ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 194

[FRL–5915–1]

RIN 2060–AG85

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

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule; opening of public comment period.

SUMMARY: The Environmental Protection Agency (''EPA'') is proposing to certify that the Department of Energy's (''DOE'') Waste Isolation Pilot Plant (''WIPP'') will comply with the radioactive waste disposal regulations set forth at 40 CFR Part 191 (Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Waste). EPA is required to evaluate whether the WIPP will comply with EPA's standards for the disposal of radioactive waste by the WIPP Land Withdrawal Act (''LWA'') of 1992, as amended. EPA's certification of compliance, if finalized, would allow the emplacement of radioactive waste in the WIPP to begin, provided that all other applicable health and safety standards have been met. The proposed certification would allow Los Alamos National Laboratory to ship TRU waste from specific waste streams for disposal at the WIPP. However, the proposed certification is subject to several conditions, notably that EPA must approve site-specific waste characterization measures and quality assurance plans before allowing other waste generator sites to ship waste for disposal at the WIPP. The Agency proposes to amend 40 CFR Part 194 by adding an appendix describing EPA's certification, and by adding a definition. Finally, EPA is proposing its decision, also pursuant to the LWA, that DOE does not need to acquire existing oil and gas leases near the WIPP in order to meet the disposal regulations. Today's notice marks the beginning of a 120-day public comment period on EPA's proposed certification decision, and on the other proposed actions described above.

DATES: Comments on today's proposal must be received by February 27, 1998. Public hearings on today's proposal will be held in New Mexico. A separate announcement will be published in the **Federal Register** to provide public hearing information.

ADDRESSES: Comments should be submitted, in duplicate, to: Docket No. A–93–02, Air Docket, Room M–1500 (LE–131), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. See additional docket information in the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Betsy Forinash or Scott Monroe; telephone number (202) 233–9310; address: Radiation Protection Division, Center for the Waste Isolation Pilot Plant, Mail Code 6602-J, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. For copies of the Compliance Application Review Documents supporting today's proposal, contact Scott Monroe at the above phone number and address.

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I. Background

Congress authorized development and construction of the Waste Isolation Pilot Plant (''WIPP'') in 1980 ''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.'' [1] The U.S. Department of Energy (''DOE'' or ''the Department'') is developing the WIPP near Carlsbad in southeastern New Mexico as a potential deep geologic repository for the disposal of defense transuranic (''TRU'') radioactive waste. TRU waste consists of materials containing alpha-emitting radio-isotopes, with half-lives greater than twenty years and atomic numbers greater than 92, in concentrations greater than 100 nano-curies per gram of waste.[2] Most TRU waste proposed for disposal at the WIPP consists of items that have become contaminated as a result of activities associated with the production of nuclear weapons, e.g., rags, equipment, tools, protective gear, and organic or inorganic sludges. Some TRU waste is mixed with hazardous chemicals. Some of the waste proposed for disposal at the WIPP is currently stored on Federal lands across the United States, including locations in Colorado, Idaho, New Mexico, Nevada, Ohio, South Carolina, Tennessee, and Washington. Much of the waste proposed for disposal at the WIPP will be generated in the future as weapons are disassembled and additional facilities are decontaminated and decommissioned.

Before disposal of radioactive waste can begin at the WIPP, the U.S. Environmental Protection Agency (''EPA'' or ''the Agency'') must certify that the WIPP facility will comply with EPA's radioactive waste disposal regulations.[3] The purpose of today's action is to propose EPA's certification decision.

II. Statutory Authority

EPA's oversight of the WIPP facility is governed by the WIPP Land Withdrawal Act (''LWA''), passed initially by Congress in 1992 and amended in 1996. The LWA delegates to EPA three main tasks, to be completed sequentially, for reaching a compliance certification decision. First, EPA must finalize general regulations which apply to all sites—except Yucca mountain—for the disposal of highly radioactive waste.[4] The regulations, located at Subparts B and C of 40 CFR Part 191 (''disposal regulations''), limit the amount of radioactive material which may escape from a disposal facility, and protect individuals and ground water resources from dangerous levels of radioactive contamination. The disposal regulations were published in the **Federal Register** in 1985 and 1993.[5]

Second, EPA must develop, by rulemaking, criteria to implement and interpret the generic radioactive waste disposal regulations specifically for the WIPP. EPA issued these ''WIPP Compliance Criteria,'' which are found at 40 CFR Part 194, in 1996.[6] The criteria describe in detail what information DOE must submit for EPA's review, and clarify the basis on which EPA's compliance determination will be made.

Third, EPA must review information submitted by DOE and publish a certification decision.[7] Today's action constitutes EPA's proposed certification decision as required by section 8 of the LWA. On October 29, 1996, DOE submitted a compliance certification application (''CCA'') containing information intended to demonstrate that WIPP will comply with the disposal regulations. Since then, DOE has submitted additional information. On May 22, 1997, EPA announced that DOE's application was deemed to be complete. (62 FR 27996–27998) EPA's evaluation of whether the WIPP will comply with the disposal regulations is made by comparing the CCA and other relevant information—including supplementary information requested by EPA from DOE, and the results of EPA's confirmatory audits and inspections—to the WIPP Compliance Criteria. The Administrator's certification of compliance depends on DOE demonstrating that it has satisfied the specific requirements of the WIPP Compliance Criteria.

III. Purpose and Scope of Today's Action

Today's action is limited primarily to the certification decision required under section 8(d) of the LWA. In addition, the proposal addresses the provision of section 4(b)(5)(B) of the LWA which requires EPA to determine whether existing oil and gas leases in the vicinity of the WIPP must be acquired by DOE. EPA has decided that it is appropriate to include this determination in this rulemaking because Congress explicitly conditioned emplacement of wastes in the repository on DOE's acquisition of the specified leaseholds, unless EPA determines that such acquisition is not required. (LWA, section 7(b)(2)) While Congress' mandate that EPA make this determination is separate and apart from the section 8(d) mandate to conduct the WIPP certification proceeding pursuant to notice-and-comment rulemaking procedures, EPA nonetheless believes it appropriate to address the leases in this rulemaking. The determination of whether potential drilling on the specified leases could possibly affect the integrity of the repository is closely related to the similar determinations that must be made under §§ 194.32(c) and 194.54(b) of the Compliance Criteria. Moreover, EPA is committed to the intent of Congress, clearly expressed in the LWA, that the public be involved in these important regulatory determinations. Therefore, by including this decision in this proposal, EPA is providing the public with the opportunity for input on this matter.

The Agency is proposing to add to the Compliance Criteria an appendix describing EPA's certification decision and to define the term ''Administrator's authorized representative.'' Except for these additions, EPA's proposed decision regarding WIPP's compliance does not otherwise amend or affect the final disposal regulations (at Subparts B and C of 40 CFR Part 191), or the final WIPP Compliance Criteria (at Subparts A through D of 40 CFR Part 194).

Today's proposal does not address all the actions required of EPA by the LWA. For example, the proposal does not address compliance with EPA's radioactive waste management regulations—found in Subpart A of 40 CFR Part 191—which are referenced in section 9(a)(1)(A) of the LWA. Instead, the Agency has issued, in a separate action, guidance describing how EPA intends to implement Subpart A at the WIPP.[8] For copies of the WIPP Subpart

[1] Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1980, Pub. L. 96–164, section 213.

[2] WIPP Land Withdrawal Act, Pub. L. 102–579, section 2(18), as amended by the 1996 WIPP LWA Amendments, Pub. L. 104–201.

[3] WIPP LWA, section 8(d).

[4] WIPP LWA, section 8(b).

[5] 50 FR 38066–38089 (September 19, 1985) and 58 FR 66398–66416 (December 20, 1993).

[6] 61 FR 5224–5245 (February 9, 1996), ''Criteria for the Certification and Re-certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations.'' (Certain aspects of the Compliance Criteria were challenged in the Court of Appeals for the D.C. Circuit. The Court upheld the Compliance Criteria in their entirety. *State of New Mexico v. Envt'l Protection Agency*, No. 96–1107 (D.C. Cir. June 6, 1997)).

[7] WIPP LWA, section 8(d).

[8] 62 FR 9188 (February 28, 1997), Notice of Availability for ''Guidance for the Implementation of EPA's Radiation Protection Standards for

Continued

A Guidance (Document Number EPA 402–R–97–001), call the EPA WIPP Information Line at 1–800–331–WIPP, or write to Betsy Forinash, Center for the Waste Isolation Pilot Plant, Mail Code 6602–J, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Finally, today's proposal does not address requirements of the LWA which must be fulfilled by other regulatory agencies. Enforcement of some parts of the hazardous waste regulations, for example, has been delegated to the State of New Mexico. The State's authority for such actions as issuing a hazardous waste operating permit for the WIPP is in no way constrained by EPA's proposed certification decision.

IV. Limits of EPA's Regulatory Authority at the WIPP

As discussed above, the LWA conveys specific responsibilities on EPA to ensure the safety of the WIPP as a permanent disposal facility. The Agency's primary responsibility, described in section 8 of the LWA, is to determine whether the WIPP facility will comply with EPA's disposal regulations. Members of the public have expressed, in written comments and in oral testimony on the Advanced Notice of Proposed Rulemaking for today's proposal, a desire for the Agency to oversee other aspects of WIPP's operation. In response to such concerns, EPA must clarify that its authority to regulate DOE and the WIPP is limited by the LWA and other statutes which delineate EPA's authority to regulate radioactive materials in general. The limitations on EPA's authority necessarily limit the scope of the current rulemaking.

Several commenters suggested that EPA should explore alternative methods of waste disposal—such as neutralizing radioactive elements—before proceeding with a certification decision. Others stated that the WIPP should be opened immediately because underground burial of radioactive waste is less hazardous than the current strategy of above-ground storage. EPA must conduct its WIPP activities in accordance with the intent of Congress as expressed in the LWA. 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. Also, Congress did not delegate to EPA the authority to weigh the competing risks of leaving radioactive waste stored above ground compared to disposal of waste in an underground repository. These considerations are outside the authority of the EPA as established in the LWA and, thus, necessarily outside the scope of this rulemaking.

Some commenters requested that EPA consider certain factors in making its certification decision. These factors include: reviews by organizations other than EPA, safety at other DOE facilities, and the political or economic motivations of interested parties. Pursuant to the LWA, EPA's certification decision must be made based on the WIPP Compliance Criteria at 40 CFR Part 194, and in accordance with requirements governing informal rulemaking proceedings. EPA is tasked only with examining the scope and quality of relevant information, and comparing such information to the objective criteria of 40 CFR Part 194. Where relevant, the Agency has considered public comments and outside reviews which support or refute technical positions taken by DOE. Emotional pleas, comments on the motives of interested parties, and the safety of sites or disposal methods other than the WIPP are factors that are not relevant to a determination of whether DOE has demonstrated compliance with the WIPP Compliance Criteria, and are therefore outside the scope of this rulemaking.

