongoing. In some cases, the Agency does not believe that formal peer review could add significant value to those activities which are already subject to the periodic reviews of such informal peer review groups as the NAS WIPP Panel and the New Mexico Environmental Evaluation Group, for example. The comments received from these reviews facilitate understanding the strengths and limitations of the activities and analyses related to the WIPP. These groups routinely

provide comments on, for example, models, experimental programs and scenarios. For these reasons, any compliance application must include records of such informal peer reviews.

Issue B: It is DOE's responsibility to judge when peer review is required, and what should be subject to review. (DOE-D, WEC-D)

1. It is not appropriate to assign responsibility to DOE to do peer review because critics of the WIPP will view peer reviews conducted by DOE as biased. The EPA itself should conduct peer review for the WIPP, similar to reviews conducted for other programs such as RCRA. (IV-G-3)

2. There are public perception problems associated with assigning DOE the responsibility for the performance of peer reviews. (IV-G-3)

Response to Issue 9.B:

Although the responsibility for conducting peer review is DOE's, the selection of the experts must follow the guidelines of NUREG-1297 with respect to the membership of the peer review group. NUREG 1297 states that participants in a peer review group should have sufficient freedom from funding considerations to ensure that the work is impartially reviewed, in addition to having been uninvolved in the original work to be reviewed. Documentation of peer review activities as required under section 194.27 must be part of the compliance applications.

Regardless of the recommendations or judgments made by the peer review groups, all decisions on the adequacy of the compliance application will be EPA's and EPA's alone. In fact, by law, it is EPA and EPA alone that conducts the rulemaking on certification. See 106 Stat. 4777, section 8(d) (Pub. L. 102-579). However, the Agency does intend to use review procedures internal to the Agency, at its discretion, during the rulemaking on certification under section 8(d) and during the periodic re-certification under section 8(f) of the WIPP Land Withdrawal Act.

Issue C: If this subsection is not deleted, then this subsection should clearly state that it will be used as a criterion to evaluate whether a reasonable expectation of compliance with 40 CFR 191.13, 191.15, and 191.24 exists. (SNL-A, SNL-C)

Response to Issue 9.C:

Several commenters have requested clarification on the relationship between compliance with 40 CFR Part 191 and the term "reasonable expectation." The term "reasonable expectation" is used to express that absolute proof of compliance is not required since absolute proof of compliance cannot be achieved for such long-term predictions. This term appears in the containment requirements -- section 13 of 40 CFR Part 191 -- in which the Agency states that a reasonable expectation of compliance is required to be considered by the Agency "on the

basis of the record before the implementing agency [EPA for the WIPP]." See 40 CFR 191.13.

Issue D: This is the creation of a standard and not a criterion. (C-28)

Response to Issue 9.D:

The final rule does not contain additional standards for the protection of human health and the environment. Rather, the final rule provides criteria for implementing 40 CFR Part 191 at the WIPP facility. It is 40 CFR Part 191 that sets the quantitative and qualitative standards for protection of public health and the environment that must be met by the WIPP. With respect to the specific implementation of these standards in 40 CFR Part 194, Subparts A and B establish the procedural requirements necessary to execute the Agency's activities mandated by sections 8(d) and 8(f) of the WIPP Land Withdrawal Act. Subpart D provides for the public's participation in those activities. Subpart C established the criteria which apply to the performance assessments and compliance assessments used to demonstrate compliance with the numerical requirements and also to the assurance requirements of the disposal regulations. This section also contains seven general requirements which apply to all aspects of the compliance application and to some of the activities conducted during its preparation. The section on peer review in 40 CFR Part 194 is one of seven general requirements which apply to all portions of the compliance application. Collectively, these seven general requirements establish the adequacy of the calculations, studies, plans and analyses that support the compliance assessments (required by 191.15 and subpart C) and performance assessments (required by 191.13) and to the assurance requirements (191.14).

Issue E: The peer review process is inconsistent with NUREGs.

1. Some of the NUREGs contain secondary references--are they incorporated in the criteria also? Perhaps EPA would be better off just incorporating the specific provisions it deemed necessary. (NMAG-G)

2. The peer review process is inconsistent with NUREG-1297, which has its own scope. (NMAG-B, NMAG-G)

3. The EPA should adopt the approach used by the U.S. Nuclear Regulatory Commission for high-level nuclear waste repositories by providing guidance rather than requirements on peer reviews, as the NRC has done in NUREG-1297. Peer reviews are not intended for routine reviews of well established scientific and technical work. (IV-D-116)

4. Peer review is likely to be much-used, and the rule must call for true independence and adherence to NUREG-1297, Peer Review for High-Level Waste Repositories. It will be important for the peer reviewers to have a clear statement of the precise question to which they are expected to address their judgment and to articulate their conclusion. (NMAG-D)

5. Any peer review documentation should follow the provisions of NUREG-1297. (SRIC-G)

Response to Issue 9.E:

As stated in the preamble to the final rule, the Agency has incorporated NUREG-1297 by reference in order to set criteria for the process used to conduct peer review. Those provisions of NUREG-1297 which provide guidance on which activities should be peer reviewed do not supersede or amend the requirements of the final rule, 40 CFR part 194. Any other discrepancies in scope between the final rule and the NUREG are superseded by the explicit requirements of the criteria.

Issue F: It is important to keep any standards and requirements for peer review.

1. The process for evaluating peer review should be open to the public and done by rule. (NMAG-G)

2. It is important to keep in place any requirements that you have for peer review. (S-16, S-53)

3. Compliance criteria must meet the standards of peer review. (S-36)

4. The intent of peer review is to add value and credibility to activities and to minimize delays that would be other wise costly after-the-fact. More value should be given to peer review especially by organizations funded specifically for that purpose. (SGNM-D)

5. The final rule should require that peer review be done by DOE, prescribe the processes used, and ensure that any peer review is fully documented. (SRIC-G)

Response to Issue 9.F:

The Agency agrees that peer review should be required. The Agency believes that the final rule's requirements on peer review will add value to the compliance application. Regardless of the extent to which peer review is used, the rulemaking on certification must be conducted by EPA. See 106 Stat. 4777, section 8(d) (Pub. L. 102-579). All decisions on the adequacy of the compliance application with respect to the disposal regulations will be EPA's and EPA's alone. However, the Agency does intend to use review procedures internal to the Agency, at its discretion, during the rulemaking on certification under section 8(d) and during the periodic re-certification under section 8(f) of the WIPP Land Withdrawal Act. The Agency's own review of the compliance application for certification will be subject to rulemaking.

Section 27 of the final rule requires DOE to conduct peer review and specifies for which activities peer review must be conducted. The final rule requires DOE to conduct peer review of three specific elements of the WIPP program. In specific, the Agency has required peer review of the selection and development of conceptual models, waste characterization assessments and the study of engineered barriers. The requirement for peer review of conceptual models will enrich DOE's process of selecting and developing conceptual models with a broad spectrum of scientific viewpoints. Waste characterization is a field in which

many new and precedent-setting techniques will be employed in areas in which no standardized practice exists. Peer review of waste characterization analyses is indicated due to the importance of a knowledge of the physical, chemical and radiological state of the waste in predictions of the long term performance of the disposal system. This section, 194.27, also requires peer review to be conducted of the study of engineered barriers so as to ensure that the best possible information is provided to DOE on the selection of engineered barriers.

Compliance applications are required to include documentation of any peer review activities that DOE may have conducted apart from those required by this rule, including those activities which are similar to peer review, such as the reviews conducted by the WIPP Panel of the National Academy of Sciences.

NUREG-1297 contains general guidance on how the process of peer review process is to be conducted and documented. The final rule specifies that this guidance applies to the peer review conducted by DOE for inclusion in a compliance application. The DOE must justify the specific methods chosen to conduct peer review and provide documentation that peer review has been adequately performed for the activities specified in section 27 of the final rule. These methods and documentation, along with all other materials submitted in the compliance application, will be subject to the Agency's review and approval as part of the rulemaking on certification and as part of the reviews for re-certification.

Issue G: There is no necessity for peer review.

1. The peer review requirements would be costly, redundant, impose new requirements, are unnecessary, and should not be required. (DOE-A, DOE-D, SNL-A, SNL-C, C-12, C-15, C-23, A-13, A-31, IV-D-06)

2. The WIPP has always had oversight by the National Academy of Sciences. The program has had adequate peer review, and there is no necessity for additional peer review. (IV-D-40)

3. It is recommended that the EPA delete the proposed universal requirement for peer review. The proposal, as presently given, seems to add little or no value to DOE or to EPA. (IV-D-100)

4. Specific requirement of any type of peer review is inappropriate because of DOE's responsibilities as the implementing agency, and because of the normal applicant/regulator roles. The peer review requirements fail to recognize the implementation of the NQA-1 program under §194.22 and the need for a graded approach towards technical reviews. It is recommended that peer review references throughout the proposed 40 CFR part 194 and Supplementary Information be deleted. Also, it is recommended that EPA's proposed strategy as discussed in the NACEPT issue paper be abandoned. (SNL-D)

5. The EPA should delete the peer review requirements from the proposed rule. (DOE-E)

6. It is recommended that the proposed use of peer review be deleted since, through the DOE quality assurance program and the EPA participation in that program, the concerns will be/are addressed. (IV-D-113)

Response to Issue 9.G:

The need for increased confidence in the disposal system and thus for peer review arises due to the uncertainty inherent in the long-term projection of the behavior of the proposed disposal system. The WIPP in particular is the first system of this type, under consideration for disposal of long-lived, highly radioactive wastes. As a result, the search for solutions to the technical issues posed by geologic repositories has elicited considerable effort, but not complete agreement among the scientists and engineers in the broader technical community. Peer review of certain activities conducted at the WIPP can ensure that a more complete spectrum of knowledge and experience will be utilized.

The EPA recognizes that some past examinations of DOE's WIPP activities could be considered to be the equivalent of, although not identical to, peer review. The final rule requires that documentation of these peer review activities be submitted as part of the compliance application. The acceptability of these past reviews will be evaluated by EPA as part of its certification decision; EPA's decisions on acceptability will take into account the similarity or compatibility of past review with the guidelines established in NUREG-1297.

Issue H: Requiring DOE to institute a peer review process for documents and analyses submitted to EPA seems to be asking the peer review group to perform a substantial part of EPA's role. (IV-D-100)

1. The responsibility for the peer review of DOE's work belongs with the EPA. In the proposed rule, the EPA seems to be requiring DOE to do the EPA's job. (IV-G-3)

Response to Issue 9.H:

The Agency does not intend for peer review of DOE's activities to supplant or replace the Agency's review of compliance applications. Although the responsibility for conducting peer review is DOE's, the selection of the participants must follow the guidelines of NUREG-1297 with respect to the membership of the peer review group. NUREG 1297 states that participants in a peer review group should have sufficient freedom from funding considerations to ensure that the work is impartially reviewed, in addition to having been uninvolved in the original work to be reviewed. Documentation of peer review activities as required under section 194.27 must be part of the compliance applications.

Regardless of the recommendations or judgments made by the peer review groups, all decisions on the adequacy of the compliance application will be EPA's and EPA's alone. In fact, by law, it is EPA and EPA alone that conducts the rulemaking on certification. See 106 Stat. 4777, section 8(d) (Pub. L. 102-579). However, the Agency does intend to use review procedures internal to the Agency, at its discretion, during the rulemaking on certification

under section 8(d) and during the periodic re-certification under section 8(f) of the WIPP Land Withdrawal Act.

Issue I: The use of peer review in the proposed rule is too broad and exceeds generally accepted standards.

1. The scope of the peer review process proposed by EPA appears to presuppose that peer review will be required to validate the entire WIPP program. The EPA needs to further evaluate the costs associated with this level of peer review. (IV-D-111)

2. The scope of the proposed peer review program appears to exceed, by far any precedent withing the nuclear or other regulated activities. Rather than mandating formal peer review for "validation," the final rule should not specify uses of peer review. (IV-D-112)

3. The NAS would not be able to meet prerequisites for peer review. (DOE-D)

4. The "peer review" included in the proposed rule is much too broad in that it appears to require peer review validation of the actions that have already been completed and subjected to review by experts (peers) under the QA Program established by the DOE. This delay would result in excessive costs and delay with minimal benefits. (IV-D-114)

5. The peer review requirement is redundant, excessive, and results in an inappropriate stewardship of resources. The present technical reviews subjected to QA program controls are sufficient oversight to provide adequate assurance of regulatory compliance. (IV-D-117)

6. It is believed that the DOE maintains the WIPP program in accordance with ASME and DOE QA requirements which are believed to be in compliance with NUREG-1297 Paragraph V. It would appear that acceptance of DOE's Quality Assurance Program satisfy the basic need for review of technical and programmatic judgments. There is no value in the proposed redundant peer review system. (IV-D-122)

7. The EPA's position of having peer reviews conducted for QA programs and plans is misguided, impractical, and unproductive. The requirement should be deleted from the Rule. (IV-D-123)

8. Since EPA proposes in §194.27 that NUREG-1297 is the base document for use in conducting peer reviews, it is significant that NUREG-1297 does not identify any criteria/conditions where the need for QA programs or plans to undergo peer review is addressed. For the EPA to propose to apply peer review to QA programs and plans would be a clear misunderstanding of the original intent of the peer review process and how it should be applied. (IV-D-123)

9. Since the DOE has in place a quality assurance program consistent with the disposal standards set forth in 40 CFR 191, and the applicable requirements of Appendix B of 10 CFR

50 and the ASME nuclear standards, there appears to be no warranted necessity to require a peer review of the entire WIPP quality assurance program. (IV-D-127)

10. The requirement to conduct peer review beyond that required by NQA seems duplicative and is probably unnecessary. (IV-D-111)

11. Particularly in the area of qualification of old data, compliance criteria must require stringent application of quality assurance standards. Peer review alone may not be appropriate in this area. (CCNS-B)

Response to Issue 9.I:

The Agency sought the advice of the WIPP Review Committee of the National Advisory Council for Environmental Policy and Technology (NACEPT) regarding which activities should be required to be peer reviewed. The Committee suggested that peer review of quality assurance programs would be unnecessary, since, by requiring DOE to adhere to a program that meets the requirements of three sets of ASME's standards, today's action would already be sufficient to control the quality assurance process. The Agency agrees with both the Committee and with similar public comment and has eliminated the requirement for peer review of quality assurance programs and plans.

The final rule provides for a separate treatment of the peer review that is performed as part of quality assurance process versus peer review that is applied at a more general level. The Agency does not believe it is useful or practical to require peer review of all aspects of a compliance application. The final rule focuses peer review on critical activities associated with the WIPP. In the context of quality assurance, peer review may be invoked in one of two ways. First, existing data will be acceptable if it meets the requirements of a quality assurance plan "equivalent in effect" to that which EPA requires of data generated after the QA programs required by the final rule are in effect. Peer review can be part of such a quality assurance plan. Alternatively, DOE may qualify existing data using a combinations of peer review, corroborating data, or confirmatory testing, subject to the Administrator's approval.

The Agency recognizes that other review and oversight activities, in addition to peer review, have occurred and will continue to occur during the WIPP's development, operation and decommissioning. These activities may be similar but not identical to peer review with respect to meeting the requirements of 40 CFR Part 194. Such review activities include the occasional reviews performed by the National Academy of Sciences' WIPP Panel. All such reviews must be documented in compliance applications.

Section 10: APPLICATION OF RELEASE LIMITS: SECTION 194.31

Issue A: The 100-year time frame for calculating the release limits on the curie activity warrants re-evaluation.

1. The assertions that DOE and Sandia have advocated calculating the release limits on the curie activity 100 years after the shafts are sealed are wrong. (DOE-D, SNL-C)

2. Use of curie activity 100 years after disposal is certainly not too long. (A-41, IV-D-51)

3. The limit should be raised to 1,000 years. (C-03)

4. The establishment of a curie activity rate should be defined as the rate 100 years after decommission. (C-14)

5. The wording implies that a release limit depends on the amount of an isotope in the WIPP depository. The proposed 100-year base for calculating release limits is a gross approximation which is unnecessary. (IV-D-06)

6. The limit of 100 years is acceptable. (NMAG-B, C-14, A-41)

7. Section 194.31 would require that the expected curie activity remaining 100 years after disposal be used as the basis for calculating applicable releases under Appendix A of 40 CFR part 191. (IV-D-112)

8. The Agency should adopt as final its proposal to measure the radionuclide content of the inventory 100 years after disposal. The 100-year date will bring the protection of 40 CFR part 191 for TRU waste much closer to parity with the protections for spent fuel than would the suggestion to use the initial inventory. (NMAG-D, SRIC-G)

9. The 100-year time period after disposal used in calculating applicable release limits is reasonable. (SGNM-D)

Issue B: The waste unit should be based on the curie content at the time of assay.

1. The text for §194.31 should be replaced to state, "The curie activity at the time the waste is assayed prior to shipment to the WIPP shall be used in calculating applicable release limits under Appendix A of 40 CFR part 191, Table 1." (IV-D-111)

2. The waste unit should be based on the curie content determined by the assay to be performed prior to shipment to the WIPP. For newly generated waste, the waste-unit curie content assay will be consistent with the derivation of 40 CFR part 191, which establishes 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. (SNL-D)

3. It is recommended 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. (DOE-E)

4. Basing release limits on the curie activity at the "time of assay" would be inappropriate and could be inaccurate. (SRIC-G)

Response to Issues 10.A and 10.B:

The proposed compliance criteria (in §194.31) included a provision that would have required that the release limits for the WIPP be calculated based on the expected curie activity in the disposal system 100 years after disposal (i.e., when the disposal system shafts are backfilled and sealed). While some comments supported this position, others stated that the release limits should be based on the curie content of the waste at some other point in time. This issue was addressed by the WIPP Review Committee of the National Advisory Council for Environmental Policy and Technology (NACEPT) at a public meeting in New Mexico in September, 1995. The NACEPT committee reached two primary conclusions: 1) that the release limits should be based on longer-lived radionuclides to reflect the long-term hazards presented by the waste; and 2) that statements in the compliance criteria on release limits should be consistent with the basis for developing the release limits in EPA's disposal regulations (40 CFR part 191). Consequently, EPA re-examined the basis of the disposal regulations.

The Agency determined that development of the release limits in 40 CFR part 191 had already incorporated the principle that long-term hazards, and thus long-lived radionuclides, should be the focus of regulation. To that end, the release limits do not require consideration of alpha-emitting radionuclides with half-lives less than 20 years. In addition, Appendix A of the disposal regulations contains instructions for adjusting the release limits in Table 1 according to the amount and type of waste in a disposal system. These conversion factors take into account the differences in radioactive characteristics between spent nuclear fuel and transuranic waste. [See 40 CFR part 191, Appendix A, Note 1.] There is no indication that the disposal regulations (or their implementing criteria) require an additional adjustment for transuranic waste. Thus, EPA concluded that the release limits for the transuranic waste planned for emplacement at the WIPP should be established consistent with the release limits for all types of waste regulated by the disposal regulations.

In reviewing the basis for the release limits in 40 CFR part 191, EPA found no technical support for setting the curie content (for any waste regulated under Part 191) at 100 years after disposal, or at the time the waste is assayed. The disposal regulations call for calculation of "the cumulative releases to the accessible environment for 10,000 years *after disposal*" [emphasis added]. See 40 CFR 191.13(a). See also 40 CFR part 191, Appendix A, Table 1. The preamble to the final disposal regulations also state that "[t]he release limits apply to radionuclides that are projected to move into the accessible environment during the first

10,000 years after disposal [50 FR 38071]." Note that the disposal regulations define disposal for a mined geologic repository as that point when "all of the shafts to the repository are backfilled and sealed [§191.02(l)]." The position that release limits should be set at the time of disposal, which is when the 10,000-year regulatory time frame begins, is consistent with the disposal regulations. Calculation of radioactive decay is readily accomplished with standard equations, and EPA does not believe it is an undue burden on the DOE to account for decay of radionuclides between the time of assay and time at which the disposal system is sealed. Based on these considerations, the Agency has chosen in the final rule to determine release limits based on the total activity, in curies, of each radionuclide in the transuranic waste predicted to be present at the time the WIPP is sealed.

Issue C: The requirements of Section 194.31 contradict 40 CFR part 191.

1. Selecting 100 years after disposal as point of time for setting release limits departs from 40 CFR Part 191 and should be a separate rulemaking. (DOE-D, WEC-D, A-41)

2. Proposed 100-year decay period is inconsistent with Agency's promulgation of an "equivalence factor" for transuranic waste. (DOE-D)

3. The approach is inappropriate because the proposed requirement is more stringent than the release limits in Appendix A to 40 CFR part 191. (SNL-C)

4. The requirement should be made consistent with Part 191 by fixing the curie content at the time that the curie content of the waste container is determined for delivery to the WIPP because this is the only time that the curie content is assayed. (SNL-A, SNL-C)

5. The waste unit for TRU waste should be as consistent as possible with the derivation of Table 1 in Appendix A to 40 CFR Part 191. (SNL-C)

6. The release limits in §191.13(a) specifically apply to radionuclides with half-lives greater than 20 years, while 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 (60 FR 5774)." (SNL-C)

7. The proposed time delay is inconsistent with the regulatory time frame established in 40 CFR part 191. (SNL-C)

8. The proposed approach is inconsistent with the spent-fuel equivalency rationale developed to allow derivation of a single set of release limits for geologic disposal of radioactive waste. EPA based the waste unit derivation on a philosophy of equivalence between the various types of waste regulated by 40 CFR part 191. (SNL-C)

9. The proposed approach directly contradicts 40 CFR part 191. (SNL-C)

10. If EPA intends to increase the stringency of the release limits, then Table 1 of Appendix A must be revised consistently through rulemaking for 40 CFR part 191. (SNL-C)

11. The part of the proposed rule appear to be a departure from the assumptions used for the development of release limits in 40 CFR part 191. The curie content of the waste should be specified at the time of assay. (IV-D-111)

12. The proposed approach of using 100 years to calculate applicable release limits is inconsistent with the spent-fuel equivalency rationale established as the basis for the single set of release limits. The waste unit determines the release limits for a specific repository. This is a significant departure from the basis for derivation of the release limits for 40 CFR part 191, and effectively imposes new release limits on the WIPP. (SNL-D)

Response to Issue 10.C:

The Agency has modified the final rule to ensure that implementation of release limits at the WIPP is consistent with the technical basis and intent of the disposal regulations at 40 CFR part 191. Upon reviewing the basis of the release limits in 40 CFR part 191, EPA concluded that the conversion factors take into account the differences in radioactive characteristics between spent nuclear fuel and transuranic waste. [See 40 CFR part 191, Appendix A, Note 1.] There is no indication that the disposal regulations (or their implementing criteria) require an additional adjustment for transuranic waste. Thus, EPA concluded that the release limits for the transuranic waste planned for emplacement at the WIPP should be established consistent with the release limits for all types of waste regulated by the disposal regulations.

In reviewing the basis for the release limits in 40 CFR part 191, EPA found no technical support for setting the curie content (for any waste regulated under 40 CFR part 191) at 100 years after disposal, or at the time the waste is assayed. The position that release limits should be set at the time of disposal, which is when the 10,000-year regulatory time frame begins, is consistent with the disposal regulations.

Calculation of radioactive decay is readily accomplished with standard equations, and EPA does not believe it is an undue burden on the DOE to account for decay of radionuclides between the time of assay and time at which the disposal system is sealed. The EPA expects that standard methods of calculating the future activity of existing inventory will be applied by DOE. Such methods would include the familiar Bateman equations, which account for both ingrowth (increase in the quantity of a radionuclide from the decay of a heavier nucleus) and decay (decrease due to decay of the nucleus of that same radionuclide). Based on these considerations, the Agency has chosen in the final rule to determine release limits based on the total activity, in curies, of each radionuclide in the transuranic waste predicted to be present at the time the WIPP is backfilled and sealed. See response to Issue 10.A for more information.

Section 11: PERFORMANCE ASSESSMENTS: SECTIONS 194.32 AND 194.34

Issue A: Scenarios should be selected that represent the entire appropriate range of processes and events.

1. Methods of conducting a Performance Assessment (PA) may be questioned including the selection of scenarios for analysis, definition of computational scenarios, assignment of probabilities to computational scenarios, development of conceptual models, transition of conceptual models to computer models, selection of values, ranges of values, and sampling methods for unknown values in conceptual models, and selection of CCDF expression for comparison with release limits. (NMAG-B, NMAG-F)

2. It is appropriate that performance assessments need not consider processes, events, or sequences of processes and events that have less than one chance in 10,000 of occurring over 10,000 years. (WEC-D, IV-D-06)

3. Performance Assessments must analyze scenarios which include post closure time periods between 10,000 and 100,000 years. (SRIC-E, CCNS-B)

4. Performance assessment should include DOE's poor track record when figuring probabilities. Risk assessment should include the low probability/high consequence scenarios. (CARD-B, CCNS-B, S-21)

5. Mining should not be excluded from performance assessments. (A-41)

6. EPA regulations should specify scenario selection and require the DOE to prove that the site can guard against for 10,000 years, the probability of intrusion by industry, the presence of radiation through karst conditions, future sinkholes, and other results of climate changes, and the possibility of compressed gas finding or causing fractures. (NMAG-G, S-40)

7. Scenario probability assignments based on “expert judgment” must be subjected to critical review. (NMAG-F)

8. Performance assessments should evaluate the impact of natural and human-initiated processes and events for a time period of 100,000 years. Such calculations would provide additional confidence in the results of CCDFs. (SRIC-G)

9. It is recommended that EPA address the issue of general classes of processes and events being subdivided. EPA should also be using a more qualitative treatment to address this issue. (NRC)

10. Criteria should require an explanation and justification of the selection of fixed and variable parameters; the establishment of range, median, and probability distribution of variable parameters; and the sampling methods, including any probability judgments implied thereby. (NMAG-B, NMAG-G)

11. The rule should require that the statements about ranges and uncertainty be supported by data and explanation. (NMAG-C)

12. In the construction of scenarios, all relevant sequences of events and processes must be considered, but the rule does not prescribe all possible sequences. (NMAG-D)

13. Low probability of occurrence, as defined in Appendix C to 40 CFR part 191, should be retained as a screening criterion for processes, events, and scenarios. (SNL-D)

14. The time period of regulatory concern for the Containment Requirements should be retained at 10,000 years, consistent with 40 CFR part 191. (SNL-D, DOE-E)

15. Consequence should be retained as a screening criterion for scenarios. (SNL-D)

16. Identifying scenarios as combinations of features, events, and processes is important, and should be specified in the rule. The selection of, and justification for, the specific procedure used in developing scenarios should be the responsibility of the DOE. (SNL-D)

17. 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. (DOE-E)

18. DOE cannot appropriately use the Appendix C guidance of 40 CFR part 191 to reject certain scenarios since the guidance is not required at the WIPP. DOE must justify excluding scenarios based on low probability or insignificant consequence. (SRIC-G)

Response to Issue 11.A:

The EPA intends to review all aspects of the analyses of performance and, in many sections of 40 CFR part 194, has required extensive justification for the different steps of the analysis. The final rule requires that the application for certification must document and explain the treatment of scenarios and variables in the analysis of disposal system performance. The Department of Energy is required to justify those conceptual models that DOE selects and develops and explain the progression of these models into mathematical, numerical and computer models.

Some comments stated that analyses of disposal system performance should model 100,000 years of performance rather than the required 10,000 years. The EPA's requirement for an analysis to extend 10,000 years was stated in 40 CFR part 191 and was the product of extensive analysis and public review. In 40 CFR part 191, the Agency stated 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 [50 FR 38076].” Since the requirement of 10,000 years was established as part of the disposal regulations, 40 CFR part 191, the Agency’s mandate in implementing these standards at WIPP does not allow or necessitate a re-assessment of the appropriateness of these disposal regulations.

Some commenters suggested that the EPA should specify which processes and events must be considered by DOE in analyses of disposal system performance. The final rule's requirements on the scope of performance assessments, including the processes and events that can affect the disposal system, were based in part on the disposal regulations. The containment requirements as provided in 40 CFR 191.13 apply at two sizes of cumulative release, calculated according to Table 1 of Appendix A of 40 CFR Part 191: releases of "size 1" must be less likely than 1 in 10, and releases of "size 10" must be less likely than 1 in 1,000. The Agency determined, for example that, if a release of size 10 were only exceeded in 1 of 1,000 cases, the public health would be adequately protected, including a margin of safety. By adding together the probability of the combinations of individual processes and events which are predicted to cause these releases, the precise probability of a size 10 release being exceeded may be determined. This "cumulative probability," so called because it is the sum of many events' probabilities, may then be compared to the 1 in 1,000 standard to test for compliance.

The disposal regulations at section 191.13(a) require analysis of cumulative releases of all "significant" processes and events. See also 40 CFR 191.12, definition of "performance assessment." Thus, the disposal regulations recognize that some processes and events are so small or unlikely that they should be excluded as insignificant. Appendix C of 40 CFR Part 191 provides guidance on this point, recommending that performance assessments not consider categories of processes and events that are estimated to have less than 1 chance in 10,000 of occurring over 10,000 years. Appendix C also provides that processes and events with a greater likelihood of occurence may be omitted from performance assessments if there is a reasonable expectation that the remaining probability distribution of cumulative releases would not be significantly changed.

The Agency recognized that, at some sufficiently small level of probability, the likelihood of the individual probabilities of processes' or events' occurring would be too small to add up to this 1 in 1,000 or to significantly affect the overall probability distribution and would therefore be too unlikely an occurrence to pose a significant threat to public health. For the purposes of the WIPP, the Agency has determined that, similar to the Appendix C guidance, this "threshold probability" would be 1 in 10,000 over 10,000 years. Even with this threshold test, however, a comprehensive spectrum of processes and events will nonetheless be included in the performance assessments used to predict cumulative releases. Such geologic events as natural seismic activity, magmatic activity would almost certainly be included performance assessments as their probability of occurrence is almost certainly above the 1 in 10,000 threshold. However, certain processes and events may safely be ruled out as being less than 1 in 10,000 likely to occur at the WIPP over the 10,000 year regulatory time frame, such as glaciation and volcanic activity.

It is further worth noting that this 1 in 10,000 threshold probability applies to categories of processes and events. For the purposes of this screening requirement, processes and events must be analyzed in the most general formulation possible; for example, the probability of dissolution must be set equal to the probability of all types of dissolution occurring anywhere in the Delaware Basin during the regulatory time frame. Performance assessments should,

however, conduct separate analyses of the different dissolution fronts which occur in the Delaware Basin so as to account for the different hydrogeologic characteristics of each. To ensure that the analysis to exclude a process and event is sufficiently rigorous and documented, the final rule, at section 194.32(e) requires documentation showing why any processes and events or sequences and combinations of processes and events that may occur in the regulatory time frame and may affect the disposal system are not included in performance assessment results.

The Agency agrees with comments stating that, should the probability of such events be established by expert judgment, then the judgment should be carefully reviewed. The Agency has therefore included a section on the use of expert judgment at §194.27 of the final rule. In addition, the final rule has specified that performance assessments "shall include an analysis of the effects of the disposal system of any activities that occur in the vicinity of the disposal system prior to and soon after disposal. Such activities shall include, but not be limited to: existing boreholes and the development of existing leases that can be reasonably expected to be developed in the near future, including boreholes and leases that may be used for fluid injection [paragraph 194.32(b)]." Thus, applications must document existing bore holes near the site and account for their potential impact over the 10,000-year regulatory time frame. Assumptions about drilling over the regulatory time frame, however, are subject to the criteria of §194.33.

Regarding the issue of how to subdivide processes and events for probability analysis, EPA has further explained the Agency's expectations on this issue for the final rule. The preamble to the final rule states: "For the purposes of this screening requirement, processes and events must be analyzed in the most general formulation possible; for example, the probability of dissolution must be set equal to the sum of the probabilities of all types of dissolution occurring anywhere in the Delaware Basin during the regulatory time frame. Performance assessments should, however, conduct separate analyses of the different dissolution fronts which occur in the Delaware Basin so as to account for the different hydrogeologic characteristics of each." See also Section 12 of this document.

Issue B: The 95 % statistical confidence level does not appear to be well justified and should be reconsidered.

1. The method for attaining statistical confidence in the mean presented in Supplemental Information of the proposal is neither correct nor appropriate. "Sequences" are confused with "combinations." (DOE-D, SNL-C)

2. EPA has wisely specified a confidence limit of 95 percent. However, the rule should define when this is achieved. (SNL-A, SNL-C)

3. Selection of a 95% level of statistical confidence for a reasonable expectation appears arbitrary and in conflict with 40 CFR part 191. (DOE-D, WEC-D, IV-D-100)

4. The number of performance assessment runs required to satisfy this requirement would exceed by three times the number of runs projected by the EPA. It is recommended that the EPA reevaluate the confidence level requirements of this proposed rule. (SNL-A, IV-D-40)

5. The proposed approach set forth in §194.34(b) is very difficult to implement. (SNL-C)

6. The Agency should start from the goal that the unconditional risk assessment have the aim of proving compliance to the level of 90% certainty--"reasonable assurance"--and from there establish the level of certainty called for in the conditional risk assessment. (NMAG-D)

7. The full uncertainty analysis of WIPP has not been done and would be extremely difficult. In this situation, it is sensible to apply a test of reasonable expectations to the results of a conditional risk analysis based on fixed hypotheses, provided that the hypotheses are globally conservative, and the mean curves correspond to high fractiles of the CCDF families. (NMAG-E)

8. A reasonable way to judge compliance is to use the curve that represents the mean population of CCDFs with a 95 percent level of statistical confidence. (SRIC-G)

9. The rationality of the mean as a relevant characteristic of a probability distribution does not apply to collective decisions (such as governmental decisions), in which the administrator is concerned not only with the probability distribution of the levels but also with the health and safety of the most exposed members of the public. (NMAG-E)

Response to Issue 11.B:

The Agency declined to base compliance with the containment requirements on a percentile value, such as the 95th percentile, as suggested in the comments. Instead, the Agency chose the mean complementary cumulative distribution function (CCDF) as the value which must be in compliance. In developing the proposed rule, the Agency considered basing compliance with the containment requirements on a CCDF other than the mean CCDF. For example, the median (50th percentile) CCDF and other percentile CCDF were considered as possible choices.

The mean CCDF was selected as the test for compliance because of several properties. First, the mean is an indicator of "central tendency," a term which indicates that the location of the mean is, in a statistical sense, at the center of the group of CCDFs. Second, the location of the mean is strongly influenced by CCDFs which are "outliers" in the group of CCDFs. In effect, an individual CCDF that is located far above or below the remaining CCDFs in a group exerts more "leverage" on the location of the mean than would more centrally located CCDFs. This rule-of-thumb becomes important in a situation in which there are several CCDFs located far above the median, the latter being the "mid-point" CCDF to indicate that an equal number of CCDFs fall above as fall below the median. The specific location of the mean CCDF, however, will depend on just how far above and how far below the median these CCDFs lie. If the CCDFs which fall below the median lie fairly close in, then the CCDFs

located far above will preferentially move the mean towards higher values. It is worth noting that the median would be immune to this "leveraging" or "over-balancing." In the case of WIPP, the groups of CCDFs generated in DOE's preliminary performance assessments do, in fact, possess this lopsided quality in which CCDFs that predict larger releases are not balanced by a similar number of CCDFs that predict small releases.

The median CCDF was also considered during the development of the final rule. Like the mean, the median has the advantage of being an indicator of the "central tendency" of a group of CCDFs, since an equal number of CCDFs fall above as fall below the numerical value of the median. As noted above, however, whereas the mean CCDF would be subject to the "leverage" of extremely high or extremely low CCDFs, the median CCDF would be relatively stable.

Some comments have suggested that the Agency should determine compliance based upon a high percentile value of the group of CCDFs that are generated, such as the 85th or 90th percentile. The percentile value of a CCDF is an indicator of the relative numerical value of one CCDF in a group with respect to all other CCDFs in that group. For example, the particular CCDF that exceeds 90 percent of the group of CCDFs would be dubbed the "90th percentile." As mentioned, the Agency considered the option of using a percentile valued CCDF to test compliance with the numerical containment requirements of section 13 of 40 CFR part 191. Higher percentiles, however, do not indicate the central tendency of a group of CCDFs and would therefore less accurately convey the best estimate of the disposal system's performance. The Agency believes that an indicator of central tendency would be more appropriate, provided that the final rule also impose many inherently conservative assumptions on the performance assessments. One such requirement is the threshold probability of 1 in 10,000 over 10,000 years which applies to processes and events. As another example, performance assessments must employ random sampling techniques that sample across the full range of possible values that a given parameter may assume, even from those values which are both unlikely and which could contribute to larger releases from the disposal system. The influence of these requirements will be conveyed to the CCDFs which are generated per the requirements of section 34 of the final rule and would obviate the need for a non-conservative CCDF to be used to test compliance. With these constraints in mind, the Agency believes that the best test for compliance can be made using some measure of the central tendency of the family of CCDFs.

The Agency chose to require that some measure of the reliability of the calculated value or a "confidence limit" should be established for the tested CCDF, regardless of whether that CCDF were the mean, median or a percentile. For a particular group of CCDFs, the mean CCDF can be calculated to within a more precise range of accuracy than the percentile CCDF. In other words, the uncertainty surrounding the numerical value of the mean CCDF would be less than the uncertainty surrounding the numerical value of a CCDF at a chosen percentile. This property of the mean CCDF makes the mean a reliable indicator to be used to test compliance.

Further comments have suggested that the mean CCDF be used, but without the 95 confidence requirement. These comments stated that the recommendations contained in Appendix C of 40 CFR part 191 with regard to which CCDF must comply with the containment requirements were not incorporated into 40 CFR part 194. Specifically, the comments state that Appendix C requires that the mean CCDF comply with the containment requirements without requiring that there be 95 percent confidence in this compliance. Appendix C did, in fact, leave open the question of requiring a confidence level. The Agency further notes that Appendix C was designated as non-binding.

The above alternate methods -- using a percentile value or the mean, but without the confidence measure -- discarded the Agency's requirement that there be a 95 percent confidence of compliance. This suggestion was at odds with the Agency's need for assurance that the WIPP be in compliance with the containment requirements, since it would have removed the objective measure used to assess this assurance. In contrast, the alternate methods provide only for a comparison of the mean CCDF, as calculated from all the CCDFs generated to test compliance, with the containment requirements. While the Agency believes that useful information might be gleaned from such a comparison, the Agency views as essential a measure of the confidence of the mean's compliance. Hence, the Agency retained the original approach in final rule, 40 CFR part 194.

The final rule at 40 CFR part 194 requires that the mean or average value of all the CCDFs generated be compared to the quantitative containment requirements of section 13 of the disposal regulations. The containment requirements limit the sizes of releases of radionuclides that might occur over the 10,000-year regulatory time frame. The size of a release is calculated using the instructions in Appendix A of 40 CFR part 191 and represents a contribution from the predicted number of curies of each radionuclide that is predicted to be released over 10,000 years. Per the containment requirements, the mean CCDF cannot predict that a 10,000-years' release of size "one" is more than 10 percent likely to occur, or, further, that a release of size "ten" is more than 0.1 percent likely to occur. Releases of these sizes are of sufficient magnitude such that, were these releases predicted to be more likely than these small percentage values permit, the disposal system's ability to isolate waste would be questionable. The Agency will assess compliance by evaluating the value of the mean CCDFs at the two relevant sizes of release, one and ten.