In addition, the hazards of transporting radioactive waste from storage sites to the WIPP have been of great concern to the public. EPA has received numerous public comments, oral and written, concerning the possible transport of TRU waste to the WIPP. Transportation is entirely outside EPA's general authority for regulating radioactive waste. Moreover, in the LWA, Congress did not authorize any role for EPA with respect to transportation. Congress addressed transportation issues by requiring DOE to (1) use only shipping containers approved by the Nuclear Regulatory Commission; (2) notify in advance States and Indian Tribes of the transport of TRU waste through their jurisdictions; (3) provide technical assistance and funding to ensure that jurisdictions along WIPP transportation routes receive appropriate training for accident prevention and emergency preparedness; (4) provide transportation safety assistance to States or Indian tribes through whose jurisdictions TRU waste will be transported; and (5) study transportation alternatives. (LWA, section 16) Transportation of radioactive waste is regulated by the Nuclear Regulatory Commission and the U.S. Department of Transportation. Because all transportation requirements for the WIPP are established and enforced by other regulators, EPA does not address the issue further in this proposal.

V. Public Participation

Section 8(d)(2) of the LWA requires that the Administrator's certification decision be conducted by informal (or ''notice-and-comment'') rulemaking pursuant to Section 553 of the Administrative Procedure Act (''APA''). Notice-and-comment rulemaking under the APA requires that an agency provide notice of a proposed rulemaking, an opportunity for the public to comment on the proposed rule, and a general statement of the basis and purpose of the final rule adopted.[9]

The WIPP is a first-of-a-kind project, and New Mexico citizens have expressed a great deal of interest in the safety of the site. The WIPP Compliance Criteria, at Subpart D of 40 CFR Part 194, established a process of public participation that exceeds the APA's basic requirements, and provides the public with the opportunity to participate in the regulatory process at the earliest opportunity. The WIPP Compliance Criteria contain provisions that require EPA to: publish an advance notice of proposed rulemaking (''ANPR'') in the **Federal Register**; allow public comment on DOE's compliance certification application (''CCA'') for at least 120 days, prior to proposing a certification decision; hold public hearings in New Mexico, if requested, on the CCA; provide a minimum of 120 days for public comment on EPA's proposed certification decision; hold public hearings in New Mexico on EPA's proposal; produce a document summarizing the Agency's consideration of public comments on the proposal, and maintain informational dockets in the State of New Mexico to facilitate public access to the voluminous technical record, including the CCA. EPA either has or will comply with each of these requirements.

In addition, EPA has taken other measures to assure that the public is involved in the present rulemaking. EPA allowed the New Mexico Environment Department, the New Mexico Environmental Evaluation Group, and more recently, the New Mexico Attorney General's Office as well, to observe meetings between EPA and DOE staff to discuss technical issues during the pre-proposal period. EPA also committed to summarize all meetings between EPA and DOE (including management level meetings

Management and Storage of Transuranic Waste at the Waste Isolation Pilot Plant ('WIPP Subpart A Guidance').''

[9] 5 U.S.C. 553.

and meetings between EPA and DOE legal staff) and to place such summaries in the public docket. While these commitments are not required by the APA, EPA believes that they are useful given the importance of this rulemaking to the nation as a whole, and New Mexico in particular.

A. Advance Notice of Proposed Rulemaking (ANPR)

EPA received DOE's CCA on October 29, 1996. Copies of the CCA and all the accompanying references submitted to EPA were placed in EPA's dockets in New Mexico and Washington, DC. Upon receipt of the CCA, EPA immediately began its review of the application in accordance with 40 CFR 194.11, ''Completeness and accuracy of compliance applications.'' On November 15, 1996, the Agency published in the **Federal Register** (61 FR 58499) an ANPR announcing that the CCA had been received, and announcing the Agency's intent to conduct a rulemaking to certify whether the WIPP facility will comply with the disposal regulations. The notice also announced a 120-day public comment period, requested public comment ''on all aspects of the CCA,'' and stated EPA's intent to hold public hearings in New Mexico.

B. Public Hearings on ANPR

The EPA published a separate notice in the **Federal Register** announcing hearings to allow the public to address all aspects of DOE's certification application. (62 FR 2988) Public hearings were held on February 19, 20 and 21, 1997, in Carlsbad, Albuquerque and Santa Fe, New Mexico, respectively. All individuals who requested an opportunity to address the EPA panel during the hearings were afforded five minutes if they were representing themselves, or ten minutes if they were representing a group. In Albuquerque and Santa Fe, EPA extended the hours of the hearings in order to accommodate all individuals who requested that they be allowed to address the panel.

C. Additional Public Input

In addition to the public hearings, EPA held three days of meetings in New Mexico, on January 21, 22 and 23, 1997, with the principal New Mexico Stakeholders, including the New Mexico Attorney General's Office, the New Mexico Environmental Evaluation Group, Concerned Citizens for Nuclear Safety, Citizens for Alternatives to Radioactive Dumping, and Southwest Research and Information Center. Detailed summaries of these meetings were placed in Docket A–93–02, Category II–E.

D. Public Comments on ANPR

The Agency received over 220 sets of written and oral public comments in response to the ANPR. All comments received on the ANPR were made available to members of the public through the public docket. (Docket A–93–02, Category II–H) In accordance with 40 CFR 194.61(f), DOE submitted to the Agency additional information specifically addressing many of the comments received; these submittals were treated by EPA as public comments.

The Agency reviewed all public comments submitted during the ANPR 120-day comment period or presented at the preliminary meetings with stakeholders. Public comments received in response to the ANPR generally focused on the completeness of the CCA, specific technical issues relating to compliance with the disposal regulations, and EPA's approach to public participation in accordance with the provisions of the WIPP Compliance Criteria, and pursuant to the LWA and the APA.

The EPA is providing responses to these comments in this preamble as well as in the compliance application review documents (''CARDs'') which are part of today's proposed certification decision. The CARDs also address late comments—and comments on completeness (see below)—received after the close of the public comment period (on March 17, 1997) but before August 8, 1997. All relevant public comments, whether received in writing, or orally during the public hearings, were considered by the Agency as the proposed certification decision was developed. Comments received after August 8 were considered by EPA, to the extent possible, in its development of the proposed rule, but were not addressed in CARDs because of time constraints. Such comments will be addressed in the Response to Comments document for EPA's final certification decision.

E. Completeness Determination

Section 8(d)(1)(B) of the LWA establishes a one-year time frame for the Administrator to reach a certification decision regarding WIPP's compliance with the disposal regulations. Section 8(d)(4) of the LWA requires that EPA make its certification determination only after DOE has submitted the ''full application'' to EPA. The Compliance Criteria, at § 194.11, interpret these requirements to mean one year from receipt of a ''complete'' certification application from DOE. This assures that the one-year review period is devoted exclusively to substantive, meaningful review of the CCA.

Upon receipt of the CCA in October 1996, EPA began reviewing the CCA for both completeness and, to the extent possible, technical adequacy. Pursuant to section 8(d)(1) of the LWA, EPA provided requests to DOE for specific information needed for completeness on December 19, 1996. (Docket A–93–02, Item II–I–1, Attachment 1) DOE submitted the requested information with letters dated January 17, January 24, February 7, February 14, and February 26, 1997. (This correspondence is available in Docket A–93–02, Category II–I.) On May 16, 1997, the Administrator informed the Secretary, in writing, that the CCA was complete. The completeness determination was announced in the **Federal Register** on May 22, 1997. (62 FR 27996–27998)

The determination of completeness meant only that all sections of the disposal regulations and Compliance Criteria had been addressed in the CCA. The completeness determination did not state or imply that compliance with the disposal regulations or WIPP Compliance Criteria had been achieved. In short, the completeness determination was an interim administrative step to announce that the CCA contained the information necessary for the Agency to proceed with its technical evaluation of compliance.

Moreover, section 8(d)(1) of the LWA specifically allows EPA to request additional information ''as needed to certify'' at any time. EPA made such additional requests in letters to DOE dated December 19, 1996, and February 18, March 19, April 17, April 25, June 6, and July 2, 1997. (Docket A–93–02, Items II–I–1, II–I–9, II–I–17, II–I–25, II–I–27, II–I–32, and II–I–37, respectively)

F. Public Comments on Completeness

The Agency received numerous public comments regarding the timing of the Administrator's completeness determination. While some comments stated that the CCA was administratively complete upon submission, others argued that the CCA was incomplete and simply should be returned to DOE. The latter set of commenters expressed that it was not appropriate for the Agency to close the public comment period on the ANPR prior to the Administrator's determination of completeness, and that the public hearings should be delayed until after the completeness determination. Other commenters

requested an additional 120-day comment period after the completeness determination was issued, as well as an additional set of public hearings during such a comment period.

In making its completeness determination, EPA considered public comments which explicitly addressed the issue of completeness and were submitted to the docket or to EPA's Office of Radiation and Indoor Air. In response to concerns expressed by commenters, the Agency notified the public in the **Federal Register** announcement regarding the completeness determination that EPA would continue to accept public comments on the CCA subsequent to the completeness determination. (62 FR 27997) (Comments on completeness received before August 8, 1997, are addressed in more detail in the CARDs supporting this proposal. Comments received after August 8 will be addressed in the Response to Comments document for EPA's final certification rule.) In accordance with § 194.62, the public is being afforded a 120-day period in which to comment on today's proposal. This comment period will provide the public with another opportunity to comment on DOE's CCA, as well as an opportunity to address EPA's proposed certification decision.

Public comments received during and after the ANPR comment period also requested that EPA clarify what specific material constitutes the ''complete'' CCA. This concern was raised because, at EPA's request, DOE supplemented the docket with substantial additional materials beyond what was initially submitted on October 29, 1996. Many of the issues raised by public comments were addressed in a December 19, 1996 letter to DOE in which EPA identified additional information necessary for the CCA to constitute a complete application. (Docket A–93–02, Item II–I–1, Attachment 1) To address completeness concerns, EPA requested additional information on (among other topics) site conditions, documentation of computer codes, and the effects of explosions—issues all identified in public comments. DOE submitted the requested information with letters dated January 17, January 24, February 7, February 14, and February 26, 1997. The complete CCA consists of the application that was submitted to EPA on October 29, 1996, and supplementary materials provided by DOE that were identified by EPA, in the December 19 letter, as necessary for completeness. A list of the specific items that comprise the complete application is located in Docket A–93–02, Item II–G–29. All correspondence between DOE and EPA regarding completeness of the CCA is available in the Agency's public dockets. (Docket A–93–02, Category II–I)

Other issues raised by commenters, such as fluid injection scenarios, were not considered relevant to the completeness determination and instead were addressed by EPA in its technical comments to DOE.

G. Proposed Certification Decision

Today's Notice of Proposed Rulemaking for certification fulfills the requirements of the WIPP Compliance Criteria at § 194.62. Today's notice announces the Administrator's proposed decision, pursuant to section 8(d)(1) of the LWA, as amended, to issue a certification that the WIPP facility will comply with the disposal regulations, and solicits comment on the proposal. Today's notice also marks the beginning of a 120-day public comment period on EPA's proposed certification decision. Finally, today's notice announces that public hearings will be held in New Mexico during the public comment period. Further information on the hearings will be provided in a subsequent **Federal Register** notice. Any comments received on today's notice will be made available for inspection in Docket A–93–02, Category IV–D.

H. Final Certification Decision

The Agency will publish a final rule in the **Federal Register** announcing the Administrator's final decision, pursuant to section 8(d)(1) of the LWA and in accordance with the Compliance Criteria at 40 CFR 194.63, whether to issue a certification that the WIPP facility will comply with the disposal regulations. EPA will review comments submitted on EPA's proposed decision. (Comments regarding the ANPR and completeness that are addressed in the CARDs for the proposed rule have already been considered and will not be addressed again in the Response to Comments document for the final rule.) A document summarizing significant comments and issues arising from comments received on today's Notice of Proposed Rulemaking, as well as the Administrator's response to such significant comments and issues, will be prepared and will be made available for inspection in Docket A–93–02.

I. Dockets

In accordance with 40 CFR 194.67, EPA maintains a public docket (Docket A–93–02) that will contain all information used to support the Administrator's proposed and final decisions on certification. The Agency established and maintains the formal rulemaking docket in Washington, D.C., as well as informational dockets in three locations in the State of New Mexico (Carlsbad, Albuquerque, and Santa Fe). The docket consists of all relevant, significant information received to date from outside parties and all significant information considered by the Administrator in reaching a proposed certification decision regarding whether the WIPP facility will comply with the disposal regulations. Copies of the CCA were placed in Category II–G of the docket. Supplementary information received from DOE in response to EPA requests was placed in Categories II–I and II–G.

The hours and locations of EPA's public information dockets are as follows: Docket No. A–93–02, located in room 1500 (first floor in Waterside Mall near the Washington Information Center), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C., 20460 (open from 8:00 a.m. to 4:00 p.m. on weekdays); (2) EPA's docket in the Government Publications Department of the Zimmerman Library of the University of New Mexico located in Albuquerque, New Mexico, (open from 8:00 a.m. to 9:00 p.m. on Monday through Thursday, 8:00 a.m. to 5:00 p.m. on Friday, 9:00 a.m. to 5:00 p.m. on Saturday, and 1:00 p.m. to 9:00 p.m. on Sunday); (3) EPA's docket in the Fogelson Library of the College of Santa Fe in Santa Fe, New Mexico, located at 1600 St. Michaels Drive (open from 8:00 a.m. to 12:00 midnight on Monday through Thursday, 8:00 a.m. to 5:00 p.m. on Friday, 9:00 a.m. to 5:00 p.m. on Saturday, 1:00 p.m. to 9:00 p.m. on Sunday); and (4) EPA's docket in the Municipal Library of Carlsbad, New Mexico, located at 101 S. Halegueno (open from 10:00 a.m. to 9:00 p.m. on Monday through Thursday, 10:00 a.m. to 6:00 p.m. on Friday and Saturday, and 1:00 p.m. to 5:00 p.m. on Sunday). As provided in 40 CFR Part 2, a reasonable fee may be charged for photocopying docket materials.

VI. National Academy of Sciences Report on the WIPP

The National Academy of Sciences (''NAS'') has long considered the issue of proper disposal of radioactive wastes. The NAS first discussed the likely suitability of salt formations as a medium for geologic disposal of high-level radioactive wastes in 1957.[10] A later study recommended the use of

[10] National Research Council (NRC), ''The Disposal of Radioactive Wastes on Land'' (National Academy Press 1957).

bedded salt formations for geologic disposal.[11]

The NAS has provided specific scientific and technical guidance to DOE regarding the WIPP since the inception of the NAS WIPP Committee in 1978. In October 1996, the NAS released a report assessing the long-term safety and performance of the WIPP disposal system. The report is available in Docket A–93–02, Item II-A–38. The WIPP committee's schedule did not allow for review of the CCA submitted to EPA in October 1996; instead, the committee examined a preliminary performance assessment (''PA'') conducted in 1992, and draft versions of DOE's CCA. For this reason and others, the NAS noted that the report was ''a review of ongoing activities and should be viewed as a progress report rather than a final evaluation.''[12]

The report reiterates NAS belief that salt is an attractive medium for geologic isolation of radioactive waste. Based on its review of the 1992 PA, the committee found no credible or probable scenario for release of radionuclides from the WIPP if it is undisturbed by human intrusion. The report concluded that disturbed scenarios—i.e., those involving deliberate or unintentional human intrusion—could compromise the integrity of the disposal system. Finally, the committee recommended several changes intended to produce a more technically defensible and more easily understood PA.

EPA considered the NAS report in developing its proposed certification decision. Specific recommendations on alternative modeling approaches or other improvements to the 1992 PA were considered by EPA in evaluating whether the CCA is adequate. The Agency treated such recommendations as public comments on the ANPR, and responds in detail to particular issues in the CARDs supporting today's proposal. EPA did not give substantial consideration to the committee's general conclusions on the PA because, subsequent to the NAS review, EPA required numerous changes to the preliminary PA considered by the committee. The committee recommended that human intrusion scenarios could be made less speculative by refining probability estimates for the occurrence of future human activities, but suggested neither a methodology for doing so, nor an alternative approach to human intrusion which could be implemented within the framework of the Compliance Criteria.[13]

VII. Codification of EPA's Certification Decision

The requirements which apply to the rulemaking process used to develop EPA's certification decision (including measures for soliciting and considering public input) do not prescribe what form the final decision must take. In analogous situations where EPA issues or denies hazardous waste no-migration petitions for landfills or other sites, public notice of the decision is provided by publication in the **Federal Register**, and such notice serves as the record of EPA's action.[14] Because of the one-of-a-kind nature of the WIPP facility, EPA has determined that it is appropriate to provide a more permanent record of the Agency's decision. To that end, EPA's decision is being published in the **Federal Register** and also will be codified as an appendix to the WIPP Compliance Criteria at 40 CFR Part 194. A lasting record of EPA's certification decision will be established since the appendix will be included each time in the future that the Code of Federal Regulations is compiled and published.

VIII. Determination of Whether the WIPP Complies With the Disposal Regulations

The proposed rule states the Agency's determination that the WIPP will comply with the disposal standards and Compliance Criteria, taken as a whole. In addition, the proposal specifies all conditions which apply to the certification. As noted previously, EPA's certification of compliance depends on DOE satisfying the specific requirements of the WIPP Compliance Criteria. The ensuing sections of the **SUPPLEMENTARY INFORMATION** address each of the technical WIPP Compliance Criteria in turn; the Agency describes the basis for evaluating compliance with each criterion, and discusses briefly how the CCA submitted by DOE, and other relevant information, demonstrated compliance with EPA's requirements. CARDs provide more detailed support for EPA's proposed decisions regarding compliance with individual criteria. The CARDs are available for public review in Docket A-93–02, Category III-B. See ''additional docket information'' in the **SUPPLEMENTARY INFORMATION**.

Not all sections of the WIPP Compliance Criteria are discussed below because not all the provisions of 40 CFR Part 194 are directly relevant to an evaluation of compliance with the disposal regulations. Some sections of 40 CFR Part 194—such as § 194.1, ''Purpose, scope and applicability''—are entirely administrative in nature. Other sections, including those related to public participation, address procedural aspects of the certification rulemaking. Still others refer to future actions which may occur, such as inspections or the need to suspend an existing certification. Such criteria are not relevant to EPA's analysis of whether information in the CCA and elsewhere demonstrates that the WIPP site will comply with EPA's disposal regulations. Some of these criteria are addressed elsewhere in the **SUPPLEMENTARY INFORMATION**. For example, EPA's adherence to the public participation requirements of the LWA and 40 CFR Part 194 is documented under ''public participation.''

A. Basis for EPA's Compliance Determination

EPA's proposed certification decision is based on the entire record available to the agency, which is contained in Docket A-93–02. The record consists of the complete DOE CCA, supplementary information submitted by DOE in response to EPA requests for additional information for technical sufficiency, technical reports generated by EPA and EPA contractors, EPA audit reports, and public comments submitted on EPA's ANPR for the certification decision.

Thus, as contemplated by Congress, EPA's compliance determination is based on more than the ''complete'' application. (LWA, section 8(d)(1)) EPA also relied on materials prepared by the Agency or submitted by DOE in response to EPA requests for specific additional information necessary to address technical sufficiency concerns. Examples of such documents include EPA technical and audit reports and letters submitted by DOE (i.e., those contained in Docket A–93–02, Category II–I).

In response to public comments regarding the precise materials EPA considered in reaching today's proposed decision, the CARDs reference the

[11] NRC, ''Disposal of Solid Radioactive Wastes in Bedded Salt Deposits'' (National Academy Press 1970).

[12] NRC, ''The Waste Isolation Pilot Plant: A Potential Solution for the Disposal of Radioactive Waste'' (National Academy Press 1996), p. 12.

[13] NAS never submitted official comments on proposed 40 CFR Part 194. In contexts other than the WIPP report, however, NAS has acknowledged the impossibility of making decisions regarding nuclear waste disposal based solely on scientific information: ''[I]t became clear in the course of our work that designing the standards requires making decisions based as much or more on policy considerations than on science. It is equally clear that there is no sharp dividing line between science and policy.'' [NRC, *Technical Bases for Yucca Mountain Standards* (National Academy Press, 1995), p. viii] The rulemaking process used to develop the WIPP compliance criteria provided a forum for EPA to gather and weigh scientific evidence, public concerns, and other policy issues regarding the treatment of human intrusion in PA.

[14] *See, e.g.*, the RCRA Conditional No-Migration Petition, 55 FR 47709.

relevant portion(s) of the October 29, 1996, CCA and any supplementary information that was relied on in reaching a particular proposed compliance decision. All materials which informed EPA's proposed decision have been placed in the WIPP dockets or are otherwise publicly available. EPA has specified in the docket the location of all reference materials to aid the public in its evaluation of such information. A full description of the supporting documentation for EPA's proposed decision and a full list of the DOE compliance documentation considered by the Agency are located at Docket A–93–02, Item III–B–1. Through these means, the Agency believes the public will have a clear indication of what materials constitute the complete CCA, and what materials constitute the record basis for EPA's proposed certification decision.