In addition, the Agency has retained the requirement that the mean CCDF must be in compliance with a 95 percent level of statistical confidence. Statistical confidence levels are a measure of the "trueness" of a calculated number. Should the mean CCDF be found in compliance with a high level of confidence, such as 95 percent, then the assertion that it is in compliance is likely to be a "true" prediction, based on the present conceptual understanding of the WIPP's performance. Absolute confidence -- in effect 100 percent confidence -- cannot be established without making an infinite number of calculations.

Demonstrating 95 percent confidence of compliance can be easier or harder to achieve depending where the value of the mean CCDF lies with respect to the numerical limits of the containment requirements. The demonstration becomes easier if the mean CCDF shows

compliance by a comfortable margin but becomes harder if the mean is close to violating the standard. For example, assume that a mean CCDF is computed that shows an extremely low likelihood -- say 1 in 1,000 -- that a release of size "one" can occur. This falls well below the maximum likelihood that the standard permits, 1 in 10 or a 10 percent chance. In this situation, fewer calculations would be necessary to establish that the requirement for 95 percent confidence has been satisfied. However, if the mean CCDF falls close to the limit of 10 percent likelihood for a size "one" release, then a far greater number of calculations would be necessary to satisfy the requirement for 95 percent confidence. Of course, a demonstration of the required confidence limit is only possible if the mean itself is in compliance.

Certain comments have suggested that an impracticably large number of calculations would be required to show that the mean CCDF is in compliance with a 95 percent confidence limit. As just noted above, the number of CCDFs required to establish 95 percent confidence will vary depending on the margin with which the mean itself complies with the containment requirements. The exact number of calculations that would be necessary can be determined by statistical methods.

Certain comments stated that the requirement for 95 percent confidence was not consistent with the containment requirements of 40 CFR 191.13. In 40 CFR part 191 -- the "disposal regulations" which apply to all highly radioactive waste repository -- the Agency recognized that absolute proof of a repository's successful compliance with the containment requirements could never be established. See §191.13(b). The requirements set the maximum likelihood with which predicted releases of waste could occur, but left open the question of what would be necessary for a specific disposal system, in this case WIPP, to show compliance. The 95 percent confidence requirement in 40 CFR part 194, discussed above, represents an appropriately rigorous level of proof given the limitations of an analysis which predicts performance 10,000 years into the future.

Certain comments stated that the rule appeared to specify that the 99th percentile CCDF must comply with the containment requirements of 40 CFR part 191.13. (The 99th percentile denotes that CCDF which would be exceeded by only 1 in 100 CCDFs, if an infinite number or "population" were to be generated. This value can be estimated, but never absolutely determined, by computer calculations.) The 99th percentile is determined separately at each value of cumulative release, i.e. at each point on the CCDF that corresponds to a different point on the horizontal axis. The final rule, 40 CFR part 194, places this requirement on the CCDFs only at cumulative releases of 1 and 10. Cumulative releases are calculated according to Note 6 of Table 1, Appendix A of 40 CFR Part 191.) In 40 CFR part 194, the Agency does not require that the 99th percentile CCDF be calculated, or be compared to the containment requirements in order to assess compliance. Rather, the DOE must determine only the probability with which the 99th percentile will be exceeded. This differs from an actual calculation of the numerical value of the 99th percentile CCDF; the probability of exceeding that quantity is determined based on the statistical properties of the complete group of CCDFs.

Issue C: Requirements regarding CCDFs should define terms more precisely, consider effects on scenario selection, and limit generation requirements to reasonable levels.

1. EPA is correct in stating that the mean is a more suitable representation of the range of CCDFs than the median. However, the regulatory compliance purpose of the 99th percentile is not clear in the proposed rule and should be stated explicitly. (SNL-C)

2. The requirement placed on the maximum CCDFs generated is excessive and could result in significant quantities of computer time. The criteria should say that number of CCDFs generated shall be sufficient to establish the distribution of the population In general, enough CCDFs should be run and sufficient statistical assessments made in order to provide a reasonable expectation of the performance required. (DOE-D, C-28)

3. If a CCDF based upon a single realization demonstrates compliance, that may be enough. If it does not, the whole should not be thrown out with out examining a sufficient family of CCDFs to clearly demonstrate the total system behavior to reveal a behavior that may have a remedial correction. (IV-D-51)

4. The definition of “population of CCDFs” needs clarification as to whether it means the entire population of CCDFs which would be generated from sampling values of parameters through an infinite number of iterations, or the CCDFs generated from sampling of particular values and generation of specific vectors using the sampling results--the “parameter values used in compliance assessments.” (NMAG-D)

5. "Population of CCDF's" should refer to the CCDFs used in compliance demonstration generated from the probability distribution of uncertain disposal system parameter values, not an infinite number of CCDFs. The "population of estimates" definition should be restricted to reasonable estimates. (DOE-D, WEC-D)

6. The inclusion of the words "all possible" in the definitions of "population of CCDF's" and "population of estimates" make these definitions impossible to implement. The definitions of "population of CCDFs" and "population of estimates" should be amended to read: "Population of CCDFs means a sufficient number of CCDFs generated so that the maximum CCDF exceeds the 90th percentile with 90% confidence," and "population of estimates means a sufficient number of estimates generated so that the maximum estimate exceeds the 90th percentile with 90% confidence." (DOE-D, SNL-C)

7. It is suggested that the requirement of a minimum number of data points would usefully inhibit the formulation of probability distribution functions which are entirely subjective. The form and parameters of the probability distribution function should be justified objectively by its proponents. (NMAG-D)

8. In reference to the processing time required to meet the requirement of 95% confidence that the maximum CCDF exceeds the 99th percentile, DOE should present more than

unsupported assertions as to the nature of the distribution and the time to perform iterations. (NMAG-D)

9. Basing compliance on a single realization is recommended against. To arrive as a "best estimate" value for each of many variable parameters would be very difficult since the performance assessment includes multiple coupled nonlinear processes. (NMAG-D)

10. The test of 95% confidence to account for sampling error should be sufficient. (NMAG-E)

11. 40 CFR part 191 states that a comprehensive performance assessment would be the basis for determining reasonable expectation of compliance while 40 CFR part 194 states new requirements in §§194.21 through 194.27 for a basis for determining compliance. In addition, Appendix C of 40 CFR part 191 requires a single CCDF to show compliance while §194.34(d) requires only the mean CCDF. The proposed rule does not establish an adequate relationship with 40 CFR part 191 because it does not specify what the applicant must do to comply with 40 CFR part 191. (SNL-A, SNL-C)

12. Clarify if probability applies to events taken collectively, or taken individually. (NMAG-G)

Response to Issue 11.C:

As some of the comments correctly note, the population of CCDFs is the ensemble consisting of an infinite number of CCDFs. The Agency recognizes the limitations imposed by this infinite size, and as a result the final rule does not require a calculation of the population of CCDFs. Nonetheless, it is possible to make statements about the relationship of statistical features of finite number of CCDFs to features of this infinite population. One statistical feature of both the finite and the infinite group of CCDFs is the 99th percentile CCDF; specifically, this CCDF would exceed 99 out of 100 CCDFs. (As noted in an earlier response in this section, the 99th percentile CCDF may be a different CCDF at each different value of cumulative release, which is the horizontal axis on the CCDF.) This CCDF can be found simply enough with a finite group of CCDFs by ranking the CCDFs from highest to lowest and choosing the top one percent. For the infinite population, the value of this CCDF which exceeds 99 out of 100 CCDFs -- the "top one percent CCDF" -- cannot be determined due to the limits of computation.

Information about the infinite population of CCDFs is essential because the infinite population is a truer representation of the possible results of the performance assessment. In particular, information about the CCDF which exceeds the 99th percentile CCDF can be useful as well. In recognition of this, the Agency requires that the relationship be established between this CCDF from the finite group and that of the infinite population. In the final rule, this requirement is stated as the probability that the top one percent CCDF of the finite group be 95 percent likely to exceed 99 out of 100 CCDFs of the population. In other words, the highest-valued CCDFs that are generated by computer must be similar to the highest-valued

CCDF that would be found if the computers were run indefinitely. As noted, this cannot be determined by a direct comparison of numerical values of the CCDFs of the finite group and infinite population, since such values are impossible to calculate, but can be evaluated using standard statistical methods.

The Agency believes that this requirement is essential to provide assurance that the full range of possible results of the performance assessment be represented. To reiterate, the Agency agrees with concern raised by comments that the numerical values of the infinite group of CCDFs cannot be calculated. Nonetheless, these probabilistic relationships can be established with a finite number of CCDFs, and hence the Agency has retained these requirements.

Comments have expressed concern that DOE would be permitted to make non-conservative assumptions in its analyses of compliance with the containment requirements. The Agency has required that parameter values used in computing CCDF's be randomly selected from across the full range of possible values for that parameter. Such a requirement would preclude the Department from pre-selecting non-conservative values for parameters (values that predict relatively small releases of radionuclides) and generating a mean CCDF that is itself non-conservative.

Comments have stated that paragraph 194.34(b) of 40 CFR part 194 would require very large numbers of calculations to be performed and is thus impracticable. The Agency's requirement is less burdensome than was interpreted by these comments, however. This section requires that a sufficient number of CCDFs be generated by computer runs such that there be a high likelihood, .95 probability, that one of the CCDFs generated will exceed the 99th percentile. (As noted above, the 99th percentile denotes that CCDF which would be exceeded by only 1 in 100 CCDFs, if an infinite number or "population" were to be generated. As noted in an earlier response in this section, the 99th percentile CCDF may be a different CCDF at each value of cumulative release, which is the horizontal axis on the CCDF.) The comments mis-interpreted this requirement to mean that the numerical value of the 99th percentile must be determined to within a .95 probability. However, determining compliance with the Agency's requirement requires an evaluation of the statistical properties of the complete group of CCDFs generated. This calculation will likely require significantly fewer calculations than would a direct calculation of the value of the 99th percentile CCDF.

Some comments have stated that the Agency has not clarified the purpose of requiring that the 99th percentile be exceeded with .95 probability. In essence, this requirement ensures that a sufficient number of CCDFs are generated by computer runs such that the range of all possible CCDFs is represented. The notion of a "range" refers to the collection of CCDFs, starting with the CCDFs that predicts the smallest size of releases of radionuclides and ranging to the CCDF which predicts the largest size of releases. Requiring that this range of CCDFs is generated ensures that the mean CCDF will include a contribution from relatively "pessimistic" predictions of disposal system performance as well as "optimistic" predictions.

Some comments correctly state that the "population of CCDFs" as defined in 40 CFR part 194, is composed of an infinite number of CCDFs; therefore it cannot be calculated.

While this is indeed true, the final rule, 40 CFR part 194, does not contain any requirement that would necessitate generating this ensemble of infinite CCDFs. In actuality, all that is required to be included in the application is that a group of CCDFs that is finite in number be generated.

Other comments have requested clarification on the relationship between compliance with 40 CFR part 191 and the term "reasonable expectation." This term is used to designate that only a reasonable expectation of compliance, not absolute proof, is required since absolute proof of compliance cannot be achieved for such long-term predictions. This term appears in the containment requirements -- §191.13 of 40 CFR part 191 -- in which the Agency states that a reasonable expectation of compliance with the containment requirements is required on the basis of the record before the implementing agency.

Comments have also noted that the analyses will contain methodological value judgments which should also be evaluated by EPA. In judging the adequacy of these analyses, the EPA intends to review the numerical calculations of compliance as well as the non-numerical scientific judgments which accompany them.

Further comments have noted that recommendations contained in Appendix C of 40 CFR Part 191 with regard to which CCDF must comply with the containment requirements were not incorporated into 40 CFR part 194. Specifically, the comment states that Appendix C requires that the mean CCDF comply with the containment requirements without requiring that there be 95 percent confidence in this compliance. Appendix C recommends the use of CCDFs to determine compliance with the containment requirements but did not address the question of requiring a confidence level. Appendix C is non-binding guidance.

The EPA published the Appendix C guidance in 1985, before EPA was legally required to regulate the WIPP. The guidance was not designed with the WIPP specifically in mind. Hence, the assumptions presented do not necessarily reflect the site characteristics of the WIPP, but instead attempted to make statements that would apply to a repository located in any salt bed at any location in the United States. Further, the guidance was made general enough to apply to all three highly-radioactive types of waste: spent nuclear fuel, high-level radioactive waste (from reprocessing of spent fuel) and transuranic radioactive waste. Because of this generality, the guidance could not be tailored to fit the technical challenges posed by transuranic waste such as is proposed for disposal in the WIPP. This specific application of a general standard to a specific site with a unique set of technical challenges was part of the statutory mandate of 40 CFR part 194. Consider, for example, that 40 CFR part 194 contains a section on waste characterization that was designed by keeping in mind the highly heterogeneous character of the transuranic waste proposed for the WIPP. In developing 40 CFR Part 194, the Agency found that only some of the guidance of Appendix C had specific relevance to the WIPP. Today's action has been guided by only those aspects of Appendix C that the Agency has determined, based on technical and policy considerations, to be applicable to the WIPP.

Commenters have requested clarification regarding whether the threshold probability of 1 in 10,000 over 10,000 years, found at section 194.32 applies to individual or to categories of processes and events. For the purposes of this screening requirement, processes and events must be analyzed in the most general formulation possible; for example, the probability of dissolution must be set equal to the probability of all types of dissolution occurring anywhere in the Delaware Basin during the regulatory time frame. Performance assessments should, however, conduct separate analyses of the different dissolution fronts which occur in the Delaware Basin so as to account for the different hydrogeologic characteristics of each. To ensure that the analysis to exclude a process and event is sufficiently rigorous and documented, the final rule, at section 194.32(e) requires documentation showing why any processes and events or sequences and combinations of processes and events that may occur in the regulatory time frame and may affect the disposal system are not included in performance assessment results.

In the proposed rule, the Agency had requested comment on whether some alternate method for generating CCDFs might be found that used the results of only one iteration to test for compliance. Regardless of what method is chosen, to be appropriate for the performance assessments of the WIPP, the method chosen for calculating CCDFs must achieve at least two goals: the method must account for both the many different scenarios which can occur at the WIPP and the many values within its full range that each parameter can assume. As currently envisioned, each CCDF taken individually accounts for the impacts of many different scenarios, but uses the same set of values from the range of possible values of each parameter. Only by generating many CCDFs, each using newly chosen parameter values, can the full range of possible values of each parameter be considered. The Agency had sought comment on whether an alternate method of calculation could account for this full range of values. The Agency has concluded that, by requiring that large numbers of CCDFs be generated, and that all significant processes and events be considered, the requirements of the final rule will be sufficient ensure that the two goals mentioned above will be realized and therefore has declined to require an alternate method in the final rule.

Issue D: Procedures are overly-reliant on statistical theory.

1. One should be careful to avoid attempting textbook application of statistical methods to an extent that becomes unrealistic. (IV-D-51)

2. Reliance on probabilistic theory for project evaluation is inadequate and probably self-defeating. (CARD-B, A-43)

3. EPA should delete 40 CFR 194.34. EPA should require that the application include a discussion of alternative conceptual models, the conservatism employed, and the sensitivity of the results to parameter variations. EPA should use this information in making its decision on certification. (NRC)

4. The statistical criteria that EPA plans to apply to the population of CCDFs are ambiguous and inappropriate. The EPA instead should provide guidance to DOE on the level of detail in

the performance assessment results that EPA believes is adequate to allow judgments to be made on compliance with the containment requirements of 40 CFR part 194. (NRC)

5. The compliance criteria should not be overly restrictive on allowable sampling techniques. EPA should replace its requirements in 40 CFR 194.34 with guidance that allows that applicant flexibility in its choice of sampling techniques and methods for demonstrating the adequacy of the sampling strategy used. (NRC)

Response to Issue 11.D:

Some comments have questioned the appropriateness and the adequacy of the statistical requirements place on CCDFs. The Agency chose to include statistical requirements in the final rule because such requirements assess the reliability of the calculations used in performance assessments. For example, the requirement that the 99th percentile of the population of CCDFs must be .95 likely to be exceeded ensures that the computer generated CCDFs collectively will cover an appropriately broad range, from optimistic to pessimistic. Additionally, the final rule requires that the mean CCDF must comply with a 95 percent level of statistical confidence. This requirement provides assurance that the value of the mean can dependably reproduced if the calculations were repeated. The Agency believes that this additional assurance is essential as part of demonstrating that there is a reasonable expectation of compliance with the disposal regulations of 40 CFR part 191. The existence of the statistical requirements in no way indicates that the Agency will ignore the non-numerical aspects of the analysis. As one comment suggests, the Agency does intend to review the alternate conceptual models, DOE's analysis of parameter sensitivity and the appropriateness of conservative assumptions when evaluating the sufficiency of the application for certification.

The Agency recognizes that the statistical properties of the CCDF, by themselves, do not adequately assess the reliability of the entire performance assessment. To this end, for example, the Agency has required extensive documentation and rationales for various stages of the performance assessment, such as the selection and development of conceptual models. As a second example, the final rule places quality assurance requirements on, among other things, the data that will be used to calculate the CCDFs. The Agency will assess the degree to which these and all of the many other requirements are met by the compliance application during the rulemaking on certification conducted pursuant to section 8(d) of the WIPP Land Withdrawal Act.

The Agency believes requiring the chosen method to sample randomly from the full range of a parameter's value still leaves the DOE with sufficient flexibility. For example, the technique of Latin Hyper-cube Sampling (LHS) would be allowable under this requirement.

Issue E: The rule should require DOE to demonstrate compliance with the containment requirements with a percentile curve other than the mean.

1. The Agency must require DOE to show compliance with the containment requirement at the level of the 85th to 90th percentile. Probability distribution functions must be supported by data. (NMAG-D)

2. The use of the mean CCDF as the primary basis for determining compliance with the containment requirements may encourage DOE to produce many CCDF's with non-conservative assumptions in order to skew the mean. (SRIC-C, SRIC-E)

3. Compliance with the containment requirements of 40 CFR part 191 should be tested by a 95th percentile curve, with a 99% tolerance limit, in addition to the mean curve plus a 95% confidence limit. (NMAG-B)

4. The Agency should require that subjective uncertainty be resolved by basing a compliance determination on the 95th percentile value. (NMAG-F)

5. The selection of the determinative curve should be made with knowledge of the level of assurance which the Agency contemplated compliance would be shown. (NMAG-D)

6. The proposed rule and the Background Information Document (BID) could be construed to determine compliance on the basis of the 99th percentile rather than the mean, and are thereby inconsistent with § 194.34(d). (SNL-C)

7. A reasonable way to address the question of uncertainties is to carefully examine the range of fractiles corresponding to the mean in the consequence distribution (supplied by Sandia National Laboratories). In the WIPP case, the choice of the mean conditional on a set of hypotheses was based on the long-term nature of the project, the fact that the computation of the mean is more robust than that of specified fractiles, and that the means (given the uncertainties) are likely to be among the high-fractiles anyway. (NMAG-E)

8. Depending on how far the current means are (assuming full probabilistic treatment of hypotheses) from a reassuring (but not sacred) 95% fractile, it may be appropriate to ask for additional analysis or a change in risk management strategy. (NMAG-E)

Response to Issue 11.E:

The Agency declined to base compliance with the containment requirements on a percentile value, such as the 95th percentile, as suggested in the comments. Instead, the Agency chose the mean CCDF as the value which must be in compliance. In developing the proposed rule, the Agency considered basing compliance with the containment requirements on some point other than the mean. For example, the median (50th percentile) and other percentile values were considered as possible choices. The mean was determined preferable for two reasons. First, like the median, the mean is an indicator of the central tendency of the larger group or "family" of CCDFs. Second, the mean is more influenced by the CCDFs that predict the highest releases than other indicators of central tendency.

The final rule at 40 CFR part 194 requires that the mean or average value of all the CCDFs generated be compared to the quantitative containment requirements of section 13 of the disposal regulations at 40 CFR part 191. The containment requirements limit the sizes of releases of radionuclides that might occur over the 10,000-year regulatory time frame. The size of a release is calculated using the instructions in Appendix A of 40 CFR part 191 and represents a contribution from the predicted number of curies of each radionuclide that is predicted to be released over 10,000 years. Per the containment requirements, the mean CCDF cannot predict that a 10,000-years' release of size "one" is more than 10 percent likely to occur, or, further, that a release of size "ten" is more than 0.1 percent likely to occur. Releases of these sizes are of sufficient magnitude such that, were these releases predicted to be more likely than these small percentage values permit, the disposal system's ability to isolate waste would be questionable. The Agency will assess compliance by evaluating the value of the mean CCDFs at the two relevant sizes of release, one and ten.

Certain comments stated that the rule appeared to specify that the 99th percentile CCDF must comply with the containment requirements of 40 CFR part 191.13. (The 99th percentile denotes that CCDF which would be exceeded by only 1 in 100 CCDFs, if an infinite number or "population" were to be generated. This value can be estimated, but never determined by computer calculations.) In 40 CFR part 194, the Agency does not require that the 99th percentile CCDF be calculated, or compared to the containment requirements in order to assess compliance. Rather, the DOE must determine only the probability with which the 99th percentile will be exceeded. This differs from an actual calculation of the numerical value of the 99th percentile CCDF; the probability of exceeding that quantity is determined based on the statistical properties of the complete group of CCDFs. See also the responses to Issues 11.B and 11.C.

Issue F: The requirements for performance assessment are incomplete, because they consider only some types of uncertainty. DOE's analysis should also consider that the fundamental assumptions regarding radiation risk are not conservative.

1. The application for certification of compliance should also demonstrate that the assumptions underlying the performance assessment as to health effects of radiation exposure, exposure pathways, and release models are conservative. (NMAG-D)

2. The 1992 performance assessment constitutes a conditional risk assessment, predicated on certain fundamental assumptions. Whether the EPA assumptions or the DOE assumptions are conservative as judged by the outcome of a full probabilistic risk assessment of the WIPP repository is not known. It is important to find out what the level of release risk obtained given the combination of EPA and DOE assumptions and the results of the corresponding conditional risk analysis. (NMAG-E)

3. Because of the controversial nature of the treatment of epistemic uncertainties by Bayesian probabilities, the solution is often to do only what can be considered a partial uncertainty analysis, focusing on randomness in statistical samples and on distributions for the variables explicitly included in the model. (NMAG-E)

4. EPA cannot simply frame a conditional risk analysis based on certain assumptions and then claim without checking that the conditional means resulting from this analysis necessarily support "reasonable expectation" of human safety. EPA must show that the combination of "reasonable expectation" for the PA and conservatism (if it is so) of the health effect model provides "reasonable assurance" of actual safety. (NMAG-E)

5. EPA should be required to fully reveal the models that they have used to come up with the release standards and list all major assumptions that they have made; then to ask the applicants to show that the combination of these models, hypotheses and their own performance analysis supports the requirement that the current conditional mean is indeed "above" the marginal (overall) mean, and then altogether, the assumptions are in fact "conservative." (NMAG-E)

6. The application should contain a complete description and justification of performance assessment methodology, indicating the theoretical bases for the methodology and demonstrating the accuracy or conservatism. (NMAG-D)

7. DOE must identify the major hypotheses in its PA and show the effects of those hypotheses on the family of release curves. (NMAG-E)

8. The final rule should state that DOE include all of the methodological value judgments that were part of determining the range of CCDFs included in Performance Assessment. (CCNS-B)

Response to Issue 11.F:

Assumptions regarding radiation risks and the level of protection of human health were incorporated in the disposal regulations of 40 CFR part 191, Subparts B and C, as part of the underlying analysis used to establish the containment requirements, individual requirements, and ground water requirements. The criteria in 40 CFR part 194 are not intended to establish a new or more stringent level of protection, but to implement the level of protection embodied in the disposal regulations. The WIPP LWA calls for EPA in this rulemaking to implement (not to fundamentally re-examine) the binding disposal regulations, which were the product of extensive technical analysis, and have undergone public rulemaking and judicial review. The criteria do not and can not amend 40 CFR part 191.

The Agency included statistical compliance criteria on the results of performance assessments to provide an additional level of assurance that the mean CCDF is in compliance, if the performance assessment in fact demonstrates that this is the case. The Agency believes that this additional assurance is essential to demonstrating a reasonable expectation of compliance with the disposal regulations of 40 CFR part 191. The existence of the statistical requirements in no way indicates that the Agency will ignore the non-numerical aspects of the analysis. As one comment suggests, the Agency does intend to review the alternative conceptual models, DOE's analysis of parameter sensitivity and the appropriateness of conservative assumptions when evaluating the sufficiency of the application for certification.

Issue G: It is important to know where the mean would fall if methods other than expert elicitation were used to obtain probability distributions for input variables. (NMAG-E)

Issue H: Concerning the selection of variable parameters for PA, the test should be whether the variations of an input value across the possible range could change the final decision. (NMAG-E)

Response to Issues 11.G and 11.H:

The final rule requires that performance assessments must be conducted using computational techniques which draw random samples from across the entire range of probability distributions. As noted in the preamble to the final rule, parameters of lesser sensitivity in performance assessments may be held constant, provided that such constant values can be justified as sufficiently conservative. These requirements, combined with statistical measures on the maximum CCDF, ensure that CCDFs generated by performance assessments represent the full range of possible outcomes and do not allow for "optimistic" solutions to dominate. The Department is precluded from pre-selecting non-conservative values for parameters (values that predict relatively small releases of radionuclides) and generating a mean CCDF that is itself non-conservative.

Even if random sampling is conducted, the results of performance assessments can be affected by the assumed or measured distributions for input parameters. The distributions for some parameters may be established through expert elicitation processes, if the necessary information cannot be reasonably obtained through data collection or experimentation. To ensure that the results of expert elicitation represent the full range of technical views on topics, EPA has placed requirements on the composition of expert panels, and required that outside groups be allowed a reasonable opportunity to present technical views [§194.26]. The Agency believes these standards are sufficiently rigorous to ensure that expert elicitation will not produce parameter distributions which are unduly "optimistic" or unduly conservative. The Agency does not believe that expert elicitations will always produce results which are less conservative that actual values would be, if they were available.

Thus, the final rule contains several criteria to ensure that parameter distributions are developed and used in a manner that produces unbiased results for performance assessments. In most cases, it is not possible to determine how a parameter distribution determined through expert elicitation would differ if developed from actual data; in fact, if such data were readily available, a parameter distribution *could not* be established through expert elicitation, according to the requirements of the final rule.

Issue I: Identification of critical performance parameters to be included in a comprehensive list of criteria parameters that EPA will require in the application should be decided through colloquy between DOE, EPA, and New Mexico Environment Department (NMED). (SGNM-D)

Response to Issue 11.I:

The final rule requires that probability distributions for all uncertain parameters distributions be included in compliance applications. Parameters of lesser sensitivity in performance assessments may be held constant, provided that such constant values can be justified as sufficiently conservative, and that justification is included as part of the compliance application. The EPA has not chosen to specify in the rule what parameters must be addressed in performance assessment. The EPA may consult with outside parties, such as the New Mexico Department of Health. However, it would be inappropriate to discuss or assign consultative rights, in this rule, to parties that do regulate the long-term disposal of transuranic waste at the WIPP.

Section 12: HUMAN INTRUSION: SECTIONS 194.32 and 194.33

Issue A: Retain 40 CFR part 191, Appendix C.

1. Retain currently existing 40 CFR part 191, Appendix C to preempt a separate examination of each type of human-initiated process. (WEC-D)

2. No justification is given by the EPA on its decision to abandon the guidance provided in Appendix C of 40 CFR part 191. (DOE-D, WEC-A, C-12, A-56)

3. EPA's reversal on the applicability of Appendix C may lead to decisions that inadvertently increase safety and environmental risks associated with other DOE environmental clean-up activities. (WEC-A, C-29)

4. The limits set in 194.33(b)(4) are more stringent than the 40 CFR part 191 Appendix C guidance because the EPA has omitted the concept of drilling frequency per unit of repository area. Omitting this concept broadens the consideration of intrusion to cover the entire disposal system, which makes the required analyses more complex. (SNL-C)

5. Proposed abandonment of Appendix C to 40 CFR 191 will result in significant changes, costly retrofits, and significant schedule delays. (DOE-D)

6. It appears that EPA is attempting to of the proposed rule to change what has already been enacted into law in 40 CFR part 191, Appendix C. The changes may result in schedule delays and costly retrofits which could be devastating to programs at the generator sites. (IV-D-111)

7. Revise 40 CFR 194.43 to acknowledge that the assumptions used in the final disposal standards are valid. This includes the assumption [embodied in Appendix C] that systematic and persistent exploitation is deterred and the assumption that inadvertent intrusion can be deterred for as long as markers are effective. (DOE-E)

8. The consequences of human intrusion on disposal-system performance should be limited by the guidance to 40 CFR part 191. How the situation is modeled should be the DOE's responsibility to determine and defend. (SNL-D)

Response to Issue 12.A:

The EPA determined that it would be inappropriate to apply Appendix C in its entirety to the compliance criteria for several reasons. The Appendix C guidance to 40 CFR part 191 was deemed necessary because 40 CFR part 191 is a generally applicable standard, meaning that the standard applies to all disposal sites for spent fuel, high-level and transuranic waste repositories (except for Yucca Mountain or other sites characterized under section 113(a) of the Nuclear Waste Policy Act). To regulate an individual site, therefore, the Department or Agency that implements the standard would be required to develop criteria describing what

requirements must be fulfilled to demonstrate compliance with 40 CFR part 191 for that site in particular.

When EPA published the Appendix C guidance in 1985, the guidance was not designed with the WIPP specifically in mind. Hence, the assumptions presented do not necessarily reflect the site characteristics of the WIPP, but instead attempted to make statements that would apply to a repository located in any salt bed at any location in the United States. Further, the guidance was made general enough to apply to all three highly-radioactive types of waste: spent nuclear fuel, high-level radioactive waste (from reprocessing of spent fuel) and transuranic radioactive waste. Because of this generality, the guidance does not necessarily fit the technical issues posed by transuranic waste such as is proposed for disposal in the WIPP. For example, the final rule, 40 CFR part 194, contains a section on waste characterization that was designed by keeping in mind the highly heterogeneous character of the transuranic waste proposed for the WIPP.

The guidance is non-binding. The guidance was published in 1985 accompanied by a statement declaring it non-binding on the implementing agency, which became EPA in 1992 with the passage of the WIPP Land Withdrawal Act. Unlike 40 CFR part 191, the regulation which it accompanied, the guidance was not issued pursuant to the Administrative Procedure Act notice and comment rulemaking requirements. See 5 U.S.C. 553.

Accordingly, while Appendix C reflects the Agency's contemporaneous assumptions and recommendations regarding the implementation of the disposal regulations, EPA believes it should not follow the guidance without first examining whether it is consistent with the legally binding disposal regulations and determining whether it should apply in the specific circumstances associated with the WIPP. The Agency found in developing 40 CFR part 194 that only some of the guidance contained in Appendix C had specific relevance to the WIPP. For example, EPA determined that the screening criteria for including scenarios in performance assessments (e.g., probability greater than 1 in 10,000 over 10,000 years) was reasonable to incorporate in 40 CFR part 194 because the reasoning that led that screening criterion is not affected by specific conditions at the WIPP. Other aspects of Appendix C have not been applied to the WIPP because site-specific conditions invalidate the assumptions in the guidance. For instance, while EPA believes that inadvertent and intermittent intrusion by exploratory drilling for resources is the most severe scenario at the WIPP, EPA has also required consideration of excavation mining because there are economically viable resources currently being mined within the Delaware Basin. Similarly, EPA has found that current practice in the vicinity of the WIPP cannot support the assumptions that markers can deter all drilling for resource development, or that drilling methods are sufficient to soon warn intruders of the presence of the disposal system. Therefore, these and other positions described in Appendix C have not been adopted in the compliance criteria. The final rule and preamble clarify the instances when Appendix C has guided or informed the development of the WIPP compliance criteria. Given their relative legal standing, 40 CFR part 194 should everywhere be construed to supersede the Appendix C guidance.

Issue B: Definitions of "human intrusion" and "human activity" should be clarified.

1. The definition for "human intrusion" could be construed as extending the consideration of human intrusion to any location anywhere within the Delaware Basin. (SNL-A, SNL-C)

Response to Comment 12.B.1:

In performance assessments, scenarios involving human intrusion anywhere in the Delaware Basin must be analyzed if they could have an effect on the repository, per §194.32(a). Section 194.32 establishes the scope of processes and events that need be considered in performance assessments (PA). The final rule logically limits the scope of PA to those events that may affect the disposal system during the regulatory time frame [§194.32(a)]. The final rule has clarified the definitions of "human intrusion" and "human activity" as described below and elsewhere in this document.

2. The terms "human intrusion" and "human activity" should be used to replace "human-initiated processes". The expression "human-initiated processes and events (60 FR 5788)" is misleading because the only disruptions initiated by human beings that are to be considered in performance assessments are drilling events. (SNL-C)

3. The definitions for "human intrusion" and "human activities" are not consistent with the usage of related terms in the supporting documents that contributed to the development of the standard. For example, see Chapter D-4.0 in report EPA 520/4-79-007D. (SNL-C)

4. The definition of "human activity" overlaps the definition of "human intrusion" and both are inconsistent with 40 CFR part 191 Appendix C with regard to the location of the waste in the disposal system. Appendix C clearly refers to intrusions in the repository, not intrusions into the disposal system. (DOE-D, WEC-D, SNL-A, SNL-C)

5. Human activity should be defined as (1) drilling or mining for resource exploration; (2) drilling or mining for resource extraction; (3) drilling or mining for underground injection of fluids; (4) water use and management activities; (5) other human activities that could affect waste disposal system. (SRIC-A, SRIC-C)

6. "Human activity" should be defined to include activities which have as their target a horizon above the disposal rooms; "human intrusion" should mean all drilling which has as its target a horizon at or below the disposal rooms. (NMAG-B)

7. The Agency is requiring additional "human activity" events to be evaluated that go beyond the "human intrusion" events that have been evaluated by the program. These analysis of these human activity events would unnecessarily delay disposal of waste in the repository. (IV-D-40)

8. "Human activity" means those human activities that may affect the disposal system, but not necessarily intercept the repository; "human intrusion" means those human activities that

intercept the repository, except intentional drilling or mining with knowledge of the repository. (EEG-C)

9. By the proposed definitions, undisturbed performance would exclude human intrusion but include human activities, which is inconsistent with 40 CFR part 191. (SNL-C)

10. “Intentional intrusion” should be defined more clearly. (NMAG-G)

11. There is no such thing as “inadvertent” drilling; the meaning of “intermittent” is highly obscure. (NMAG-B)

12. It is recommended that evaluations of the "undisturbed performance” of the repository do not include any human-initiated processes and events. (NRC)

Response to Comments 12.B.2 through 12.B.12:

In §194.32 and §194.33 of the final rule, the Agency has provided further clarification on which activities fall within the scope of human intrusion, and, in response to public comments, has modified the terms used to avoid confusion. Section 194.33 of the final rule requires that two types of activities be analyzed -- deep drilling and shallow drilling. Deep drilling (referred to as “human intrusion” in the proposed rule) is defined as drilling events in the Delaware Basin that reach or exceed a depth of 2150 feet below the surface (the level of the waste in the disposal system). Shallow drilling (referred to as “human activity” in the proposed rule) is defined as those drilling events in the Delaware Basin that do not reach a depth of 2,150 feel below the surface relative to where such drilling occurred. Thus, in addition to revising the nomenclature to clarify its consideration of deep and shallow drilling, the final rule clarifies the depth at which an event is classified as deep or shallow, using the depth of the disposal system as the benchmark. However, EPA believes it is reasonable and practical to use the actual depth, not the target depth. The definitions of the terms are found in §194.2 of the final rule.

Consistent with the changes in defined terms, §194.33 in the final rule is titled *Consideration of drilling events in performance assessments* (rather than *Consideration of human-initiated processes and events*, the title used in the proposed rule). This clarifies the Agency’s intent that neither deep drilling nor shallow drilling events shall be considered in analyses of undisturbed performance of the disposal system. The term human intrusion should not be interpreted as being confined to drilling only. The preamble accompanying the final rule explains the various types of drilling activities encompassed by the terms deep and shallow drilling. Further, as discussed in §194.33(c)(1), those ancillary activities which are associated with drilling, such as borehole sealing, are within the scope of this term. In response to public comments, EPA has also required consideration of excavation mining events as described in §194.32(b).

The consideration of human intrusion is limited to those events which are made without knowledge of the repository’s presence. This type of event would constitute an “inadvertent

intrusion." Any disruptive event that might result from sabotage, for example, should be classified as an intentional intrusion and should not be analyzed.

Issue C: The rule should consider a broader range of activities as possibilities for human intrusion and human activity.

1. All types of mining and drilling (including potash) must be considered based on recent practices in the local area. (DOE-D, SGNM-A, EEG-B, EEG-C, NMAG-A, NMAG-B, CCNS-B, C-14, C-28, A-08, S-12, S-58, IV-D-13, IV-D-14, IV-D-15, IV-D-16, IV-D-17, IV-D-18, IV-D-19, IV-D-20, IV-D-21, IV-D-22, IV-D-23, IV-D-24, IV-D-25, IV-D-26, IV-D-30, IV-D-31, IV-D-32, IV-D-33, IV-D-34, IV-D-35, IV-D-37, IV-D-38, IV-D-42, IV-D-43, IV-D-46, IV-D-47, IV-D-48, IV-D-52, IV-D-53, IV-D-54, IV-D-55, IV-D-56, IV-D-57, IV-D-58, IV-D-59, IV-D-60, IV-D-61, IV-D-62, IV-D-63, IV-D-66, IV-D-67, IV-D-68, IV-D-69, IV-D-70, IV-D-71, IV-D-72, IV-D-74, IV-D-75, IV-D-79, IV-D-80, IV-D-83, IV-D-87, IV-D-88, IV-D-92, IV-D-99)

2. EPA should require in the criteria consideration of the potential effects of mining on the WIPP disposal system. (SGNM-C, EEG-A, EEG-B, NMAG-B, SRIC-G)

3. The human intrusion criteria need to include future mining, future oil and gas drilling. (NMAG-B, S-12)

4. Delete Section 194.33(b)(1). This WIPP site requires a full consideration of existing and anticipated activities and can not be limited to drilling as the most severe scenario. (EEG-C)

5. The following subsections should be added to Section 194.33(b)(3)(ii):
   (B) Underground blowouts during drilling.
   (C) Water and brine injection adjacent to the WIPP Site.
   (D) Fluid injection to enhance petroleum recovery on adjacent properties.
   (E) Human induced crossflow between formations.
   (F) Actual well abandonment practices on BLM properties. (EEG-C)

6. It is incumbent upon EPA to look closely at how EPA addresses secondary oil recovery by water flooding in surrounding areas. (SGNM-C)

7. Add the following subsections to Section 194.33(b)(6)(b):
   (3) Water flooding for petroleum resources within five miles of the WIPP Site Boundary and within the WIPP Site will reflect the experience in Southeast New Mexico in fields overlain by the Salado Formation.
   (4) Potash will be mined by either conventional methods or by solution mining.
   (5) Assumptions about well abandonment practices will follow the future states assumption. (EEG-C)

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

activities. The exclusion of "human activity" from analysis of individual and ground-water protection would not be justified. (NMAG-D)

9. EPA should require the facility to demonstrate compliance under conditions of nearby solution mining in addition to multiple boreholes penetrating the site. (SRIC-G)

10. Let the DOE decide for themselves what is the most severe human intrusion. Do not let them off of the hook by limiting their scope of considerations. (NMAG-G, IV-D-06)

11. The compliance criteria on mining and drilling are not stringent enough. (A-01, A-08, A-18, A-26, A-46)

12. It is suggested that EPA exclude site characterization activities from contributing to rates of human intrusion or human interference with the repository. (NRC)

Response to Issue 12.C:

The final rule requires consideration of oil and gas drilling and various other drilling activity, whether deep or shallow, that involve creating a borehole. In response to public comments, EPA has expanded the scope of human intrusion compared to the requirements of the proposed rule. The final rule requires that DOE specifically consider the effects of deep drilling, shallow drilling, and mining in performance assessments. In addition, performance assessments must account for the potential effects over the regulatory time frame of boreholes and other resource extraction activities which exist at the time the compliance application is prepared.