B. Compliance Application Review Documents (CARDs)

The preamble for today's proposed rule describes the basis for the Agency's compliance determination for each of the relevant WIPP Compliance Criteria. The detailed technical rationale for EPA's proposed decision is contained in the Compliance Application Review Documents (CARDs) supporting today's action. Taken as a whole, the CARDs are analogous to the Background Information Document usually provided for EPA rulemakings. These documents are found at Docket A–93–02, Item III–B–2.

The CARDs discuss DOE's compliance with the individual requirements of the WIPP Compliance Criteria. Each CARD is a section in the document which is numbered according to the section of 40 CFR Part 194 to which it pertains. For example, CARD 23 addresses § 194.23, ''Models and Computer Codes.'' In the section of each CARD called ''Compliance Review Criteria,'' EPA restates the specific requirement and identifies the relevant information expected in the CCA, as described in the ''Compliance Application Guidance for the WIPP: A Companion Guide to 40 CFR Part 194'' (''CAG,'' EPA 402–B–95–014, March 1996). EPA also clarifies the Agency's rationale for evaluating the CCA's completeness and technical adequacy.

After explaining the Agency's compliance review criteria, each CARD summarizes DOE's approach to compliance and describes EPA's compliance review. CARDs also list additional EPA technical support documents and any other references used by EPA in rendering a proposed decision on compliance. All technical support documents and references are found in Docket A–93–02 with the exception of generally available references and those documents already maintained by DOE or its contractors in locations accessible to the public. DOE has committed to make such documents readily available to the public. Instructions for obtaining access to DOE documents can be found at Docket A–93–02, Item III–B–1.

Finally, CARDs contain EPA's response to comments received on the Agency's ANPR of November 15, 1996 (61 FR 58499) and on other comments received prior to August 8, 1997. For more discussion of EPA's response to these comments, see ''Public Participation'' in the **SUPPLEMENTARY INFORMATION**.

For technical information or more detailed discussion on EPA's evaluation of compliance with any individual provision of 40 CFR Part 194, readers should refer to the corresponding CARD in Docket A–93–02, Item III–B–2.

IX. Section 194.14, Content of Compliance Certification Application

40 CFR Part 194 sets out those elements which the Agency requires to be in a complete compliance application. In general, compliance applications must include information relevant to demonstrating compliance with each of the individual sections of 40 CFR Part 194 to determine if the WIPP will comply with the Agency's radioactive waste disposal regulations at 40 CFR Part 191, Subparts B and C. The Agency published the ''Compliance Application Guidance for the Waste Isolation Pilot Plant: A Companion Guide to 40 CFR Part 194'' (''CAG'') which provided detailed guidance on the submission of a complete compliance application.

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. 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.

Much of the information referenced by DOE as demonstrating compliance with § 194.14, and EPA's review of the information, was principally used to demonstrate compliance with other sections of the Compliance Criteria. Thus, this section of the preamble discusses many of the requirements of § 194.14 only briefly because they are fully discussed in other sections of the preamble. EPA thoroughly reviewed DOE's compliance certification application (''CCA'') submitted on October 29, 1996, and additional information submitted by DOE.

A. Site Characterization

40 CFR 194.14(a) requires DOE to describe the characteristics of the WIPP site, including the natural and engineered features that may affect the performance of the disposal system. The characteristics of the site and identification of potential pathways are crucial to the conceptual models and computer modeling that is done to determine compliance with the containment requirements at 40 CFR 191.13 and the individual and ground-water protection requirements. In addition to a general understanding of the site, EPA required specific information on hydrologic characteristics with emphasis on brine pockets, anhydrite interbeds, and potential pathways for transport of waste. EPA also required DOE to project how geophysical, hydrogeologic and geochemical conditions of the disposal system would change due to the presence of waste.

EPA examined the CCA and determined that it and the supplemental information provided by DOE contained an adequate description of the WIPP geology, geophysics, hydrogeology, hydrology and geochemistry of the WIPP disposal system and its vicinity, and how these conditions change over time. The CCA discussed that very few potential pathways exist for radionuclide transport. DOE projected future geophysical, hydrogeologic and geochemical conditions due to the presence of waste. A brief overview of the site is provided below.

The WIPP is located in the Delaware Basin of New Mexico and Texas and is approximately 26 miles southeast of Carlsbad, New Mexico. This area of New Mexico is currently arid, but precipitation increases were accounted for in the performance assessment (''PA''). The Delaware Basin contains thick sedimentary deposits (over 15,000 feet (4572 meters) thick) that overlay metamorphic and igneous rock (1.1 to 1.5 billion years old). The WIPP repository is a mine constructed approximately 2,150 feet (655 meters) below ground surface in the Permian age (~200–250 million years old) Salado Formation, which is composed primarily of salt (halite).

DOE considered the primary geologic units of concern to be (from below the repository to the surface): (1) Castile Formation (''Castile''), consisting of

anhydrite and halite with pressurized brine pockets found locally throughout the vicinity of the WIPP site; (2) Salado Formation (''Salado''), consisting primarily of halite with some anhydrite interbeds and accessory minerals and approximately 2,000 feet (600 meters) thick; (3) Rustler Formation (''Rustler''), containing salt, anhydrite, clastics, and carbonates (primarily dolomite), with the Culebra dolomite member of the Rustler as the unit of most interest; and, (4) Dewey Lake Red Beds Formation (''Dewey Lake''), consisting of sandstone, siltstone and silty claystone. The geologic formations below these were included in the screening of features, events, and processes, but were not included in PA calculations because they did not affect the performance of the disposal system. See § 194.32 for a detailed discussion of screening of features, events, and processes.

DOE indicated that the major geologic process in the vicinity of the WIPP is dissolution. To the west, the slight (one degree) dip in the Salado has exposed the formation to dissolution processes, and commenters argued that lateral dissolution processes will affect the WIPP's ability to contain radionuclides. However, DOE estimated that the dissolution front will not reach the WIPP site for at least hundreds of thousands of years—well past the regulatory time frame. EPA agrees with DOE's conclusion that while deep dissolution has occurred elsewhere in the Delaware Basin, the process of deep dissolution, if it occurs under the WIPP site, would occur at such a slow rate that it would not affect the containment capabilities of the WIPP during the regulatory time period.

Many commenters suggested that WIPP can not contain radionuclides because WIPP is in a region of karst (topography created by the dissolution of rock). EPA reviewed information submitted by DOE and stakeholders regarding the occurrence and development of karst at the WIPP (e.g., Docket A–93–02, Items II–H–46 and II–D–102). EPA concluded that while the WIPP site is in a karst region and karst features are found to the west of the site in Nash Draw, only limited evidence exists that dissolution-related features occur near the WIPP boundary (e.g., well WIPP–33). These features are neither pervasive nor associated with any identified preferential groundwater flow paths or anomalies. WIPP field mapping and site-specific hydrologic information (e.g., well tracer tests) do not indicate that any cavernous or other karst-related flow is present at the WIPP site. As stated in a technical document submitted by one commenter, ''the karst phenomena do not appear to warrant a rejection of the WIPP site.'' (Docket A–93–02, Item II–D–102) EPA agrees and concludes that karst is not a problem at WIPP and that geologic evidence of the last approximately 500,000 years and results from DOE's groundwater modeling indicate that future development of karst at the WIPP is not likely.

DOE conducted geologic studies and field measurements as part of its evaluation of the hydrology of the WIPP site and identified two potential pathways for radionuclides in the disposal system: the Culebra dolomite and Salado anhydrite markerbeds 138 and 139. However, only the Culebra dolomite has the capability to transmit significant amounts of radionuclides. The Salado markerbeds have very low permeability and are the primary pathways in the undisturbed case. The results of the CCA PA indicated that radionuclide transport through the anhydrites does not contribute significantly to total releases. The Culebra dolomite is a potential pathway only in intrusion scenarios. Commenters stated that the Dewey Lake should be considered a potential pathway and thus needed better characterization; however, the CCA PA results indicated that no contaminated brine traveled up an intrusion borehole past the Culebra to the Dewey Lake or other units. While DOE did identify the Dewey Lake as a potential underground source of drinking water, the CCA PA results indicated that the Dewey Lake did not play an active role in radionuclide release scenarios. EPA concludes that the Culebra dolomite and the Salado anhydrite markerbeds 138 and 139 are the only ground-water radionuclide transport pathways in the disposal system.

As the primary radionuclide pathway during an intrusion, the Culebra was the subject of many public comments, especially related to karst (discussed above), K_d values (distribution coefficients used in calculating the retardation factor) and geochemistry and flow directions. In DOE's conceptual model the Culebra is characterized as a fractured dolomite that has dual-porosity and acts to physically retard movement of contaminants. In a dual-porosity rock unit, ground-water is believed to flow through the fractures, but water and contaminants can access the pore space within the rock matrix away from the fractures. Movement of water and contaminants into the pore space slows (retards) their respective forward movement. This physical retardation is necessary in order to have chemical retardation. In the process of chemical retardation, contaminants diffuse from the fractures into the pore space where they can adsorb onto the rock mass.

The CCA indicated that there were no contributions to total releases from the ground-water pathway. This was due, in large part, to the fact that radionuclides adsorbed into the Culebra dolomite did not move with the ground-water flow. That is, the movement of the radionuclides were retarded with respect to the ground-water flow. The estimate of the extent of the retardation was based on laboratory tests using crushed rocks and small columns of rock. EPA concluded that the laboratory tests were conducted appropriately and that the K_d values DOE derived from this testing are reasonable given the experimental evidence. However, EPA believes that a lognormal distribution is a more appropriate representation of the data distribution, and required the use of a lognormal distribution in the Performance Assessment Verification Test (PAVT). For further discussion of the PAVT, refer to the preamble for § 194.34.

DOE indicated in the CCA that there is considerable variation in the groundwater chemistry of the Culebra member of the Rustler Formation. In addition, DOE provided supplemental information pertaining to Culebra groundwater flow and geochemistry which contended that the observed geochemistry and flow directions can be explained with the ground-water basin modeling. (Docket A–93–02, Item II–I–17) The ground-water basin model addressed near surface hydrologic conditions (including the water table and potential recharge areas) and reconciled inconsistencies between the geochemistry data and the current ground-water flow direction.

The probability of intercepting a Castile brine reservoir (i.e., brine pocket) and the characteristics of a brine reservoir once it has been hit were the subject of many public comments as well as a source of EPA concern. Because of the low permeability of the Salado Formation, there is no natural connection between a Castile brine pocket and the waste panel area. However, in the case of a deep drilling intrusion that goes through a waste panel and into the Castile, it is possible that the drilling will intercept brine in the Castile and create a pathway for Castile brine to flow into the repository and interact with the waste.

In the 1992 PA, Sandia National Laboratory (''SNL'') considered the probability of hitting a brine pocket under the waste area an uncertain parameter that required sampling over a

range of 0.25 to 0.62. This range of probabilities was based on geophysical work that suggested brine may be present. For the CCA PA, SNL conducted a new analysis based on a geostatistical analysis of oil and gas wells in the vicinity of WIPP. From this study, SNL identified the probability of hitting brine as 0.08, partly because the brine is expected to be in fractures that are oriented vertically or slightly less than vertical. EPA reviewed the CCA and public comments and concluded that, while the probability of hitting a brine pocket may be low, there was no justification for assuming a fixed value for such an uncertain parameter. EPA therefore directed DOE, for the PAVT, to change the probability of hitting a brine pocket to a range that incorporated low to moderate probabilities (0.01 to 0.6).

The potential volume of brine reservoirs was also the subject of numerous comments claiming that, in the PA, DOE underestimated the brine volume. DOE assumed that passive institutional controls (''PICs'') will limit the available brine pocket volume to that within the area covered by the surface berm used to mark the subsurface location of the waste panels. EPA reviewed information in the CCA, public comments, and the SNL Records Center. EPA concluded that the approach of excluding Castile brine pocket volumes based on the waste panel ''foot print'' is inappropriate because the efficacy of drilling in the area outside the berm cannot be reasonably defined. EPA directed DOE, for the PAVT, to change the brine pocket volume to a volume that is more representative of data from site characterization activities (i.e., the WIPP–12 exploratory well). The PAVT also omits the credit for PICs.

The results of the PAVT indicated that changing the probability of hitting a brine pocket has a negligible effect on releases, but changing the brine volume from 160,000 cubic meters to 17 million cubic meters does have a noticeable effect on releases for the scenarios in which a brine pocket is hit. Nevertheless, the PAVT results indicated that, even with these changes combined with other parameter changes, the PAVT results are similar to those in the CCA and still meet the containment requirements by more than one order of magnitude. EPA believes that the PAVT verifies that the original CCA Castile brine reservoir parameters were adequate for use in PA and comparison against the radioactive waste containment requirements. See the preamble for § 194.34(f) for additional information on the results of the PAVT.

EPA agrees with DOE's conclusion in the CCA that the most important extractable resources near the WIPP are hydrocarbons, potassium salts (potash), and water. DOE indicated that some of the geologic formations below the repository area contain oil and gas resources that are currently being exploited in the Delaware Basin. According to DOE's analysis, most of the water in the vicinity of the WIPP is highly saline, with the closest dependable potable aquifer associated with the Capitan Reef at the edge of the Basin. With respect to potash, the CCA indicated that only the 4th and 10th potash zones qualify as economic reserves. Commenters noted that the extent of potash identified by DOE is different than that identified by the Bureau of Land Management in its map of resources. EPA concludes that DOE's presentation is reasonable, given the 40 CFR Part 194 requirements that DOE assess resources relative to those currently being mined.

The projected effect of waste on the disposal system are primarily limited to gas generation that increases repository pressure and actinide solubility. Gas will be generated: (1) By corrosion of metals and (2) as a byproduct of microbial degradation of cellulosics, plastics and rubbers. Gas generation primarily affects spallings (due to high pressures) and direct brine releases (due to high pressures and increasing solubility). DOE indicated that magnesium oxide (''MgO'') backfill emplaced with transuranic waste would mitigate the solubility-enhancing effects of carbon dioxide from waste degradation. EPA concurs with DOE's assessment. Refer to § 194.44 for further discussion of the effects of MgO.

Although commenters questioned DOE's characterization of the WIPP site, especially the hydrology, EPA concluded after extensive review that DOE identified, characterized, and used in the calculations the major components of the geologic and hydrologic system around the WIPP. DOE provided a detailed discussion of the geology and identified the few geologic units that are important to PA. DOE also identified that very few geologic units could transmit fluids and transport radionuclides; after an intrusion, only the Culebra dolomite is a significant pathway above the Salado with other overlying units not receiving any contaminated brine. EPA reviewed DOE's discussion on dissolution and karst and concludes that these processes are not currently significant and will not affect WIPP over the regulatory time period. EPA disagreed with DOE's characterizations of the Castile brine pocket and required changes for the PAVT; however, PAVT results verified that the original parameters were acceptable for use in the PA.

B. Disposal System Design

Section 194.14(b) requires DOE to describe the design of the disposal system, including natural and man-made materials, and architectural and structural aspects of the disposal system. DOE also must describe the computer codes and standards that have been applied to the design and construction of WIPP.

The CCA contained a general description of the WIPP facility and a detailed description of the underground disposal system (including the engineered barriers in the repository and shaft system as well as the geologic units). The WIPP repository is an underground mine that will eventually have eight panels (each of which will include seven football-field long rooms) connected by drifts. Waste will be emplaced in the WIPP through the waste shaft. An exhaust shaft, salt handling shaft, and air intake shaft also penetrate the WIPP repository. The underground mine is attended by surface equipment and buildings that will handle waste prior to its emplacement in the WIPP. DOE intends to pack bags of magnesium oxide (''MgO'') around the waste containers, and will seal each panel after it is filled with waste. The Salado salt will eventually ''creep'' and close WIPP rooms and panels. The WIPP was designed to take advantage of this encapsulation so that transuranic waste emplaced in the WIPP will be completely enveloped by salt, thus minimizing the potential for waste migration.

The major disposal system engineered features related to long-term performance are the general design, shaft seals, panel closures, borehole plugs, and the additional engineered barrier of backfill around the waste. The purpose of the shaft seal system is to limit fluid flow within the shafts after the WIPP is decommissioned and to ensure that the disposal system shafts will not become pathways for radionuclide release. The shaft seal system has 13 elements that fill the shaft with engineered materials possessing high density and low permeability, including concrete, clay, compacted salt, cementitious grout, and earthen fill. DOE identified the compacted salt column as the most critical element in the long-term performance of the shaft seal. The compacted salt column component of the system within the Salado is intended to serve as the

primary long-term barrier by limiting fluid transport along the shaft during the 10,000-year regulatory period. The other components of the shaft seal within the Salado are intended to prevent migration of radionuclides in the short term and protect the compacted salt column until it is sufficiently consolidated to act as an effective long-term barrier. Components of the seal system within the Rustler are intended to limit the commingling of groundwater between the water bearing members. The seal system overlying the Rustler will consist of compacted earthen fill. The shaft seal design in the CCA received extensive technical review by DOE, and was also subjected to an independent design review. EPA concludes that the shaft seal design is adequate because the system can be built and is expected to function as intended.

The purpose of borehole plugs is to mitigate the potential for migration of contaminants toward the accessible environment. DOE indicated that it will abide by the applicable State oil and gas well plugging requirements. While there are four deep research wells drilled in the disposal system, DOE stated that ''the ERDA–9 exploratory hole was the only hole within the underground development area which was permitted to penetrate the Salado formation to the underground facility horizon.'' ERDA–9 did not penetrate an area that will become a waste panel and DOE has indicated that abandoned boreholes more than a meter away from the waste can be screened out of PA due to low consequence. EPA agrees with DOE's assessment that these boreholes are not significant to performance of the disposal system and can be screened out of PA.

The primary long-term effect of the panel closure will be to block the flow of brine between panels. DOE provided four design options for panel closures but did not specify in the CCA which panel closure option would be used at WIPP, an omission that was pointed out in public comments. (Docket A–93–02, Item II–H–10) In reviewing the four panel closure design options, EPA identified Option D in the CCA as the most robust design, and reviewed that design as the basis for an evaluation of compliance. EPA found that the design for Option D would be expected to perform as described, but that the use of a Salado mass concrete (consistent with the type specified for the shaft seal system) rather than fresh water concrete would be more consistent with the permeability assumptions used in PA. EPA determined that such a design is adequate to achieve the long-term performance modeled in PA, and therefore proposes to find that DOE complies with § 194.14(b). However, because EPA is basing its proposed compliance determination on the Option D panel seal design, the EPA is also proposing to establish a certification condition requiring DOE to implement the Option D design, with Salado mass concrete replacing fresh water concrete. (See Condition 1 in the proposed Appendix A to 40 CFR Part 194.) Although EPA's sensitivity analysis indicates that the panel closure permeability is not a sensitive parameter, especially with the disturbed rock zone at the same or higher permeability, the Agency believes it is important to ensure that the proposed design on which compliance was based is actually implemented at the site. Because of the presence of the disturbed rock zone, EPA expects that gas flow between panels for long-term performance purposes would be relatively unaffected by the design choice.

C. Results of Assessments

Section 194.14(c) requires the CCA to present the results of assessments of the WIPP's performance, given human intrusion into the disposal system (performance assessment) and undisturbed conditions (compliance assessment). EPA determined that DOE's results showed compliance with the containment (§ 191.13), individual (§ 191.15), and ground water (40 CFR Part 191, Subpart C) requirements of the disposal regulations. Refer to discussions of § 194.34 and § 194.55 for EPA's full evaluation of results of assessments. Based on EPA's finding that information submitted by DOE was sufficient for compliance with §§ 194.34 and 194.55, the Agency proposes to find that DOE also complies with § 194.14(c).

D. Input Parameters to Performance Assessments

40 CFR 194.14(d) requires DOE to describe the input parameters to the PA and discuss the basis for their selection. DOE provided descriptions of input parameters to the PA. EPA's evaluation of this information is addressed in the discussion of § 194.23 of this preamble. Based on EPA's finding that information was sufficient for compliance with § 194.23, the Agency proposes to find that DOE also complies with § 194.14(d).

E. Assurance Requirements

Section 194.14(e) requires documentation of measures taken to meet the assurance requirements. EPA considers DOE to have complied with § 194.14(e) if it provided the information required for §§ 194.41 through 194.46. Based on EPA's determination of compliance for all six assurance requirements (active institutional controls, monitoring, passive institutional control, engineered barriers, consideration of the presence of resources, and removal of waste), EPA proposes to find that DOE also complies with § 194.14(e).

F. Waste Acceptance Criteria

Section 194.14(f) requires DOE to describe waste acceptance criteria and the measures taken to assure adherence to such criteria. EPA reviewed documentation provided by DOE and observed DOE audits and other activities, and concluded that DOE provided satisfactory descriptions of actions that will be followed to ensure adherence to the waste acceptance criteria. EPA therefore proposes to find DOE in compliance with § 194.14(f). Refer the preamble discussion of § 194.24 for a complete discussion of EPA's review of waste acceptance criteria and other waste characterization information.