Many comments suggested that analysis of the long-term effects of conventional mining performed using shafts and tunnels should be required. The proposed rule had excluded excavation mining from consideration, but EPA has re-evaluated this position in light of numerous public comments on this issue. On the one hand, EPA believes its position in the proposed rule that inadvertent and intermittent intrusion by drilling for resources is the most severe and therefore the most important human intrusion scenario to be examined. Nevertheless, some known natural resources in the vicinity of the disposal system can be extracted by mining. These resources lie within geologic formations found at significantly shallower depths than the mined portion of the disposal system, and do not lie vertically above the repository. Thus, mining could not result in direct penetration of waste drums in the disposal system. However, EPA believes that mining could alter the hydrologic properties of overlying formations -- including the most transmissive layer (for groundwater travel) in the disposal system, the Culebra dolomite -- so as to either increase or decrease ground water travel times to the accessible environment. For the purposes of modeling these hydrologic properties, this change can be well represented by making corresponding changes in the values for the hydraulic conductivity, or the rate at which water moves through the geologic units of the disposal system. The Agency has conducted a review of the data and scientific literature discussing the effects mining can induce in the hydrologic properties of a formation. Based on its review of available information, the Agency expects that mining can, in some

instances, increase the hydraulic conductivity of overlying formations by as much as a factor of 1000, although smaller or even negligible changes can also be expected to occur.

The final rule requires DOE to consider the effects of mining in performance assessments (PA). The assessment by DOE of the effects of mining may be limited to changes in the hydraulic conductivity of the hydrogeologic units of the disposal system from excavation mining for natural resources [§194.32(b)]. Thus, in order to consider the effects of mining, DOE may use the location-specific values of hydraulic conductivity (established for the different spatial locations within the Culebra dolomite), and treat them as sampled parameters with each having a range of values varying between unchanged and increased 1000-fold relative to the value that would exist in the absence of mining. The Agency recognizes that other numerical changes to the hydraulic conductivity values might be more appropriate for use in representing the effects of mining. If DOE were to use other values, then the Department would need to support those values in the compliance application. The Agency further recognizes that some parameter other than hydraulic conductivity might be demonstrated to incorporate, equally and perhaps better, the potential effects of mining in PA. The DOE may elect to use another parameter, provided that DOE can demonstrate that the use of this parameter is equally or more appropriate than hydraulic conductivity in reflecting the potential effects of mining on the disposal system. The final rule and preamble require that the effects of mining be analyzed as described above. The consideration of mining in terms of the effects of examining excavation mining on hydraulic conductivity is consistent with the Agency's position that resource-specific extraction techniques cannot be assumed to occur in the future except in a very general way (i.e., digging a hole for mining, or drilling a hole). This principle is discussed in greater detail in the following paragraphs.

Comments also suggested that the final rule require analysis of disposal of brine that accumulated during the extraction of oil and of secondary recovery of oil performed using water-flood injection. The Agency considered this comment in the larger context of the nature of potential human intrusion during the 10,000-year regulatory time frame, and of what assumptions might hold true during that time. First, the Agency recognized that, because oil is a depletable resource, the techniques specific to its extraction are unlikely to be in use during much of the 10,000-year regulatory time frame. Nonetheless, the Agency must still provide a method by which to establish the future drilling rate. To accomplish this, the Agency assumes that today's drilling activities will act as surrogates for the type of drilling activity that will occur in the future. Specifically, while the resources drilled for today may not resemble those drilled for in the future, the Agency believes it is reasonable for the average rate to be projected over the next 10,000 years, based on the assumption that while oil and natural gas may be depleted, other resources (which are not currently economical to recover, or whose uses are not yet evident) may become more valuable. This assumption leads to the conclusions that it is reasonable to project oil and gas drilling rates (based on the historical record) over the regulatory time frame; and second, that since these rates are surrogates for other potential resources, it is inappropriate to include consequences of activities or secondary recovery techniques specific to oil drilling. Thus, over the long term the final rule requires consideration of making a borehole, but not the specific techniques that might be used to recover a particular resource. However, in the short-term, some limited

predictions can be made. Specifically, there are existing oil leases surrounding the WIPP and it is likely that they will ultimately be developed. Therefore, the final rule at §194.32(c) requires consideration of any activities that occur in the vicinity of the disposal system prior to disposal as well as activities that are expected to occur soon after disposal, including fluid injection activities.

Similarly, the historical record of the past 100 years of resource extraction activities in the Delaware Basin provides a reasonable basis for predicting the nature of future mining activity. Accordingly, the Agency examined the records of past mining of mineral resources in the Delaware Basin, using data supplied by the U.S. Bureau of Land Management. The Agency found that the areal extent of mining in the immediate vicinity of the WIPP over the past 100 years covered roughly one percent of the land area of the entire Delaware Basin and used this information to predict the likelihood that a mining event would occur in succeeding centuries. Accordingly, the final rule requires performance assessments to assume that, in each century after closure of the repository, there will be a 1 in 100 chance that a single mining event will occur within the controlled area. The assumed mining event would remove all of the existing mineral deposits lying within the controlled area that are of similar quality and type to those minerals currently extracted in the Delaware Basin. The mineral deposits that will be mined in the future may consist of minerals of current economic interest, or of materials not useful or valuable in present-day terms. The final rule specifies that mining should be assumed to occur within the controlled area, with the size and shape of the mine conforming to existing mineral deposits, because it would be too speculative to use other means to try to establish the size and shape of future mines. Thus, EPA has chosen to use existing mineral deposits as "stand-ins" to be used to determine the size, shape and depth of the unknown mineral deposits that might be mined in the future.

In summary, the final rule requires that, when determining the drill rate, DOE must include all boreholes used for exploration or recovery of resources in the Delaware Basin, including those used for secondary recovery. (However, a borehole should not be "counted" twice, if it was used for more than one purpose -- e.g., for both exploration and recovery.) In addition, boreholes drilled for the purpose of site characterization should not be used in calculating future drilling rates. Analyses of the consequences of drilling events should be confined only to the drilling activity (i.e., making a hole) and the subsequent effect of the borehole's presence (including the likelihood it is sealed and the type of seal it has), but need not include an analysis of extraction and recovery activities which would occur subsequently. In a similar fashion, the chance of a mining event occurring in the controlled area during the regulatory time frame is based on the historical record of the past 100 years of resource extraction activities in the Delaware Basin. The size and location of the mining event is based on existing minerals deposits similar in quality and type to those currently being extracted in the Delaware Basin. Finally, the consequences of mining events are confined only to the effects of making a hole -- i.e., changes in hydraulic conductivity, but do not include an analysis of extraction and recovery activities which occur subsequently. A more detailed analysis of the potential effects is not appropriate because it would overrely on the exact method used for mining.

The Agency recognizes that resource extraction and fluid injection activities which are currently performed in the Delaware Basin can alter the hydrogeologic properties of the initial state of the disposal system (i.e., at the start of the 10,000-year regulatory time frame). The final rule requires that performance assessments and compliance assessments must include the effects of all types of fluid injection (including solution mining) and all boreholes which can have an effect on the disposal system and which have been or will have been drilled prior to or soon after disposal, based on existing plans and leases for drilling. See paragraph 194.32(c). Those boreholes shall be assumed to affect the properties of the disposal system for the entire 10,000-year time frame.

The final rule also requires consideration of well abandonment practices, as suggested by commenters. The final rule requires performance assessments to assume over the regulatory time frame that the fraction of boreholes that are sealed by humans are consistent with current practices in the Delaware Basin.

Issue D: Limits on drilling rates should be dropped or modified.

1. Maximum and minimum drilling rates are arbitrary and indefensible. (DOE-A, EEG-A, EEG-B, SNL-A, SNL-C, SRIC-C, A-43, A-45, A-48, S-11, S-12, S-17, S-39, IV-D-35)

2. It is recommended that EPA refine its application of bounds on the drilling rates used in the performance assessment. EPA should establish bounds on the drilling rates used in the performance assessment using available drilling rate information, rather than rates using the rates assumed in the derivation of the generally applicable environmental standard. (NRC)

3. The minimum drilling rate in §194.33(b)(4)(ii) is reasonable. (EEG-D)

4. The number of boreholes per square kilometer may not be enough due to secondary oil recovery which may have as much as 41 boreholes per km^2 x 2.5 = 102.5. (SGNM-D)

5. To be consistent with the earlier guidance provided in 40 CFR part 191, the guidance in 40 CFR part 194.33 should re-establish the upper limit of inadvertent and intermittent exploratory drilling for natural resources at 30 boreholes/km^2 of repository area/10,000 years as the most reasonable worst-case assumption. The guidance should not include a lower limit different from that in Appendix C to 40 CFR part 191. (SNL-D)

Response to Issue 12.D:

The final rule eliminates the proposed upper cap and lower cap (62.5 or 25 boreholes per square kilometer per 10,000 years, respectively) on the rate of deep drilling into the disposal system. The Agency concluded that the rate of drilling into the disposal system used in performance assessments should be derived solely from the historical record of drilling in the region surrounding the WIPP and are not bounded by rates assumed in the derivation of the general disposal regulations. The future rate of drilling is based on the average rate of actual drilling in the Delaware Basin in the past, and is not based on the maximum drilling density

allowed by current drilling regulations (which, as noted in a comment, is 41 boreholes per square kilometer). The final rule specifies that the rates of both deep drilling and shallow drilling are to be set based on data from the 100-year record of resource extraction activities ending at the time when DOE prepares the compliance application.

Issue E: Borehole sealing assumptions should be based on current practices. (WEC-D, SNL-C)

Response to Issue 12.E:

The treatment of sealing of boreholes must assume, per §194.33(c) of the final rule, that borehole depths, diameters and seals will remain consistent with current practice in the Delaware Basin. In addition, an examination of current practice must be used to determine the fraction of boreholes which are sealed by humans (as opposed to natural processes).

Issue F: The 50 year time frame for drilling rates is inappropriate.

1. The past 200 years should be used for the Delaware Basin. (C-14)

2. Use 100-year time frame since this is the period of known drilling in Delaware Basin. (A-45)

3. The 50-year period for drilling rates in the Delaware Basin is inappropriate. (S-47)

4. Change the 50-year time frame to state "the complete time period during which exploratory drilling has occurred in the Delaware Basin." No rationale is given for selecting this 50-year time period. (SNL-C)

5. Using the record over the past 50-year time frame is inappropriate because resources will become more desirable due to scarcity in the future. (C-03)

6. Use 75-year human-initiated event period rather than 50 years. The total rate of human intrusion should be the sum of the rates of each type of human intrusion. (DOE-D)

7. Compliance criteria should evaluate all human intrusions using the analysis of historic record which Criteria currently recommend only for its human activity estimations. (CCNS-B)

Response to Issue 12.F:

Because future drilling is treated probabilistically in the disposal regulations, the criteria must establish a rate of drilling to be projected into the future. The Agency notes that any rate is expressed as a quantity per time, such as miles per hour. Therefore, it is necessary to divide the number of boreholes by a time period so that drilling can be expressed as boreholes per area per year. (The drill rate is expressed as boreholes *per area* per year, which also requires division by an area; this decision is discussed in the response to Issue 12.G.) In the proposed

rule, the Agency suggested that the past 50 years of drilling history be used to establish the historical record of drilling in the region surrounding the WIPP. The Agency also proposed to bound this rate based on drilling rate assumptions made in deriving the general disposal regulations. Several comments suggest that other time frames would be more appropriate.

The Agency recognizes that some resources may become scarce or may increase or decrease in economic value in the future, but believes that no basis exists that would permit speculation about such changes and their effects on fluctuations in future drill rates. The extrapolation for 10,000 years of the average drill rates, calculated from a fixed period in the past, may be based on reliable data, and foregoes the need for unbounded speculation. Because the historical drilling rate will be applied over a 10,000-year regulatory time frame, acting as a surrogate for unknown future resources (not solely oil or natural gas), EPA believes it is appropriate to use the longest historical record for which reliable drilling data is available. That is, EPA recognized that drilling activity has been at a maximum in the past 50 years because of intense exploration and development of petroleum resources. Examination of drilling records for the past 100 years shows a broader range of drilling rates, more appropriate for application over the long-term future, when it can be expected that drilling rates will consist of periods of high and low drilling activity, as specific resources may become more or less valuable. Further examination of available records in Texas and New Mexico led the Agency to conclude that reliable data for drilling in the Delaware Basin can be found dating back nearly 100 years. Therefore, the final rule specifies that the rates of both shallow drilling and deep drilling are to be set based on data from the 100-year period ending at the time DOE prepares the compliance application.

Issue G: The Delaware Basin should be carefully defined in the rule.

1. Subareas of the Delaware Basin may be used to develop historical drilling rates if their structural characteristics are similar to those of the WIPP site. (SNL-C, C-4)

2. The Capitan reef should not be included in the Delaware Basin because this inclusion would result in higher drilling rates. (DOE-D, SNL-C)

3. The Delaware Basin should be defined as the area of sedimentary rock within the inner boundary of surface and subsurface expressions of the Capitan Reef, and the projection of the reef where it's absent to form an enclosed basin. (DOE-D, DOE-E)

4. It is inappropriate to exclude the Capitan Reef from the definition of the Delaware Basin. The reality of the Delaware Basin being a leading potash mining area must be recognized in certifying whether or not WIPP will comply with the disposal regulations. (SRIC-C)

5. The Delaware Basin, as defined in the geologic community, appears to be reasonable. Whether the entire basin should be used, or a subset, depends upon what a drilling activity map looks like. (A-29, IV-D-51)

6. The rule should state that the Delaware Basin includes all the surface and subsurface areas within the central basin area and the area overlying the Capitan Reef. (NMAG-D)

7. The definition of the Delaware Basin should exclude the Captain Reef and the immediately adjacent sedimentary rocks deformed by the presence of the reef. (SNL-D)

8. In reference to a definition of the Delaware Basin, a 1955 source was used to characterize the Salado Sea. It would be advisable to research a more current author. (SGNM-D)

Response to Issue 12.G:

The final rule includes a definition of the term "Delaware Basin," used to establish the area over which past drilling is to be averaged in order to calculate the rate of drilling used in performance assessments of the 10,000-year regulatory time frame. Many comments discuss whether the Capitan Reef should or should not be included as part of the "Delaware Basin." In arriving at its decision on this issue, the Agency weighed these concerns and re-examined information on the geologic and hydrologic formations which contain the WIPP versus those of the Capitan Reef. The EPA determined that the Capitan Reef is more permeable to the flow of water and was formed from organic material which differs markedly from the salt formation that immediately surrounds the WIPP. In addition, as noted in several comments, the reef's distinct structural characteristics influence the type and quality of resources found there, as compared with the interior of the Delaware Basin. Thus, the Capitan Reef differs markedly from the interior of the Delaware Basin in terms of geology, hydrology, and natural resources. Because the "Delaware Basin" defined in the rule will be used to derive historical drilling rates to be used in performance assessments, EPA believes that the area defined by the term should fully encompass the area within the vicinity of the WIPP, be sufficiently large to provide a reliable population of data, and be representative of the characteristics of the WIPP site. For these reasons, consistent with its stated intent to define the Basin to be the largest contiguous area that has similar geologic properties to the WIPP, the final rule defines the Delaware Basin as those formations which lie inside the inner-most edge of the Capitan Reef. In those places along the perimeter where the Capitan Reef is absent, the boundary of the Delaware Basin shall be those features lying on a straight line drawn from the southeastern point of the Davis Mountains to the most southwestern point of the Glass Mountains. This definition can be found in the final rule at §194.2. This encompasses an area of approximately 9700 square miles. The Background Information Document for the final rule describes the information sources used to define the boundaries of the Delaware Basin and Capitan Reef; the Agency has made every effort to update references. Regarding mining, the chance of mining in the future has been based on the historical record of mining over the past 100 years in the Delaware Basin, as defined in the final rule; see response to Issue 12.C for further discussion of the treatment of mining in the final rule.

Issue H: Treatment of human intrusion is not satisfactory.

1. It should be assumed with certainty that there will be human intrusion. DOE's performance assessment should analyze the various reasonable human intrusion scenarios for their consequences and for potential mitigation measures. (SRIC-F)

2. The rule provides unrealistic limitations related to the possibility of human intrusion. (C-29)

3. The human intrusion scenario is unrealistic. (WEC-A, C-03, C-14)

4. It is very difficult to predict the likelihood of human intrusion in the next 10,000 to 240,000 years. (IV-D-05)

5. The human intrusion scenarios should increase the likelihood of intrusion. (A-53)

6. Intrusion scenarios must be considered with as much realism as possible. (S-37)

7. What kind of guarantees do we have that the human-intrusion scenario has been considered with the utmost seriousness? (S-11)

8. DOE has been generally silent about the expert panel's predictions on inadvertent human intrusion in the WIPP. (IV-D-05)

9. The proposed rule should be based on a smaller borehole density and a realistic assessment of future drilling activities, perhaps 40 acres per borehole for oil drilling and 10 acres for tertiary recovery. (IV-D-40)

Response to Issue 12.H:

The Agency has developed the human intrusion criteria to prevent unbounded speculation about future drilling, while at the same time accounting for the presence of natural resources near the WIPP (and the associated potential for future human intrusion). The Agency does not believe it is possible to state with absolute certainty that human intrusion will penetrate the disposal system, just as EPA does not believe it is supportable to declare that human intrusion will definitely not disturb the disposal system. Thus, EPA established systematic methods to estimate future drilling rates and mining probabilities and consequences as realistically as possible, while limiting highly uncertain speculation about the future.

For example, the final rule states that drilling should be assumed to occur randomly in space, rather than assuming that current drilling patterns -- based primarily on oil -- will endure throughout the regulatory time frame. The final rule requires that performance assessments analyze human intrusion, in recognition of the history of drilling for resources in the Delaware Basin. As discussed in the response to Issue 12.C, the Agency assumes that today's drilling activities will act as surrogates for the type of drilling activity that will occur in the future.

Because the resources drilled for today may not resemble those drilled for in the future, and since these historical rates are surrogates for other potential resources, it is inappropriate to include consequences of activities or secondary recovery techniques specific to oil drilling.

In order to make drill rates as objective and site-specific as possible, the Agency concluded that the rate of drilling into the disposal system used in performance assessments should be derived solely from the historical record of drilling in the region surrounding the WIPP. The final rule eliminates the proposed upper cap and lower cap (62.5 or 25 boreholes per square kilometer per 10,000 years, respectively) on the rate of deep drilling into the disposal system. The final rule specifies that the rates of both deep drilling and shallow drilling are to be set based on data from the 100-year period ending at the time when DOE prepares the compliance application.

The requirements in the final rule regarding treatment of mining in performance assessments are also based on historical records and current practices in order to minimize speculation about the patterns and methods of future mining. As with drilling scenarios, the minerals currently mined in the Delaware Basin act as a surrogate for future minable resources, since it is not possible to predict what those might be. The probability of mining occurring in any given century during the regulatory time frame is derived from the historical record of mining in the Delaware Basin over the past 100 years. The size and shape of a future mine in the controlled area is based on currently mined resources in the Basin; it would be extremely speculative to try to establish with other methods what such a mine would look like, since the size and shape of mines are highly irregular. As noted in the response to Issue 12.C, analysis of the consequences of mining are limited to changes in hydraulic conductivity -- the effects of "making a hole." The DOE is not required to examine resource recovery techniques such as solution mining, since these methods depend on the specific resource being mined.

The EPA does recognize that resource extraction and fluid injection activities which are currently performed in the Delaware Basin could alter the hydrogeologic properties of the initial state of the disposal system. Thus, while the consequences of such activities will not be analyzed under future human intrusion scenarios, performance assessments and compliance assessments must analyze the effects of all types of fluid-injection and all boreholes which can have an effect on the disposal system and which have been or will have been drilled prior to or soon after closure. These boreholes shall be assumed to affect the properties of the disposal system for the entire 10,000-year regulatory time frame. The Agency believes that the final rule provides an objective and reasonable method to project the effects of drilling and mining activities for unknown future resources over the regulatory time frame.

Issue I: Other issues with regard to drilling need to be addressed.

1. Only exploratory drilling is inadvertent and intermittent and this is the only drilling that should be considered. (DOE-D, SNL-C)

2. It is unrealistic to assume that in the drilling of an exploratory well, the core would not be examined and the waste discovered. (C-14)

3. "Exploratory well" and "development" should be added as definitions to distinguish which human intrusions are intentional and those that could be inadvertent. (WEC-D)

4. 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. (DOE-E)

5. There is no reason to believe that any type of well would be less intrusive than any other type of well drilled through the repository. Non-exploratory holes should be used to project future drilling rates. (SGNM-D)

6. The mode of human intrusion that will be considered in performance assessments should be exclusively limited to inadvertent and intermittent exploratory drilling for natural resources. Any incorporation of human-initiated processes and events, other that exploratory drilling for resources, in 40 CFR part 194, would result in an unjustified departure from the bases and assumptions applied during the promulgation of 40 CFR part 191. (SNL-D)

7. Consistent with the underlying rationale of the guidance to 40 CFR part 191, the consideration of human intrusion in performance assessment analyses should be limited to inadvertent and intermittent exploratory drilling for natural resources. (SNL-D)

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

9. 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. (DOE-E)

10. The simple deletion of the word “exploratory” in §194.33(b)(1) has expanded the range of human-initiated processes and events to include frequency estimates for developmental and production activities, as well as for exploratory drilling. Appendix C guidance reflects the Agency’s assumptions relative to human intrusion and should be retained, unchanged, in 40 CFR part 191. (IV-D-112)

11. The application of drilling rates for all types of drilling is more restrictive (i.e., results in a more restrictive interpretation of 40 CFR part 191) than the application of drilling rates for exploratory drilling. The reasoning for this deviation from the intent of the original rule is not explained by the EPA, giving the impression that the EPA is arbitrarily reversing its policy without having a rational basis for the reversal. (SNL-D)

12. It is recommended that "human intrusion" and "human activity" include only exploratory drilling (without resource extraction). (NRC)

Response to Comments 12.I.1 through 12.I.12.:

The Agency does not exempt developmental wells from being included in the calculation of the rate of human intrusion. Several comments suggested that by including consideration of developmental wells, EPA was violating the assumptions outlined in the Appendix C guidance to the disposal regulations. As noted in the response to Issue 12.A of this document, EPA determined that it would be inappropriate to apply Appendix C in its entirety to the compliance criteria for several reasons. First, the guidance is non-binding on the implementing agency, in this case EPA. Second, Appendix C was not designed to apply to the specific characteristics of the WIPP site or of transuranic waste. As a result, the Agency found in developing 40 CFR part 194 that only some of the guidance contained in Appendix C had specific relevance to the WIPP.

The Appendix C guidance provides that "inadvertent and intermittent intrusion by exploratory drilling for resources...can be the most severe scenario assumed by the implementing agencies." The commenters provide insufficient evidence, based on current drilling practice, to support the conclusion that developmental drilling that may affect the disposal system will be precluded by exploratory drilling. Future exploratory wells that find resources yet miss the disposal system may nonetheless be followed by several developmental wells, any of which could strike the waste in the disposal system. One cannot assume that, out of one set of exploratory wells plus associated developmental wells, the exploratory wells would be the first to affect the disposal system or that even if an exploratory well detected waste, that associated development would necessarily be abated. In determining the drilling rate, performance assessments therefore may not assume that drill operators would detect the waste during exploration and then cease the current drilling or otherwise mitigate the consequence of their actions. Even if future drilling practices were such that the disposal system would be detected by drill operators, the disposal system may not be discovered until after several developmental wells have been drilled. Hence, the Agency declines to exclude developmental wells when establishing the historical drilling rate for use in performance assessments.

13. It is certain that human intrusion that passes through the Salado Formation will encounter large amounts of brine under sufficient pressure to flow to the surface. (SRIC-F)

14. Claiming to understand the brine in the Castile formation based on only two boreholes is ludicrous. (CARD-B, A-12, S-21)

Response to Comments 12.I.13 and 12.I.14:

The final rule requires that performance assessments shall consider natural processes and events, mining, deep drilling, and shallow drilling that may affect the disposal system during the regulatory time frame. The analysis of consequences for excavation mining has been limited to changes in hydraulic conductivity. The examination of the consequences of drilling may be limited to the effects of "drilling the hole," and need not consider specific resource recovery techniques for future drilling events. The final rule has not established other

limitations on the analysis of consequences, and has not dictated what specific release scenarios must be included in PA. Pursuant to §194.32(a), performance assessments shall consider processes and events that may affect the disposal system during the regulatory time frame; any decision to exclude processes, events, or sequences and combinations of processes and events from analysis under PA must be documented and justified [see §194.32(e)]. Further, §194.14 and §194.25 require detailed information relative to the geology and hydrology of the disposal system. As part of its review of any compliance application, EPA will examine all information contained therein and determine if the conclusions drawn are consistent with the quality and breadth of the available data described in the application.

Issue J: Clarifications are needed regarding "current practice" for drilling and borehole sealing practices.

1. The Agency must make clear how the "current practice in the Delaware Basin (§194.33(b)(6))" and the borehole sealing (§194.33(b)(1)) will be established. (NMAG-D)

2. The following should be added to §194.33(b)(6) "seals will isolate all ground water zones consistent with the NM State Engineer's Rules and 4-20.2 &4-19.1." (SGNM-D)

3. To be consistent with §194.33(b)(6), the wording of paragraph 194.33(c)(1) should be revised to read: Boreholes will be sealed at a rate consistent with regulatory requirements of the State of New Mexico for the Delaware Basin when the certification application is submitted. (SNL-D)

Response to Comments 12.J.1 through 12.J.3:

The final rule states that, in performance assessments, the Department shall assume that future drilling practices and technology will remain consistent with practices in the Delaware Basin at the time a compliance application is prepared [§194.33(c)(1)]. The rule further states that such drilling practices shall include (but not be limited to) the types and amounts of drilling fluids; borehole depths, diameters, and seals; and the fraction of such boreholes that are sealed by humans. Such drilling practices shall not include techniques used for resources recovery subsequent to the drilling of the borehole, since performance assessments are required to analyze the consequences only of drilling a borehole. The analyses of current practice must be substantiated in any compliance application, showing references and the factual basis used to establish "current practice." The Agency believes that the criteria in the final rule provide adequate direction to DOE.

The human intrusion criteria are used to establish drilling rates and assumptions regarding the consequences of potential future drilling over the 10,000-year regulatory time frame. The rate and the consequences are based on past and current practices, because EPA believes that they are appropriate surrogates for exploration and recovery of future resources which may or may not be similar to resources currently being extracted.

4. In §194.33(second b)(2), a reference to the existence of older, abandoned wells including the drilling, completion, and plugging procedures in use at the time and the potential for degradation should be made. (SGNM-D)

Response to Comment 12.J.4:

The final rule requires DOE to examine the effects of activities that occur in the vicinity of the disposal system prior to disposal and of activities that are expected to occur in the vicinity of the disposal system soon after disposal. The boreholes resulting from such activities shall be analyzed for their effects on the properties of the disposal system for the entire 10,000-year regulatory time frame. Predictions about the effects of such existing boreholes should be based on the actual characteristics of the boreholes, as far as it is practicable to determine them. Such characteristics would include drilling, completion, and plugging procedures.

Issue K: The probability of second and subsequent human-initiated processes and events should be adjusted upwards from the random value to reflect the success of the initial intrusion. (NMAG-D)

1. Why should human-initiated processes occur at random intervals in space? Exploration for mineral resources has always been a structured and planned exercise. (C-28)

Response to Issue 12.K:

The proposed rule would have required that drilling in performance assessments be assumed to occur at random intervals in space and in time. This approach would not allow for assumptions that drilling would occur in specific patterns, either on land area or over time. Some comments suggested that the final rule should require performance assessments to assume that drilling will occur in cluster patterns similar to those which occur when a successful exploratory well is immediately followed by the drilling of several nearby developmental wells. The fact that drilling activity is planned does not mean that its placement or orientation can be predicted with confidence over 10,000 years. Conversely, an unsuccessful exploratory well could indicate a lack of useful resources and lead to a time period with reduced drilling rates or the absence of drilling activity in an area. Geophysical techniques may supplant reliance on exploratory drilling. Economic considerations, including factors unrelated to resource recovery, may affect an individual or organization's decision to drill or not drill in a particular time or place, as may land usage or land ownership factors.

In developing the final rule, the Agency considered that such patterns are associated with a specific resource; oil wells have their own distinct practices which may affect the configuration of exploratory and developmental boreholes. In contrast, other resources, such as water, employ different practices, and can have different orientations or can be devoid entirely of discernable patterns. As a further consideration, the Agency realized that it is nearly impossible to anticipate which resources not currently used may be of future interest. It is also doubtful that any one of today's resources will last for the entire 10,000-year regulatory time frame. Further, it is very difficult to predict to what extent resources currently

used but not present in economically viable quantities may have an economic demand in the future. The EPA believes there is little value in engaging in unsupportable speculation regarding what resources will be of interest over the next 10,000 years, whether there may be any associated drilling "pattern," or what constitutes a "typical" or "characteristic" drilling pattern. Therefore, the Agency has retained the requirement in the final rule that performance assessments assume drilling events to occur randomly in space (throughout the Delaware Basin) and time during the regulatory time frame [§194.33(b)(2)].

Issue L: Section 194.33(b)(4)(iv) should be deleted in response to DOE's concern about confusing language. (EEG-D)

Response to Issue 12.L:

The final rule retains the provision from the proposed rule which would have permitted DOE to decrease the rate of human intrusion in performance assessments, based on the forecasted effectiveness of passive institutional controls. The final rule allows the Department to propose reductions in the likelihood of future human intrusion that is used in performance assessment by an amount corresponding to the predicted effect of PICs, as demonstrated in the compliance application. The EPA has clarified in the preamble to the final rule that this reduction cannot be a 100 percent reduction and must be limited to no more than approximately 700 years past the time of disposal. This issue was addressed by the WIPP Review Committee of the National Advisory Council for Environmental Policy and Technology (NACEPT) at a public meeting in New Mexico in September, 1995. The Committee agreed that PICs are likely to have a positive influence on deterring intrusion for a relatively short time period and should be implemented at the site. However, like many commenters, the Committee expressed skepticism over whether such controls would be effective for more than a small fraction of the 10,000-year regulatory time frame. Hence, the final rule limits the time frame over which EPA may even consider approving credit to no more than approximately seven percent of the regulatory time frame, and such credit, or a smaller credit, will be approved only if DOE demonstrates, to the satisfaction of the Administrator, that the PICs described in the compliance application will be effective in reducing the likelihood of human intrusion. See Section 15 of this document for further information.

Issue M: In defining analogs to the controlled area for the purpose of establishing rates of human activity, the analog areas should have similar type and quality of resources as well as similar recoverable quantities as the controlled area. (SNL-D)

1. §194.33(b)(5)(ii) allows for the identification of analogs to the controlled area for the purpose of establishing rates of human activities while not fully describing the characteristics that make an area an analog. If 191.33(b)(5) is retained, an upper limit on the rate of human activity should be added and justified. (SNL-C)

Response to Issue 12.M:

The Agency recognizes that certain resources can vary in quality from one area to the next within the Delaware Basin, and that the uses for that resource can vary with that quality. For example, water that is unfit to drink may still be useable for dust control. The Agency also recognizes that the frequency with which water, for example, is extracted for one purpose may differ significantly from the rate it is extracted for other uses. The final rule allows for shallow drilling rates (referred to as "human activity" in the proposed rule) to be based on the historical rate of drilling for resources of similar type and quality to those in the controlled area. Any compliance application must substantiate the choice of such "similar" resources based on the type and quality. The Agency does not believe it is relevant to compare recoverable quantities in different geographic areas when determining resources of similar type and quantity to those in the controlled area. Different quantities of resources will be reflected in the number of boreholes drilled. The DOE must include all boreholes, for drilling resources of similar types and quality, within the Delaware Basin (as defined in the final rule) when determining historic drilling rates for shallow drilling.

Section 13: ACTIVE INSTITUTIONAL CONTROLS: SECTION 194.41

Issue A: The effectiveness of active institutional controls (AIC) is questionable.

1. It is overly optimistic to assume that any active institutional controls would be sustained more than a decade or two, much less a century. (CARD-B)

2. Accurately determining the contribution of the institutional controls to compliance is heavily dependent on assumptions as to future-states conditions. (SGNM-A)

3. It is recommended that EPA use the presence of institutional controls to limit the scenarios that need to be considered when evaluating the effect of human-initiated processes and events on the behavior of the repository, similar to the way used by NRC in 10 CFR 60.2. (NRC)

Response to Comments 13.A.1 through 13.A.3:

The final rule allows DOE to account for the effectiveness of active institutional controls (AICs) when conducting performance assessment (PA) calculations. The presence of active controls could be used to limit the scenarios considered in PA, or to reduce the probability of occurrence of scenarios in PA calculations, if such assumptions can be supported. For instance, active institutional controls may be designed to limit access to the WIPP site and thus discourage any potential drilling into the disposal system.

The EPA recognizes that the success of active institutional controls to deter access to the WIPP depends on the continued existence of numerous legal and social structures. The effectiveness of active institutional controls may not be assumed based solely on the future states assumptions of §194.25. Any assumptions about the effectiveness of controls in reducing releases must be described and justified [§194.41(a)]. Because of the uncertainty in how society will change, credit for the effectiveness of active institutional controls has been limited to 100 years. Credit for active institutional controls being effective for 100 years will not be automatically assumed by EPA. The DOE must demonstrate, to EPA's satisfaction, that the active institutional controls provided for in DOE's compliance application will effectively deter human intrusion for the number of years specified in the application, not to exceed 100 years. The active institutional controls submitted by DOE will be a part of the certification application; therefore it will be open to public scrutiny and comment.

4. Effectiveness of active institutional controls should be established by expert judgment/peer review. (NMAG-G)

5. Further requirements for active institutional controls should require DOE to present evidence of the feasibility and effectiveness of the plan and the methodology, in the form of records and evidence about the application of similar methods at other sites. (NMAG-C)

Response to Comments 13.A.4 and 13.A.5:

The EPA will decide whether or not to grant credit for the use of active institutional controls and for what time period such credit is granted. This decision will be made in the certification rulemaking and, therefore, is subject to review and comment by the public. The final rule requires DOE to document and demonstrate the effectiveness of active institutional controls for EPA to evaluate. As part of its demonstration, DOE may rely on peer review or expert elicitation to establish effectiveness of active controls if such expert judgement does not substitute for information that could reasonably be obtained through data collection or experimentation. For example, DOE may support proposed credit based on expert judgment about whether current examples of effective controls at other sites (such as those with security needs similar to the WIPP) could be successfully applied and implemented at the WIPP. Any such process is subject to the expert judgment criteria at §194.26.

Issue B: Limiting AICs to 100 years has not been substantiated.

1. Limiting active controls to 100 years is contrary to current practices. (C-12)

2. The proposed rule limits the consideration in the application for contributions from active institutional controls to 100 years. There is no apparent basis for this limitation in the Supplementary Information of the Background Information Document. It is not necessary to arbitrarily stipulate this limitation in the rule. (A-41, IV-D-76)

3. Requirements to limit the human control to only 100 years are unrealistic. (C-18)

Response to Issue 13.B:

The limitation of 100 years for credit for the effectiveness of AIC's in performance assessment calculations is required by §191.14(a): ". . . [P]erformance assessments that assess isolation of the waste from the accessible environment shall not consider any contribution from active institutional controls for more than 100 years after disposal." Not only did EPA promulgate this requirements, it was reinstated by the LWA, Section 8(a)(1). The limitation is a legal requirement which has gone through the public rulemaking process, judicial review, and legislative review, and cannot be changed without a new rulemaking on 40 CFR part 191.

Credit for the effectiveness of active institutional controls has been limited to 100 years because of uncertainty about how society will change. The EPA agrees that it will be prudent for DOE to continue to implement and maintain active institutional controls beyond the 100-year time period; it is not, and was never, the Agency's intention to require or recommend that DOE cease such controls 100 years after closure. In fact, §191.14 provides that active institutional controls should be continued for as long as is practicable. The final compliance criteria, at §194.41, call for DOE to demonstrate, in its compliance certification application, the period of time that the controls are proposed to remain active.

Issue C: Strengthening the requirements for AICs is necessary.

1. It is imperative that some kind of physical devices be created to warn potential intruders and negate their activity. The surface structure would be insufficient. (IV-D-73)

Response to Comment 13.C.1:

Active institutional controls are measures that require human attention in order to perform their intended function. For example, these controls may include guard patrols, human-operated cameras or detectors, site maintenance, remediation or clean-up, etc. The comment relates more to "passive," as opposed to "active" institutional controls. Passive institutional controls, required under §194.43, encompass physical devices requiring no human attention and which warn against or minimize the effects of human intrusion. The final rule requires more than a surface structure of the repository alone. Therefore, the commentor's concerns are addressed by the requirements under §194.43.

2. The active control regulations should be strengthened. (A-68)

Response to Comment 13.C.2:

The final rule is stringent while simultaneously providing DOE with flexibility in determining how to meet the requirements. Any compliance certification application presented by DOE must be well justified in order to demonstrate to EPA and the public that any amount of credit should be granted; and in no case shall credit be granted for a period exceeding 100 years.

Issue D: Excluding the possibility that clean-up and controls may be needed is not appropriate. (A-41)

Response to Issue 13.D:

Nothing in the final rule excludes the possibility that clean-up and controls may be needed at the WIPP site. In fact, §191.12 defines active institutional controls as "...maintenance operations or remedial actions...controlling or cleaning up releases at a site..." This definition applies as well to the final rule.

Issue E: DOE should show specific financial and contractual commitments made to support a system of controls. (NMAG-B)

1. The following subsection should be added to the rule in §194.41, "The application for certification of compliance shall include specific financial and contractual commitments made to support the operation of the active institutional controls." (NMAG-D)

2. The application for certification cannot be allowed to assume a higher level of active controls than those specifically provided for in law or in binding contractual agreements. (SRIC-G)

3. Compliance criteria should direct performance assessments to consider the disruption of active institutional controls, either through funding cuts or societal disruption. (CCNS-B)

Response to Issue 13.E:

In EPA's review of DOE's compliance certification application, EPA will evaluate, with public input, whether DOE's assumptions regarding AICs and their effectiveness are reasonable. This would include consideration of whether AICs are likely to be disrupted. Specific funding or contractual commitments by DOE could increase confidence that active controls will be implemented as described in a certification application. If EPA certifies compliance, then DOE must implement all measures and conditions that are the basis of EPA's certification, or DOE must seek modification of the certification. Any activities which depart from the basis on which EPA determines compliance will subject any compliance certification to modification, suspension or revocation, as described in §194.4. Any modification or revocation of a certification in turn is subject to notice and comment rulemaking and judicial review. Therefore, DOE will be held "accountable" to implementation of the active institutional controls included in its certification application.

Section 14: MONITORING: SECTION 194.42

Issue A: By requiring pre-closure monitoring, EPA is exceeding its authority.

1. The scope of the proposed operational monitoring system is outside the scope of this regulation. (DOE-D, SNL-C)

2. Monitoring during waste emplacement is not authorized by 40 CFR 191 subparts B and C. (SNL-C)

3. The EPA cannot require pre-closure monitoring under its certification authority. (DOE-D)

4. The requirements for monitoring the disposal rooms of WIPP during waste operations and prior to closure of the repository are not required in 40 CFR 191 subpart A. (DOE-D)

5. Criteria should be provided for monitoring after disposal consistent with 40 CFR part 191. Providing a monitoring program prior to the certification and during the operational time frames is clearly a modification of existing regulations which Congress did not authorize. (WEC-D)

6. Pre-closure monitoring program is technically infeasible and would result in significant risk to operating staff. (DOE-D)

7. Should require pre-closure monitoring of parameters relevant to repository performance, to verifying modeling reliability, or providing data useful for recertification. (SRIC-C)

8. The EPA clearly has the authority to conduct pre-closure monitoring at the WIPP. (SRIC-G)

Response to Comments 14.A.1 through 14.A.8:

Provided that the WIPP receives a certification of compliance from the Agency, EPA is required to make a determination of continued compliance (re-certification) five years after the initial receipt of waste and every five years thereafter until the end of the decommissioning phase. Through the re-certification process, EPA must ensure that the conditions under which the initial compliance certification was granted are still acceptable, including the actual performance of the disposal system compared with the expected performance based on DOE's performance assessment submitted with the initial compliance application. The 1992 WIPP LWA [sec.8(f)(1)] gave the Agency the authority to determine continued compliance of the WIPP after the initial certification. The primary reason for this re-certification process is to evaluate whether the WIPP is performing as expected. Without data from pre-closure monitoring, this evaluation cannot occur.

The Agency has determined that pre-closure monitoring will provide valuable insight into the post-closure performance of the disposal system. The information gathered during the pre-

closure monitoring phase will form the basis of any future evaluation for releases of radionuclides, which in turn will be the basis of any future re-certification decisions. The Agency believes it is within EPA's authority to impose such a requirement for DOE to examine and determine which pre-closure monitoring parameters are important to waste containment and feasible to monitor without jeopardizing the containment of waste in the disposal system. The determination of whether it is feasible to monitor a certain parameter should also take into account any increase in risk to operating personnel. The results of this analysis, as well as a detailed pre-closure monitoring plan, will be submitted to the Agency as part of the initial compliance application.

9. The EPA is planning on implementing, developing, and issuing criteria or guidance for the management of the storage phase and therefore we believe that requirement quite properly belongs in guidance for 40 CFR part 191, Subpart A. The criteria for 194 applies solely to the disposal phase. (EEG-B)

Response to Comment 14.A.9:

The Agency has the authority to include requirements in the compliance criteria which implement the requirements of 40 CFR part 191, Subparts B and C. Since monitoring of disposal systems is required to detect substantial and detrimental deviations from expected performance [§191.14(b)], it is appropriate to address any pre-closure monitoring which can provide a baseline for detecting deviations from expected performance.

10. It is inappropriate to use the terms "pre-closure" and "closure" in these proposed regulations. (SNL-C)

Response to Comment 14.A.10:

The Agency believes that pre-closure monitoring is necessary to determine baseline performance, which will be used in determining continued compliance after closure (the time at which the shafts of the disposal system are backfilled and sealed), should an initial certification of compliance be granted. The inclusion of pre-closure monitoring provides a 20-30 year opportunity during which information can be gathered about important parameters of the disposal system, within the disposal system itself, without jeopardizing waste containment.

11. Contaminant movement should not be addressed in certification criteria. (DOE-D)

Response to Comment 14.A.11:

Not all types of contaminant movement are addressed under the compliance criteria. Compliance with 40 CFR part 191 will ensure that releases of certain radionuclides into the environment do not exceed the limits established in §191.13(a). The Agency acknowledges, however, that some contaminant movement within the controlled area is allowed under the disposal regulations.

12. It is appropriate for the Agency to seek pre-closure monitoring and to obtain monitoring data before an initial determination of compliance for the purpose of assisting the compliance determination. (NMAG-D)

13. The final rule should require that monitoring be implemented at the WIPP as soon as the compliance criteria become effective. (SRIC-G)

Response to Comments 14.A.12 and 14.A.13:

The purpose of the compliance criteria is to implement 40 CFR part 191, subparts B and C specifically at the WIPP site. While the disposal regulations do not explicitly require pre-closure monitoring, EPA has determined that such monitoring is a necessary adjunct of post-closure monitoring. The purpose of pre-closure monitoring is related to re-certification. The Agency believes it is appropriate for the monitoring plans required in §194.42(e) to be reviewed by EPA and the public as part of the certification rulemaking before extensive resources are expended to implement the plans.

The final rule requires in §194.42(c) that, "[pre-closure] monitoring shall begin as soon as practicable; however, in no case shall waste be emplaced in the disposal system prior to the implementation of pre-closure monitoring." It is unclear to the Agency how pre-closure monitoring data obtained before an initial certification of compliance would be used, since waste cannot be emplaced in the disposal system until a certification is granted. The DOE is currently monitoring the site; and the data obtained, to the extent that they relate to the disposal standards, should be part of the compliance application.

Issue B: A subsection should be added to 194.42 stating that monitoring shall comply with the provisions of 40 CFR 191.14(b), 194.14, 194.41, 194.43, and 194.44; Subsection 194.42(b)(1) should be deleted. (DOE-D, SNL-C)

Response to Issue 14.B:

The criteria of §194.42 have been developed to meet the requirements of §191.14(b) and in many places take the language directly from §191.14(b). In order to meet the requirements of §194.42, the DOE must perform an analysis of parameters to be monitored and develop monitoring plans based on the results of this analysis. The plans that are developed must specify a length of time to monitor each parameter, and describe how each parameter will be used to evaluate the performance of the disposal system. Any compliance application must demonstrate that the requirements of §194.42 have been met.

The criteria of §194.14 describe the content of the compliance application and include requirements regarding monitoring data. The EPA does not believe that the requirements, as written, conflict with one another. Therefore, it is unnecessary to refer in §194.42 to other sections of the final rule.

Issue C: Clarification of portions of the rule is requested.

1. Section 194.42(b)(I)(4) requires the monitoring of the facility parameters (presumably with waste in the facility) yet the rule suggests that placement of the waste is precluded until the monitoring is completed. (WEC-D)

Response to Comment 14.C.1:

The final rule has been clarified in §194.42(c) to state that pre-closure monitoring must be conducted of significant disposal system parameters identified in DOE's analysis required in §194.42(a). Such monitoring must begin as soon as practicable; however, in no case can waste be emplaced in the disposal system prior to the *implementation* (versus "completion") of pre-closure monitoring. The Agency is requiring the pre-closure monitoring plan to be in effect prior to the emplacement of any waste, to continue throughout the emplacement period, and to end when the shafts of the disposal system are backfilled and sealed. Following closure of the facility, the post-closure monitoring plan will become effective.

2. On page 5778, par. (3), this misleading phrase appears: "tracers intentionally released to the ground water in the repository." There is no such water in the repository. There is some above the repository. (IV-D-51)

Response to Comment 14.C.2:

The ground water mentioned in the paragraph is above the disposal system. Any such references in the future will clarify this point.

3. The compliance criteria should specify that the monitoring plan should cover the time frame "until there are no concerns," which is the point at which all the radionuclides have decayed (therefore, longer than 10,000 years). Also, clarification is needed that monitoring cannot jeopardize the isolation of the waste. Furthermore, EPA should set guidelines as to the levels of monitored parameters that will trigger action (and DOE should have to report the results of monitoring and any variations in results). (NMAG-G)

Response to Comment 14.C.3:

The Agency concurs with this comment and clarified in §194.42(d), pursuant to §194.14(b), that the disposal system must be monitored until "the Department can demonstrate to the satisfaction of the Administrator that there are no significant concerns to be addressed by further monitoring." The inclusion of a specific monitoring requirement exceeding 10,000 years exceeds the requirements set forth in the disposal regulations, which specifies a 10,000-year regulatory time [§191.13(a)].

The final rule clarifies in §194.42(d), pursuant to §194.14(b), that post-closure monitoring shall be conducted with techniques that "do not jeopardize the containment of waste in the disposal system."

Regarding "trigger levels," the final rule requires in §194.4(b)(3)(ii)-(iii) that DOE notify EPA within 24 hours if radionuclide releases, radiation doses, or radionuclide concentrations have or are expected to exceed the containment, individual, or ground water requirements, respectively, of 40 CFR part 191.

Issue D: The requirements are excessive and not consistent with good management practices.

1. The requirements for performance monitoring of the repository performance after the closure that do not affect performance of the repository appear to be infeasible with present technology. (DOE-A)

2. It is not appropriate for EPA to require DOE to provide monitoring for radionuclides at WIPP after disposal, because no contaminant migration is expected to occur at WIPP. All contaminant movement should be dealt with under Subpart A of 40 CFR part 191 and should not be addressed in the certification criteria. (IV-D-111)

3. The regulations for monitoring could place the DOE in the position of expending resources on the development of unnecessary, or even unachievable, monitoring. (SNL-C)

4. The subject of monitoring can easily expand into a monster in which much money is spent to continuously measure zeros with great accuracy. The DOE should define and propose a monitoring program that is realistic and cost effective; this should not be specified by the EPA. (IV-D-51)

5. It is recommended that EPA review the proposed pre-closure monitoring requirements and include only those aspects which are characteristic of an operational facility rather than of a test facility. The proposed rule should continue to require that DOE conduct a study of monitoring for both the pre-closure and post-closure periods and to recognize that it may not be technically nor economically feasible to implement a monitoring program which will not compromise containment integrity. (IV-D-100)

6. Since monitoring methods must be tailored to fit site, technology, and *design* constraints, it is recommended that their regulation under this standard be flexible. (NRC)

Response to Issue 14.D:

The Agency is requiring monitoring of the disposal system to confirm that the disposal system is performing as predicted in the performance assessments and confirm that radiation from the disposal system poses no more risk to the public than allowed by the disposal regulations. The Agency recognizes the balance between developing requirements that would provide meaningful data and developing requirements which may not be practicable. In recognition of this balance, the final rule has been clarified so that no specific pre-closure monitoring parameters are required to be monitored pursuant to §194.42(c). Instead, the parameters the EPA believes to be important are now listed under §194.42(a), which includes parameters that

must be analyzed to determine if they are significant to the containment of waste in the disposal system or to the verification of predictions about future performance of the disposal system. These parameters (brine quality, flux, composition, and spatial distribution; gas quantity and composition; and temperature distribution) are believed by the Agency to provide indications on the expected performance of the disposal system and have been linked to performance of the disposal system through previous performance assessments.

The determination of whether monitoring a parameter is practicable should include an evaluation of technical feasibility, cost/benefit considerations, and inherent value of expected results. Infeasible monitoring technologies may be screened out with the proper justification. However, the Agency will thoroughly review each screened technology to confirm that potentially valid monitoring techniques have not been excluded.

Issue E: EPA should re-examine the requirement that monitoring be consistent with RCRA regulations.

1. The EPA must realize that monitoring consistent with the regulations under RCRA could result in a conclusion that no monitoring is needed. RCRA does not require an applicant to pursue monitoring in a particular media if it can be shown that there is no possibility of migration through that media. (WEC-D)

2. Literal application of 194.42(a)(1) with respect to incorporating RCRA-based monitoring criteria is incompatible with 40 CFR 191.14(b) strictures regarding protection of the disposal system. (NMAG-B, SNL-C)

3. Monitoring programs should be complementary rather than consistent. The terminology "shall be consistent [60 F.R. 5789]" is not clearly explained in the proposed rule itself or in the Supplementary Information. (DOE-D, SNL-C)

4. It is appropriate to require radionuclide and federal hazardous waste monitoring programs to be consistent; it will require coordination between NMED and EPA. (SGNM-D)

Response to Issue 14.E:

The final rule has been clarified to require that monitoring conducted pursuant to §194.42 must be complementary to monitoring conducted under applicable requirements of the Resource Conservation and Recovery Act (RCRA), contained at 40 CFR Parts 264, 265, 268, and 270. The requirement has been clarified to eliminate potential overlap, so that information yielded by one monitoring program is not required to be duplicated by the other.

As noted in several comments, a situation could exist where no monitoring is required under RCRA. In such an instance, the Agency believes that it would still be necessary and appropriate for DOE to conduct monitoring in order to confirm that the disposal system is performing as expected. In order to clarify that monitoring must be conducted to meet the requirements of the compliance criteria (even if not required by RCRA), the final rule has

been revised to require that monitoring in §194.42 must be *complementary* (versus "consistent") to the RCRA requirements.

Issue F: The prescriptive list of parameters is not justified.

1. The prescriptive list of parameters for monitoring is made without technical justification; the monitoring programs should be based on results of performance assessment analyses. (DOE-D)

2. The regulation prescribes operational activities for monitoring that are not consistent with good management practices. (WEC-A)

3. It is premature and technically inappropriate to specify (by rule) the specific components of any monitoring system (either pre- or post-operational). (SNL-C)

4. The operational activity related to monitoring are not consistent with good management practices; the requirements in §194.34 are premature and not likely to be necessary. (C-29)

5. Monitoring requirements should be required for all specific parameters listed. (C-03)

6. Monitoring program should give special attention to gas generation. (CARD-B)

Response to Issue 14.F:

The Agency believes the following parameters can affect the containment capability of the WIPP: brine quantity, flux, composition, and spatial flux, gas quantity and composition, and temperature distribution. As requested by one of the comments, attention has been given to monitoring gas quantity and composition because such parameters may indicate potential explosions.

In the final rule, EPA requires DOE to analyze parameters found to be either significant to the containment of waste in the disposal system or significant to the verification of predictions about the future performance of the disposal system. While EPA believes the parameters listed above are significant for at least one of the reasons just described, the final requires that the parameters be analyzed first to confirm that they are indeed appropriate parameters to be monitored. The parameters listed in paragraphs §194.42(a)(1)-(7) are parameters that the Agency believes could be useful indicators of disposal system performance. The Agency believes that establishing the minimum parameters to be included in the analysis is reasonable, and does not impose undue burden on DOE.

Issue G: Compliance criteria should include a Best Available Technology requirement for monitoring equipment. (CCNS-B)

Response to Issue 14.G:

The term Best Available Technology (BAT) is used by the Agency when referring to process changes and treatment methods for complying with the Clean Water Act (CWA). Direct use of this definition is not appropriate for 40 CFR part 194 requirements, which implement the 1992 WIPP Land Withdrawal Act and 40 CFR part 191, subparts B and C. In general, BAT and similar terms usually refer to an achievable reduction in some pollutant, or a percent reduction in contaminant levels. For example, BAT is defined in the CWA as the very best *control or treatment technologies* that have been or are capable of being achieved. This is not a useful concept for monitoring (as opposed to control) technology, which must weigh different factors not as easy to quantify, such as whether the technique does not jeopardize the containment of waste [see §194.42(d)].

Issue H: Monitoring should be required and should be thorough.

1. Ensure that everything has been done so that the waste will not escape that site. (S-06, S-11)

2. Permanent, on-site, long-term monitoring should be required. (A-68, IV-D-12)

Response to Issue 14.H:

In §191.13, the Agency included numerical requirements for the containment of radionuclides in the disposal system which limit releases into the environment. Although absolute proof that radionuclides will not escape the disposal system is impossible, the limits on the releases set forth in the disposal standards are intended to provide a reasonable expectation that there will not be a release of radionuclides toward the accessible environment.

Additionally, the Agency included assurance requirements in §191.14. These requirements are meant assure that wastes are not released into the environment above the desired level of protection. The monitoring requirements outlined in §194.42 implement the assurance requirement set forth in §191.14(b). The Agency believes that the monitoring, along with the other assurance requirements, will provide the additional level of protection necessary to assure that releases to the environment will not exceed acceptable levels.

The inclusion of a specific requirement for permanent monitoring falls outside of the Agency's authority to implement the disposal regulations, since §191.13(a) specifies a regulatory time period of 10,000 years. The Agency states in the compliance criteria [§194.42(d)] that monitoring should be conducted until there are “no significant concerns to be addressed by further monitoring.” A certification of compliance will not be granted by EPA unless the monitoring plan included in the compliance application satisfies this requirement.

Issue I: Explosive materials need to be closely monitored.

1. I am concerned about the salt slabs falling down in many-ton chunks, and landing on the casks of possibly explosive waste. (S-38)

2. Explosive material is of concern for operational activities and is outside the scope of these proposed regulations. (SNL-C)

3. There is the possibility that a critical mass build-up would occur resulting in a more dangerous explosion than just the gaseous one. (S-03, S-38)

4. The radioactive waste materials placed in containers could very well explode. (S-42)

Response to Issue 14.I:

The Agency is concerned with explosive hazards and has indicated its concern to the Department. The DOE will be evaluating the explosion scenario to determine the probability and impact on the performance assessment. If parameters related to explosiveness affect containment, then they must be analyzed, as required in §194.42(a). Effects of potential explosions other than those on containment are addressed by other regulations, such as those under the Occupational Safety and Health Act (related to worker safety) or the Resource Recovery and Conservation Act (related to the hazardous properties of materials).

Issue J: The establishment of monitoring criteria and additional requirements is necessary.

1. DOE should supply necessary data before a monitoring regulation is developed. (NMAG-B)

2. The EPA should require the use of specific monitoring methods which should be updated with new scientific technology. (C-03)

3. In reference to the CAG, DOE should be asked to submit evidence of the feasibility and effectiveness of the monitoring approaches planned, and the Agency should take on the responsibility for determining that the methods will be feasible and effective. (NMAG-C)

Response to Comments 14.J.1 through 14.J.3 :

The monitoring approach taken by EPA is consistent with the approach taken elsewhere in the final rule. The EPA has established criteria requiring DOE to thoroughly analyze disposal system parameters that may affect the containment of waste in the disposal system and develop pre- and post-closure monitoring plans for inclusion in the compliance application. EPA will in turn review the adequacy of the analysis and submissions during the public certification rulemaking. The Agency believes this to be a reasonable approach which is consistent with the WIPP Land Withdrawal Act and 40 CFR part 191.

In general, EPA believes it is the responsibility of DOE, as owner and operator of the WIPP, to research and substantiate the feasibility of monitoring techniques proposed for use at the WIPP. The DOE is required to submit the results of the analyses performed pursuant to §194.42(a) in its compliance application. The EPA, as regulator, will evaluate, during the public certification rulemaking, the quality and feasibility of DOE's monitoring plans as part of the Agency's review of the compliance application.

4. It is simply not credible that the natural barriers would fail during a several hundred year period, and that site-wide monitoring would show any evidence of radioactive contamination for the WIPP. The issue should be that the project identify performance goals for the release of radionuclides for the repository sealing system and develop engineering plans and technologies to meet them. (IV-D-40)

Response to Comment 14.J.4:

The Agency included monitoring requirements in the final rule because: (1) such requirements are set forth in §191.14(b); and (2) monitoring will serve as means to confirm that the disposal system is performing as expected. By establishing in the disposal regulations a limit on radionuclide releases to the environment, the Agency has developed performance goals for the disposal system. It is up to the Department to meet these standards. If the commenter is correct in saying that natural barriers would not fail, then any detection of releases would be a significant discovery.

5. This section should not limit monitored parameters to those that may "affect the transport" of radionuclides. This section should also include those parameters that "indicate the movement of radionuclides" which would be the ultimate test of satisfying §191.14. (SGNM-D)

Response to Comment 14.J.5:

The final rule does not limit monitoring to only those parameters that may affect the transport of radionuclides. Section 42(a) of 40 CFR 194 requires that DOE analyze "the effects of disposal system parameters on the containment of waste in the disposal system," and use the results of such analysis to develop plans for pre-closure and post-closure monitoring. Parameters that may affect the containment of waste may very likely include parameters that

"indicate movement of radionuclides," as mentioned by one of the commenters. Further, the DOE must substantiate decisions not to monitor parameters analyzed pursuant to §194.42(a) based on two criteria: whether the parameter is insignificant to the containment of waste, or whether the parameter is insignificant to the verification of predictions about the future performance of the disposal system.

6. Monitoring results should include radiological and RCRA constituent background concentrations and should not update the established background concentrations, but should be used to determine constituent releases or deviations from background levels and should continue through the "post-closure care period," 30 years for 40 CFR 264.117 and an unspecified duration for 40 CFR 191.14. (SGNM-D)

Response to Comment 14.J.6:

The purpose of the monitoring assurance requirement set forth in §191.14(b) is to "detect substantial and detrimental deviations from expected performance." The EPA expects that monitoring results will be analyzed in this context, but may also be used to refine performance assessments and thus predictions of post-closure performance. Post-closure monitoring must be used to determine constituent releases or deviations from baseline performance.

The final rule requires that monitoring conducted under §194.42 be complementary to monitoring required under RCRA, in order to eliminate duplication between the two sets of requirements. However, it is not the purpose of the final rule to enforce RCRA regulations. The EPA's final rule at 40 CFR part 194 implements 40 CFR part 191, subparts B and C at the WIPP regarding radioactive waste disposal standards. The requirement for complementary monitoring does not mean that monitoring conducted according to the compliance criteria will be identical to that required by RCRA. For example, while 40 CFR part 264 may require monitoring for 30 years following closure of the facility; §194.42 requires that post-closure monitoring continue until the Department can demonstrate that there are no significant concerns to be addressed. Similarly, §194.42 may require monitoring of non-radiological parameters if they can have an impact on the containment or release or radionuclides from the disposal system, or if they can be used to verify predicted performance of the system. It is beyond the scope of this rulemaking to require that DOE monitor RCRA hazardous constituents if they are not relevant to the requirements of the disposal regulations. The requirements of RCRA are established and enforced independently from those of the disposal regulations and compliance criteria.

7. A study of the effects of the disposal system parameters on waste containment shall include subsidence caused by withdrawal of oil/gas resources. (SGNM-D)

8. Long-term, remote, and intra-repository monitoring of the geomechanical parameters is not feasible. It would be more appropriate to include an engineered barrier to compensate for migration of radionuclides and/or hazardous materials through this pathway. (SGNM-D)

9. "Brine and repository horizons"should be added to the list of media requiring background concentrations. (SGNM-D)

Response to Comments 14.J.7 through 14.J.9:

The final rule does not explicitly require that DOE monitor subsidence, or brine and repository horizons. However, pursuant to §194.42(a), if these parameters are significant to the containment of waste in the disposal system or to verification of predictions about the future performance of the disposal system, then they should be considered when developing monitoring plans. According to §194.42(b), DOE is required to substantiate, based on these criteria, any decision not to monitor a particular disposal system parameter.

The development of monitoring plans should take into account the feasibility of monitoring a particular parameter, the ability of the monitoring parameter to provide useful information regarding performance of the disposal system, and the potential for the monitoring method to jeopardize the containment of waste in the disposal system. Monitoring specific parameters, such as geomechanical parameters, is not required if it is determined to be infeasible, of insignificant value in confirming disposal system performance, or jeopardizes waste containment.

Engineered barriers are addressed separately in §194.44 of the final rule.

Issue K: There is a motivation to sabotage either the monitoring signals or the resulting data by spiking ground water with radionuclides or implanting contaminated material. This threat should be addressed. (IV-D-51)

Response to Issue 14.K:

The threat of sabotage to the monitoring program should be addressed by the Department in the active institutional controls requirements (§194.41). An effective active institutional controls program will minimize any concerns of sabotage to the monitoring data.

Issue L: The monitoring should be administered by an independent agency.

1. The EPA should require independent monitoring of the post disposal phase. This phase should be on-going. (IV-D-06, IV-D-26, IV-D-28, IV-D-92)

2. The monitoring systems should be designed and administered by an independent agency. (CARD-B, S-17)

Response to Issue 14.L:

There is no indication that DOE will misrepresent monitoring results. Therefore, the Agency does not believe it is necessary or appropriate to require independent monitoring of the disposal facility. However, the inspections requirements in the compliance criteria allow the

Agency to obtain samples, including split samples, for independent analysis in order to monitor and measure disposal system performance [§194.21(d)]. Further, the Agency may be obtaining the assistance of experts in the monitoring field to review and determine the adequacy of the monitoring plan submitted by the Department.

Issue M: The following passage should be added to §194.42 "at least one parameter should be monitored during the disposal phase and for as long as practicable following closure." (SGNM-D)

Response to Issue 14.M:

The final rule has been modified in §194.42(d) to clarify that post-closure monitoring must continue until "the Department can demonstrate to the satisfaction of the Administrator, that there are no significant concerns to be addressed by further monitoring." The EPA does not believe it would be prudent to require at least one parameter to be monitored, since such a requirement could be fulfilled by monitoring a parameter which does not provide information relevant to disposal system performance.

As part of the certification rulemaking, EPA will determine if DOE's post-closure monitoring plan adequately implements §191.14(b). As required in §194.42(e), this monitoring plan must identify the parameters that will be monitored, indicate how each parameter will be used to confirm disposal system performance, and discuss the length of time over which each parameter will be monitored. The Agency does not believe it is appropriate to specify a parameter to be monitored prior to DOE's analyses, which will be submitted in the compliance application.

Section 15: PASSIVE INSTITUTIONAL CONTROLS: SECTION 194.43

Issue A: The effectiveness of passive institutional controls (PICs) is dubious.

1. Use of monuments should be regarded as having the effect of increasing, not decreasing, the likelihood of inadvertent human intrusion. (CARD-B, SRIC-E)

Response to Comment 15.A.1:

The final rule [§194.43(a)] requires that "[a]ny compliance application shall include detailed descriptions of the measures that will be employed to preserve knowledge about the location, design, and contents of the disposal system." The EPA recognizes that monuments alone could have the effect of increasing the likelihood of inadvertent human intrusion into the WIPP due to the innate curiosity of man. However, the full implementation of the PICs requirements includes both markers (e.g., monuments) and archival records; specifically, section 191.14(c) of the disposal regulations requires that disposal sites be designated by the most permanent markers, records, and other passive institutional controls practicable to indicate the dangers of the wastes and their location. In adopting these provisions of the disposal regulations, the Agency generally assumed that passive institutional controls "should reduce the chance of inadvertent intrusion compared to the likelihood if no markers and records were in place." See 50 Fed. Reg. 38080. This statement reflects the conclusion based on a balance of considerations that PICs are more likely than not to deter intrusion.

In developing this section of the final rule, the Agency considered the treatment of PICs in the disposal regulations, the input received in public forums and the public comments received on the proposed rule. The EPA recognizes that there will always be a chance that some individuals will overlook or misunderstand the markers. However, in adopting the final disposal regulations, the Agency examined whether PICs should be taken into account to some degree when estimating the likelihood of inadvertent human intrusion and concluded that "a limited role for passive institutional controls would be appropriate when projecting the long-term performance of mined geologic repositories to judge compliance with [the containment requirements of 40 CFR Part 191]." See 50 Fed. Reg. 38080. At the same time, the Agency explicitly determined that PICs should not be assumed to completely prevent the possibility of inadvertent human intrusion.

As noted in the Supplementary Information for 40 CFR part 191, "[t]he 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 is reasonable to assume that information regarding the disposal system is more likely to reach (and presumably deter) people undertaking such organized efforts . . . [50 FR 38080]." PICs designed especially for the WIPP may convey information to future generations about the hazards of the disposal system for a limited period of time. The final rule also requires any compliance application to "include the period of time passive institutional controls are expected to endure and be understood." See § 194.43(b). Thus, in evaluating the adequacy

and efficacy of PICs during the compliance certification public rulemaking EPA will examine to what extent the particular PICs proposed are expected to be understood.

2. We see no assurance that DOE can keep people away for 10,000 years. (A-07, A-25, S-40)

3. Given that: (1) all languages change; (2) all civilizations eventually collapse and suffer language loss; (3) the difficulties of deciphering written languages; and (4) meanings become different over time, it is inconceivable that we can send a message 10,000 years ahead. (A-10)

4. The EPA cannot guarantee that markers can be placed that would be understandable in 10,000 years. (SRIC-A, A-34, A-35)

5. How can we expect warnings that we post over WIPP to deter folks 500, 1,000, 5,000 years from now, or even understand its meaning? (S-09, S-29)

Response to Comments 15.A.2 through 15.A.5:

The DOE must demonstrate in its compliance application the period of time PICS are expected to endure and be understood by potential intruders. The description of PICs proposed to be employed, as presented in DOE's compliance application, will be reviewed and judged by EPA and the public through the certification rulemaking process. The DOE may propose in its compliance application to reduce the rate of human intrusion by a fractional amount, extending over a technically supportable period of time, and must justify this "credit" using the plans for the implementation for PICs and associated evidence of their effectiveness.

The Agency agrees with the commenters that PICs in no instance should be assumed to protect against human intrusion for the entire 10,000-year regulatory time frame. The final rule constrains the period over which EPA may entertain credit for PICs to no more than "several hundred years." Thus, after considering the public comments regarding PICs, the Agency decided that it would not consider granting credit for a time period of more than several hundred years.

This does not mean that PICs are without benefit and should not be required. Nor does it mean that it is inappropriate for EPA to consider the potential efficacy of PICs in reducing the likelihood of human intrusion for some limited period of time.

While the Agency recognizes that some languages have been lost over long time periods, it is also true that other written languages have survived for hundreds of years. Historic cultures also did not have the advantages of the global knowledge which is available today. This global knowledge allows for the transmission, dissemination, translation, and archival of information at a speed and of a magnitude that was not available to historic cultures. The EPA recognizes that the message is more likely to endure and be understood if it is conveyed in multiple languages and on durable materials. The EPA will consider such factors in its evaluation of DOE's plan to implement PICs.

While §191.14(c) requires that PICs should be designed to be as permanent as practicable, 40 CFR part 194 does not require that the entire message conveyed by passive institutional controls be effective for the entire 10,000-year regulatory time period. And while the Agency may consider approving a limited reduction in the likelihood of human intrusion, such reduction will not be approved by the Administrator unless DOE adequately demonstrates that the PICs described in the compliance application will be effective for the proposed period of time. See also response to Comment 15.A.1.

6. At the rapid pace of change, another great concern is how well the site will be marked to ensure that the waste will be kept from the public and the environment. (S-11)

7. Ensure that monuments around the WIPP site will reduce future drilling and mining. (S-03)

Response to Comments 15.A.6 and 15.A.7:

The final rule requires the compliance application to include detailed descriptions of the PICs that will be employed to preserve knowledge about the location, design, and contents of the disposal system [§194.43(a)]. Further, with respect to markers, the compliance application must demonstrate that identification of the controlled area by markers will be designed, fabricated, and emplaced to be as permanent as practicable [§194.43(a)(1)]. The EPA will evaluate this information in conjunction with the Agency's review of the compliance certification application. The message conveyed by passive institutional controls may not be completely effective or understood for the entire 10,000-year regulatory time frame. The passive institutional controls required are intended to reduce the uncertainty associated with predicting long term performance of the repository, but cannot be expected to eliminate the likelihood of human intrusion.

Issue B: Passive institutional controls are likely to be effective and should be included in the rule.

1. Any human civilization living 1000 to 10,000 years from now will be smart enough to understand records and markers. (C-24)

Response to Comment 15.B.1:

While it is possible that society will continue to evolve and that records and markers will be understood, the possibility also exists that, while knowledge of current languages may exist in future societies, such knowledge may not be widespread. For example, while the archeology department of any major university today probably has scholars who can read and understand markers written in 10th-century English, ancient Egyptian or Babylonian, very few people in the general population can do so. For a marker to be effective in deterring intrusion, it must be understood by the person contemplating or attempting intrusion, not by a scholar in a location remote from the WIPP. Furthermore, the possibility also exists that, in the distant future, society may suffer a decline through war, climate change, or other force which cannot

be predicted. In addition, for passive institutional controls to deter human intrusion, the message provided by the controls must first survive and second, be discovered. The EPA will evaluate these factors in its review of the compliance application, but in no case may the Department assume that PICs will eliminate the potential for human intrusion entirely, or decrease the rate of human intrusion for a time period longer several hundred years past the time of disposal.

2. References to statements that passive institutional controls have failed are inaccurate and inappropriate. The consideration of passive controls in the performance assessment is appropriate and consistent with past guidance. (DOE-D)

Response to Comment 15.B.2:

The Supplementary Information to the proposed 40 CFR part 194 discusses the historical record regarding passive institutional controls. The historical record is an important source of information about what factors could influence the ability of a marker to survive and effectively convey its message. While EPA generally believes that PICs can reduce the likelihood of inadvertent human intrusion for some period of time, EPA believes it is appropriate and reasonable to discuss uncertainty regarding performance of PICs, and to examine past examples of markers, both successful and unsuccessful. After consideration of public comments and NACEPT recommendations, EPA determined that it is appropriate to constrain the period of time over which EPA will consider granting credit for PICs to several hundred years. To further acknowledge uncertainty, the Agency will not allow such credit to eliminate entirely the potential for inadvertent human intrusion.

Issue C: Credit for and the quantification of the PICs should not be considered.

1. It is unwise for the criteria to assume that if the DOE constructs monuments it will reduce future mining and drilling in the area. The DOE should not be allowed to take credit for such passive institutional controls. (A-43, IV-D-43)

2. No or minimal "credit" should be given for passive institutional controls used at the site. This seems inconsistent with purpose of the assurance requirements. (CARD-B, EEG-A, EEG-B, EEG-C, NMAG-A, NMAG-B, SRIC-A, SRIC-C, SRIC-G, A-08, A-18, A-60, S-3, IV-D-13, IV-D-14, IV-D-15, IV-D-16, IV-D-17, IV-D-18, IV-D-19, IV-D-20, IV-D-21, IV-D-22, IV-D-23, IV-D-24, IV-D-25, IV-D-30, IV-D-31, IV-D-32, IV-D-33, IV-D-34, IV-D-37, IV-D-38, IV-D-42, IV-D-46, IV-D-47, IV-D-48, IV-D-51, IV-D-52, IV-D-53, IV-D-54, IV-D-55, IV-D-56, IV-D-57, IV-D-58, IV-D-59, IV-D-60, IV-D-61, IV-D-62, IV-D-63, IV-D-66, IV-D-67, IV-D-68, IV-D-69, IV-D-70, IV-D-71, IV-D-72, IV-D-74, IV-D-75, IV-D-79, IV-D-80, IV-D-83, IV-D-87, IV-D-88, IV-D-99)

3. It is not appropriate for performances assessments to consider contributions from passive institutional controls. (SRIC-E)

4. The Compliance criteria must be changed so that no credit is received for providing warning against future drilling. (S-39)

5. No guidance is provided as to what is required to justify taking credit for passive institutional controls in the performance assessment. This guidance should be provided in the regulation. (DOE-D, SNL-C)

6. There is no need to quantify benefits of implementing passive institutional controls. (EEG-B)

7. The approach of using passive institutional controls to reduce the rate of human intrusion and human activities is acceptable. (SNL-C)

8. Delete §194.33(b)(4)(iv) and §194(b)(5)(iv). (EEG-C)

9. The EPA is vague on the issue of passive controls. Markers and records are not that effective. (NMAG-B, A-41)

10. The EPA should provide additional context for the applicant to propose credit for the presence of passive institutional controls. It is recommended that EPA adopt an approach that establishes additional context for evaluating the contributions of institutional controls. (NRC)

11. The EPA should require DOE to provide sufficient information in its application to enable EPA to make a regulatory decision, if the Administrator decides that no credit, or less than proposed credit, will be awarded for the effectiveness of the institutional controls. (NRC)

12. No credit may be allowed for the supposed effectiveness of passive institutional controls in reducing human intrusion. If there can be a criterion to determine the effectiveness of passive institutional controls, the Agency must set it forth in compliance criteria. (NMAG-D)

13. The proposed provision, at 40 CFR part 194.43(c), that the Administrator "shall" allow credit for passive institutional controls provided DOE can demonstrate that such credit is justifiable should be retained. 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. (SNL-D)

14. It is encouraged that the inclusion of credit be given for passive controls in 40 CFR part 194; however, as discussed in the specific comments that follow, it is suggested that it may be appropriate to revise 40 CFR part 194.43(c) slightly for clarification purposes. (SNL-D)

15. Revise the second sentence of §194.43(c) to say: 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. (SNL-D)

16. 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." (DOE-E)

17. In its performance as part of its demonstration of compliance with the disposal regulations, no markers or assumptions should be allowed to permit DOE to assume that there will not be human intrusion. (SRIC-F)

Response to Issue 15.C:

As explained in the preamble of the final rule, EPA believes it is consistent with the disposal regulations and appropriate as a policy matter to consider the effect of PICs in reducing the likelihood of human intrusion in the performance assessment for the WIPP. At the same time, after considering public comments and the recommendations of the WIPP Review Committee of the National Advisory Council for Environmental Policy and Technology (NACEPT), EPA does not think it is reasonable to expect that PICs will endure and be understood for the entire 10,000-year regulatory time frame. At a NACEPT public meeting in New Mexico in September 1995, the Committee agreed that PICs are likely to have a positive influence on deterring intrusion for a relatively short time period and should be implemented at the site. However, like many commenters, the Committee expressed skepticism over whether such controls would be effective for more than a small fraction of the 10,000-year regulatory time frame. Thus, in the final rule EPA constrains the time frame that credit for PICs may be considered to several hundred years and provides that in no case shall PICs be assumed to eliminate the likelihood of human intrusion entirely. Both restrictions are consistent with the disposal regulations which contemplated some role albeit a limited one for PICs in projecting long-term performance of mined geologic repositories and determined that PICs not be assumed to completely prevent the possibility of inadvertent human intrusion. See 50 FR 38080 (Sept. 19, 1985). Further, entertaining a limited role for PICs in reducing the likelihood of human intrusion creates an additional incentive for DOE to use effective, enduring, comprehensive PICs.