G. Background Radiation

40 CFR 194.14(g) requires DOE to describe the background radiation in air, soil and water in the vicinity of the disposal system and the procedures employed to determine such radiation. DOE provided information regarding the levels of background radiation in air, soil, surface water, sediments, groundwater, and biota. DOE also provided a description of the procedures used to determine the background radiation. DOE indicated that background radiation in the vicinity of the WIPP site is influenced by natural sources of radiation, fallout from nuclear tests, and one local research project (Project Gnome, which involved the underground detonation of a nuclear device on December 10, 1961, at a site approximately 8 miles (13 kilometers) southwest of the WIPP site).

EPA found that DOE provided sufficient discussion of background radiation levels and associated procedures to monitor these media for radiation. EPA, therefore, proposes to find that DOE complies with § 194.14(g).

H. Topographic Maps

40 CFR 194.14(h) requires DOE to provide one or more topographic maps of the vicinity of the disposal system. At least one map must show boundaries of the controlled area and the location of active, inactive and abandoned injection and withdrawal wells in the controlled area and in the vicinity of the disposal

system. The CCA must include topographic maps with a contour interval sufficient to show clearly the pattern of surface water flow in the vicinity of the disposal system.

DOE provided four topographic maps that show the pattern of surface water flow in the vicinity of the WIPP. The CCA included three figures showing the locations of the controlled area within the U.S. Public Land Survey coordinate system, as well as a map showing the location of active, inactive, and abandoned injection and withdrawal wells in the controlled area and in the vicinity of the disposal system. EPA reviewed the topographic maps provided in the CCA to determine their sufficiency. EPA determined that DOE met the requirements of § 194.14(h) because it provided multiple, appropriately scaled, topographic maps of the vicinity of the disposal system.

I. Past and Current Meteorological Conditions

40 CFR 194.14(i) requires DOE to describe past and current climatologic and meteorological conditions in the vicinity of the disposal system. DOE is also required to project how these conditions are expected to change over the regulatory time frame.

DOE described past glaciation events, climatic changes, and precipitation and temperature averages. DOE also discussed how historical climatic conditions were used to anticipate climatic conditions 10,000 years in the future. DOE described current climatic conditions in the WIPP area, including summaries of recent rainfall, temperature, and wind data. DOE discussed how climate changes were incorporated in conceptual models.

Based on public comments and EPA's review of the CCA, EPA requested additional information on dissolution. Supplemental information submitted by DOE addressed EPA's concerns. EPA concluded that the description of past and present climatic changes and associated impacts on the WIPP disposal system were adequately addressed, and therefore proposes to find DOE in compliance with § 194.14(i).

J. Other Information Needed for Demonstration of Compliance

40 CFR 194.14(j) requires DOE to provide additional information, analyses, tests, or records determined by the Administrator or the Administrator's authorized representative to be necessary for determining compliance with 40 CFR Part 194. After receipt of the CCA dated October 29, 1996, EPA formally requested additional information from DOE in seven letters dated December 19, 1996, and February 18, March 19, April 17, April 25, June 6, and July 2, 1997. (Docket A–93–02, Items II–I–1, II–I–9, II–I–17, II–I–25, II–I–27, II–I–33, and II–I–37, respectively). The information requested in these letters was necessary for EPA's completeness determination and technical review. EPA staff and contractors also reviewed records maintained by DOE or DOE's contractors (e.g., records kept at the Sandia National Laboratories Records Center in Albuquerque, New Mexico). No additional laboratory or field tests were conducted by DOE at EPA's specific direction; however, DOE did conduct and document laboratory tests after October 29, 1996, in order to present additional data to the Conceptual Model Peer Review Panel.

The preamble for other sections of the Compliance Criteria discuss in greater detail DOE's responses to EPA's formal requests for additional information and any other supplementary information reviewed by EPA after October 29, 1996. All documents sent to EPA are available in the EPA docket. Additional documentation that was not sent to EPA but was reviewed by the Agency (e.g., calculations of actinide solubility for americium, plutonium, thorium and uranium) is also publicly available. Documentation of peer review panel meetings conducted after receipt of the CCA has been placed in the EPA docket. See Docket A–93–02, Item III–B–1 for further information on the location of all documentation reviewed by EPA.

EPA determined that DOE responded adequately to EPA's formal requests for additional information, analyses, and records; and therefore proposes to find that DOE complies with § 194.14(j).

K. Conclusion

Based on the information provided in the CCA and additional information submitted by DOE, EPA proposes that DOE demonstrates compliance with all subsections of § 194.14. For additional information on EPA's evaluation of compliance for § 194.14, see CARD 14.

X. General Requirements

The general requirements of 40 CFR Part 194, Subpart C, are intended to ensure that any compliance certification application (''CCA'') is based on dependable and verifiable information and that EPA has the right to confirm the accuracy of such information. Although they have no direct corollary in the disposal regulations, EPA issued these requirements in implementing the disposal regulations because the Agency believes that a reasonable expectation of compliance with the containment requirements (discussed in subsequent portions of this preamble) can be achieved only if the information and methods used to conduct performance assessments are valid and reliable. To that end, the general requirements at §§ 194.22 through 194.27 establish requirements for quality assurance programs, models and computer codes, waste characterization, future state assumptions, expert judgment, and peer review.

A. Section 194.22, Quality Assurance

Section 194.22 establishes quality assurance (''QA'') requirements for the WIPP. QA is a process for enhancing the reliability of technical data and analyses underlying DOE's CCA. Section 194.22 requires DOE to (a) establish and execute a QA program for all items and activities important to the containment of waste in the disposal system (including waste characterization activities, environmental monitoring, field measurements, computer codes, procedures for expert elicitation, disposal system designs, and data), (b) qualify data that were collected prior to implementation of the required QA program, (c) assess data for their quality characteristics, to the extent practicable, (d) demonstrate how data are qualified for their use in the CCA, and (e) allow verification of the above measures through EPA inspections. The DOE's QA program must adhere to specific Nuclear Quality Assurance (''NQA'') standards and requirements issued by the American Society of Mechanical Engineers (''ASME'').

The EPA assessed compliance with the QA requirements in two ways. First, EPA reviewed QA information in the CCA and associated reference documents. EPA's second level of review consisted of visits to the WIPP site, as well as WIPP-related facilities, to perform audits and inspections to verify DOE's compliance with the QA requirements. For example, EPA conducted audits to verify the proper execution of the QA program at DOE's Carlsbad Area Office (''CAO''), Sandia National Laboratories (''SNL''), and Westinghouse's Waste Isolation Division (''WID'') at the WIPP facility. In this way, EPA was able to review voluminous records required by the NQA standards, but not required to be submitted as part of the CCA.

Section 194.22(a)(1) requires DOE to adhere to a QA program that implements the requirements of the following: (1) ASME NQA-1–1989 edition; (2) ASME NQA–2a-1990 addenda, part 2.7, to ASME NQA–2–1989 edition; and (3) ASME NQA–3–

1989 edition (excluding Section 2.1 (b) and (c), and Section 17.1). DOE incorporated these requirements in the Quality Assurance Program Document (''QAPD'') contained in the CCA. The QAPD is the documented plan for the WIPP project, as a whole, to comply with the NQA requirements; it applies to all activities and items important to containment of waste in the WIPP. The QAPD addresses the 18 basic requirements of NQA–1, including supplemental requirements as established by NQA–1; the computer software requirements as established by NQA–2a, part 2.7; and the collection of scientific and technical information requirements for site characterization of high level nuclear waste repositories as established by NQA–3. The QAPD is implemented by DOE's CAO, which provides overall coordination of WIPP activities and has authority to audit all other organizations associated with waste disposal at the WIPP (such as WID, SNL and waste generator sites) to ensure that their lower-tier QA programs conform to the QAPD. EPA audited DOE's QA program at CAO and determined that DOE properly adhered to a QA program that implements the NQA standards and requirements. Therefore, EPA proposes to find DOE in compliance with § 194.22(a)(1). (For information on the incorporation of NQA requirements into lower tier program plans, refer to the subsequent discussion of § 194.22(a)(2), which addresses specific activities under the direct control of organizations other than DOE's CAO.)

Section 194.22(a)(2)(i) requires DOE to include information which demonstrates that the QA program has been established and executed for waste characterization activities and assumptions. In the CCA, DOE provided the QAPD and referenced criteria for the review and approval of a site-specific Quality Assurance Project Plan (''QAPjP'') to address technical criteria and implementation procedures. The CCA listed five waste generator site QAPjPs that have been approved by DOE. DOE proposed that sites also will prepare site certification Quality Assurance Plans (''QAPs'') that, together with the QAPjPs, are intended to establish all the NQA requirements applicable to waste characterization.[15] EPA finds that the QAPD, as it applies to waste characterization, is in conformance with the NQA requirements. As discussed below, the Agency intends to verify the adequacy of site-specific QA programs in the future.

Another important activity related to waste characterization is the ability to track waste shipped to and emplaced in the WIPP. The WIPP Waste Information System (''WWIS'') is a computer database and reporting program that will track and tally the waste that comes to the WIPP. The WWIS is covered by QA programs both at the WID and at waste generator sites. At Westinghouse, the WID QAPD, which addresses the specific requirements of the NQA standards, governs operation of the system. In September 1997, EPA performed an inspection of the WID QA program applicable to the WWIS. At that time, the WWIS was demonstrated to be operational, and EPA determined that a QA program had been properly executed for the WWIS in accordance with the applicable NQA requirements.

The Compliance Criteria require that QA programs be established and executed specifically with respect to the use of process knowledge and a system of controls for waste characterization. (§§ 194.22(a)(2)(i) and 194.24(c)(3) through (5)) To accomplish this, waste generator site-specific QA programs and plans must be individually examined and approved by EPA to ensure adequate waste characterization programs are in place before EPA allows individual waste generator sites to transport waste for disposal at the WIPP. Since waste characterization activities have not begun for most TRU waste generator sites and storage facilities, EPA has not yet evaluated the compliance of many site-specific QA plans (QAPs and, where applicable, QAPjPs) and programs.

To date, one WIPP waste generator site, Los Alamos National Laboratory (''LANL''), has been approved by EPA to have established adequate QA programs (encompassed in a QAP and QAPjP) and to have properly executed QA procedures in accordance with the applicable NQA requirements. Prior to approval of LANL's site-specific QA program, EPA conducted an audit of DOE's overall WIPP QA program and approved its capability to perform audits in accordance with the requirements of NQA–1. EPA then inspected three DOE audits of LANL's QA program. Based on the results of the inspections, the EPA inspectors determined that the QA program had been properly executed at LANL. Therefore, EPA proposes to find that the requirements of § 194.22(a)(2)(i) have been met for the WID QAPD, the WWIS, and waste characterization activities at LANL.