In the final rule, the Agency allows the Department to reduce the likelihood of future human intrusion that is used in performance assessment by a proposed amount corresponding to the predicted effect of PICs, as demonstrated in the compliance application. However, as noted, this reduction cannot be a 100 percent reduction and must be limited to no more than approximately 700 years past the time of disposal. Hence, the final rule limits possible credit to no more than approximately seven percent of the regulatory time frame, and such credit, or a smaller credit, will be approved only if DOE demonstrates, to the satisfaction of the Administrator, that the PICs described in the compliance application will be effective in reducing the likelihood of human intrusion. Any decision about the actual credit to grant for PICs in reducing the likelihood of human intrusion will be made by EPA in the public certification rulemaking reviewing DOE's WIPP compliance application. During the rulemaking on certification, EPA could determine that the compliance application does not adequately justify the degree of proposed credit assumed by DOE and therefore disallow some or all of the proposed credit.

Issue D: Criteria for the records and granting credit need to be established.

1. Criteria should be more detailed about what kinds of records need to be kept. (NMAG-G)

Response to Comment 15.D.1:

The disposal regulations at 40 CFR § 191.14(c) provide that "[d]isposal sites shall be designated by the most permanent markers, records, and other passive institutional controls practicable to indicate the dangers of the wastes and their location." PICs are defined to include "public records and archives." 40 CFR § 191.12. These provisions are general and EPA has broad discretion in implementing them at the WIPP. The comment does not identify a specific deficiency with the records required to be kept and therefore is difficult to evaluate. The final compliance criteria for the WIPP require compliance applications to include detailed descriptions of the measures that will be employed to preserve knowledge about the location, design, and contents of the disposal system. Regarding records, the final compliance criteria also require the placement of records in the archives and land record systems of local, State, and Federal governments, and international archives, that would likely be consulted by individuals in search of unexploited resources. The criteria require the records to identify: (1) the location of the controlled area and the disposal system; (2) the design of the disposal system; (3) the nature and hazard of the waste; (4) geologic, geochemical, hydrologic, and other site data pertinent to the containment of waste in the disposal system, or the location of such information; and (5) the results of tests, experiments, and other analyses relating to backfill of excavated areas, shaft sealing, waste interaction with the disposal system, and other tests, experiments, or analyses pertinent to the containment of waste in the disposal system, or the location of such information. The final rule establishes specific criteria about the kind of information that must be provided, without specifying actual records. The EPA will review the information provided in response to these criteria in the certification rulemaking, which will include significant opportunity for public input.

2. Information placed in records should explain the nature of the biohazard. (CARD-B)

Response to Comment 15.D.2:

Material placed in archives is required to explain "[t]he nature and hazard of the waste [§194.43(a)(2)(iii)]." The more general term "hazard" includes biohazards.

3. Concerning record archives, the records to be included should be carefully selected so as to not overburden future agencies. (IV-D-51)

Response to Comment 15.D.3:

Section 194.43(a)(2)(i)-(v) states that, "[s]uch records shall identify: (i) [t]he location of the controlled area and the disposal system; (ii) [t]he design of the disposal system; (iii) [t]he nature and hazard of the waste; (iv) [g]eologic, geochemical, hydrologic, and other site data pertinent to the containment of waste in the disposal system; and (v) [t]he results of tests, experiments, and other analyses relating to backfill of excavated areas, shaft sealing, waste interaction with the disposal system, and other tests, experiments, or analyses pertinent to the containment of waste in the disposal system." The final criteria require placement of records in archives that would likely be consulted and to describe the period of time PICs are expected to endure and be understood. In evaluating the plan for PICs contained in the compliance application, EPA intends to consider whether the sheer volume of material will diminish the likelihood that the information endures, causing it to be lost, discarded, or whether the sheer volume of material will render it unlikely to "be consulted by individuals in search of unexploited resources"

4. Information is the key to the success of passive institutional controls. These markers should be codified so their definitions can be referenced in libraries as well as other places where checks and balances are applied to zoning, purchase/sale of property, and permits for buildings, drilling, exploration. (CCNS-B)

Response to Comment 15.D.4:

Section 194.43(a)(2) requires, "[p]lacement of records in the archives and land record systems of local, State, and Federal governments, and international archives, that would likely be consulted by individuals in search of unexploited resources." This requirement includes records used for zoning; purchase/sale of property; and permits for buildings, drilling, and exploration.

5. Neither the Supplementary Information nor the proposed rule tells how credit for passive institutional controls is to be taken. Both the Supplementary Information and §194.43(b) need to provide specific criteria for allowing credit for passive institutional controls. The effectiveness will be established by the Department. (DOE-E)

6. Guidance is needed for establishing how credit for passive institutional controls is to be evaluated. (SNL-D)

7. The role of the "reasonable expectation" concept is not clearly defined in the context of 40 CFR part 194.43(c). 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. (SNL-D, DOE-E)

Response to Comments 15.D.5 through 15.D.7:

The final rule provides that DOE may propose in its compliance application to reduce the rate of human intrusion by a fractional amount, extending over a technically supportable period of time (but within the time limit stated in the final rule), and must justify this using the plans for the implementation for PICs and associated evidence of their effectiveness. This credit may take the form of a constant reduction in the rate of human intrusion lasting several hundred years or may be a reduction in the rate which tapers off in size over several hundred years. Such credit cannot be assumed to eliminate completely the possibility of human intrusion, even for a short period of time after the active institutional controls at the WIPP are assumed to be ineffective. During the rulemaking on certification, the Agency could determine that the description of the PICs does not adequately justify the degree of proposed credit assumed by DOE and therefore disallow some or all of the credit proposed by DOE in the compliance application.

Issue E: Changes are needed to Section 194.43 (references to 40 CFR 191).

1. Paragraph 194.43(a) except for subparagraphs (1) and (2) and paragraph (b) are appropriate material for 40 CFR part 194. In the remainder of this section, EPA is exceeding its authority. (WEC-D)

Response to Comment 15.E.1:

Paragraph 191.14(c) of the disposal regulations requires that, "[d]isposal sites shall be designated by the most permanent markers, records, and other passive institutional controls practicable to indicate the dangers of the wastes and their locations." In § 194.43 paragraphs (a) and (b), EPA requires the compliance application to include detailed descriptions of the PICs to be implemented and the period of time the PICs are expected to endure and be understood, in accordance with the requirement for use of the most permanent PICs practicable. Subparagraphs (1) and (2) of § 194.43(a) address the requirement for markers and records, both of which are PICs specifically required in the disposal regulations. The compliance criteria are derived directly from the disposal standards and EPA has not exceeded its authority in implementing compliance criteria for PICs at the WIPP.

2. The requirement to install markers prior to submitting the compliance certification application should be amended such that this requirement would be in effect after the compliance certification application is submitted. (SNL-C)

Response to Comment 15.E.2:

The final rule clarifies in §194.43(a)(1) that the Agency does not require markers to be in place prior to the submission of a compliance certification application. The rule states that, "[a]ny compliance application shall include....identification of the controlled area by markers that have been designed, and *will be* fabricated and emplaced..."

3. The list of record requirements in 40 CFR 194.43(a)(2) proposed by the EPA is generally appropriate with the exception of the requirement to include all test results. (SNL-C)

Response to Comment 15.E.3:

The test results required in §194.43(a)(2)(v) are those related specifically to how the system is backfilled and sealed, how the waste is expected to interact within the disposal system, and other tests pertinent to the containment of the waste. This is a limited subset of tests which will provide the most useful information to future generations. The Agency recognizes that such test results are not typically included in government archives and land records and, as other commenters have noted, too much information may diminish the likelihood that it endures; therefore, this provision of the rule has been revised to include an alternative that the *location* of such test results may be included in the archives and records.

4. A subsection should be added to 194.43 stating that passive institutional controls shall comply with the provisions of 40 CFR 191.14(c), 194.14, 194.41, and 194.44. (DOE-D, SNL-C)

Response to Comment 15.E.4:

Section 194.43 of the compliance criteria is the specific implementation of §191.14(c) of the disposal regulations. Therefore, it is not necessary to reference the §191.14(c) requirements in §194.43. The Agency believes that the provisions of 40 CFR part 194 are internally consistent, and that it is unnecessary to refer to §194.14, §194.41, or §194.44.

Issue F: There is no easy answer for the implementation of PICs. (NMAG-G)

Response to Issue 15.F:

Passive institutional controls are a complex issue on which EPA has sought input from numerous technical experts, other regulatory agencies, the public, social scientists, and others. The EPA appreciates the recognition of the complexity of this issue.

Issue G: DOE should erect a fence/wall/barrier around the WIPP. That barrier would seem to obviate a lot of controls that would otherwise be needed. (IV-D-06)

Response to Issue 15.G:

The EPA has not specified a particular type of passive marker/barrier because it is unclear what type of passive institutional control would provide the best level of protection and last the longest. A fence/wall/barrier, depending on its construction, may be subject to collapse, erosion, or burial due to shifts in the sand caused by wind, rain, or other natural forces. In addition, a fence may not effectively convey the hazards of the WIPP. DOE, as owner and operator of the facility, is responsible for demonstrating in its compliance certification application that it has employed the type of markers that will be most effective. The DOE must demonstrate that PICs will endure and be understood in order to fulfill the PICs assurance requirement.

Issue H: Requirement for placement of records in "local, state, federal,...and international archives (60 F.R. 5789)" overlooks placement with Mexican government entities and Native American governments. (CARD-B)

Response to Issue 15.H:

Native American governments are within the scope of "local" governments from a regional geographic standpoint. Native American governments and the Mexican government would also be considered "international" because of their status as independent and self-governing nations.

Issue I: Passive institutional controls should be considered part of DOE's "defense in depth" approach. (CCNS-B)

Response to Issue 15.I:

As stated in § 191.14 of the disposal regulations, the purpose of assurance requirements is to "provide the confidence needed for long term compliance . . . ." In the compliance criteria, the Agency addresses this needed confidence by implementing the six assurance requirements for the WIPP. Passive institutional controls are an element of the assurance requirements. See also response to Issue 15.C.

Issue J: The DOE should be considered in violation if it cannot persuasively demonstrate the probable delivery of warning communication at least to the 10,000-year horizon. (CARD-B, A-38)

Response to Issue 15.J:

Consistent with 191.14(c) of the disposal regulations, the final rule requires that DOE's compliance certification application contain the most permanent markers, records, and other PICs practicable to indicate the location of the wastes and their danger. Neither the disposal regulations nor the compliance criteria require that PICs be definitively effective for 10,000 years; both regulations require that the most permanent measure practicable must be

employed. The EPA will evaluate the adequacy of PICs, including the period of time they are expected to endure and be understood, in EPA's review of the compliance certification application. Further, with respect to the 10,000-year time frame, specifying "at least to the 10,000-year horizon" implies regulation beyond the regulatory time frame prescribed in the disposal regulations. See also response to Issue 15.C.

Issue K: Converting certification requirements to conditions subsequently denies them any force and defeats public process. The DOE should present evidence of financial support for and commitment to construction of markers. Rulemaking must be reopened to determine whether plan is actually carried out. (NMAG-B)

1. The following subsection should be added to the rule in §194.43, "The application for certification of compliance shall include specific financial and contractual commitments made to support the implementation of the plans as to passive institutional controls." (NMAG-D)

Response to Issue 15.K:

Section 43 of 40 CFR part 194 requires DOE to describe in its compliance application passive institutional controls that will be employed to preserve knowledge about the location, design, and contents of the disposal system. Consistent with the rest of the application, that plan will be subject to public scrutiny during the certification rulemaking. The Agency will fully consider public input before EPA certifies compliance with the radioactive waste disposal standards. With respect to PICs, EPA must be satisfied that the measures described by DOE in the application will actually be implemented as planned.

To further ensure that DOE fulfills all commitments made in the compliance application, any activities which depart from the basis on which EPA determines compliance will subject any compliance certification to modification, suspension or revocation, as described in §194.4. Among other things, §194.4 states that any modification (or change in condition) of the certification is to be conducted in a public rulemaking. A rulemaking re-opening the initial certification would also be subject to judicial review.

There may be instances, however, where departing from the certification could be more protective because of advances in technology. While disposal system changes would be subject to review, they may actually provide further protection.

Section 16: ENGINEERED BARRIERS: SECTION 194.44

Issue A: The EPA is exceeding its authority (references to 40 CFR part 191).

1. Part 191 requires a total systems approach and does not specify barriers as a discrete subsystem. (DOE-D)

Response to Comment 16.A.1:

"Barriers," both engineered and natural, are specified in the WIPP Land Withdrawal Act [Public Law 102-579, Sec. 8(g)] and the disposal regulations in §191.14(d). Engineered barriers are explicitly required [§191.14(d) and §194.44] as an "assurance" requirement intended to provide the confidence needed for long-term compliance with the containment requirements. The assurance requirements of §191.14 identify six elements, including engineered barriers. The compliance criteria do not specify engineered barriers as a "subsystem" of the "total disposal system."

2. Section 194.44(a) imposes substantial new requirements with regard to compliance at the WIPP facility. (WEC-D)

Response to Comment 16.A.2:

Section 194.44(a) implements §191.14(d) which states, "[b]oth engineered and natural barriers shall be included."

3. Subsections 194.44(b), 194.44(e), 194.44(c)(1)(ii), 194.44(c)(1)(iv), and 194.44(c)(1)(vi) should be eliminated. (DOE-D, SNL-C)

4. A combination of engineered barriers should be required to provide additional assurance for the integrity of the repository in view of the inherent uncertainties in projecting the long-term performance of the repository. (EEG-D)

5. The EPA should delete "public" in 40 CFR 194.44(c)(1)(vi). The evaluation should consider increased or reduced confidence in the performance of the disposal system and should not be limited to public confidence. (NRC)

Response to Comments 16.A.3 through 16.A.5:

When DOE analyzes an engineered barrier option [as in DOE's 1991 Engineered Alternatives Task Force (EATF) Report on Engineered Alternatives for the WIPP, DOE/WIPP 91-007], some barriers, when combined with others, may show marked improvement or, in some cases, significant reductions in disposal system performance. The nine factors specified in §194.44(c)(1) combine to give a complete evaluation of a potential engineered barrier. For example, the risk to workers from increased handling activities, and to the public and the environment from increased transportation, are essential concerns in considering engineered

barriers. The evaluation criteria were chosen to ensure that 1) engineered barriers are thoroughly examined and 2) fulfilling the requirement does not inadvertently lead to actions which could compromise the overall system performance or increase overall risk.

The EPA recognizes that "public confidence" is difficult to measure; therefore, this factor was changed in the final rule to "public comments requesting specific engineered barriers," the intent of which is to ensure that DOE consider the public's input before selecting the engineered barrier(s) for the disposal system.

6. Subsection 194.44(e) should cross reference compliance standards contained in 40 CFR 194.41, 194.42, 194.43, and 194.44. The requirement to consider transportation and worker exposure in evaluating engineered barriers is outside the scope of this proposed rule. (SNL-C)

Response to Comment 16.A.6:

The WIPP facility as a whole must comply with the disposal standards set forth in 40 CFR part 191. The EPA believes the compliance criteria are internally consistent, and that it is not necessary to cross reference standards contained in one section of the rule to all other sections where they may be applicable. The EPA believes that it is essential that the implementation of an engineered barrier (or combination of barriers) not increase the overall risk to the public and the environment. For that reason, the increased or reduced risk from transporting or handling the waste is a part of a comprehensive engineered barrier evaluation. See also the response to Comment 16.A.3.

7. The imposition of such cost/benefit studies would impose substantial new time and cost constraints not previously indicated by 40 CFR part 191. (DOE-D, WEC-D, SGNM-A, EEG-B, SRIC-C, C-28, A-11, A-13, A-45, IV-D-56)

8. The EPA should use the results of their research to assist in setting reasonable criteria within the scope of the Land Withdrawal Act, and the 40 CFR 191 regulations. (IV-D-40)

9. The inclusion of the requirement for the engineer barrier study in the proposed rule is inappropriate. (DOE-A)

10. The wisdom of mandating the preparation of an analysis of benefits and costs related to engineered barriers is questioned. These criteria should provide guidance relating to appropriate actions to be undertaken by the applicant. (SGNM-C, EEG-A, EEG-B)

11. It is not appropriate for EPA to require DOE, by rule, to perform the study. This is not specified in 40 CFR part 191 and it is doubtful whether such a study would add any real value to enhance health and safety. (IV-D-111)

Response to Comments 16.A.7 through 16.A.11:

The assurance requirements of §191.14 require the use of engineered barriers. As a result of discussions at public meetings, DOE has already agreed to undertake an evaluation of engineered barriers. The nine factors specified in the final rule in §194.44(c)(1) are intended to rationalize and guide the evaluation. The engineered barriers evaluation provides an objective mechanism for justifying decisions made regarding the implementation of the engineered barriers requirement in §191.14(d). The requirements for the evaluation outline the information that must be included in an evaluation, and presented in a compliance application.

Issue B: Other engineered barriers need to be considered.

1. Waste should be emplaced in glass or cement and the walls between the rooms should also be barriered to minimize the inevitability of human intrusion. (C-03)

2. Vitrification and other barriers (plugs and seals) mentioned should be evaluated to reduce the potential for the waste migration. (CARD-B, SRIC-C, SRIC-E, A-41)

3. The EPA must insist that DOE build more durable containers to help isolate the waste. (S-11, IV-D-82, SRIC-G)

4. Canisters are inappropriate due to gas generation. (C-03)

5. The compliance criteria should require waste containers to meet standards of resistance to corrosion, crushing, and inadvertent drilling. (A-68)

6. The criteria must specify which engineered barriers are required and what information on them must be in the application. (S-37)

7. Criteria for barriers, containers, and protection must be specified and strengthened and control of remote handled wastes. Old packaged wastes should not be exempt form review and necessary repackaging. (IV-D-12)

8. Without a criterion, the engineered barrier requirement is substantially reduced in effectiveness. (NMAG-C)

9. The EPA should indicate how it plans to seal off the doors after it puts the material in the rooms. (C-08)

10. Engineered barriers should contain some form of alarming identity to hazardous material if encountered by human intrusion. In addition, prior to cementing drilling contractors should sandblast to insure a better bond. (SGNM-D)

11. The criteria should mandate the use of properly engineered backfill; plugs and seals in drifts, panel entries, and shafts; and complete sealing of any drill holes. (SRIC-G)

Response to Issue 16.B:

Several options are required to be evaluated as part of the engineered barriers evaluation. Specifically, §194.44(b) states, "[i]n selecting engineered barriers for the disposal system, the Department shall evaluate the benefit and detriment of engineered barrier alternatives, including, but not limited to: cementation, shredding, supercompaction, incineration, vitrification, improved waste canisters, grout and bentonite backfill, melting of metals, alternative configurations of waste placements in the disposal system, and alternative disposal system dimensions." It is DOE's role as facility owner and operator to propose the engineered barrier(s) to be used at the WIPP and to justify and support the choice(s). It is EPA's role as regulator to evaluate the adequacy of DOE's decision, and this will be accomplished through the compliance certification rulemaking. The EPA believes it is inappropriate to require the use of specific barriers without an evaluation of their impact on the overall system. The Agency believes barriers should be selected based on an objective evaluation, and has specified the criteria for such a process. For comments regarding performance standards, see also the response to Comment 16.F.

Issue C: The evaluation of the engineered barriers needs to be extended over a longer time period.

1. WIPP should be considered in a state of non-compliance if acceptable safeguards are not in place. (S-28)

2. The compliance criteria should require DOE to analyze the effects of engineered barriers on reducing uncertainties over 100,000 years, as its own regulation requires for any other repository. (SRIC-E, SRIC-F)

Response to Issue 16.C:

Section 191.13(a) limits consideration of significant processes and events that may effect the disposal system to 10,000 years. The WIPP Land Withdrawal Act in Section 8(a)(1) reinstated this requirement of 40 CFR part 191. The compliance criteria implement the 40 CFR part 191 disposal standards. As EPA noted in promulgating the disposal standards of Part 191, "[t]here 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 containment requirements for 10,000 years would continue to protect people and the environment well beyond 10,000 years [50 FR 38076]." The 10,000-year regulatory time frame of the disposal standards was reviewed and supported by the EPA Science Advisory Board.

Issue D: The EPA needs to clarify its responsibility related to WIPP.

1. The LWA does not authorize DOE to reject engineered barriers; rather, that is EPA's responsibility. (EEG-B)

Response to Comment 16.D.1:

Neither the LWA, 40 CFR part 191, nor therefore 40 CFR part 194 prescribe the type, number, or performance standards of engineered barriers. The EPA established criteria to be considered in the selection or rejection of engineered barriers with the intention that DOE would systematically evaluate potential barriers. The results of this evaluation will indicate options that optimize protection of the public and the environment at a reasonable cost. If EPA were to require specific engineered barriers to be used, the Agency would be designing the facility and then approving its own design; this is the type of self-regulation the WIPP LWA aimed to avoid. Under the law, it is DOE's responsibility, not EPA's, to design the facility. In the certification rulemaking, EPA will thoroughly review DOE's evaluation and have final say, informed by the public, on the adequacy of engineered barriers proposed for the WIPP.

2. The EPA's decision to require the applicant to enhance public confidence attempts to shift from EPA to the applicant the responsibility for public health and environmental protection. (A-11)

Response to Comment 16.D.2:

The WIPP Land Withdrawal Act clearly defines the roles and responsibilities for EPA and DOE. Both agencies have the responsibility to protect public health and the environment: the EPA is responsible for implementing the disposal regulations specifically at the WIPP; and DOE is responsible for designing and operating the WIPP in a manner that is consistent with the requirements in the compliance criteria. The reference in §194.44(c)(1)(vi) to evaluate the increased or reduced public confidence in the performance of the disposal system (60 F.R. 5790) was intended to measure the perception of safety within the public at large. In the final rule, this factor has been revised to require DOE to consider public comments requesting specific engineered barriers. This does not shift responsibility but provides an opportunity for public input to DOE's analysis, in addition to an opportunity EPA will provide to the public in reviewing the adequacy of the evaluation in the certification rulemaking.

Issue E: Performance standards should be specified for engineered barriers.

1. Of the four approaches for EPA to use its authority regarding engineered barriers in the "Background Information," the approach which assigns minimum performance objectives to major sub-elements of the disposal system so as to lessen uncertainty is recommended. (SRIC-F)

2. The EPA must give a specific guide for how long prevention of any contaminant release to the environment is expected to be ensured by the inclusion of engineered barriers. This would help to clarify the intention that engineered barriers are an essential requirement. (DOE-D)

3. It is recommended that EPA address areas of regulatory uncertainty, such as "substantially delay," "all conceptual models not considered (60 F.R. 5790)" (§194.23), the application of future state assumptions (§194.25), and ambiguities in the protected individual (§194.51). (NRC)

4. The EPA should require engineered barriers and prescribe performance measures to assess their efficacy, similar to those found in 10 CFR 60.113. (EEG-B, EEG-C)

5. A performance target for the engineered barriers is suggested. This would provide an effective decision making tool for the DOE and a compliance measurement tool for the EPA. (EEG-C)

6. The DOE opposes specifying performance standards for engineered barriers and believes that such action would require changing Part 191 disposal regulations through rulemaking. (DOE-D)

7. The EPA shouldn't adopt a performance standard for evaluation of engineered barriers. (SNL-C)

8. A performance standard similar to that specified in 10 CFR Part 60 should not be adopted. (SNL-C)

9. A provision needs to be added to state that for contact-handled transuranic waste and remote-handled transuranic waste, the barriers should maintain the integrity of the barrier such that no more that one part in 100,000 per year of the radionuclide inventory of the barrier shall be released from the container. (NMAG-D)

10. The final rule should require specific containers with performance standards to prevent any releases from remote-handled waste. (SRIC-G)

Response to Issue 16.E:

The disposal regulations clearly establish standards in §191.13(a) for performance of the overall disposal system. By definition, in §191.12(a), "'[d]isposal system' means any combinations of engineered and natural barriers that isolate spent nuclear fuel or radioactive waste after disposal." Thus, performance of the disposal system is not evaluated by examining discrete elements independently, but by evaluating the disposal system as a whole. Further, EPA believes 40 CFR part 191 contains a relevant standard, which is "to [prevent] or substantially delay the movement of water or radionuclides toward the accessible environment" [see §191.12(d)]. This standard has been employed in the final compliance

criteria. Due to the complexity of the WIPP system, it is difficult to know, a priori, whether a barrier is helpful to containment or not. The evaluation of engineered barriers required in the final rule will ensure that DOE's decision on what barrier(s) to include is based on the best possible information. To ensure that the rationale for DOE's selection of engineered barriers is made public, the requirements for the evaluation outline the information that must be presented in a compliance application.

Under the final criteria, DOE, as owner and operator of the facility, must thoroughly analyze the appropriate engineered barrier(s) to employ, and EPA, as regulator, will judge the appropriateness of this determination.

Issue F: The EPA should require that, pending compliance certification, DOE take no action rendering it substantially more difficult for DOE or EPA to apply the engineered barrier requirement. For example, DOE should not repack waste or mine waste rooms in such a way that an engineered alternative such as shredding or different disposal room dimensions becomes more expensive, thereby prejudicing an analysis based in part on "total system costs." (NMAG-G)

1. The following text should be added to §194.44, "In considering the benefit and detriment of alternative disposal system dimensions, the benefit and detriment of alternative dimensions for parts of the disposal system now constructed (as of 1994) as well as parts to be constructed (after 1994) shall be considered." (NMAG-D)

Response to Issue 16.F:

The EPA does not expect the evaluation of engineered barriers to be prejudiced, and, in §194.44(b), DOE is required to examine alternative disposal system dimensions. In addition, EPA does not believe that it is appropriate to impose a ban on certain WIPP-related activities due to a bias concern.

Issue G: The inclusion of criteria for evaluating engineered barriers is needed.

1. Engineered barrier options should be studied by DOE and results included in the certification submission, but the EPA should not specify in detail what is to be included. (SGNM-C, EEG-C, IV-D-51)

2. Proposing criteria for selecting engineered barriers is undesirable micro management. (IV-D-06)

3. The EPA shouldn't specify by rule the criteria to be used to evaluate engineered barriers. (SNL-C)

Response to Comments 16.G.1 through 16.G.3:

Section 44 of the compliance criteria balances not specifying particular engineered barriers at this juncture with establishing criteria for what is to be included in the evaluation of engineered barriers to be submitted with the certification application. The regulation allows DOE reasonable flexibility. The EPA has, however, specified the minimum information that is necessary for DOE to make an informed decision. The nine factors that are specified ensure that each barrier considered receives a balanced evaluation. For example, if transportation risk were not a required factor for consideration, a barrier that shows significant reduction in the uncertainty with respect to projecting long term repository performance may have a substantial "hidden" risk to the public and the environment due to increased transportation risk.

4. The EPA must specify that the effect of engineered barriers must be considered in the pre-certification review of all design evaluations, quality assurances, and safety margins. The criteria must require these plans to consider the inclusion of engineered barriers from their initial planning stages. (CCNS-B)

Response to Comment 16.G.4:

Engineered barriers, an assurance requirement, are required "to provide the confidence needed for long-term compliance with the requirements of 191.13" (See §191.14). Engineered barriers will fall under the same rigors of quality assurance as all other areas of WIPP design. In addition, the engineered barrier evaluation required in §194.44(b) must be subject to peer review as required in §194.27(a)(3). See also response to Comment 16.F.1.

5. The proposed rule provides no criteria or basis for the selection of engineered barriers other than the outcome of the benefit/detriment analysis. (EEG-A, SNL-C)

Response to Comment 16.G.5:

The evaluation factors specified in §194.44(c)(1)(I)-(ix) were chosen to ensure that: (1) engineered barriers fulfill the purpose of the assurance requirements; and (2) fulfilling the assurance requirement does not inadvertently lead to actions which could compromise the overall system performance or increase overall risk. The EPA believes that the results of the evaluation will provide an adequate basis upon which decision makers can base their conclusions with regard to fulfilling the requirement in §194.44(a).

6. The compliance criteria must require DOE to use engineered barriers that are designed to eliminate releases from the environment. (A-09, A-08, A-18, IV-D-28)
Response to Comment 16.G.6:

Some releases within the controlled area are acceptable. The compliance criteria implement the disposal regulations by requiring use of engineered barriers that "prevent or substantially

delay the movement of water or radionuclide toward the accessible environment" [see §194.44(a)].

7. The EPA should provide specific criteria for evaluating alternative engineered barriers in terms of total system performance for compliance with 40 CFR 191.13(a). (WEC-D)

8. The regulations for engineered barriers are weak and need to be strengthened. There is particular concern with the dependence on the benefit/detriment analysis to make decisions as outlined in the proposed rule. (EEG-B, EEG-C)

9. Consideration of single engineered barriers alone is an inappropriate exercise when undertaken without consideration of the total system. (SNL-C)

Response to Comments 16.G.7 through 16.G.9:

The WIPP must comply with the requirements set forth in §191.13(a). Engineered barriers are required "to provide the confidence needed for long-term compliance with the [containment] requirements of 191.13" (see §191.14). The evaluation of engineered barriers must take into account total system performance in reducing uncertainty and risk. The nine factors specified in §194.44(c) describe a total system approach. See also the responses to Issues 16.B and 16.E.

10. The DOE should be requested to complete its study of engineered barriers promptly, and the Agency should use the study in drafting an engineered barrier criterion. The Agency's criterion should place a limit on releases from the room. (NMAG-B)

11. Specifics need to be developed on engineered barriers to prevent water intrusion. (A-68)

12. Engineered barriers should virtually eliminate any release of radioactivity. Current criteria only require DOE to study various barriers. (EEG-B, NMAG-A, A-09, A-29, A-46, IV-D-13, IV-D-14, IV-D-15, IV-D-16, IV-D-17, IV-D-18, IV-D-19, IV-D-20, IV-D-21, IV-D-22, IV-D-23, IV-D-24, IV-D-25, IV-D-30, IV-D-31, IV-D-32, IV-D-33, IV-D-34, IV-D-37, IV-D-38, IV-D-42, IV-D-43, IV-D-46, IV-D-47, IV-D-48, IV-D-51, IV-D-52, IV-D-53, IV-D-54, IV-D-55, IV-D-56, IV-D-57, IV-D-58, IV-D-59, IV-D-60, IV-D-61, IV-D-62, IV-D-63, IV-D-66, IV-D-67, IV-D-68, IV-D-69, IV-D-70, IV-D-71, IV-D-72, IV-D-74, IV-D-75, IV-D-79, IV-D-80, IV-D-83, IV-D-87, IV-D-88, IV-D-92, IV-D-99)

Response to Comments 16.G.10 through 16.G.12:

The engineered barrier evaluation includes evaluation of an engineered barrier's ability to "prevent or substantially delay the movement of water or radionuclides toward the accessible environment" [see §194.44(a)]. For further discussion of performance standards, see the responses to Comments 16.A.7 through 16.A.11, Issues 16.B, 16.E, 16.F, and Comment 16.G.6.

13. The DOE should be required to incorporate barriers into WIPP, not just study them. (A-60, CARD-B)

14. Engineered barriers are required by 191 and LWA, and must be required by 194. (SRIC-C)

Response to Comments 16.G.13 and 16.G.14:

The DOE is required to incorporate engineered barriers into the disposal system by §191.14 (d), and this requirement is reiterated by the WIPP LWA in section 8(g). Section 194.44 of the compliance criteria implements this requirement, while allowing DOE enough flexibility to design its own facility. The evaluation that is required in §194.44(b) is intended to provide DOE with a means to select engineered barriers based on a reasonable combination of performance, cost, risk, etc. Engineered barriers *may* be used to meet the containment requirements, but *must* be used to meet the assurance requirements.

Issue H: The criteria for engineered barriers should be eliminated.

1. Resources would be used more efficiently if only a few engineered barriers were chosen as opposed to the numerous barriers listed in 194.44(b). (SNL-A)

Response to Comment 16.H.1:

The purpose of the engineered barrier evaluation is to determine the most effective engineered barriers based on a variety of relevant factors. In addition, §194.44(c)(2) allows DOE to reject a particular engineered barrier if the Department can demonstrate that such barrier should be ruled out before evaluating all nine factors. Thus, resources will be allocated appropriately.

2. Engineered barriers that will not be implemented do not need to be studied. (SNL-A)

Response to Comment 16.H.2:

The only prudent way to determine which barriers should be implemented is to evaluate and compare the various alternatives. The provision under §194.44(c)(2) allows DOE to rule out unreasonable engineered barriers early in the process (see response to comment 16.H.1).

3. 40 CFR 194.14 and 194.15 should be revised to clarify that design criteria are applicable only to the engineered barrier components of the disposal system. (SNL-C)

Response to Comment 16.H.3:

The inclusion of design information as specified in §194.14 and §194.15 is not limited to the engineered barrier components of the disposal system.

4. The requirement for evaluation of specifically identified engineered barriers should be eliminated from 194.44(b). (SNL-C)

Response to Comment 16.H.4:

The EPA believes that the barriers specified in §194.44(b) are among appropriate barriers to be considered. Further, these barriers have been included in past DOE evaluations such as the 1991 EATF Report [DOE/WIPP 91-007].

5. The proposed rule imposes de facto requirements for the incorporation of multiple engineered barriers in the disposal system beyond those that would be required to provide the assurance mandated by 40 CFR 191.14(d). (SNL-C)

Response to Comment 16.H.5:

Section 191.14 requires the use of one or more engineered barriers. Section 194.44 does not intend to require the use of multiple engineered barriers; it simply implements 40 CFR part 191 at WIPP. The DOE must evaluate and propose in its compliance application engineered barriers necessary to comply with the containment and assurance requirements of the disposal regulations.

Issue I: The cost-benefit studies allow DOE to self-regulate.

1. A cost-benefit study of engineered barriers conducted by EPA should include a risk analysis. (A-41)

Response to Comment 16.I.1:

The DOE, as owner and operator of the facility, is required to conduct the evaluation of engineered barriers. The compliance criteria require that risk be one of the factors that must be considered in DOE's evaluation. For example, §194.44(c)(1) requires, "(ii) the impact on worker exposure to radiation both during and after incorporation of engineered barriers; . . . (iv) the increased or reduced risk of transporting the waste to the disposal system."

2. Directing DOE to determine benefits and detriments and determine what should be used allows the DOE to regulate itself. (NMAG-B, SRIC-A)

3. These regulations would instruct DOE to do the underlying analysis, which involves self-regulation. The EPA should do the necessary studies. (NMAG-A)

Response to Comment 16.I.2 and 16.I.3:

The disposal regulations at §191.14(d) state, "[d]isposal system shall use different types of barriers to isolate the waste from the accessible environment. Both engineered and natural barriers shall be included." To gain the most assurance that the public and environment will

be protected, an evaluation of possible engineered barrier alternatives is required by 40 CFR part 194. It is DOE's role, as facility owner operator, to evaluate and propose the engineered barriers to be used at the WIPP and to justify and support those choices. It is EPA's role, as regulator, to evaluate thoroughly the adequacy of DOE's decision. The EPA believes it is inappropriate to require the use of specific barriers without an evaluation of their impact on the overall system. The Agency believes barriers should be selected based on an objective evaluation, and has specified the criteria for such a process.

Issue J: Engineered barriers is the least that can be expected from the public in order to preserve our safety. (S-16)

Response to Issue 16.J:

Engineered barriers are required by the disposal regulations in order to protect the public and the environment. The EPA will grant a compliance certification only if this requirement is fulfilled.

Issue K: As an assurance requirement, the engineered barriers requirement independent of and separate from the containment requirements.

1. It is a fundamental mistake for the Agency to accept the idea that engineered barriers shall be adopted, or not, based on whether they improve performance measures under the containment requirements. (NMAG-C)

2. Since every effort should be made to control the future internal state of the repository, the EAs need to support confidence in the long-term performance of the repository. (SGNM-D)

3. The engineered barrier requirement must be given independent force. It is not satisfied by a showing of compliance with the containment requirement, because of the uncertainties in such a showing and the nonconservatism of that rule. (NMAG-D)

4. Engineered barriers are a requirement out of 40 CFR part 191 and should be included in the proposed rule. (NMAG-D)

5. Reject the notion of using engineered barriers as component of the Containment Requirement of 40 CFR part 191. To be consistent, maintain engineered barriers as an Assurance Requirement. (EEG-D)

Response to Issue 16.K:

While engineered barriers are required pursuant to the assurance requirements at §194.14(d), engineered barriers are not necessarily required to meet the containment requirements at §191.13. However, DOE may choose to use an engineered barrier(s) to meet compliance with the containment requirements.

By definition, in §191.12(a), "'[d]isposal system' means any combinations of engineered and natural barriers that isolate spent nuclear fuel or radioactive waste after disposal." Thus, performance of the disposal system is not evaluated by examining discrete elements independently, but by evaluating the disposal system as a whole.

Consistent with the requirements found in §191.13, that DOE analyze the performance of the *complete* disposal system, any engineered barriers that are implemented at the WIPP must be considered by the Department and, ultimately, by EPA when evaluating compliance with both the containment requirements in §191.13 and the assurance requirement in §191.14(d). The effects of engineered barriers employed at the WIPP must be considered in performance assessments; excluding such barriers from consideration would result in inaccurate modeling of the disposal system as defined in §191.12(a).

Issue L: The Agency should obtain the results of the engineered barrier study promptly from DOE so that this issue will be addressed promptly rather than being further postponed. (NMAG-D)

1. The engineered barrier study should be submitted one year in advance of the application. (NMAG-D)

2. Any study of engineered barriers must be submitted to EPA at least one year before a compliance application to allow adequate time for public and agency review. (SRIC-G)

Response to Issue 16.L:

The engineered barrier evaluation required under §194.44 is part of the overall compliance application that will be submitted to EPA by DOE. As such, the evaluation, along with the rest of the application, will be reviewed by EPA and the public as part of the certification rulemaking. The EPA will base its certification decision on the total application, all of which must demonstrate compliance with the disposal standards of 40 CFR part 191, as well as the compliance criteria of 40 CFR part 194. The EPA believes this approach is consistent with the approach taken elsewhere in the compliance criteria.

Section 17: CONSIDERATION OF THE PRESENCE OF RESOURCES: SECTION 194.45

Issue A: Consideration of resource recovery is inconsistent with 40 CFR part 191.

1. "Resource Recovery" activities fall outside the scope of the limitations. (SNL-C)

2. The Supplementary Information, by requiring consideration of "resource recovery" is inconsistent with the basis for 40 CFR part 191, particularly with the basis for promulgation of the release limits. (SNL-C)

3. The scope of the required evaluation in the Supplementary Information is inconsistent with the proposed wording of the rule. (SNL-C)

Response to Issue 17.A:

The final rule has been revised from the proposed rule to clarify EPA's intentions regarding the assurance requirement for presence of resources, §191.13(e). The final rule states that the compliance application must demonstrate that the favorable characteristics of the disposal system compensate for the presence of resources in the vicinity of the disposal system and the likelihood of the disposal system being disturbed as a result of the presence of those resources. The final rule further provides that the requirements of §191.13(e) and §194.45 will be fulfilled if performance assessments, taking into account human intrusion, predict that the numerical release limits of the disposal regulations will be met. This approach reasonably implements §191.13(e) at the WIPP because performance assessments must account for the increased potential for human intrusion into the disposal system due to the presence of resources, based on historical rates of drilling and of mining in the vicinity of the WIPP. Analysis of human intrusion must consider exploratory and developmental drilling of all resources in the Delaware Basin, as well as mining, consistent with the disposal regulations which state that performance assessments must consider events that may affect the disposal system during the regulatory time frame.

The 40 CFR part 191, Appendix C guidance which discussed exploratory drilling is non-binding on the implementing Agency, which is EPA for the WIPP. Appendix C was designed to apply to all geologic repositories for the disposal of highly radioactive wastes, not necessarily to the specific site characteristics of the WIPP and not only to transuranic waste. As a result, EPA found in developing the final rule that only some of the guidance contained in Appendix C has specific relevance to the WIPP. In the case of developmental drilling, the EPA has determined, based on technical and policy considerations, that the Appendix C guidance is not applicable to the WIPP. As noted in the responses to Section 12 of this document, EPA has found unpersuasive the contention that exploratory drilling would definitely locate the disposal system, or, even if it did, that it would necessarily eliminate the likelihood of related exploration and development. Thus, the Agency has retained its requirements to consider developmental drilling under human intrusion. See responses to Section 12 of this document for further discussion of this issue.

Issue B: The WIPP has conducted previous research into the presence of resources with the first important study being conducted in 1981. It is not apparent how additional research would benefit the project nor the EPA to coming to a compliance determination. (IV-D-40)

Response to Issue 17.B:

Section 194.45 does not necessarily require research of past or potential future resource exploration and recovery activities beyond what is already required to document compliance of performance assessment (PA) results with EPA's containment requirements under 40 CFR part 191 and the compliance criteria. As noted in the prior response, the final rule clarifies that the requirements of §191.13(e) and §194.45 will be fulfilled if performance assessments, taking into account human intrusion, predict that the numerical release limits of the disposal regulations will be met. This approach reasonably implements §191.13(e) at the WIPP because performance assessments must account for the increased potential for human intrusion into the disposal system due to the presence of resources, based on historical rates of drilling and of mining in the vicinity of the WIPP. Past exploration and extraction of resources in the vicinity of the WIPP will be used as the basis for modeling potential future human intrusion into the disposal system, as specified in §194.32 and §194.33 of the final rule.

Issue C: The rule should be more explicit about what resource information is needed.

1. The rule should state the scope and level of exposure scenarios presentation necessary to satisfy "full consideration of potential effects" of resource recovery activities. (CARD-B)

2. EPA should explicitly delineate scope, specificity, and presentation format of resource information needed. (SGNM-C, IV-D-56)

Response to Issue 17.C:

The proposed compliance criteria provided that "[a]ny application for certification of compliance shall include information that demonstrates that the favorable characteristics of the disposal system compensate for the presence of resources in the vicinity of the disposal system and the likelihood of future human-initiated processes and events as a result of the presence of those resources [60 FR 5790]." In the Supplementary Information to the proposal, the Agency elaborated: "If, after full consideration of the potential effects of resources recovery activities the WIPP is still predicted to meet the requirements of 40 CFR part 191, then the Agency will assume that the requirements of this part and section 14(e) of 40 CFR part 191 have been fulfilled [60 FR 5780]." The Agency requested additional comment on this approach.

As explained in the prior responses, EPA has explicitly adopted this approach in the final rule. The final rule provides that EPA will assume that the assurance requirement will be met if performance assessment (PA) results demonstrate compliance with the containment

requirements of 40 CFR part 191. Thus, to fulfill this requirement, a full consideration of the potential effects of resource recovery activities at the WIPP must include the following: 1) PA analyses for "disturbed scenarios" must consider potential human intrusion for resources, including drilling and excavation mining, according to the criteria in §194.32 and §194.33, and as explained in the preamble to the final rule; and 2) PA analyses and compliance assessments for "undisturbed performance" must consider the effects on the disposal system of any activities that occur in the vicinity of the disposal system prior to disposal and of activities that are expected to occur in the vicinity of the disposal system soon after disposal (based on development of existing leases). The scope of performance assessments and accompanying documentation are in turn clearly specified in the final rule.

Issue D: Resources should be identified and extracted before waste is stored.

1. All resources should be extracted before the radioactive waste is stored. (A-53)

2. Drilling should take place in the present to identify potential resources to avoid the possibility of future drilling. (C-12)

Response to Issue 17.D:

The EPA is primarily concerned with consideration of resource recovery activities as potential mechanisms to release waste accidentally from the repository, and thus is most concerned about drilling in the controlled area at the WIPP. The EPA has considered that allowing or even requiring recovery of known resources above the WIPP in the immediate future could be a way to reduce the potential for future intrusions related to recovery of these resources. This approach was rejected because of the possibility that active mining or drilling above the repository could create unexpected new pathways for movement of radionuclides from the disposal system and compromise its performance. In addition, mining presently identified resources cannot mitigate intrusion for resources not currently identified, or resources which are not now, but could become, economically feasible to recover. Finally, Congress has specifically prohibited, under the WIPP LWA, "surface or subsurface mining or oil or gas production, including slant drilling . . . on lands on or under the Withdrawal" area containing the WIPP site [Public Law 102-579, Sec. 4(b)(5)(A)]. The EPA's rulemaking cannot and does not affect this prohibition. For these reasons, EPA has not changed the final rule to allow or encourage recovery of resources above the WIPP site.

For similar reasons, EPA concludes that it is inappropriate to pursue drilling now to identify potential resources. Resources in the vicinity of the WIPP have been documented and mapped. The potential of identifying resources that have not been documented, and the uncertainty in speculating about resources that may become valuable, does not outweigh the risk of creating additional release pathways and, in any event, does not overcome the statutory prohibition on drilling.

Issue E: Special provisions for consideration of resources is unnecessary since this will be handled through performance assessment. (DOE-D)

Response to Issue 17.E:

As noted, the final rule provides that the resources assurance requirement will be met if PA results which take into account resource recovery activities demonstrate compliance with the Agency's requirements under 40 CFR parts 191 and 194. This presupposes that performance assessments fully consider the effects of resources, as specified in this part, and are rigorous and well-documented. See responses to Issues 17.A and 17.C of this section for more information. The final rule has been revised to clarify EPA's intent in determining compliance with the assurance requirement.

Issue F: Consideration of resource conflicts in compliance certification should also include increased likelihood of intrusion occurrence and severity based on real-life regulatory experience with extractive industries. (CARD-B)

Response to Issue 17.F:

The effects of actual experience are accounted for in performance assessments that require the likelihood for human intrusion to be calculated based on the historical drilling and mining activity in the Delaware Basin. Further, EPA requires that DOE implement active institutional controls [§194.41] at the WIPP site in addition to passive institutional controls (PICs) [§191.43], which include government ownership and regulations regarding land or resource use. Active institutional controls include monitoring and any means other than PICs of controlling access to a site, such as walking patrols at the site perimeter. The final rule limits reductions in the likelihood of human intrusion that may be allowed for implementing active institutional controls to the first 100 years after disposal, and any such reductions must be supported by the DOE. The final rule also limits the time period for which PICs may be assumed to reduce the likelihood of human intrusion to several hundred years after disposal. Further, the presence of PICs can never be assumed to eliminate the possibility of human intrusion. The EPA believes that the implementation of active and passive controls, as required by the final rule, will deter attempts to recover resources in the vicinity of the WIPP. However, in recognition of the uncertainty surrounding the effectiveness of these measures, the final rule limits the assumptions which may be made regarding the effectiveness of such controls in performance assessments by, among other things, placing constraints on the time period for which they may be considered in reducing the likelihood of inadvertent human intrusion.

Issue G: No waste should be stored at WIPP if there are resources and/or mining activity.

1. Radioactive waste should not be stored where there is mining activity and active or potential drilling for oil reserves. (S-56)

2. Many valuable resources are in the area and it is 100 percent certain that the WIPP site will be invaded by a drilling rig in the 10,000 years it is being planned for. (S-23)

3. The WIPP site should be disqualified from consideration if there are oil, gas, and potash resources near the site. (S-17)

4. The rich natural resources of the area need to be addressed since something like WIPP is supposed to be placed where there are no such resources. (A-35, S-12, IV-D-07)

5. The WIPP is in an area that contains valuable resources that are of great interest to industry. We see no benefit that would compensate for the contamination as a result of mining or drilling near the WIPP site. (S-40)

6. Because WIPP is located on some oil, gas, and potash-rich area, EPA must evaluate the WIPP from another characteristic that would justify violating existing EPA regulations. (EEG-A, A-09, A-33, A-43, A-48, A-54, A-64)

7. The siting of WIPP in a resource rich area does not meet basic EPA regulations. (EEG-C, S-21, IV-D-26, IV-D-73, IV-D-91)

8. A demonstration that the favorable characteristics of the WIPP compensate for resource considerations should have been considered as long ago as when the site was selected. (EEG-C, IV-D-06, IV-D-28, IV-D-51)

9. Contrary to claims by some parties, recent updated information on mineral resources near the WIPP does not cause the WIPP to be in violation of the EPA's regulations. (DOE-E)

Response to Issue 17.G:

The presence of resources and resource-related activity at the WIPP does not necessarily disqualify it from use as a radioactive waste disposal facility. When EPA was developing the final radioactive waste disposal regulations, EPA proposed to prohibit use of sites where there is a reasonable expectation that future exploration for scarce or easily accessible resources might occur. See 47 FR 58205 (Dec. 29, 1982). In adopting the final radioactive waste disposal standards, EPA concluded that the presence of resources should not disqualify a site that may have compensating features. Thus, the final disposal regulations provide that:

> Places where there has been mining for resources, or where there is a reasonable expectation of exploration for scarce or easily accessible resources, or where there is a significant concentration of any material that is not widely available from other sources, should be avoided in selecting disposal sites. . . . Such places shall not be used for disposal *unless the favorable characteristics of such places compensate for their greater likelihood of being disturbed in the future.*

See 40 CFR 191.14(e) (emphasis added).

Congress authorized development of the WIPP in section 213(a) of the Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1980

(1980 DOE Act): "The Secretary of Energy shall proceed with the Waste Isolation Pilot Plant construction project authorized to be carried out in the Delaware Basin of southeast New Mexico (project 77-13-F) in accordance with the authorization for such project as modified by this section. Notwithstanding any other provision of law, the Waste Isolation Pilot Plant is authorized as a defense activity of the Department of Energy . . . for the express purpose of providing a research and development facility to demonstrate the safe disposal of radioactive wastes resulting from the defense activities and programs of the United States. . . ." See Pub. L. No. 96-164. In the 1992 WIPP LWA Congress withdrew WIPP and surrounding lands from the public domain and reserved such lands "for the use of [DOE] for the construction . . . of WIPP as set forth in section 213 of the [1980 DOE Act] and this Act."

In the final compliance criteria for the WIPP, EPA has provided that the provisions §191.14(e) will be fulfilled if performance assessments predict that the disposal system meets the containment requirements. The EPA has in turn revised the performance assessment requirements in the final rule to ensure that they include consideration of relevant resources, including "mining for resources" in the vicinity of the WIPP, even though inadvertent drilling for resources is the most severe human intrusion scenario at the WIPP. Thus, at this stage in the regulatory process, the performance assessments for the WIPP provide a rigorous analytical methodology to determine with reasonable certainty whether the WIPP has compensating features to provide overall protection of public health and the environment notwithstanding the presence of resources.

Issue H: The WIPP requirements could harm resource recovery industries.

1. The WIPP requirements for boreholes would limit the development and production of possible petroleum reserves in the area. (S-47)

2. The WIPP regulations would have a harmful affect on the potash and mining industries. (C-20, C-21)

Response to Issue 17.H:

Congress specifically prohibited, under the WIPP LWA, “surface or subsurface mining or oil or gas production, including slant drilling from outside the boundaries of the Withdrawal . . . on lands on or under the Withdrawal” area containing the WIPP site. [See Public Law 102-579, Sec. 4(b)(5)(A).] There are currently active mineral and petroleum leases and drilling permits (managed by the U.S. Department of the Interior) on lands adjacent to the WIPP Land Withdrawal Area.

Because of the likelihood of future resource exploitation, the final compliance criteria require that DOE consider the potential effects on disposal system performance from resource exploration and recovery near the WIPP; such effects are included in the performance assessment (PA) scenarios. Drilling and mining rates established under the criteria apply to hypothetical scenarios to be included in PA calculations, based on historical drilling and

mining activities. The compliance criteria do not establish limits on drilling and mining in the area outside the Withdrawal.

Issue I: It is not clear how an evaluation of "favorable characteristics" can be done; the term implies a comparison, and sites to be compared are not identified. EPA should specify hypothetical disposal systems to be built in areas which are not exploration targets. Then, comparisons of sites should be done by an objective test. (CARD-B, NMAG-B, NMAG-G)

1. The following section should be added to §194.45, "Such demonstration shall compare that disposal system with alternative systems which would be located at sites which contain no resources and shall show that the likelihood or releases in violation of the disposal standards is lower at the WIPP site than at such other sites." (NMAG-D)

2. In order to demonstrate that the favorable characteristics compensate for resources near the WIPP, the rule should require DOE to compare the WIPP to other disposal sites without the presence of such resources, and to demonstrate that the likelihood of releases from the WIPP is lower than at such other sites. (SRIC-G)

Response to Issue 17.I:

The regulatory text provides that: "Such places [with resources] shall not be used for disposal of the wastes covered by this part unless the favorable characteristics of such places compensate for their greater likelihood of being disturbed in the future." See 40 CFR 191.14(e). The language does not expressly mandate a comparison with other disposal sites. The regulatory text can be construed to call for comparison of the characteristics of a disposal system under consideration--an evaluation of the favorable characteristics of a site in comparison with the greater likelihood that the site will be disturbed due to its unfavorable characteristics, the presence of resources.

Moreover, Congress has ratified the selection of WIPP as a proposed radioactive waste disposal site in section 213(a) of the Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1980 (1980 DOE Act) and again in the 1992 WIPP LWA when, among other things, Congress withdrew the site from the public domain for specific consideration for transuranic radioactive waste disposal. See Pub. L. Nos. 96-164 & 102-579. Congress called for EPA to issue specific criteria to certify whether the WIPP facility will comply with the general radioactive waste disposal regulations at the same time it withdrew the WIPP site from the public domain for specific consideration. The EPA has acted consistently with Congressional action by developing criteria to rigorously evaluate whether the WIPP facility complies with the disposal regulations. In light of Congressional action ratifying the WIPP as a candidate disposal site and calling for specific regulatory examination of the WIPP site, EPA declines to require an examination of whether some other site might comply with the disposal regulations or have characteristics more favorable than the WIPP site.

Nevertheless, EPA has revised the final rule to ensure that resources at the WIPP site are fully examined. The EPA proposed to require the WIPP performance assessment to evaluate drilling activities at the WIPP, because drilling for resources is the most severe human intrusion scenario. Because the final rule allows DOE to rely on the results of the performance assessments to demonstrate whether their are compensating characteristics for the presences of resources at the WIPP, EPA has expanded the scope of WIPP performance assessment to include the effects of mining for resources. This approach ensures a comprehensive analysis of the potential detrimental affects from the presence of resources, consistent with the assurance requirement of §191.14(e).

The EPA also notes that DOE has examined alternatives to the WIPP in its environmental impact analysis of the WIPP site pursuant to the National Environmental Policy Act.

Issue J: The types of resources need to be addressed.

1. The nature of resources found at WIPP should be taken into consideration. Some minerals, such as those present in attractive quantities at WIPP are more prone to inveterate intrusion than others. (CARD-B)

Response to Comment 17.J.1:

This concern regarding the nature of resources at the WIPP is addressed in §194.32 and §194.33, which address the type of resources to be included in consideration of human intrusion. The final rule requires consideration of drilling activities for potash, water, and other resources in addition to oil and gas, if they have the potential to affect the waste disposal system, and also requires consideration of excavation mining, based on resources which are currently extracted in the Delaware Basin. See Section 12 of this document for further discussion of drilling and mining rates and consequences.

The second issue raised by this comment is the possibility that minerals present in attractive quantities could prompt extreme efforts to recover the resources found near the WIPP. The primary concern here is that extraction industries might ignore drilling regulations in their quest for valuable resources. See response to Comment 17.F of this Section for a discussion of this issue.

In the final rule, EPA clarified its expectations for demonstrating compliance with §194.45; this demonstration is tied directly to PA results and consideration of human intrusion processes and consequences. Sections 194.32 and 194.33 address the range of resources to be considered in performance assessments.

2. The resources should be of the same type, quality, and quantity as resources in the controlled area. (SNL-C)

Response to Comment 17.J.2:

The Agency agrees that the type and quality of resources present in the vicinity of the WIPP should be considered in evaluating their impact on the WIPP. The final rule states that, for shallow drilling, historical rates could be determined based on "resources of similar type and quality of resources in the controlled area [§194.33(b)(4)(iii)]." It is difficult to determine directly the quantity of resources in the controlled area; rather, EPA chose to take this into account by examining historical records of drilling near the WIPP site (i.e., in the Delaware Basin). Further, predictions of undisturbed performance of the disposal system must account for effects of past and current drilling, which are related to the estimated quantity of resources near the WIPP.

Section 18: REMOVAL OF WASTE: SECTION 194.46

Issue A: The EPA has exceeded its authority (references to 40 CFR part 191).

1. The requirement for the WIPP to prepare plans for the removal of the waste is unnecessarily restrictive given the safeguards that exist with the rule in demonstrating compliance with 40 CFR part 191. (IV-D-40)

2. Requiring a plan for removal of the waste is unnecessary, because it inappropriately extends the requirements of 40 CFR part 191. To meet this assurance requirement, it only need be technologically feasible to be able to mine the sealed repository and recover the waste. (SNL-C)

3. Part 191 says removal shall not be precluded for a reasonable period after disposal, Part 194 should require and evaluation of preclusion, not a removal plan. (C-12, C-28)

Issue B: The waste removal proposal is infeasible and unnecessary.

1. EPA's proposal for development of a removal plan is unmeaningful and virtually impossible. (DOE-D, WEC-D, C-03)

2. EPA's proposal for retrieval of wastes is unnecessary. (C-26, IV-D-40)

3. It is not meaningful to require development of a removal plan when there is no intent to remove the waste, and until a reason for removal is established, a meaningful plan cannot be established; the rule should be reworded so that a discussion of the feasibility of waste removal is achieved instead of a plan. (DOE-D)

Response to Issues 18.A and 18.B:

Upon consideration of these comments, EPA agrees that development of a removal plan is unnecessary, and has deleted this requirement in the final rule. The EPA believes that any plan will be based on the specific circumstances necessitating removal, and the technology available at the time. However, §194.14(f) provides that "[d]isposal systems shall be selected so that removal of most of the wastes is not precluded for a reasonable period of time after disposal." The preamble accompanying the adoption of the disposal regulations explained "that future generations should have options to correct any mistakes that this generation might unintentionally make [50 FR 38082]." To implement the disposal regulations, the final rule requires that the compliance application include documentation which demonstrates that removal of waste from the disposal system is feasible for a reasonable period of time after disposal. The final rule also requires that DOE submit in its compliance application an evaluation of the technical feasibility of mining the sealed disposal system, given current technology levels at the time the compliance application is prepared.

Issue C: Guidance for waste removal is requested.

1. Removal criteria are mentioned but are not specified. (A-68)

Response to Comment 18.C.1:

The EPA declines to dictate in the compliance criteria what represents a reasonable period of time after disposal. The EPA believes that judgment may properly be made in the compliance certification based on the compliance application and public input. Further, as noted above, EPA believes that it would be difficult and may be impossible to develop a meaningful removal plan without knowing the reasons or conditions for undertaking removal of the waste. For the same reason, EPA believes that specifying removal criteria would be inappropriate, and none have been included in the final rule.

2. Criteria should require the DOE to provide more specificity to the standard's "reasonable period" for removability of waste. The longer the waste is accessible, the better the chance of taking advantage of advances in technology. (NMAG-B, IV-D-06)

3. The EPA should specify time frame for removal. (NMAG-G)

Response to Comments 18.C.2 and 18.C.3:

The disposal regulations at 40 CFR part 191, §191.14(f), require that "[d]isposal systems should be selected so that removal of most of the wastes is not precluded for a reasonable period of time after disposal." The preamble accompanying the adoption of the disposal regulations explained "that future generations should have options to correct any mistakes that this generation might unintentionally make [50 FR 38082]." The final rule requires that DOE document the technological feasibility of mining the sealed disposal system, given current technology levels at the time the compliance application is prepared. Such an evaluation is expected to help provide the basis for an informed judgment about what period of time is reasonable.

Issue D: Waste removal plan must be consistent with DOE's obligations under its agreement with New Mexico. (NMAG-B)

Response to Issue 18.D:

As explained above, the requirement for DOE to develop a plan has been revised in the final rule. The EPA's responsibility in this rulemaking is to implement 40 CFR part 191, subparts B and C, not to implement of enforce the independent agreement between the State and DOE. In any event, the EPA's review of the agreement in question indicates it applies to operational activities of the repository, and is not affected by the removal requirements of §194.46 of the final rule. Subpart A of 40 CFR part 191 is concerned with operation of the WIPP facility; Subpart A guidance will be issued by the Agency at a later date if deemed necessary.

Issue E: The EPA should ask for separate retrieval plans for pre-and post-closure time periods to cover the problem of entering the disposal facility after all access has been back-filled. (CCNS-B)

Response to Issue 18.E:

The Agency agrees that significantly different conditions would exist for removal of waste from the repository after closure compared to retrieval during operation of the facility. For example, removal of waste after closure could be complicated by backfill material placed in shafts during repository closure. The EPA's disposal regulations and compliance criteria do separately address the issues of pre- and post-closure retrieval of waste. Pre-closure retrieval is covered under §194.04(b)(1), which requires that waste be retrieved (to the extent practicable) if certification is revoked. Removal of waste after closure of the repository is addressed by the requirements of §194.46. The EPA does not believe that it is appropriate to require plans for implementing removal in either situation, since it is difficult to predict what conditions would necessitate removal of the waste. Neither the WIPP LWA nor the disposal regulations of 40 CFR part 191 require submission of a plan. For further discussion of this issue, see response to Issue 18.A and Section 2 of this document.

Section 19: INDIVIDUAL AND GROUND WATER PROTECTION: SECTION 194.51 through SECTION 194.55

Issue A: The rule needs to address reasonable expectation criteria with regard to individual protection and ground water protection. (DOE-D)

Response to Issue 19.A:

Sections 191.15 and 191.24 of the disposal regulations require that the disposal system be designed to provide a "reasonable expectation" that the undisturbed performance of the system will not cause an exceedance of the annual committed effective dose in any individual or an exceedence of radioactivity in any underground source of drinking water (USDW) above applicable regulatory levels. The Agency applied the term "reasonable expectation" to the Individual and Ground Water Protection Requirements in acknowledgment of the analytical uncertainties which stem from conducting compliance assessments over a 10,000-year regulatory period. The term "reasonable expectation" denotes EPA's recognition that "unequivocal numerical proof of compliance is neither necessary nor likely to be obtained [58 FR 66412]."

Compliance with the Individual and Ground Water Protection Requirements is demonstrated through the use of compliance assessments. Similar to performance assessments, which are used to demonstrate compliance with the Containment Requirements, a compliance assessment examines the performance of the disposal system over the 10,000-year regulatory period. Unlike performance assessments, however, the compliance assessment only examines the undisturbed performance of the disposal system. Nevertheless, a compliance assessment projects disposal system performance over a long period of time (10,000 years) giving rise to a number of uncertainties. Due to the uncertainties, projections cannot be shown to be unequivocally correct. As a result, EPA requires that a "reasonable expectation" of compliance be demonstrated. The final rule applies the concept of "reasonable expectation" to compliance assessments by establishing statistical requirements on the results of compliance assessments to ensure that uncertainties in compliance assessments are treated systematically and thoroughly.

Section 194.55 specifies that the number of estimates of doses to individuals and of radionuclide concentrations in ground water shall be large enough that the maximum estimates of doses and concentrations exceed the 99th percentile of the population of estimates with at least at 0.95 probability. The final rule does not require that the 99th percentile CCDF be calculated; rather the DOE must determine only the probability with which the 99th percentile will be exceeded, based on the statistical property of the complete group of CCDFs generated. This requirement is essential to provide assurance that the full range of possible results of the compliance assessment will be represented. The mean estimate provides a measure of compliance that expresses the average impacts of the disposal system on individuals and ground water as well as the probabilities of uncertain disposal system parameter values; the median estimate provides a measure of compliance that expresses the central tendency of a population of estimates. Insofar as both statistics provide

useful information, the final rule requires that both the mean and the median of the range of estimated radiation doses and the range of estimated radionuclide concentrations must meet the requirements of the disposal regulations (§191.15 and 40 CFR part 191, subpart C, respectively) with at least a 95 percent level of statistical confidence. Consistent with the requirements in the disposal regulations regarding "reasonable expectation, " the final rule does not require that compliance be demonstrated with a 100% level of statistical confidence. However, the EPA believes it is essential to provide for an objective measure of the confidence in compliance. The exact number of calculations required to establish 95 percent confidence will vary depending on the margin with the mean and median demonstrate compliance with the requirements of the disposal regulations. Thus, the statistical requirements described above represent EPA's interpretation of "reasonable expectation of compliance," and are fully within the Agency's authority in implementing the disposal regulations. See also the response to Issue 19.G of this document.

Issue B: No mention is made of whether or not criteria identified in qualitative requirements set forth in Sections 21 through 27 of the regulation need to be met for individual and ground water protection. (SNL-C)

Response to Issue 19.B:

The General Requirements of the final rule (§194.21 through §194.27) must be met by all portions of and all activities associated with compliance applications; this includes compliance assessments related to the individual and ground water requirements. For example, it is important that the experimental data used to support predictions of disposal system performance be adequately quality assured, regardless of whether such data are used in performance assessments or in compliance assessments. Section 194.22 provides quality assurance requirements to ensure that this occurs. Application of the General Requirements to compliance assessments is clarified in the preamble to the final rule.

Issue C: Some references to Subpart C of 40 CFR part 191 are not relevant. (SNL-C, DOE-D)

Response to Issue 19.C:

To demonstrate compliance with 40 CFR part 191, Subpart C, Environmental Standards for Ground Water Protection, a compliance assessment must show that the undisturbed performance of the disposal system over the 10,000-year regulatory period will not result in releases of radionuclides to an underground source of drinking water (USDW) in the accessible environment above allowable regulatory limits. These limits, specified in 40 CFR Part 141, are the maximum permissible levels of a contaminant in an USDW. Proposed Sections 194.51 and 194.52, *Consideration of the protected individual* and *Consideration of exposure pathways*, respectively, were relevant to the individual protection requirements and were not intended to be applied to the ground water protection requirements, for the reasons discussed below. It is not necessary to know the location of the person who might ultimately consume water obtained from a USDW in order to demonstrate compliance under the ground-

water protection limits. Similarly, the exposure pathways from the disposal system to an individual and the amount of water consumed by that individual also are not applicable to demonstrating compliance with the ground-water protection requirements. Rather, the concentration of radionuclides found in the USDW itself is the determining factor of compliance, as specified in Subpart C of the disposal regulations. Section 194.53 of the final rule, Consideration of underground sources of drinking water, applies to the ground water protection standards; that section addresses relevant consideration of USDWs and the contaminant migration pathways from the disposal system to the USDWs. The final rule has been revised from proposal to clarify applicability of §§194.51-191.53.

Issue D: Sections 194.51 and 194.52 would require the individual to reside at two different locations to satisfy calculational assumptions. The individual should thus be assumed to reside outside the controlled area. (SNL-C)

Issue E: Section 194.51 would require significantly different assumptions about the protected individual depending on whether the exposure pathway being considered is drinking water or other pathways. (SNL-C)

Response to Issues 19.D and 19.E:

In the preamble to the disposal regulations which established limits on radiation doses to individuals, EPA explained that "[g]round water withdrawn for consumption directly from within the controlled area need not be included in the analyses because geologic media within the controlled area are an integral part of the disposal system's capability to provide long-term isolation [58 FR 66403]." In the December 1993 Response to Comments For Amendments to 40 CFR part 191, EPA further stated that ". . . if an individual intrudes into the controlled area to obtain water for drinking or other purposes, such exposures are not to be considered in the context of the individual or ground-water protection requirements [EPA 402-R-93-072, pp. 2-10]." Consistent with these statements, §191.15 and §191.24 of the disposal regulations specify that the exposed individual and affected USDW are located in the accessible environment. The accessible environment is defined in §191.12(k) as that area ". . .beyond the controlled area." Similarly, both §194.51 and §194.52 of the final rule require that the exposed individual be assumed to reside in the accessible environment only.

Compliance assessments should separately estimate doses to the exposed individual pursuant to §191.15, and doses and radionuclide concentrations pursuant to subpart C of 40 CFR part 191. For the purposes of these different analyses, the protected individual is treated separately for each set of requirements; therefore, different assumptions may be applied (and different locations assumed) for the individual requirements compared to the ground water requirements. These differences in conducting compliance assessments are necessary and reasonable because different measures of compliance are specified in the disposal regulations for individual requirements (at §191.15) and ground water requirements (subpart C of 40 CFR part 191). While the protected individual for the purposes of the groundwater protection requirements must be using water from an underground source of drinking water, and is therefore assumed to be located at a USDW, the protected individual under §191.15 could be

located anywhere in the accessible environment, whether or not there is a USDW at that location. See response to Issue 19.C for further discussion of this issue.

The language in §194.52 of the proposed compliance criteria could have been interpreted to mean that different locations should be assumed in calculating the total radiation dose to an individual from all exposure pathways (pursuant to §191.15). The final rule has been revised to clarify that, for the purpose of analyzing doses to individuals, compliance assessments should separately analyze the doses received by individuals from each pathway. However, compliance assessments should assume that the protected individual resides at the *single geographic point* where the maximum dose would be received, calculated by the sum of all pathways.

Issue F: 40 CFR part 194 evidences no standards for protection of non-human animals, plants, nor soil. This should be remedied. (IV-D-06)

Response to Issue 19.F:

The EPA's responsibility in this rulemaking is to implement the disposal regulations of Subparts B and C at 40 CFR part 191 for the WIPP. The disposal regulations are binding for the disposal of transuranic waste at the WIPP. The disposal regulations clearly establish that the releases of regulatory concern at a disposal facility such as the WIPP are 1) radionuclide releases to the accessible environment, 2) radiation doses to humans from all exposure pathways, and 3) radiation exposure and radionuclide concentrations in underground sources of drinking water. The disposal regulations do not contemplate separate standards for protection of non-human animals, plants, or soil; protection of these elements is afforded through the release limits of the disposal regulations, which limit radionuclide releases to the accessible environment (which is defined to include all areas outside the controlled area of the WIPP). In this rulemaking, EPA is developing criteria to implement the disposal regulations specifically at the WIPP; and therefore, revisions which are outside the purview of 40 CFR part 191 are outside the scope of this rulemaking.

Issue G: There is no definition needed for unlikely natural event.

1. No definition of "unlikely natural event" is needed. (SNL-C)

2. There is no definition needed for "unlikely natural event;" "undisturbed performance" should be classified to exclude human activities. (DOE-D)

3. It is recommended that additional clarification on the delineation between the categories of "likely" and "unlikely" events. The clarification should not make it more difficult to submit or review an application through the introduction of uncertainty or ambiguity; move the focus of the review away from the issue of how the repository performs under a range of likely perturbations; or arbitrarily remove from consideration of events, processes, or combinations of processes and events with a similar probability of occurrence as those required for the analysis of the "disturbed performance" of the repository. (NRC)

4. EPA may wish to provide guidance, without applying a strict numerical limit, on the processes and events that are to be considered for evaluations of the “undisturbed performance” of the repository. (NRC)

5. It is appropriate that EPA define “unlikely natural events” and develop a list of probabilities for qualifying events specific for the WIPP. (SGNM-D)

Response to Comments 19.G.1 through 19.G.5:

Unlike the containment requirements, the individual and groundwater protection requirements do not apply to cumulative releases nor do they contain probabilistic requirements, such as the requirement that certain releases be less than 1 in 1,000 likely to be exceeded (191.13). Instead, the individual and groundwater requirements apply to the doses received during one individual's lifetime, versus 10,000 years for the containment requirements. Further, the expected value of the dose received -- the mean value -- must be less than the applicable dose limit, for example, 15 mrem in the case of the individual protection requirements. There is no regulatory significance to the probability with which the dose limit will be exceeded, and hence these requirements cannot be treated analogously to the probabilistic containment requirements. Therefore, providing a numerical cut-off for probability, such as the 1 in 10,000 threshold test applicable to performance assessments, would not be applicable. However, some screening of processes and events was contemplated in 40 CFR Part 191, which in the definition of "undisturbed performance" in 40 CFR Part 191 state that compliance assessments may exclude from consideration any unlikely natural processes and events.

Several differences emerge upon examination of the performance assessments needed for the containment requirements and the compliance assessments needed for the individual and groundwater protection requirements. For example, the individual protection requirements apply only to the accumulation of dose over an individual's lifetime versus 10,000 years in the containment requirements. Second, as just explicated, the individual and groundwater protection requirements are not probabilistic, unlike the containment requirements. Third, whereas the focus of the individual and groundwater protection requirements is on the contribution of natural processes and events to doses to individuals, the containment requirements focus on the contribution such processes and events make toward releases of radionuclides to the accessible environment. In view of these considerations, the Agency recognized that the significantly different form of the containment requirements versus the individual and groundwater protection requirements necessitated a different treatment of the screening of processes and events.

In compliance assessments, therefore, the Agency requires that a qualitative judgment be made regarding the likelihood with which groundwater and individual exposure pathways will be affected, over the time scale of an individual's lifetime (not 10,000 years as in the containment requirements) by the occurrence of different natural events. Although the universe of processes and events considered in the performance assessments (for the

containment requirements) will closely resemble that of compliance assessments, the different regulatory requirements attending each analysis, as noted above, might allow for subtle differences regarding whether the individual events should be included in the analysis. As with performance assessments, the final rule at 194.54(a) requires compliance applications to document why any processes and events or sequences of processes and events that may occur over the regulatory time frame were not included in compliance applications.

In the preamble to the proposed rule, EPA solicited comment on whether or not there is a need for clarification of what constitutes an "unlikely" natural event within the context of undisturbed performance. Only one comment suggested that additional clarification be provided. The comment stressed, however, that such clarification should not: (1) cause or introduce additional uncertainty or ambiguity, (2) change the focus away from how the disposal system is likely to perform, or (3) arbitrarily remove from consideration processes and events having a similar probability as those required in evaluating disturbed performance. Instead of defining "unlikely," EPA has chosen in the final rule to require that DOE document, in any compliance application, why any processes, event, or sequence of processes and events which may occur over the regulatory time frame is not included in compliance assessments. The Agency believes its review of DOE's compliance application during the public certification rulemaking will ensure that the full range of possible events which could occur during the regulatory time frame have been analyzed to determine their impact on compliance with the individual and ground water requirements.

6. The definition of undisturbed performance should be clarified as follows: "undisturbed performance means the predicted behavior of a disposal system, including characterization of the uncertainties in predicted behavior, if the disposal system is not disturbed by human intrusion, human activities, or the occurrence of unlikely natural events." (SNL-C)

Response to Comment 19.G.6:

Undisturbed performance is defined in §191.12(p) as "the predicted behavior of a disposal system . . . if the disposal system is not disrupted by human intrusion . . . [§191.12(p)]." In the context of 40 CFR part 191, the term "human intrusion" is meant to include all those activities caused by humans which may have an effect on the disposal system performance. The proposed rule used the broader term, "human-initiated processes and events" to describe this same concept with respect to the WIPP. "Human-initiated processes and events" were subdivided into "human intrusion" and "human activity." In response to public comments, and to minimize confusion, EPA in the final rule replaced the terms "human intrusion" and "human activity" with "deep drilling" and "shallow drilling," respectively. "Deep drilling" includes those drilling events that reach or exceed a depth of 2,150 feet below the surface relative to where such drilling occurred. "Shallow drilling" includes those drilling events that may affect the disposal system, but do not reach a depth of 2,150 feet below the surface relative to where the drilling occurs. Section 194.33, named *Consideration of Human-initiated processes and events* in the proposal, has be re-named *Consideration of drilling events in performance assessments* in the final rule, consistent with the use of this term in 40 CFR part 191 and in the definition of undisturbed performance. In the final compliance

criteria, "human intrusion" includes both deep drilling and shallow drilling, as well as mining. Since all these activities are included under "human intrusion, and since all are events which may occur inside the boundaries of the controlled area, they fall under the category of disturbed performance. The change in terminology for human intrusion clarifies that potential future drilling and mining, as well as ancillary activities (such as borehole sealing), need not be considered in undisturbed performance scenarios. See Section 12 of this document for further discussion.

The Agency recognizes that resource extraction and fluid injection activities which are currently performed in the Delaware Basin can alter the hydrogeologic properties of the initial state of the disposal system (i.e., at the start of the 10,000-year regulatory time frame). The final rule requires that performance assessments and compliance assessments must include the effects of all types of fluid injection (including solution mining) and all boreholes which can have an effect on the disposal system and which have been or will have been drilled prior to or soon after disposal, based on existing plans and leases for drilling. Those boreholes shall be assumed to affect the properties of the disposal system for the entire 10,000-year time frame. The final rule requires, in paragraph 194.54(b), that performance assessments must analyze the effects on the disposal system of existing boreholes in the vicinity of the disposal system, with attention to the pathways they provide for migration of radionuclides from the site; and of any activities that occur in the vicinity of the disposal system prior to or soon after disposal.

Issue H: To what "member" (most exposed or average) does 40 CFR part 191 limit doses? (IV-D-06)

Response to Issue 19.H:

The disposal regulations at §191.15 limit doses to "any member of the public in the accessible environment." Thus, the limits apply to the most exposed individual, rather than an individual subject to average exposure. The final rule has clarified that compliance assessments that analyze compliance with §191.15 shall assume that an individual resides at the single geographic point on the surface of the accessible environment where that individual would be expected to receive the highest dose from radionuclide releases from the disposal system (see §194.51). Compliance assessments should separately analyze the doses received by individuals from each pathway, and then assume that the individual resides at that single point on the surface where the maximum dose would be received, calculated by the sum of all pathways.

Issue I: Should specify that maximally exposed individual resides on the surface. The term "exposure" should not be used to make the rule clearer. (NMAB-B, NMAG-G)

Response to Issue 19.I:

The final rule specifies that the exposed individual should be assumed to reside on the surface; also, the term "exposure" has been replaced in the final rule with the term "dose."

The final rule has clarified that compliance assessments that analyze compliance with §191.15 shall assume that an individual resides at the single geographic point on the surface of the accessible environment where that individual would be expected to receive the highest dose from radionuclide releases from the disposal system (see §194.51). Compliance assessments should separately analyze the doses received by individuals from each pathway, and then assume that the individual resides at that single point on the surface where the maximum dose would be received, calculated by the sum of all pathways.