With respect to other waste generator sites, EPA proposes to certify compliance with § 194.22(a)(2)(i) conditioned on separate, subsequent approvals from EPA that site-specific QA programs for waste characterization activities and assumptions have been established and executed in accordance with applicable NQA requirements at each waste generator site.

As waste generator facilities subsequent to LANL establish QA programs, EPA will assess their compliance with NQA requirements. In making any determination to approve a site-specific QA program for a waste generator, EPA will conduct an audit or an inspection of a DOE audit of a waste generator site. EPA will publish a notice in the **Federal Register** announcing its scheduled audit or inspection of a DOE audit and will provide at least a 30-day comment period during which interested parties may submit written comments. EPA will place in the docket copies of the site-specific QA program documents and other documentation relevant to the audit or audit inspection. Thus, the Agency's decision whether to approve the establishment and execution of a QA program at a specific waste generator site will be informed by both public comments and the results of the Agency's own independent evaluation of the site's compliance with the applicable NQA requirements.

EPA believes that approval of site specific QA programs is required by, and that this proposed procedure is consistent with the provisions of § 194.22(a)(2)(i) because it requires DOE to demonstrate ''establishment and execution'' of quality assurance programs for waste characterization assumptions and activities at the individual waste generator sites prior to shipment of wastes from such sites. EPA requests comment on whether the Agency should place a condition on its certification of compliance at WIPP consisting of future demonstrations by DOE that QA programs have been established and executed at individual waste generator sites, prior to shipment of TRU waste to WIPP from such sites. In particular, EPA requests comment on

[15] NQA–1 (Element II–2) requires that organizations responsible for activities affecting quality (in the case of the WIPP, affecting the containment of waste in the disposal system) must have documented QA programs in accordance with the applicable NQA requirements. The documentation for such programs is commonly referred to as a ''quality assurance program plan,'' or ''QAPP.'' For WIPP waste generator sites, the role of the QAPP is fulfilled by documents with other titles, such as the QAP or the QAPjP. The ''TRU QAPP'' referenced by DOE in the CCA is not a QAPP as described by the NQA standards; rather, it is a technical document that describes the quality control requirements and performance standards for characterization of TRU waste coming to the WIPP facility. The TRU QAPP is addressed more specifically in the preamble discussion of § 194.24, ''Waste Characterization.''

its preliminary conclusion that the proposed procedures for determining whether adequate quality assurance programs have been established and executed by DOE are consistent with Part 194. However, if, based upon public comment on today's proposed action, EPA concludes that it would be appropriate to make clarifying changes to Part 194 that specifically set forth these procedures, EPA may do so as part of its final action on today's proposal.

EPA will indicate its approval of site-specific QA programs by a letter from the Administrator's authorized representative to the Department; a copy of the *letter* will be placed in EPA's public docket. (As part of the certification rulemaking, EPA is proposing to define the Administrator's authorized representative as the ''director in charge of radiation programs at the Agency,'' in order to clarify the delegation of responsibilities for 40 CFR Part 194, including activities such as requesting additional information from DOE, and inspecting and approving quality assurance programs.) After approval of site-specific QA programs, EPA will exercise its authority under §§ 194.21 and 194.22(e) to conduct unfettered inspections of approved waste generator sites to confirm that the approved plans are being properly maintained for waste characterization activities. For specific language on the quality assurance conditions of compliance, see Condition 2 of the proposed Appendix A to 40 CFR Part 194. For further discussion of waste characterization programs and certification of individual waste streams from generator sites, see the discussion of § 194.24 in this preamble.

Section 194.22(a)(2)(ii) requires DOE to include information which demonstrates that the QA program has been established and executed for environmental monitoring, monitoring of performance of the disposal system and sampling and analysis activities. Westinghouse's WID was responsible for implementing this requirement under the WID QAPD described in the CCA. The WID developed a WIPP Environmental Monitoring Plan (''EMP''), which applies to current site characterization and also to proposed pre-closure monitoring in accordance with § 194.42. The EMP included QA procedures for radiological and non-radiological environmental monitoring. Also included in the EMP were sample handling, laboratory procedures, required records and reports, and data analyses guidelines. DOE stated that the EMP is consistent with applicable elements of ASME NQA–1.

The EPA determined during its audit of WID that the requisite QA program had been established and executed for environmental monitoring, sampling and analysis activities. Therefore, EPA proposes to certify compliance with § 194.22(a)(2)(ii). Continued adherence to the executed QA program as it applies to disposal system monitoring will be confirmed by EPA in future inspections under its authority at §§ 194.21 and 194.22(e).

Section 194.22(a)(2)(iii) requires DOE to include information which demonstrates that the QA program has been established and executed for field measurements of geologic factors, groundwater, meteorologic, and topographic characteristics. EPA conducted an audit of the WID QA program and found the QAPD to be adequate and to be implemented in accordance with the applicable NQA requirements. Therefore, EPA proposes to find DOE in compliance with § 194.22(a)(2)(iii).

Section 194.22(a)(2)(iv) requires DOE to include information to demonstrate that the QA program has been established and executed for computations, computer codes, models and methods used to demonstrate compliance with the disposal regulations. In the CCA, DOE provided the CAO QAPD, which incorporates the application NQA requirements for computation and computer code information. Software development and management are controlled in accordance with criteria established by SNL software QA procedures and the WID QAPD. EPA reviewed information in the CCA and conducted audits of both SNL and WID QA programs. The Agency found that DOE's computer codes were documented in a manner that complies with the applicable NQA requirements, and that DOE's software QA procedures were implemented in accordance with ASME NQA–2a, part 2.7. EPA therefore proposes to determine that DOE complies with § 194.22(a)(2)(iv).

Section 194.22(a)(2)(v) requires DOE to include information which demonstrates that the QA program has been established and executed for procedures for implementation of expert judgment elicitation. EPA found that the requirements of this regulation were met with the implementation of CAO Team Procedure (''TP'') 10.6 (Revision 0), CAO Team Plan for Expert Panel Elicitation (Revision 2), and CAO Technical Assistance Contractor (''CTAC'') Experimental Programs Desktop Instruction No.1 (Revision 1). EPA proposes to find DOE in compliance with § 194.22(a)(2)(v). The process of expert judgment elicitation is discussed in further detail in the preamble for § 194.26 of the Compliance Criteria.

Section 194.22(a)(2)(vi) requires DOE to include information which demonstrates that the QA program has been established and executed for design of the disposal system and actions taken to ensure compliance with the design specifications. Design work for the repository sealing system was conducted under the SNL QA program. The repository seal system design was extensively reviewed by DOE, SNL, WID, and CAO Technical Assistance Contractor personnel, as well as independent design reviewers. The QA procedures established and implemented by SNL and WID address the requirements of the NQA standards; design verification was accomplished by a combination of NQA–1 Supplement 3S–1 methods. EPA audits of SNL and WID showed that the QA programs are adequate and properly executed. Therefore, EPA proposes to find DOE in compliance with § 194.22(a)(2)(vi).

Section 194.22(a)(2)(vii) requires DOE to include information which demonstrates that the QA program has been established and executed for the collection of data and information used to support compliance applications. SNL adequately addressed these requirements by implementing numerous QA procedures to ensure the quality of data and information collected in support of the WIPP. EPA's audit of SNL concluded that the QA program was adequate and appropriately implemented. Therefore, EPA proposes to find DOE in compliance with § 194.22(a)(2)(vii).

Section 194.22(a)(2)(viii) requires DOE to include information which demonstrates that the QA program has been established for any other item or activity not listed above that is important to the containment of waste in the disposal system. DOE has not identified any other item or activity important to waste isolation in the disposal system that require QA controls to be applied as described in the CAO QAPD. EPA has also not identified to date any other items or activities which require controls. However, EPA has reviewed the CAO QAPD and conducted audits of the CAO, SNL, and WID QA programs. The EPA audits determined that the QA organizations of CAO, WID, and SNL have sufficient authority, access to work areas, and organizational freedom to identify other items and activities affecting the quality of waste isolation. Therefore, EPA proposes to find DOE in compliance with § 194.22(a)(2)(viii).

Section 194.22(b) requires DOE to include information which demonstrates that data and information collected prior to the implementation of the QA program required by § 194.22(a)(1) have been qualified in accordance with an alternate methodology, approved by the Administrator or the Administrator's authorized representative, that employs one or more of the following methods: peer review; corroborating data; confirmatory testing; or a QA program that is equivalent in effect to § 194.22(a)(1) ASME documents. The CCA listed existing data that were reviewed by an Independent Review Team and that DOE determined to have been collected under a QA program equivalent to the NQA standards. DOE also provided information on NUREG–1297 peer reviews that were conducted to qualify existing data for engineered systems, natural barriers, waste form, and disposal room data. Finally, DOE identified data from literature sources.

EPA conducted two audits that traced new and existing data to their qualifying sources. The two audits found that equivalent QA programs and peer review had been properly applied to qualify existing data used in the PA. EPA also concluded that the use of existing data from peer-reviewed technical journals was appropriate, since the level of such reviews was likely to provide QA equivalent to NUREG–1297 peer reviews conducted by DOE. Therefore, EPA proposes to find DOE in compliance with § 194.22(b). Furthermore, the Agency is proposing to approve the use of any one of the following three methods for qualification of existing data: (1) peer review, conducted in a manner that is compatible with NUREG–1297; (2) a QA program that is equivalent in effect to ASME NQA–1–1989 edition, ASME NQA–2a–1990 addenda, part 2.7, to ASME NQA–2–1989 edition, and ASME NQA–3–1989 edition (excluding Section 2.1(b) and (c) and Section 17.1); or (3) use of data from a peer-reviewed technical journal.

Sections 194.22(c)(1) through (5) require DOE to provide information which describes how all data used to support the compliance application have been assessed, to the extent practicable, for specific data quality characteristics (''DQCs''). In the CCA, DOE stated that in most cases it was not practicable to document DQCs for parameters, but asserted that the intent of DQCs was fulfilled by other QA programs and quality control measures. In response to EPA's request for additional information, DOE clarified but did not substantially alter its approach. (Docket A–93–02, Items II–I–17 and II–I–24)

The Agency agrees that it is not appropriate to apply DQCs to parameters in the PA (e.g., anhydrite permeability parameter), but believes that they can be applied to measured data (i.e., field monitoring and laboratory experiments) on which parameter values are based. Because DOE misinterpreted EPA's requirements as applying to parameters, EPA found that the CCA and supplementary information did not systematically or adequately address DOE's consideration of DQCs for measured data. Therefore, the Agency reviewed additional materials—primarily data record packages at the SNL records center—to independently determine whether DQCs had been assessed for data used in PA. Data record packages document measured data considered by DOE in developing parameter values. EPA found that for recent data (five to ten years old), DOE's experimental program plans in the data record packages generally addressed data quality in measured data, including accuracy, precision, representativeness, completeness, and comparability during measurement and collection.