Issue J: EPA should revise the proposed approach to compliance certification to be consistent with the International Commission on Radiation Protection (ICRP) approach, or to clarify the basis for this inconsistency in the Supplementary Information supporting issuance of the final rule. (IV-D-76)

Issue K: EPA should ensure that the individual protection standards should be sufficiently strict.

1. The rule should be made so that incidences of cancer and the incidences of brain damage and breast cancer are minimized to a much greater extent. (S-23)

2. The EPA should stand by what has been set forth as standards of testing, standards of safety, and protection for future generations in Southern New Mexico. (S-09)

Issue L: EPA must take into account another rate, the rate of lowering exposure standards over the last 50 years. (S-17)

Issue M: It is not well understood how much radiation actually harms people, and the numbers are rather arbitrary. (S-09)

Response to Issues 19.J through 19.M:

The EPA's responsibility in this rulemaking is to implement the disposal regulations of Subparts B and C at 40 CFR part 191 for the WIPP. The disposal regulations are binding for the disposal of transuranic waste at the WIPP. The disposal regulations clearly establish that the releases of regulatory concern at a disposal facility such as the WIPP are 1) radionuclide releases to the accessible environment, 2) radiation doses to humans from all exposure pathways, and 3) radiation exposure and radionuclide concentrations in underground sources of drinking water. The disposal regulations established specific standards for each of these areas based on radiation dose-response effects consistent with the widely held views of national and international scientists. There is no evidence that 40 CFR part 191 standards are unsound or inappropriate.

Specific methods are required to be used for calculating annual committed effective doses to exposed individuals, according to Appendix B of the disposal regulations. These methods were established consistent with the International Commission on Radiation Protection (ICRP) Publication 60 guidelines available at the time that the disposal regulations were

developed. Appendix B of 40 CFR part 191 is an integral part of that standard, and underwent proposal and public notice and comment when the disposal regulations were promulgated. Nowhere does 40 CFR part 191 contemplate using a different methodology. In this rulemaking, EPA is developing criteria to implement the disposal regulations specifically at the WIPP; and therefore, revisions which are outside the purview of 40 CFR part 191 are outside the scope of this rulemaking.

Issue N: EPA should take into account the potential for worker exposure and the As Low As Reasonably Achievable provisions established by DOE Order 5480.11 for DOE's Government Owned Contractor Operated facilities. (IV-D-11)

Response to Issue 19.N:

The EPA is also concerned about limiting worker radiation exposures. Several comments have suggested that required waste characterization under the proposed rule would subject workers to unnecessarily high radiation exposures. The EPA believes that the waste characterization requirements of the final rule balance flexibility with prescription to assure that waste characterization is rigorous and reliable for those waste parameters important to containment of waste in the disposal system. The Agency shares the concern for occupational exposure to the workers who are involved in characterizing the waste, but believes it is also inappropriate to jeopardize future generations from potential releases to the accessible environment because this generation failed to study and characterize the waste that could significantly impact the total performance of the repository.

As to the ALARA principle, DOE is responsible for implementing radiation protection measures with its work force, and is explicitly obligated through its Orders to address ALARA; this is not an EPA regulatory function. The EPA has tried to afford sufficient flexibility to DOE to carry on an effective ALARA program for its workers while also addressing the important issue of protection of the public and the environment through demonstration of compliance with EPA disposal regulations. For further discussion of this issue, see response to Issue 6.L of this document.

Issue O: The rule should consider the entire cycle of transuranic wastes.

1. Consideration should be given to health risks for the complete cycle for transuranic wastes and decisions regarding performance assessment in nuclear waste disposal in a repository be evaluated in light of environmental risk of maintaining the current *status quo*. (IV-D-40)

2. The consideration of Underground Sources of Drinking Water should be system-wide in scope. It should include the current storage of transuranic wastes at existing facilities, and that the consideration be given to the detriment to ground water at existing facilities be included as part of the WIPP compliance determination. (IV-D-40)

Response to Issue 19.O:

Under the 1992 WIPP LWA, Congress directed EPA to implement the disposal regulations of Subparts B and C at 40 CFR part 191 for the WIPP, not to examine the comparative risks of nuclear waste management policies. The disposal regulations are binding for the disposal of transuranic waste at the WIPP. Subparts B and C of 40 CFR part 191 address requirements for *disposal* of transuranic waste, and for releases and exposures which may occur from waste during the 10,000-year regulatory time frame after disposal. The requirements of the final criteria involve activities during the operational phase (i.e, while waste is being emplaced, and before the disposal system is sealed) only insofar as information on activities or performance are necessary to support compliance applications relative to the disposal regulations. In this rulemaking, EPA is developing criteria to implement the disposal regulations specifically at the WIPP; and therefore, revisions which are outside the purview of 40 CFR part 191 are outside the scope of this rulemaking. The DOE is required by a number of environmental statutes to manage currently stored transuranic waste in a manner which is protective of human health and the environment. See also the response to Comment 6.F.13.

Issue P: The EPA should address, and resolve if necessary, the potential inconsistency between the water consumption rates established in the compliance criteria and those recommended in the EPA draft guidance on public exposures. (NRC)

Response to Issue 19.P:

Section 194.52 states that it shall be assumed that individuals consume 2 liters per day of drinking water from any underground source of drinking water in the accessible environment. As stated in the preamble to the proposed rule, this approach was selected to be consistent with the Safe Drinking Water Act requirements. The draft guidance to which the comment refers is discussed in a December 23, 1994, Federal Register Notice [59 FR 66414]. In this notice, EPA proposed recommendations for the development of new guidance concerning radiation protection from all sources to the general public. The EPA noted that any new guidance developed in response to the December 23, 1994 notice would not supersede any statutory responsibilities of Federal agencies. Rather, the Agency's intent in proposing to develop the guidance would be to provide a common framework for the consistent and protective management of radiation exposure in the United States. The guidance examines the combined radiation exposure to an individual from all sources, while the individual protection requirements in the final compliance criteria examine the radiation exposure to an individual from one source, in this case WIPP. The Agency emphasizes again that, in this rulemaking, EPA is developing criteria to implement the disposal regulations specifically at the WIPP; and therefore, revisions which are outside the purview of 40 CFR part 191 are outside the scope of this rulemaking.

Issue Q: It is suggested that EPA establish clear guidance that addresses the consideration of the protected individual. It is also suggested that this guidance be consistent with the framework established under 40 CFR 194.25. (NRC)

Response to Issue 19.Q:

The final rule considers protection of individuals by implementing the individual protection requirements of the disposal regulations. The final rule clarifies that compliance assessments should analyze the doses received by individuals from each pathway. Compliance assessments should then assume that the protected individual resides at the single geographic point on the surface where the maximum doses would be received, calculated by the sum of all pathways.
Regarding §194.25 of the final rule, future state assumptions, the preamble to the final rule clarifies that the general requirements of the compliance criteria (i.e., §§194.21-27) must be met by all portions of and all activities associated with compliance applications, including compliance assessments. Therefore, assumptions about the future state of society, as used in compliance assessments, must be established in accordance with the requirements of §194.25. See also the responses to Issues 19.B, 19.D, 19.E, 19.H, and 19.I.

Issue R: The implementation strategy in 194.52 should not simply parallel that for §194.34 because the latter implementation strategy is not totally applicable to 194.51, 194.52, or 194.53. (SNL-C)

Response to Issue 19.R:

Compliance with the Individual and Ground Water Protection Requirements is demonstrated through the use of compliance assessments. Similar to performance assessments, which are used to demonstrate compliance with the Containment Requirements, a compliance assessment examines the predicted performance of the disposal system over the 10,000-year regulatory time period. In this sense, compliance assessments and performance assessments are similar and therefore would necessitate a similar overall methodology. Unlike performance assessments, however, the compliance assessment examines only the undisturbed performance of the disposal system. In addition, the results of the computational techniques used for compliance assessments as opposed to performance assessments are dissimilar. Performance assessment analyses are used to generate complementary cumulative distribution functions, while computational techniques for compliance assessments are used to generate a range of (1) estimated radiation doses and (2) estimated radionuclide concentrations. As a result, the methodology at this point diverges. This is reflected in §194.54 and §194.55 of the final rule. Section 194.54 limits the scope of compliance assessments to undisturbed scenarios; only existing boreholes and other activities which occur before disposal must accounted for in compliance assessments (since such current human activities constitute part of the baseline site characterization). Section 194.55 of the final rule establishes statistical measures to ensure that the results of compliance assessments demonstrate a reasonable expectation of compliance with the limits established in the disposal regulations. The EPA believes it is necessary and reasonable to establish such statistical requirements. See also the responses to Issue 19.A and Issue 19.G of this document.

Issue S: The impermeability of the site and exposure pathways warrant further study.

1. The Criteria don't address the problem of permeable layers at the salt layer. (A-06)

2. The extent of the salt deposits needs to be studied further. (A-47)

3. It was originally believed that the WIPP site was dry and the salt formations were impermeable, which was later demonstrated not to be the case. Numerous pathways no exist for the movement of radioactive materials. Where are the materials traveling to? (S-37)

Response to Issue 19.S:

40 CFR part 191 requires that performance assessments and compliance assessments be conducted to show that there is a reasonable expectation of compliance with the disposal regulations and, therefore, that human health and the environment will be protected over the regulatory time frame. 40 CFR part 194 provides criteria which apply specifically to the WIPP's compliance with these standards. The criteria include requirements for the consideration of all applicable and relevant information. For example, in conducting the performance and compliance assessments, information regarding the site and its surrounding environmental media must be taken into account. This would include information concerning the permeability of the salt and anhydrite layers of the Salado Formation as well as any pathways (existing and potential) from the disposal system to the accessible environment.

Issue T: In reference to consideration of protected individual, guidance regarding the assumptions that should or should not be made is appropriate for Part 191 and should be handled accordingly. (WEC-D)

Response to Issue 19.T:

The final rule provides criteria for certifying and determining whether the WIPP complies with the disposal regulations set forth in 40 CFR part 191. The criteria provide further information, clarification, and explanation of how compliance with the disposal regulations may be measured or determined. Given the complexity of performance and compliance assessment analyses and the length of the regulatory time period over which compliance must be projected, EPA believes that it is appropriate to specify certain assumptions in the criteria; providing criteria regarding assumptions ensures that such assumptions are transparent, and are applied consistently throughout analyses. For example, the final rule at §194.51 states that it should be assumed that the protected individual is residing at the single geographic point on the surface of the accessible environment where that individual would be expected to receive the highest dose from radionuclide releases from the disposal system. Were this assumption provided as non-binding guidance, the analysis could be conducted using other locations inconsistent with the intent of the 40 CFR part 191 disposal regulations. It is entirely within EPA's authority to specify such assumptions as part of implementing the disposal regulations specifically at the WIPP.

Issue U: "Likely" should be clarified to mean "reasonable expectation;" not over 50% probability. (NMAG-G)

Response to Issue 19.U:

The ground water requirements of subpart C of 40 CFR part 191 apply to doses received from and concentrations of radionuclides in “underground sources of drinking water” (USDWs) only. These requirements apply only to USDWs that are located outside of the controlled area. The proposed implementing criteria provided that the DOE analyze those USDWs outside the controlled area that are “likely to be affected by the disposal system over the regulatory time frame [60 FR 5790].” The term “likely” was used to confine the analysis to those USDWs which could be reached by pathways from the disposal system within 10,000 years. A “likely” USDW would therefore not include USDWs whose location is sufficiently remote from the WIPP or to which no known pathway for travel of ground water exists. The EPA has clarified in the final rule that compliance assessments for the ground-water protection requirements shall consider all USDWs in the accessible environment that are “expected” to be affected by the disposal system over the regulatory time frame.

Unlike the containment requirements, the individual and groundwater protection requirements do not apply to cumulative releases nor do they contain probabilistic requirements, such as the requirement that certain releases be less than 1 in 1,000 likely to be exceeded (191.13). Instead, the individual and groundwater requirements apply to the doses received during one individual's lifetime, versus 10,000 years for the containment requirements. Further, the expected value of the dose received -- the mean value -- must be less than the applicable dose limit, for example, 15 mrem in the case of the individual protection requirements. There is no regulatory significance to the probability with which the dose limit will be exceeded, and hence these requirements cannot be treated analogously to the probabilistic containment requirements. Therefore, providing a numerical cut-off for probability, such as the 1 in 10,000 threshold test applicable to performance assessments, would not be applicable. However, some screening of processes and events was contemplated in 40 CFR Part 191, which in the definition of "undisturbed performance" in 40 CFR Part 191 state that compliance assessments may exclude from consideration any unlikely natural processes and events.

Several differences emerge upon examination of the performance assessments needed for the containment requirements and the compliance assessments needed for the individual and groundwater protection requirements. For example, the individual protection requirements apply only to the accumulation of dose over an individual's lifetime versus 10,000 years in the containment requirements. Second, as just explicated, the individual and groundwater protection requirements are not probabilistic, unlike the containment requirements. Third, whereas the focus of the individual and groundwater protection requirements is on the contribution of natural processes and events to doses to individuals, the containment requirements focus on the contribution such processes and events make toward releases of radionuclides to the accessible environment. In view of these considerations, the Agency recognized that the significantly different form of the containment requirements versus the individual and groundwater protection requirements necessitated a different treatment of the screening of processes and events.

In compliance assessments, therefore, the Agency requires that a qualitative judgment be made regarding the likelihood with which groundwater and individual exposure pathways will be affected, over the time scale of an individual's lifetime (not 10,000 years as in the containment requirements) by the occurrence of different natural events. Although the universe of processes and events considered in the performance assessments (for the containment requirements) will closely resemble that of compliance assessments, the different regulatory requirements attending each analysis, as noted above, might allow for subtle differences regarding whether the individual events should be included in the analysis. As with performance assessments, the final rule at 194.54(a) requires compliance applications to document why any processes and events or sequences of processes and events that may occur over the regulatory time frame were not included in compliance applications.

The final rule also requires that in determining whether underground sources of drinking water (USDWs) are expected to be affected by the disposal system, underground interconnections among bodies of surface water and USDWs must be considered. In reviewing the DOE's compliance application, EPA will, with public input, ensure that these requirements are adequately fulfilled.

Issue V: If no releases are expected to the accessible environment, no further work should be required.

1. The proposed regulation would require compliance with 40 CFR part 191, Subpart C by determining whether the Maximum Contaminant Levels (MCLs) for radionuclides in ground water are exceeded. This process should be reversed. (DOE-D, SNL-C)

2. There is no justification for requiring characterization of ground waters and analyses of commingling and interconnection between aquifers unless releases are expected. (SNL-C)

3. If releases of radionuclides to ground water outside the controlled area are not expected to occur, no further work should be required. (DOE-D)

Response to Issue 19.V:

Compliance with the Ground Water Protection Requirements is demonstrated through the use of a compliance assessment, which examines the undisturbed performance of the disposal system over the 10,000-year regulatory time frame. If it has been determined through the compliance assessment that a release might occur, then all USDWs that are located in the accessible environment and are expected to be affected by the disposal system must be examined. Upon identification of such USDWs, the radionuclide concentration in those USDWs should be calculated to determine if the MCL has been exceeded. If no releases are expected to occur over the regulatory time frame, then the number of USDWs expected to be affected by such release would obviously be negligible, but any such assertions must be rigorously supported.

The disposal regulations, which are being implemented specifically for the WIPP by this rulemaking, require specifically that compliance with the groundwater protection requirements be demonstrated relative to maximum contaminant levels (MCLs) established at 40 CFR part 141. The EPA believes that compliance could not be demonstrated without an examination of how predicted releases to groundwater relate to such MCLs.

Issue W: The geological and hydrological aspects of the WIPP need to be more thoroughly examined.

1. The Pecos River must be monitored at various places downstream, and the salt lagunas must be checked for radionuclides. (C-03)

2. Two boreholes into the Castile are insufficient to adequately characterize the brine in the Castile. (S-10)

3. The Dewey Bed water flow and the Rustler aquifer have not been fully characterized. (S-10)

4. Before any consideration of the site is put forward, a complete review of all past geological evaluations needs to be made. (IV-D-95)

5. Not enough is really known about the hydrology and the geology of the site to safeguard valuable water resources nearby. (A-38, A-48, A-54, A-58, S-27)

6. No waste should not be put in place until it is known how much water flows through the site and where the recharge and discharge is. (C-03)

7. Geohydrology at WIPP has not been studied comprehensively. (CARD-A, A-07, A-28, A-58)

8. There are significant geological problems at WIPP: 1) Pressurized brine; 2) Brine in the salt rock; 3) Rock fractures; 4) Karst; 5) Pressurized gases; and 6) Climate changes. (IV-D-29)

9. The basic hydrogeology of the area needs to be completely studied, not only in a computer model. (CARD-B, S-12)

10. The geological makeup of the WIPP site makes it unlikely that the DOE can ensure containment. (S-40)

11. WIPP is very dangerous with the water and other geologic factors. (S-38)

Response to Issue 7.W:

40 CFR part 191 requires that performance assessments and compliance assessments be conducted to show that there is a reasonable expectation of compliance with the disposal regulations. The rule provides criteria which apply specifically to the WIPP's compliance with these standards. The criteria contain requirements for the consideration of all applicable and relevant information, including that of the site and its surrounding environmental media. For example, DOE must provide a description of the geology, geophysics, hydrogeology, hydrology, and geochemistry of the disposal system and show these conditions are expected to change and interact over the regulatory time frame.

In submitting its application for certification of compliance, therefore, DOE is required to provide this information (see §194.14). Compliance assessments must consider all USDWs which are expected to be affected by the disposal system. The final rule clarifies that in determining whether underground sources of drinking water are expected to affected by the disposal system, compliance assessments must consider underground interconnections among bodies of surface water, ground water, and underground sources of drinking water.

Compliance assessments must demonstrate a reasonable expectation that concentrations of radionuclides in ground water will not exceed specified limits over the regulatory time frame after disposal. In addition, the requirements of §194.25 state that DOE should consider and document the effects of potential future hydrologic, geologic and climatic conditions over the regulatory time frame. The EPA believes that these requirements are reasonable and adequate to ensure that ground water in the vicinity of the WIPP is protected.

Issue X: EPA should conduct an independent evaluation.

1. A full and thorough new survey should be made by the EPA totally independent of DOE for geological evaluations. (IV-D-95)

2. As well as relying on basic statistics that are gathered independent of DOE, EPA should develop its own model for ground water flow and transport. EPA should adopt NRC's exemplary policy of relying on the fastest water flow time in determining compliance. (CARD-B)

Response to Issue 19.X:

The DOE must submit a compliance application containing any and all necessary evaluations, studies, and modeling to demonstrate compliance with the applicable environmental regulations. The EPA is responsible for: (1) developing the criteria for implementing the radioactive disposal regulations at the WIPP, (2) determining whether the WIPP complies with those regulations, and (3) enforcing DOE's continued compliance with those regulations, if initial certification is granted. In its regulatory oversight role, EPA will thoroughly evaluate the information presented by DOE in a public certification rulemaking and has authority to require or obtain additional information if warranted.

Issue Y: Water protection regulation should extend to a 10,000-year period of regulation and beyond. (IV-D-97)

Response to Issue 19.Y:

The EPA's responsibility in this rulemaking is to implement the binding disposal regulations of Subparts B and C at 40 CFR part 191 for the WIPP. The regulatory time frame of 10,000 years after disposal was established in Subparts B and C of 40 CFR part 191. The provisions of the disposal regulations and of the final rule require that compliance assessments predict affects of the disposal system on ground water over the entire 10,000-year regulatory time frame. The EPA believes that a disposal system which demonstrates compliance over a 10,000-year time frame will likely contain waste effectively for a longer time period. However, it is outside the scope of this rulemaking to extend the regulatory time frame. In this rulemaking, EPA is developing criteria to implement the disposal regulations specifically at the WIPP; and therefore, revisions which are outside the purview of 40 CFR part 191 are outside the scope of this rulemaking.

Issue Z: These requirements must include water use or irrigation and grazing downstream. (C-03)

Response to Issue 19.Z:

The EPA believes that the final rule ensures that all relevant exposure pathways will be considered. The final rule requires that compliance assessments consider doses to individuals from all exposure pathways. In addition, compliance assessments must demonstrate that projected radionuclide concentrations in groundwater, due to releases from the disposal system, will not exceed specified levels during the regulatory time frame.

Issue AA: Gas build-up may force out brine slurries resulting in liquid radioactive contamination of the waterways and channels. (S-3)

Response to Issue 19.AA:

Compliance with the Ground Water Protection Requirements is demonstrated through the use of a compliance assessment, which examines the undisturbed performance of the disposal system over the 10,000-year regulatory period. Section 194.54 requires an evaluation of the effects of potential processes, events or sequences of processes and events that may occur over the regulatory time period. This would include the consequences of gas buildup should that occurrence be identified as a potential process, event or sequence of processes and events expected to occur during the regulatory time frame.

Issue BB: The phrase "sequence of processes and events" must be replaced with "processes and events" throughout Subsections 194.54(a) through 194.54(c) and the Supplemental Information. (DOE-D, SNL-C)

Issue CC: Defining combinations (not sequences) of processes and events in §194.55 Results of compliance assessments. is not applicable to the definition of undisturbed conditions. (SNL-C)

Response to Issues 19.BB and 19.CC:

Compliance with the Individual and Ground Water Protection Requirements is demonstrated through the use of a compliance assessment, which examines the undisturbed performance of the disposal system over the 10,000-year regulatory period. In conducting a compliance assessment, processes and events are identified and evaluated to estimate the potential consequences. In a 10,000-year time period, a number of processes and events could occur in any given area. Such processes and events can be organized into sequences (more commonly referred to as scenarios) to determine the cumulative effect of their occurrence. The decision as to whether the processes and events should be organized as a sequence is dependent upon the type of processes and events which are being considered. The term "combination of processes" have been removed from the final rule.

Issue DD: Clarification of §194.55 is necessary.

1. Neither 194.55(b) nor 194.55(d) address compliance appropriately. (SNL-A, SNL-C)

2. §194.55 is not clearly related to certification of compliance with 40 CFR part 191. (DOE-D, SNL-C)

3. Paragraph 194.55(b) should be amended to reflect a percentile with a .90 probability. (DOE-D, SNL-C)

4. It is recommended that EPA delete 40 CFR 194.55 from the compliance criteria. It is also recommended that EPA provide guidance to the applicant on the level of detail in the compliance assessment results that EPA believes is appropriate to allow judgments to be made on compliance with the individual and ground water protection requirements of Part 191. (NRC)

Response to Issue 19.DD:

Section 194.55 places specific requirements on the analysis necessary to show compliance with two specific parts of the disposal regulations, the individual protection requirements and the ground water protection requirements. As mandated by the WIPP Land Withdrawal Act, the task of rulemaking for 40 CFR part 194 is to establish the criteria which must be met in order to show that the WIPP is in compliance with these disposal regulations. Accordingly, the section in question, entitled "results of compliance assessments," is necessary to establish the various procedures to be followed by DOE in analyzing doses to individuals and contamination of ground water. The Agency has included therein specific criteria on the treatment of uncertainty in values for parameters and the treatment of these parameters in computational (computer) techniques. A criterion was also included which established the

procedure for comparing the results of the analyses to the numerical requirements of 40 CFR part 191 as described below.

In 40 CFR part 194, the criteria for WIPP's compliance, the Agency has specified that the mean and median "estimate" - the computed dose to individuals through all pathways, and dose from the concentrations present in ground water -- must be in compliance with the numerical limits of 40 CFR part 191 with a 95 percent level of confidence. The appropriate limits are found in §191.15, for individual protection all pathways, and 40 CFR part 191 Subpart C for ground water requirements. Statistical confidence levels are a measure of the "trueness" or "falseness" of a calculated number. Should be the mean estimate be found to be in compliance with a high level of confidence, such as 95 percent, then the result of the calculations was likely to be a "true" prediction of the dose and concentrations, based on the present conceptual understanding of the WIPP's performance. For further discussion of the statistical requirements placed on the results of compliance assessments, see response to Issue 19.A and Issue 19.G.

Issue EE: The "population of estimates" definition should read: Population of estimates means all possible estimates that can be generated from sampling disposal system parameter values an infinite number of times, conditioned on specific probability distribution functions. (NMAG-D)

Response to Issue 19.EE:

The comment correctly notes that the population of estimates refers to a theoretical, infinite number of estimates, as stated in similar terms in the definition in the final rule. While the definition in the final rule does not require that estimates be conditioned on specific probability distribution functions, §194.55 of the final rule does, in fact, contain this requirement. Specifically, §194.55 requires that computational techniques used in compliance assessments draw random samples from across the entire range of values of each probability distribution. Therefore, the definition of "population of estimates" in the final rule (at §194.2), taken together with the requirements of §194.55, have the same effect as would adopting the definition suggested in the comment.

Issue FF: Compliance assessments should consider the effects of natural and human-initiated processes and events for 100,000 years after closure, in order to provide additional confidence in the results of CCDFs. (SRIC-G)

Response to Issue 19.FF:

The EPA's responsibility in this rulemaking is to implement the binding disposal regulations of Subparts B and C at 40 CFR part 191 for the WIPP. The regulatory time frame of 10,000 years after disposal was established in Subparts B and C of 40 CFR part 191 and was the product of extensive policy and technical analysis, as well as rigorous pubic and judicial review. The provisions of the disposal regulations and of the final rule require that compliance assessments predict affects of the disposal system on ground water over the entire

10,000-year regulatory time frame. The EPA believes that a disposal system which demonstrates compliance over a 10,000-year time frame will likely contain waste effectively for a longer time period. However, it is outside the scope of this rulemaking to extend the regulatory time frame and, in any event, commenters have offered no specific or compelling basis to re-examine the central, underlying standards. Similarly, the disposal regulations specify that compliance with the individual and ground-water protection requirements must be demonstrated based on undisturbed performance of the disposal system over the regulatory time frame, specifically excluding examination of human intrusion in compliance assessments. In this rulemaking, EPA is developing criteria to implement the disposal regulations specifically at the WIPP; and therefore, revisions which are outside the purview of 40 CFR part 191 are outside the scope of this rulemaking. In order to ensure that a reasonable expectation of compliance is demonstrated, the final rule establishes statistical requirements on the results of compliance assessments (see §194.55).

Section 20: PUBLIC PARTICIPATION: SECTIONS 194.61 through 194.67

Issue A: There should be more public participation in the regulatory process.

1. Compliance criteria should be amended to include public involvement at critical junctures including in EPA's consideration of DOE's Draft Compliance Certification Application, any determination by the Administrator which questions the continued emplacement of waste at WIPP, on EPA's plans to modify, suspend or revoke WIPP's certification, and on inspection reports. (SGNM-B, SGNM-C, CCNS-A, CCNS-B)

2. There is not enough public participation in the regulatory process. (S-50)

3. The EPA should provide every opportunity for feedback and comment on the assumptions and rationale EPA adopts in its decision making process. (CCNS-B)

4. The public needs to be considered in all aspects of rulemaking (such as inspections, access to models, communications, determinations of completeness, evaluations of compliance with any conditions, etc.). The rule, as written, is grossly deficient in this process. (NMAG-G)

5. It is important to include public comment on the notice of proposed rulemaking. (NMAG-B)

6. The public should be invited to comment on whether DOE's application is sufficient to show compliance after it has been determined to be complete. A public hearing where proponents of the application testify should be held both before the Agency prepares its proposed decision and after the proposed decision is published. (NMAG-B, NMAG-G)

7. Additional public hearings should be held after an application is deemed complete. Such hearings should allow unrestricted time for qualified experts to testify. (SRIC-G)

Response to Issue 20.A:

Section 8 of the WIPP LWA calls for EPA's certification by the rulemaking procedures at 5 U.S.C. § 553 and within one year of application receipt. The WIPP LWA also provides that periodic re-certification under section 8(f) of the Act may not be subject to judicial review and calls for EPA's determination whether the WIPP continues to be in compliance within 6 months of receiving documentation from DOE. The EPA is committed to providing ample opportunity for public participation in the certification and re-certification process, consistent with the WIPP LWA. The final compliance criteria bind EPA to specific public participation procedures. Subpart D of the compliance criteria binds the Agency to provide opportunities for public input -- written comments and public hearings -- at critical junctures in the certification rulemaking process, including when an application is received and when EPA proposes its certification decision. Any modification or revocation of a certification will also be done by rulemaking (see §194.4), including **Federal Register** notices and opportunities for public comment. Subpart D of the final rule has been revised to clarify the procedures to

modify or revoke a certification; see §§194.65-194.66. In instances where actions are not subject to rulemaking, such as for re-certification or for some inter-Agency communications, EPA is committed to ensuring public access to information by promptly placing information in public dockets, as described in §194.67 of the final rule.

The Agency values public participation and input and intends to place inspection reports or other relevant information in the docket for public examination. At the same time, EPA will be performing many activities in implementing the compliance criteria. Neither the WIPP LWA nor 40 CFR part 191 require EPA to specify in the WIPP compliance criteria that inspection reports be made publicly available. The EPA thinks it more appropriate to address this and other similar implementation issues in policy statements and in how the Agency elects to exercise its discretion in implementing the compliance criteria, considering the circumstances that arise during the implementation phase. It is not possible or reasonable to codify in the rule all commitments and procedures for information exchange among EPA, DOE and the public. For further discussion of inspection reports, see the response to Issue 3.C of this document.

In the discussion below, EPA addresses the comments about specific issues. Further discussion of pre-application procedures, the process for completeness determination, and procedures for modification is provided in Sections 1 and 2 of this document.

Issue B: More opportunities for public comment are requested.

1. Actual hearings in New Mexico are desired, not merely the opportunity for them. (IV-D-06)

2. New Mexico does not have any power to determine its own future. (A-36)

3. After the Notice of Proposed Rulemaking, criteria are needed for the public hearing to be held in New Mexico. In addition, a public comment period should be made available after the Notice of Proposed Rulemaking. (NMAG-D)

Response to Comments 20.B.1 through 20.B.3:

The EPA is committed to providing ample opportunity for interested parties to participate in the certification process. The EPA has held hearings in New Mexico numerous times in the past, including December 1992 (explaining EPA's oversight role at the WIPP); February 1993 (hearings on proposed waste disposal regulations, 40 CFR part 191); March 1995 (hearings on proposed WIPP compliance criteria, 40 CFR part 194). Hearings were held in multiple locations across the State, in Carlsbad, Albuquerque, and Santa Fe.

Section 8(d) of the WIPP LWA calls for EPA to certify whether the WIPP facility complies with the disposal regulations by rule pursuant to 5 U.S.C. § 553. Section 553 of Title 5, United States Code, authorizes but does not require EPA to provide "opportunity for oral presentation." The final compliance criteria, in §194.61, provide that EPA will hold a public

hearing on an Advance Notice of Proposed Rulemaking (ANPR), if a written request is received by EPA within 30 days of ANPR publication. The EPA would hold any such public hearing in New Mexico. The final rule, in §194.62, has been revised to state that a public notice will "announce public hearings in New Mexico" on the Administrator's proposed decision regarding compliance certification. Thus, the Agency is firmly committed to holding hearings in New Mexico on the Notice of Proposed Rulemaking (NPR). The final rule also provides a public comment period of at least 120 days following publication of the NPR regarding certification.

4. After EPA has published regulations outlining the substance of a performance assessment, DOE should be required to submit a report that is exposed to public comment. (NMAG-F)

Response to Comment 20.B.4:

The EPA's requirements for compliance applications are clearly outlined in the final WIPP compliance criteria (40 CFR part 194), which have been developed with substantial opportunity for public input. Compliance applications must describe and justify the scope of performance assessments, including exclusion of scenarios (see §194.32 and §194.33); and must document and substantiate all models and codes used to support any compliance application (see §194.23). In addition, compliance applications must display the full range of complementary cumulative distribution functions (CCDFs) generated, and must demonstrate that the results fulfill specific statistical requirements related to the containment requirements (see §194.34). The EPA will place any draft performance assessments received from DOE in the public certification rulemaking docket. The Agency will provide substantial opportunity for public comment once EPA has received a final compliance application. There are numerous opportunities for public input at critical junctures in the certification decision-making process. These measures will provide ample opportunity for public review and comment on the performance assessment and other aspects of the compliance application.

5. A number of inadequacies exist in current DOE plans for assisting state, tribal, and local governments in meeting their respective responsibilities related to the WIPP. (IV-D-97)

Response to Comment 20.B.5:

The WIPP LWA requires DOE to provide specific coordination with State and Tribal governments, related, for example, to transportation of waste. These provisions of the WIPP LWA directly apply to DOE. By contrast, EPA's authority in this rulemaking is to establish criteria for determining whether the WIPP facility complies with EPA's general radioactive waste disposal regulations. The disposal regulations deliberately do not address transportation and such issues are outside the purview of this rulemaking. The EPA is committed to providing public access to information pertaining to this rulemaking, the certification rulemaking and re-certification decisions and will continue to place relevant information received by the Agency in public dockets for inspection [see §194.67 of the final rule].

Issue C: Certain organizations need to be explicitly included in the public participation process.

1. The rule should include provisions for including NAS, EEG, State and public. (NMAG-C, NMAG-G)

2. The EPA should establish a procedure that recognizes the additional participation that some parties can have. (SRIC-E)

3. The State, NAS and EEG should have free and timely access to data relating to health, safety, or environmental issues at WIPP and be able to verify the results of computer simulations. DOE and all other parties to the rulemaking should mail a copy of all communications filed with the Administrator in connection with certification to all other parties to the rulemaking. (NMAG-D)

4. Interested persons or organizations should be granted "party status" and thus gain access to all communications between EPA and DOE. (SRIC-G)

5. Subpart D must contain several additional subsections covering such issues as "party status" to the certification rulemaking, pre-application procedures, processes for completeness determination, and procedures for modification or change. (SRIC-E)

Response to Comments 20.C.1 through 20.C.5:

Section 17 of the WIPP LWA contain provisions requiring DOE to provide certain information to the State of New Mexico, the New Mexico Environmental Evaluation Group (EEG), and in some instances the National Academy of Sciences. Sections 17 and 20 of the WIPP LWA also address responsibilities that DOE has to consult and cooperate with EEG and the State of New Mexico. These are responsibilities independent of EPA's compliance criteria that directly apply to DOE under the WIPP LWA.

In this rulemaking, implementing criteria for determining whether the WIPP facility complies with the disposal regulations, EPA has maintained and established specific docketing procedures to ensure all members of the public have access to relevant information. Thus, the EPA will facilitate public access to information by promptly placing copies of relevant information received by the Agency into public dockets in New Mexico and Washington, D.C., as established in §194.67 of the final rule. Subpart D of the compliance criteria binds the Agency to certain procedures to provide ample opportunity for public input -- written comments and public hearings -- at critical junctures in the certification rulemaking process, including when an application is received and when EPA proposes its certification decision. Any modification or revocation must also be done by public rulemaking. The EPA considers input from all commenters at the public forums, and declines to establish in this rulemaking special status for particular parties. See also Section 5 of this document.

6. Tribal officials need to be included in the regulatory process. (A-23)

Response to Comment 20.C.6:

Several tribal organizations are included on EPA's WIPP mailing list and receive EPA publications as they are produced. The EPA also maintains a toll-free WIPP hotline to disseminate information to the public. The EPA is exploring ways that it can work with Tribal organizations to pass on information of EPA's WIPP oversight to their constituencies. As noted in the response to Comment 20.C.1, the final compliance criteria bind EPA to provide advance notice of its certification rulemaking, to maintain dockets in New Mexico and Washington, D.C., and to provide ample opportunity for written and oral comments to facilitate public input. The Agency will consider input from all commenters at the public forums (i.e., public hearings and written public comments) provided for in Subpart D of the final compliance criteria. Also see response to Issue 20.A.

Issue D: Public education has never been done in Spanish. (A-28)

Response to Issue 20.D:

The EPA has made concerted efforts to provide WIPP information in Spanish. Several Hispanic organizations are included on the WIPP mailing list and receive documents in Spanish as they are produced. Spanish translators are also available at many public meetings and all public hearings in New Mexico. Numerous documents and fact sheets are available in Spanish, including *EPA and the WIPP, EPA's Role Under the Land Withdrawal Act, Proposed and Final Amendments to 40 CFR part 191*. A brochure explaining EPA's WIPP public participation program will soon be published in Spanish and English. The EPA also produced and made available a Spanish translation of the proposed compliance criteria (40 CFR part 194) for public comment.

The toll-free WIPP Information hotline offers a recorded message about current EPA WIPP activities in both Spanish and English; information cards advertising the telephone line are also printed in Spanish. Newspaper announcements for public meetings and hearings are published in Spanish newspapers.

The EPA will continue these efforts and is also exploring new ways that it can work with Hispanic community-based organizations to pass on WIPP information to their constituencies.

Issue E: Hearings should be modeled after 40 CFR Part 124 subpart F.

1. The hearing for the final approval/disapproval should be modeled after 40 CFR Part 124 subpart F. (CCNS-A)

2. The inclusion of a nonadversary hearing process both before the completeness determination and before the notice of final rule is recommended. In addition, EPA should

include an interactive hearing process for its final approval or disapproval of WIPP. (CCNS-A, CCNS-B)

3. The Agency must develop procedures for public hearings. (NMAG-F)

Response to Issue 20.E:

Section 8(d) of the WIPP LWA calls for EPA to certify whether the WIPP facility complies with the disposal regulations using the informal rulemaking procedures set out at 5 U.S.C. § 553. The 40 CFR part 124, subpart F contains formal hearing procedures that apply to permitting actions under other environmental statutes that EPA administers. The formal hearing procedures provide an opportunity for cross-examination, briefing, and appeal to EPA's Environmental Appeals Board. These procedures fulfill different purposes recognizing various areas of expertise within the agency.

The EPA declines to adopt the formal hearing procedures for entirely different practical and legal circumstances. Instead, EPA has exercised its discretion, consistent with 5 U.S.C. § 553, to hold informal public hearings during its WIPP certification rulemaking. Subpart D of the final compliance criteria allows for public comment and hearing upon receipt of an application for certification of compliance, and again after EPA announces its proposed decision on certification of the WIPP. In addition, EPA will ensure that the application for certification of compliance is made available for public inspection and comment. These procedures will allow ample opportunity for interested parties to raise substantive issues pertinent to the application review and certification decision, and to have these concerns addressed by EPA. As with the prior informal public hearings EPA held, for example, in conjunction with the compliance certification rulemaking, EPA will provide advance notice of the public hearings and allow interested persons to present oral views to a panel of EPA officials.

Issue F: The public needs an opportunity to comment on the completeness of the application.

1. The public needs an opportunity to comment on the completeness of DOE's final application for approval. (NMAG-B, NMAG-C, S-37)

2. Compliance criteria should specify an opportunity for public comment on the completeness of DOE's application before EPA goes on to evaluate its content. (S-27)

3. The EPA should provide for a public comment period on application completeness. (SGNM-A, CARD-B, SRIC-C, CCNS-A, CCNS-B, S-09, S-37, IV-D-12, IV-D-56)

4. The section on completeness and accuracy of compliance applications must be totally revised to allow for public comment on the completeness issue. (NMAG-C)

5. The EPA should refrain from including a formal completeness review process in the certification criteria. Adoption of any additional public hearings not mentioned in the Land Withdrawal Act would likely keep the Agency from meeting that deadline with little, if any, offsetting benefit relative to the final approval, or disapproval, of the application. (SNL-D)

6. The rule needs to establish provisions in the event that application is not complete or the case where additional information is requested. These provisions should include additional public hearings and advance notices. (NMAG-D)

7. Should the occasion arise for the Agency to consider seeking further information, the public should have an opportunity to comment on the scope and form of the request. (NMAG-D)

8. The determination of whether an application is complete must be subject to public comment and public hearings. (SRIC-G)

Response to Issue 20. F:

The concept of "completeness" is an administrative tool EPA is utilizing to screen a final compliance application received from DOE that because of incompleteness does not even warrant further EPA and public scrutiny. If EPA determines a final compliance application "complete," then the compliance application will be subject to public notice-and-comment rulemaking procedures pursuant to 5 U.S.C. § 553 and as elaborated in the final compliance criteria. The determination of completeness will be made by the Administrator, who will then inform DOE in writing of any such decision, pursuant to §194.11 of the compliance criteria. Any such written notification to DOE would also be placed in the dockets, described under §194.67 of the final rule, for public examination.

Upon receipt of a final compliance application from DOE and before a determination of completeness is made, EPA will publish in the **Federal Register** an Advance Notice of Proposed Rulemaking announcing receipt of the application. A copy of the application will be made available for inspection in the Agency docket, written public comments will be accepted, and a hearing will be held if requested. This comment period will allow interested parties to comment on all aspects of the application, including any aspects that commenters believe are incomplete or inadequate.

Issue G: The public needs to be involved in other aspects of the rulemaking.

1. The public should be informed of all activities between EPA and DOE concerning modifications, suspensions, changes in conditions, or activities pertaining to the disposal system that depart from the application. (CCNS-A)

2. It is contrary to the WIPP LWA for EPA to conduct procedures affecting the validity of terms of certification in any forum other than an open public rulemaking. Any proposal by DOE to obtain EPA's consent to changes in the terms of certification must be announced to

the public; EPA and others must have ample time to obtain information (see §194.C-1) and comment; and EPA must respond to the comments. In particular, to allow DOE to make changes in operations so long as it gives at least 30 days notice is unacceptable. (NMAG-G)

Response to Comments 20.G.1 and 20.G.2:

The terms of certification, if it is granted, are established at the time of initial certification, based on the compliance application submitted at that time. The terms of certification at the WIPP can be changed only through modification or revocation rulemakings. Re-certification is a periodic review, but is not a process to be used to change a certification in effect. If review of information submitted for re-certification, or review of other information, indicates that information, activities or conditions depart significantly from those upon which certification has been based, it may be necessary to modify the terms or conditions of certification. Any such modification would be conducted by rulemaking (including published notices in the **Federal Register** and opportunity for public comment), as described in §194.65 and §194.66, to allow for the same level of public scrutiny as the initial certification received. The results of such a modification rulemaking re-opening the initial certification would also be subject to judicial review. The definitions of modification, suspension, and revocation in the final rule clarify that these actions apply to the certification, if any, in effect at the WIPP, and are thus subject to the public participation provisions of the final rule. Further, as provided in the final rule, EPA will docket all relevant information received from DOE. If any member of the public believes that a change in condition or activity at the WIPP facility has occurred that warrants modification, suspension or revocation of the underlying certification, then they may petition EPA for action pursuant to 5 U.S.C. § 553(e).

3. EPA should address public's role in development of guidance. (EEG-A, EEG-B, SGNM-A)

Response to Comment 20.G.3:

The EPA understands that the public has an interest in the development of compliance application guidance (CAG). The CAG is intended to summarize and interpret the final compliance criteria to provide non-binding guidance regarding the contents of a complete compliance application and is expected to be issued some time after the compliance criteria. The CAG will not undergo formal rulemaking procedures since it is non-binding guidance and not a regulation. However, in recognition of public interest, EPA published a notice of availability (among other steps) for the draft guidance in the fall of 1995 [60 FR 53921-53922, October 18, 1995]. At that point, a copy of the draft CAG was made available for inspection in EPA's WIPP dockets, and public comments were accepted for 60 days. These comments are being considered in revising the guidance. The Agency believes it is inappropriate to codify such procedures in the rulemaking establishing the binding compliance criteria.

4. The EPA must insist that DOE include enough technical background in its application that the public can reproduce and confirm DOE calculations. Compliance criteria should clearly state levels of uncertainty in a way that the public can understand. (CCNS-B)

Response to Comment 20.G.4:

The EPA has endeavored to make compliance certification for the WIPP as objective and straightforward as possible. The EPA will require that DOE include sufficient technical background in its application so that EPA can interpret the information and determine whether compliance has been demonstrated. However, given the long-term nature of performance assessments (PA) and their associated uncertainties, compliance certification is necessarily technical and complex.

The Agency has worked to increase its own and public confidence in the results of performance and compliance assessments by requiring that data and analytical methods used by DOE undergo rigorous quality assurance and peer review (§194.22, §194.23, §194.26, §194.27). In addition, compliance applications received by EPA will be made available promptly (upon receipt by the Agency) for inspection in the WIPP dockets, to allow as much time as possible for interested parties to analyze the document with the means available to them (§194.61, §194.64). Finally, EPA and DOE have held several technical exchanges to discuss some of the complex issues related to PAs; all these meetings have been announced on the WIPP hotline and open to the public to allow opportunities for public education and discussion of technical issues.

Thus, while the PA and compliance assessment calculations are very complex, EPA has and will continue to provide opportunities for public access and education on these topics.

5. Another hearing is requested so that the public has the opportunity to point out the omitted issues with 40 CFR part 194. (S-11)

Response to Comment 20.G.5:

Two series of public hearing have been held since 1992 in Carlsbad, Santa Fe, and Albuquerque, New Mexico. The hearings held in March 1995 provided an opportunity for the public to comment on the proposed compliance criteria. In addition, EPA provided multiple opportunities for interested parties to submit written comments on the proposal. An initial 90-day comment period opened on January 30, 1995, when the proposal was published in the **Federal Register**. In response to a written request to re-open the public comment period for at least 30 days, the comment period was re-opened for 45 days (from August 1 to September 15, 1995) to allow additional time and opportunity for public comments. The EPA believes that the opportunities for public comment have been adequate, especially in view of the statutory deadlines for promulgating the final rule and lawsuits filed to compel the agency to expeditiously finalize the criteria. See also discussion in Section 1 (General Comments and Issues) of this document.

6. EPA should include public hearings and comment on the retrieval plan. (NMAG-B, CCNS-A)

Response to Comment 20.G.6:

The final compliance criteria, under §194.4, revise the requirement for a retrieval plan as part of compliance applications. The criteria require retrieval, to the extent practicable, if certification of the facility is revoked. Any revocation decision would be made pursuant to rulemaking, including public notices and opportunity for comment on proposed actions. In addition, the criteria, at §194.46, require the compliance application to include documentation demonstrating that removal of waste from the disposal system is feasible for a reasonable period of time after disposal, including an analysis of the technological feasibility of mining the sealed disposal system, given technology levels at the time a compliance application is prepared. This documentation will be subject to public scrutiny during the compliance certification rulemaking proceeding. See also Section 1 and Section 18 (Removal of waste) of this document.

7. A comment period of longer than 90 days on the proposed criteria is necessary so that the public can examine how the draft application affects the Compliance Criteria. (SRIC-C)

8. The EPA should have provided a longer time for comment when the public comment period was re-opened, as the Agency pledged to do in April 1995. (SRIC-G)

Response to Comments 20.G.7 and 20.G.8:

In total, EPA provided 135 days of formal public comment period. An initial comment period was in effect from January 31 to May 1, 1995. The comment period on the proposed compliance criteria was re-opened for 45 days (August 1 to September 15, 1995) in response to public comments. The comment period was re-opened after EPA received the second of two parts of a draft application submitted by DOE to EPA. The re-opening provided an opportunity for the public to comment on the proposed compliance criteria in light of DOE's draft compliance certification application, which was placed in EPA's docket A-93-02 for public inspection. The EPA also accepted and considered all public comments received by the Agency in the time between the formal comment periods (i.e, from May 1 to July 31, 1995). The EPA has also endeavored to fully consider all late comments.

The EPA was sued in two separate lawsuits for its failure to meet the WIPP LWA October 30, 1994 statutory deadline for the final compliance criteria. See New Mexico v. EPA, No. 95-1273 (D.C. Cir. filed May 26, 1995) & Southwest Research and Information Center v. EPA, No. 95-1285 (D.C. Cir. filed June 1, 1995) (The latter case was filed by the commenter above, who is requesting longer time for public comment.) These two petitions asserted that EPA had unreasonably delayed issuance of the final compliance criteria and requested the D.C. Circuit to issue an order requiring EPA to promulgate the final criteria by December 31, 1995. The petitions, and subsequent requests for rehearing, were rejected by two separate panels of the D.C. Circuit. See New Mexico, No. 95-1273 (D.C. Cir. July 19, 1995) (Judges Silberman,

Sentelle and Tatel) & Southwest Research and Information Center v. EPA, No. 95-1285 (D.C. Cir. Aug. 14, 1995) (Judges Wald, Ginsburg and Randolph). The court's orders reasoned that while EPA had not issued the final compliance criteria by the statutory deadline, the agency's delay was not so egregious to warrant a writ of mandamus, particularly in view of EPA's plans to reopen the public comment period (see 60 Fed. Reg. 39,131, Aug. 1, 1995) and issue final compliance criteria by February 1996. In light of the court orders, EPA has undertaken additional steps to expedite the rulemaking and ensure that it issues the final compliance criteria by February 1996, including closing the public comment period on September 15, 1995. See also the response to Comment 20.G.5 and discussion in Section 1 of this document.

Issue H: With regard to continued compliance, there is no provision for public hearings, notice of proposed decision, response to public comments, statement of fact finding, conclusions, or rationale. (NMAG-B, NMAG-G)

1. In reference to continued compliance, criteria are needed for the public hearing to be held in New Mexico. In addition, a public comment period should be made available after the public hearing. (NMAG-D)

Response to Issue 20.H:

Section 8(f) of the WIPP LWA specifically exempts from rulemaking or judicial review the Administrator's determination whether or not the WIPP facility continues to be in compliance with the disposal regulations. The WIPP LWA also establishes a statutory review period of six months for re-certifications. [See §194.4(a) of the final rule, and Section 2 of this document for further discussion of the statutory review period.] The Agency is committed to allowing public participation in the re-certification process, to the extent permitted by the constraints established by the statute. To that end, the final rule [§194.64] specifies that EPA will docket all re-certification documentation materials submitted to EPA by DOE; will publish public notices upon receipt of such materials; will provide a public comment period and accept written public comments regarding re-certification; and will publish a public notice announcing the Administrator’s decision (and rationale) on whether or not to re-certify the WIPP facility. The EPA believes these provisions provide adequate opportunity, within the requirements of the WIPP LWA, for public input on re-certification decisions.

Issue I: Dockets should be maintained in New Mexico in a timely fashion (§194.65). (NMAG-F, NMAG-G)

Response to Issue 20.I:

The EPA makes every effort to keep the dockets current. The Agency recognizes the importance of providing timely information, since the dockets are the source of many documents pertinent to public participation in EPA’s WIPP rulemakings and other activities. The final rule addresses dockets in §194.67.

Issue J: The public needs to be informed of all releases.

1. DOE must notify the public of all releases, even those which are considered to be within the standard. (CCNS-B)

2. The public should be informed if DOE informs the administrator that a release has occurred or is likely to occur. (EEG-A, CCNS-A)

3. When it comes to reporting releases, the people living around the site need to know if something has escaped the facility. (S-16)

4. DOE should be obligated to report releases of waste from the disposal system to the environment in excess of what is permitted under the disposal regulations. (NMAG-D)

Response to Issue 20.J:

In the final compliance criteria, DOE is required to notify EPA within 24 hours if the Department determines that a release of waste to the accessible environment in excess of the release limits (under 40 CFR part 191) has occurred or is expected to occur [§194.4(b)(3)(ii)-(iii)]. If EPA determines that such a release is related to factors involving the long-term containment of waste, then the Agency may take action to modify, suspend, or revoke a certification. The Administrator may suspend a certification to mitigate an immediate hazard to the public. Any action to modify or revoke certification will be done through formal rulemaking procedures (see §194.4(b)(1)) including public notices in the **Federal Register**. The DOE must also submit information on releases from the WIPP below the release limits, if such releases indicate conditions that depart from those that formed the basis of a certification of compliance (see §194.4(b)(3)). The EPA will docket any information the Agency receives on releases of waste from the WIPP so that such information will be available to the public. See §194.67 of the final rule; see also Response to Comments 20.G.1 and 20.G.2.

Issue K: Access to information is critical for the compliance determination; it is suggested that EPA regulate access to the data by Agency staff so the compliance determination process in not be impeded by disputes over access to data. (NMAG-B, NMAG-F)

Response to Issue 20.K:

The EPA agrees that information and data will be very important for the Agency to thoroughly scrutinize the compliance application and make a sound decision regarding compliance for the WIPP. The final compliance criteria establish detailed documentation requirements that DOE must address in its compliance application. The EPA will accept public comment on DOE's application and, before beginning an evaluation of compliance, must determine that the application is complete and accurate (and so notify the Secretary -- see §194.11). The EPA may request DOE to submit additional information in order to qualify an initial application as complete and accurate. Any requests for additional information will

be by written correspondence; both EPA's request and DOE's response will be docketed and available for public review. Because the evaluation of compliance does not begin until after the application is deemed complete, the criterion is a strong incentive for the Department to provide timely and accurate information to EPA.

APPENDIX A:
LIST OF COMMENTERS

Public Hearings on the proposed 40 CFR 194 were conducted in three New Mexico sites. The dates of the proceedings were as follows: Carlsbad, March 21, 1995; Albuquerque, March 22, 1995; Sante Fe, March 23 and 24, 1995. The following is a list of those individuals who testified including their place of residence, title and affiliation, if applicable. An asterisk (*) is used to denote that the individual submitted written documentation to complement his/her oral testimony.

Carlsbad Hearing

C-01	George Dials, Manager of Carlsbad Area Office, Department of Energy.
C-02	Gary Perkowski, Mayor of Carlsbad and President of the New Mexico Municipal League.
C-03	Betty Richards.
C-04	Dick Manus, Manager of Carlsbad Resource Area, Bureau of Land Management.
C-05	* Carl Cox, General Manager, Westinghouse Electric Corporation.
C-06	Richard White, White City, New Mexico.
C-07	Robert Light, State Representative of New Mexico, Eddy County.
C-08	Charles Loftus.
C-09	* Jennifer Salisbury, Secretary, New Mexico Department of Energy, Minerals, and Natural Resources.
C-10	Randy Foot, General Manager, Mississippi Potash.
C-11	Louis Whitlock.
C-12	Mark Donham, Executive Director, Carlsbad District Department of Development.
C-13	Cliff Stroud.
C-14	John Heaton, WIPP Task Force.
C-15	Leigh Barnes, Manager, Day and Zimmerman.
C-16	George Shoup, WIPP Task Force.
C-17	Marvin Watts, Vice President, Carlsbad Department of Development.
C-18	Mike Currier, President, Garret Title.
C-19	Lucy Janez, President, Hispano Chamber of Commerce.
C-20	Jim Wilcox, Manager of Human Resources, IMC Global Operations.
C-21	Bill Pierce, President, Union of United Steel Workers, Carlsbad, New Mexico.
C-22	Gene Hornbach, Carlsbad Chamber of Commerce.
C-23	Fred Fernandez, Safety and Environmental Manager, Western Agricultural Minerals Company.
C-24	* Mary Gale Wood, for Congressman Joe Skeen.
C-25	V.C. (Andy) Anderson.
C-26	Larry Coalson.
C-27	Norbert Rempe, Carlsbad, New Mexico.
C-28	* Stanley Patchet.

C-29 Dale Janway, Manager of Safety and Security, Eddy Potash Incorporated.
C-30 Louis Methola, President, United Steel Workers' of America (read by Janway).

Albuquerque Hearing

A-01 Max Bartlett, New Mexico Progressive Alliance for Community Empowerment.
A-02 * Mike McFadden, Assistant Manager of Carlsbad Area Office, Department of Energy.
A-03 Cameron Adair, Westinghouse Electric Corporation.
A-04 Tom Metcalf.
A-05 Richard Sauder.
A-06 Dave Mitchell, President, Valencia County Concerned Citizens Association.
A-07 Dorelen Bunting.
A-08 * Lila Bird, Water Information Network.
A-09 Floy Barrett.
A-10 * Caroline Epple.
A-11 * Sharla Bertram, Albuquerque, New Mexico.
A-12 * Harry Willson, Albuquerque, New Mexico.
A-13 * Kenneth Nemeth, Southern States Energy Board.
A-14 * Robert Neill, Environmental Evaluation Group.
A-15 Don Hancock, Southwest Research and Information Center.
A-16 Ronald Ross, Manager for Environmental Programs, Western Governors' Association.
A-17 Susan Diane.
A-18 Jeffrey Rich.
A-19 Glenna Voitht.
A-20 Angela Wieback.
A-21 Sally Alice Thompson.
A-22 Joe Shunkamolah.
A-23 * Mervyn Tilden.
A-24 Jock Cobb, Professor Emeritus, Department of Preventive Medicine, University of Colorado.
A-25 Bob Anderson.
A-26 Beverly Gensemer.
A-27 * Julie Ahern.
A-28 Lauro Silva.
A-29 Jeri Rhodes.
A-30 John Leahigh, Office of Social Justice of the Catholic Archdiocese of Santa Fe.
A-31 Leif Erikkson.
A-32 Lee Simms.
A-33 Sharon Williams, National Organization for Women at University of New Mexico.
A-34 Caren Seglinda Neuhauser.
A-35 Sue Chavez.

A-36 Judy Pratt, New Mexico Organizing Committee.
A-37 Diana Drake.
A-38 Dave Pace.
A-39 Penny Mainz.
A-40 Damacio Lopez, Progressive Alliance for Community Empowerment (PACE).
A-41 Susan Gorman, The Sierra Club.
A-42 Lily Rendt.
A-43 Eva Khoury.
A-44 William Beams, Albuquerque, New Mexico.
A-45 * Ruth Weiner, Albuquerque, New Mexico.
A-46 Robin Seydel, Albuquerque, New Mexico.
A-47 Charles Powell.
A-48 Rick Packie.
A-49 Linda Sperling, Albuquerque, New Mexico.
A-50 Jerry Messick, Vice President, Albuquerque Chapter of 1199 New Mexico Health Care and Hospital Workers.
A-51 Silvania D'Ouville.
A-52 Mark Rudd, Instructor, Albuquerque Technical Vocational Institute.
A-53 Jim Radford, Business People Concerned About WIPP.
A-54 Karen Navarro.
A-55 Don Schrader.
A-56 * John Hart.
A-57 Alan Cooper.
A-58 Rich Weiner, New Mexico Chapter of the National Lawyers Guild.
A-59 Janet Greenwald, Citizens for Alternatives to Radioactive Dumping (CARD).
A-60 Garland Harris, All Peoples Coalition.
A-61 Robert Light, State Representative of New Mexico, Eddy County.
A-62 Lee Shepard, Project Manager for WIPP, Sandia National Laboratory.
A-63 Karen Boneme, Albuquerque, New Mexico.
A-64 Jack Uhrick.
A-65 John Fishburn.
A-66 Carla Callan-Fishburn.
A-67 Paul Alan Haynes.
A-68 Dan Kerlinsky, President, New Mexico Physicians for Social Responsibility.
A-69 Andy Lenderman.
A-70 Frederick Williams, Albuquerque, New Mexico.

Sante Fe Hearing, Day 1

S-01 George Dials, Manager of the Carlsbad Area Office, Department of Energy.
S-02 Cameron Adair, Westinghouse Electric Corporation.
S-03 * Rebecca Briggs, Sante Fe, New Mexico.
S-04 Robert Light, State Representative of New Mexico, Eddy County.
S-05 Jennifer Salisbury, Secretary, New Mexico Department of Energy, Minerals, and Natural Resources.

S-06 Bonnie Bramble.
S-07 * Jeff Radford, Business People Concerned about WIPP.
S-08 Richard Dayo.
S-09 Jean McFarland.
S-10 Sandy Clarke.
S-11 Dominique Mazeaud.
S-12 Anna Katherine.
S-13 Loretta Johnston.
S-14 Anharo Lovato.
S-15 Ray Schmidt.
S-16 Susan Hirschberg.
S-17 Margaret Reisely, Los Alamos Study Group.
S-18 * Don Hancock, Southwest Research and Information Center.
S-19 Robert Neill, Environmental Evaluation Group.
S-20 Zack Richards, Sante Fe, New Mexico.
S-21 Deborah Reade, Sante Fe, New Mexico.
S-22 Tom Udall, Attorney General of New Mexico.
S-23 Suchi Soloman.
S-24 Daniel Zelinger.
S-25 Julianna Young, Sante Fe, New Mexico.
S-26 Laurie Richards.
S-27 Rhea Goodman.
S-28 Bill Gould.
S-29 Dan Gibson.
S-30 Sosha Pyle.
S-31 Angela Lyon.
S-32 Jim Trout.
S-33 Ron Lieberman.
S-34 Elizabeth Ruben.
S-35 Mr. Christophe.
S-36 Jean Crawford, Earth First.
S-37 * Bob Pinkus.
S-38 Bonnie Bonneau.
S-39 Janet Degan.
S-40 Penelope McMullen, Sister of Loretta.
S-41 Ditto Nowakoski.
S-42 Julia Coyne.
S-43 John Ussery, New Mexico Green Party.
S-44 Margret Carde, Research Analyst, Concerned Citizens for Nuclear Safety.
S-45 Dave Mitchell.
S-46 Amy Bunting, Sante Fe, New Mexico.
S-47 Jeremy Boak, Sante Fe, New Mexico.
S-48 Medora Raborg, Sante Fe, New Mexico.

Santa Fe Hearing, Day 2

S-49 * Wendell Weart, Sandia National Laboratories.
S-50 Karen Balkany.
S-51 Jim Tollison, Albuquerque, New Mexico.
S-52 Deirdre Boak, Sante Fe, New Mexico.
S-53 John Otter.
S-54 Peter Cummings.
S-55 * Helen Corneli.
S-56 Virginia Miller, Sante Fe, New Mexico.
S-57 Leonard Trimmer.
S-58 Maurice Weisberg, Sante Fe, New Mexico.
S-59 Elaine Govando, Sante Fe, New Mexico.
S-60 Bill Doyle, Sante Fe, New Mexico.
S-61 Emmy Koponen.
S-62 Tom Morgan.
S-63 Carol Adams.
S-64 Medora Raborg.
S-65 Kathy Sabo.
S-66 * Catherine Montano, Las Vegas, New Mexico.

Written comments on the proposed rule 40 CFR 194 were submitted to Docket Number A-92-56. There were three series used to catergorize the comments at this docket. The following is a list of commentors, state of residence (if known), and where appropriate, the organizations they represent.

Series IV-D (Comments received by the Agency after Federal Register publication of proposal)

IV-D-05 Benjamin Radford, Corrales, New Mexico.
IV-D-06 John Otter, Sante Fe, New Mexico.
IV-D-07 Aanya Adler Friess, Albuquerque, New Mexico.
IV-D-08 Deirdre Boak, Sante Fe, New Mexico.
IV-D-09 Paul S. & Neva Reifsnyder, Bosque, New Mexico.
IV-D-10 Sandia National Laboratories, Albuquerque, New Mexico, signed by Les Shephard, WIPP Project Management Department.
IV-D-11 Floyd R. Hertweck, Jr., Oxford, Ohio.
IV-D-12 Barbara Conroy, Sante Fe, New Mexico.
IV-D-13 Unable to read signature.
IV-D-14 Susanne Thobe, Albuquerque, New Mexico.
IV-D-15 Tracie J. Sipple, El Prado, New Mexico.
IV-D-16 Kathryn Zijerinc, Sante Fe, New Mexico.
IV-D-17 Oris Gene Salazar, Albuquerque, New Mexico.
IV-D-18 Tammy Prothero, Corrales, New Mexico.
IV-D-19 Bryant Roberson.
IV-D-20 Annette Velasquez-Aguayo, Albuquerque, New Mexico.
IV-D-21 Robyn L. McCormick, Albuquerque, New Mexico.

IV-D-22 Sandy Bartston.
IV-D-23 Unable to read signature.
IV-D-24 Michael McRee, Albuquerque, New Mexico.
IV-D-25 Andra Stewart, Sante Fe, New Mexico.
IV-D-26 Gina Covinn, Vallecitos, New Mexico.
IV-D-27 Thora Guinn, Albuquerque, New Mexico.
IV-D-28 Concerned Citizens of Cerrillos, Cerrillos, New Mexico, signed by Ross Lockridge, President and Dennis Overman, Vice President.
IV-D-29 Maurice A. Weisberg M.D., Sante Fe, New Mexico.
IV-D-30 Renee Fox.
IV-D-31 Marla Gourdin.
IV-D-32 Deborah J. Lujan, Taos, New Mexico.
IV-D-33 Donald Woodman, Belen, New Mexico.
IV-D-34 Judy Chicago, Belen, New Mexico.
IV-D-35 Don Kidd, New Mexico State Senator, District 34.
IV-D-36 Robert R. Richards, Albuquerque, New Mexico.
IV-D-37 Unable to read signature.
IV-D-38 Jane Hiltbrand, Albuquerque, New Mexico.
IV-D-39 Environmental Evaluation Group, Albuquerque, New Mexico, signed by Robert H. Neill, Director.
IV-D-40 John B. Case, P.E., Albuquerque, New Mexico.
IV-D-41 Attorney General of New Mexico, Sante Fe, New Mexico, signed by Lindsay A. Lovejoy, Jr., Assistant Attorney General.
IV-D-42 Mabuba Rasul, Albuquerque, New Mexico.
IV-D-43 Physicians for Social Responsibility, Colorado Chapter, Denver, Colorado, signed by Samuel H. Cole, Executive Director.
IV-D-44 Susan Diane
IV-D-45 Marjorie Williams, Albuquerque, New Mexico.
IV-D-46 Charles A. Galbreath.
IV-D-47 Nancy B. Grover.
IV-D-48 Unable to read signature.
IV-D-49 Southwest Research and Information Center, Albuquerque, New Mexico, signed by Don Hancock, Director of Nuclear Waste Safety Project.
IV-D-50 New Mexico Chapter of the National Lawyers Guild, Albuquerque, New Mexico, signed by Angela Cornell and Rich Weiner.
IV-D-51 Dr. Stanley E. Logan, Sante Fe, New Mexico.
IV-D-52 Kurt Smith.
IV-D-53 Jane H. Klenck, Albuquerque, New Mexico.
IV-D-54 Teresa Holle.
IV-D-55 Rebecca J. Briggs, Sante Fe, New Mexico.
IV-D-56 Unable to read signature.
IV-D-57 John Fred Hohes.
IV-D-58 Martha J. Harlow, Albuquerque, New Mexico.
IV-D-59 Unable to read signature.

IV-D-60 Louise R. Hendrix.
IV-D-61 Patricia R.S. Hiben, Albuquerque, New Mexico.
IV-D-62 Unable to read signature.
IV-D-63 Elaine Sandoral.
IV-D-64 Rob P. Rechard, Albuquerque, New Mexico.
IV-D-65 Virginia Power, Glen Allen, Virginia, signed by M. L. Bowling, Manager of Nuclear Licensing and Programs.
IV-D-66 Unable to read signature.
IV-D-67 Unable to read signature.
IV-D-68 Bennie J. Merideth.
IV-D-69 Unable to read signature.
IV-D-70 Unable to read signature.
IV-D-71 Gay Lynn Habegger.
IV-D-72 Joseph G. Hzilow, Albuquerque, New Mexico.
IV-D-73 Victor Ferkin, Corrales, New Mexico.
IV-D-74 Christopher B. Mixon, Albuquerque, New Mexico.
IV-D-75 Unable to read signature.
IV-D-76 Nuclear Energy Institute, Washington, DC, signed by John F. Schmitt, Director of Radiological Protection, Emergency Preparedness & Waste Regulation.
IV-D-77 Concerned Citizens for Nuclear Safety (CCNS), Santa Fe, New Mexico, Margret Carde, Nuclear Waste Research Analyst.
IV-D-78 Rob P. Rechard, Albuquerque, New Mexico (same as IV-D-64).
IV-D-79 Marla Gourdin.
IV-D-80 Nancy Oestreicher, Albuquerque, New Mexico.
IV-D-81 Westinghouse Electric Corporation, Pittsburgh, Pennsylvania, signed by S. A. Green, Manager of Government ES&H Programs Environmental Affairs.
IV-D-82 Dominique Mazeaud, Sante Fe, New Mexico.
IV-D-83 Christopher L. Habegger, Sante Fe, New Mexico.
IV-D-84 Citizens For Alternatives To Radioactive Dumping (CARD), Albuquerque, New Mexico, submitted by Garland Harris, Liason for CARD.
IV-D-85 Energy, Minerals and Natural Resources Department of New Mexico, Sante Fe, New Mexico, signed by Jennifer A. Salisbury, Cabinet Secretary and Chair of New Mexico Radioactive Waste Consultation Task Force.
IV-D-86 Thora Guinn, Albuquerque, New Mexico (same as IV-D-27).
IV-D-87 Brian Sablatura.
IV-D-88 Pamela J. McCann, Albuquerque, New Mexico.
IV-D-89 Kristina Faught-Holla, Bluewater, New Mexico.
IV-D-90 Department of Energy, Washington DC, signed by Thomas P. Grumbly, Assistant Secretary for Environmental Management.
IV-D-91 Susan Linnell, Albuquerque, New Mexico.
IV-D-92 Don Schrader, Albuquerque, New Mexico.
IV-D-93 Holly Rucker.
IV-D-94 Nuclear Regulatory Commission, Washington, DC, signed by Carl J. Paperiello, Director of Office of Nuclear Material Safety and Safeguards.

IV-D-95 Philip Hall, Los Lunas, New Mexico.
IV-D-96 Y. M. Lee, Ramah, New Mexico.
IV-D-97 Pueblo of Acoma, Acoma, New Mexico, signed by Ron D. Shutiva, Governor.
IV-D-98 John E. Trowbridge, Deming, New Mexico.
IV-D-99 Cathy Pitt.
IV-D-100 Zordan Associates Incorporated, Murrysville, Pennsylvania, signed by Tom A. Zordan.
IV-D-101 Southwest Research and Information Center, Albuquerque, New Mexico, Don Hancock, Director Nuclear Waste Safety Project.
IV-D-102 Office of Attorney General of New Mexico, Sante Fe, New Mexico, signed by Lindsay A. Lovejoy, Assistant Attorney General, New Mexico.
IV-D-103 Office of Attorney General of New Mexico, Sante Fe, New Mexico, signed by Lindsay A. Lovejoy, Assistant Attorney General, New Mexico.
IV-D-104 Southwest Research and Information Center, signed by Don Hancock.
IV-D-105 Concerned Citizens for Nuclear Safety, signed by K. Sabo.
IV-D-106 Office of Attorney General of New Mexico, Sante Fe, New Mexico, signed by Tom Udall, Attorney General, New Mexico.
IV-D-107 Office of Attorney General of New Mexico, Sante Fe, New Mexico, signed by Tom Udall, Attorney General, New Mexico.
IV-D-108 Jim Bernadoni.
IV-D-109 Lisa Lopez.
IV-D-110 Department of Energy.
IV-D-111 Michael M. Strum, Boulder, Colorado. (Same as IV-D-118)
IV-D-112 Michael A. Glora, Albuquerque, New Mexico.
IV-D-113 Sandy Wander, Albuquerque, New Mexico.
IV-D-114 William E. McConnell, Jackson, Michigan.
IV-D-115 Concerned Citizens for Nuclear Safety (CCNS), Santa Fe, New Mexico, signed by Margret Carde, Nuclear Waste Research Analyst. (Same as IV-D-77.)
IV-D-116 Merritt E. Langston, Rockville, Maryland.
IV-D-117 Walter R. Coutier, Burke, Virginia.
IV-D-118 Michael M. Strum, Boulder, Colorado. (Same as IV-D-111)
IV-D-119 Sandia National Laboratories, Carlsbad, New Mexico, signed by Les Shepard, Manager, WIPP Project.
IV-D-120 Attorney General of New Mexico, Santa Fe, New Mexico, signed by Lindsay A. Lovejoy, Jr., Assistant Attorney General.
IV-D-121 Attorney General of New Mexico, Santa Fe, New Mexico, signed by Lindsay A. Lovejoy, Jr., Assistant Attorney General.
IV-D-122 N&E Enterprises, Hampstead, North Carolina, signed by Edwin Bajada.
IV-D-123 Craig G. Walenga, Rockville, Maryland.
IV-D-124 State of New Mexico Environment Department, Santa Fe, New Mexico, signed by Neil S. Weber, Chief, Department of Energy Oversight Bureau.
IV-D-125 Department of Energy, Carlsbad, New Mexico, signed by George E. Dials, Manager, Carlsbad Area Office.
IV-D-126 New Mexico Environmental Evaluation Group (EEG), Albuquerque, New Mexico, signed by Rober H. Neill, Director.

IV-D-127 Allen E. Winegard, Baldwinsville, New York.
IV-D-128 Southwest Research and Information Center, Albuquerque, New Mexico, signed by Don Hancock.
IV-D-129 Nuclear Regulatory Commission, staff review.

Series IV-G (Comments received by the EPA after the close of the second part of the public comment period; i.e. after September 15, 1995)
IV-G-1 U.S. Nuclear Regulatory Commission, Washington, DC, signed by Carl J. Paperiello, Director of the Office of Nuclear Material Safety and Safeguards.
IV-G-2 State of New Mexico Environment Department, Santa Fe, New Mexico, signed by Neil S. Weber, Chief, Department of Energy Oversight Bureau. (Same as IV-D-124.)
IV-G-3 John S. Hart, Albuquerque, New Mexico.
IV-G-4 Southwest Research and Information Center, Albuquerque, New Mexico, signed by Don Hancock, Director of Nuclear Waste Safety Project.
IV-G-5 Unable to read signature, Albuquerque, New Mexico.
IV-G-6 U.S. Nuclear Regulatory Commission, Washington, DC, signed by Carl. J. Paperiello, Director of the Office of Nuclear Material Safety and Safeguards.

Series II-D (Comments pertaining to drafts previous to Federal Register publication of the proposed rule)
II-D-09 Attorney General of New Mexico, Sante Fe, New Mexico, signed by Tom Udall, Attorney General.
II-D-25 Attorney General of New Mexico, Sante Fe, New Mexico, signed by Tom Udall, Attorney General.
II-D-29 Southwest Research and Information Center, Albuquerque, New Mexico, signed by Don Hancock, Director of Nuclear Waste Safety Project.

Series II-E (EPA Memoranda of meetings prior to Federal Register publication of proposal)
II-E-12 Southwest Research and Information Center, Albuquerque, New Mexico, submitted by Don Hancock, Director of Nuclear Waste Safety Project.

COMMENTOR LIST FOR ORGANIZATIONS SUBMITTING MULTIPLE COMMENTS

Ten agencies and organizations submitted multiple written and/or oral comments. To facilitate the identification of these organizations, a separate identification scheme is employed. The following list provides the name of the organization that submitted comments, the abbreviation used in the above list of comments, and the letter that corresponds to the numbering scheme produced above. For example, the denotation DOE-A represents comment C-1 provided by the Department of Energy.

Agency:	**Abbreviation:**	**Identification:**
Department of Energy	DOE	A: C-1 B: A-2 C: S-1 D: IV-D-90 E: IV-D-125
Westinghouse Electric Corporation	WEC	A: C-5 B: A-3 C: S-2 D: IV-D-81
State Government of New Mexico	SGNM	A: C-9 B: S-5 C: IV-D-85 D: IV-D-124
Citizens for Alternatives to Radioactive Dumping	CARD	A: A-59 B: IV-D-84
Environmental Evaluation Group	EEG	A: A-14 B: S-19 C: IV-D-39 D: IV-D-126
New Mexico Attorney General	NMAG	A: S-22 B: IV-D-41 C: IV-D-102 D: IV-D-120 E: IV-D-121 F: II-D-09 G: II-D-25

Agency:	**Abbreviation:**	**Identification:**
Sandia National Laboratories	SNL	A: A-62 B: S-49 C: IV-D-10 D: IV-D-119
Southwest Research and Information Center	SRIC	A: A-15 B: S-18 C: IV-D-49 D: IV-D-101 E: II-D-29 F: II-E-12 G: IV-G-4
State Representative for New Mexico	SRNM	A: C-7 B: A-61 C: S-4
Concerned Citizens for Nuclear Safety	CCNS	A: S-44 B: IV-D-77 C: IV-D-115
Nuclear Regulatory Commission	NRC	IV-D-128

APPENDIX B:
LIST OF ACRONYMS

AEA	Atomic Energy Act [42 U.S.C. §2011 *et seq.*, as amended]
AIC or AICs	Active Institutional Controls
ALARA	As Low As Reasonably Achievable
ASME	American Society of Mechanical Engineers
BAT	Best Available Technology
BID	Background Information Document
CAG	Compliance Application Guidance
CCDFs	Complementary Cumulative Distribution Function
CFR	Code of Federal Regulations
CH	Contact Handled
CWA	Clean Water Act [33 U.S.C. §1251 *et seq.*, as amended]
DOE	Department of Energy
DOT	Department of Transportation
EATF	Engineered Alternatives Task Force (DOE)
EB	Engineered Barriers
EEG	Environmental Evaluation Group
EPA	Environmental Protection Agency
FR	Federal Register
ICRP	International Commission on Radiation Protection
LHS	Latin Hypercube Sampling
LWA	Land Withdrawal Act [Public Law 102-579, 1992]
MCL	Maximum Contaminant Levels
MTHM	Metric Tons Heavy Metal
NACEPT	National Advisory Council for Environmental Policy and Technology
NAS	National Academy of Sciences
NQA	Nuclear Quality Assurance
NRC	Nuclear Regulatory Commission
NUREG	NRC Regulation
OMB	Office of Management and Budget
ORIA	Office of Radiation and Indoor Air, EPA
OSW	Office of Solid Waste, EPA
PA	Performance Assessment
PIC or PICs	Passive Institutional Controls
QA	Quality Assurance
QAMS	Quality Assurance Management Staff
RCRA	Resource Conservation and Recovery Act [42 U.S.C. §6901 *et seq.*, as amended]
RH	Remote Handled
SDWA	Safe Drinking Water Act [42 U.S.C. §300f *et seq.*, as amended]
TRU	Transuranic
USDW	Underground Sources of Drinking Water
WIPP	Waste Isolation Pilot Plant

WPA Whistleblower Protection Act [5 U.S.C. §2302]

NOTE:
- Abbreviations in citations are explained under “List of Commentors.”
- For definitions refer to 40 CFR Part 194 and referenced documents.