For older existing data, EPA found less documentation of assessment of DQCs. However, laboratory notebooks—which provide first-hand documentation of measurement procedures and results—supporting data record packages provided some information related to the quality of measurements (e.g., how well DOE's measured values compared with values found in peer-reviewed publications). Many existing data were also subject to peer review in order to qualify them for use in the compliance application; EPA concluded that the peer review panels considered the use of DQCs in determining that such data were adequate. EPA also agreed with DOE's argument in supplementary information that for most of the existing data, collection under a program equivalent to the NQA standards in § 194.22(a)(1) provided adequate evidence that the quality of data had been evaluated and controlled. Finally, EPA concurred with DOE's conclusion that the uncertainties in measured data reflected in DQCs have a small effect on compliance certainty, compared to other uncertainties in the PA (such as extrapolation of processes over 10,000 years).

Based on its review of data record packages, the Agency finds that DOE has assessed DQCs, to the extent practicable, for data used in the compliance application. EPA thus proposes to find that DOE complies with § 194.22(c). The Agency expects that DOE will assess DQCs for future waste characterization and monitoring activities; EPA will confirm assessment of DQCs for such measured data through inspections and evaluation of any compliance re-certification applications.

Section 194.22(d) requires DOE to provide information which describes how all data are qualified for use. SNL generated a table providing information of how all data in the PA were qualified. EPA audited the existing QA programs and determined that the data were qualified for use by independent and qualified personnel in accordance with NQA requirements. On this basis, EPA proposes to find DOE in compliance with § 194.22(d).

Section 194.22(e) allows EPA to verify execution of QA programs through inspections, record reviews, and other measures. As discussed above, EPA has conducted numerous audits of DOE facilities, and intends to conduct future inspections of waste generator site-specific QA plans under its authority. The Agency plans to conduct additional inspections, including audits, of CAO, SNL, and WID prior to publishing a final certification decision. The purpose of these inspections will be to verify that the QA programs for these organizations—which have already been found to be properly executed in accordance with the applicable NQA requirements—are being appropriately maintained. EPA will docket the results of these inspections, but will not consider them for the purpose of the proposed or final rule unless the inspections result in new information that indicates that the programs are no longer in conformance with the applicable NQA requirements.

In summary, EPA proposes to find DOE in compliance with the requirements of § 194.22 subject to the condition that EPA separately approve the establishment and execution of site-specific QA programs for waste characterization activities at waste generator sites. (See Condition 2 of the proposed Appendix A to 40 CFR Part 194.) For further information on EPA's evaluation of compliance for § 194.22, refer to CARD 22.

B. Section 194.23, Models and Computer Codes

Section 194.23 sets forth specific requirements for the models and computer codes used to calculate the results of performance assessments (''PA'') and compliance assessments. In order for these calculations to be reliable, DOE must properly design and implement the computer codes used in

the PA. Design of computer codes begins with the development of conceptual models. Conceptual models consider the design of the repository and the features, events, processes, and scenarios that may occur at the WIPP which could affect the containment or release of radionuclides. In order for the final computer codes to obtain realistic solutions, the underlying conceptual models must be sound. DOE must next develop mathematical models from the conceptual models. Mathematical models set up a mathematical expression to describe the conditions in the repository and its surroundings. Numerical models are then created to describe how to solve the equations in the mathematical models. Since most of the mathematical models are sufficiently complex that analytical solutions are not possible, numerical models are used to provide iterative, approximate solutions to the mathematical models. Finally, DOE must program the numerical solutions from the numerical models into computer codes that perform calculations to estimate the cumulative releases of radionuclides caused by all significant processes and events.

In examining models and computer codes, EPA evaluated the development of the underlying conceptual models, evaluated the derivation of mathematical models and implementation of numerical models and computer codes, verified the quality assurance of computer codes, and performed its own independent computer calculations. In order to allow EPA to evaluate the underlying conceptual models, § 194.23 of the compliance criteria requires descriptions of conceptual models and scenario construction (§ 194.23(a)(1)), consideration of alternative conceptual models (§ 194.23(a)(2)), and documentation of peer review of the conceptual models (§ 194.23(a)(3)(v)). To ensure proper implementation of these conceptual models, § 194.23 also requires documentation that: future states of the disposal system are reasonably represented by conceptual models (§ 194.23(a)(3)(i)); mathematical models (or algorithms) reasonably represent the conceptual models (§ 194.23(a)(3)(ii)); numerical models (or solution methods) provide stable solutions to the mathematical models (§ 194.23(a)(3)(iii)); and computer codes accurately implement the numerical models and are free from coding errors and produce stable solutions (§ 194.23(a)(3)(iv)). In addition, DOE must describe the theoretical background of models and their method of analysis; how the computer codes operate and were developed; methods of data collection, data reduction and analysis; parameters developed from source data; the structure of the computer codes and a complete listing of source codes; and the effects of parameter correlation (§§ 194.23(c)(1) through (6)). Section 194.23(b) requires DOE to document that models and computer codes were developed in accordance with the specified QA requirements contained in the ASME NQA standards. Finally, § 194.23(d) requires DOE to provide all necessary data, information, software, and any other material to enable EPA to conduct its own independent computer simulations.

1. Conceptual Models

a. *Description of Conceptual Models.* Section 194.23(a)(1) requires the CCA to describe the conceptual models and the scenarios used in the CCA PA calculations. DOE developed 24 conceptual models to describe the WIPP disposal system. DOE also undertook an extensive screening process to determine which features, events, and processes (FEPs) were applicable to the disposal system. From the list of applicable FEPs, DOE developed scenarios to describe both undisturbed performance (natural processes and events) and disturbed performance (human intrusion, including mining and deep drilling) of the repository. The CCA included scenarios that satisfy the specific requirements of §§ 194.32 and 194.33 concerning the scope of PA and consideration of drilling events in PA. (See preamble discussions of §§ 194.32 and 194.33 for further details.)

EPA reviewed the descriptions of the 24 conceptual models and the scenario construction methods in the CCA and supplementary information and found them to be presented with sufficient clarity to permit full understanding of the descriptions and methods. However, both EPA and public commenters did not believe that DOE had performed sufficient analyses to rule out the potential effects of fluid injection related to oil production on the disposal system. Therefore, EPA required DOE to perform additional analyses of fluid injection. Based on supplementary information provided by DOE, EPA concluded that fluid injection can be screened out from the PA based upon low consequences to disposal system performance. EPA and commenters also had concerns about DOE's conceptual model for spallings.[16] The results of the spallings model were eventually determined to be reasonable and adequate for use in PA. For further discussion of the spallings model, refer to the discussion of models and computer codes later in this section.

The CCA and supporting documents contain a complete and accurate description of each of the conceptual models used and the scenario construction methods used. The conceptual models include those characteristics and attributes of the WIPP disposal system and its surroundings that adequately describe the possible future performance of the disposal system. The conceptual models contain appropriate simplifications of the characteristics, attributes, and processes of the disposal system. The scenario construction descriptions include sufficient detail to understand the basis for selecting some scenarios and rejecting others and are adequate for use in the CCA PA calculations. Based on its review of DOE's descriptions of the conceptual models and the scenario construction procedures presented in the CCA and supporting documents, the Agency proposes to determine that the DOE has demonstrated compliance with the requirements of § 194.23(a)(1).

b. *Alternative Conceptual Models.* Section 194.23(a)(2) requires the CCA to describe plausible, alternative conceptual models that DOE seriously considered but did not use to support compliance, and to explain why DOE decided the alternative conceptual model does not accurately portray performance of the disposal system. This requirement allows EPA to evaluate whether the conceptual models underlying the PA and compliance assessment are appropriate and adequate.

DOE provided information on alternative conceptual models in the CCA, both in its discussion of FEPs and in its documentation of the conceptual models peer review panel. The peer review panel identified no major issues concerning alternative models.

EPA reviewed information on alternative conceptual models in the CCA and in documentation from the peer review panel. EPA requested, and DOE provided, supplementary information containing a focused, detailed description of plausible alternative conceptual models considered but not used in the PA. DOE also explained the reasons why these alternative models were not used to

[16] ''Spallings'' refers to releases of solids forced up and out of an intrusion borehole by gas pressure in the repository.

describe the performance of the repository. EPA determined that DOE sufficiently documented the rationale and approach used to select the conceptual models employed in the CCA PA and to reject other models.

As discussed elsewhere in this section, the conceptual models peer review panel and EPA had concerns specifically with the spallings conceptual model. Because the conceptual models peer review panel initially judged the spallings model used in the CCA to be inadequate, DOE developed an alternative mechanistically-based computational approach to estimate the volume of spallings released to the accessible environment. The volumes of radioactive waste to be released that were calculated by the alternative mechanistically-based model were less than one tenth those predicted in the model used in the CCA. Because the original spallings model results used in the CCA were conservative, the conceptual models peer review panel and EPA found the predicted results from the original model to be acceptable for use in the PA.

Based on information provided in the CCA together with supplementary information provided by DOE in response to specific EPA requests, EPA concluded that DOE provided an adequate and complete description of alternative conceptual models seriously considered but not used in the CCA. DOE provided adequate discussion of why these alternative models were not deemed to adequately portray the performance of the disposal system. Therefore, EPA proposes to find DOE in compliance with § 194.23(a)(2).

c. *Future States of the Disposal System and Peer Review.* Section 194.23(a)(3)(i) requires the CCA conceptual models and scenarios to reasonably represent future states of the disposal system. Section 194.23(a)(3)(v) requires the CCA to document that conceptual models have undergone peer review in accordance with § 194.27, which requires that the peer review meets the guidance of NUREG–1297. Under this guidance, the peer review must include the following: A listing of the reviewers; requirements for the acceptability of each reviewer; individual statements by peer reviewers reflecting dissenting views, if any; a discussion of the conceptual models peer reviewed; an evaluation of data and information used to develop conceptual models; an evaluation of the validity of conceptual model assumptions; an evaluation of alternative conceptual models; an evaluation of the uncertainty in the conceptual models and a discussion of consequences if the conceptual model chosen is inappropriate for the site; a statement indicating the adequacy of the conceptual models used for the disposal system; a statement of the accuracy of the results based on the conceptual models employed; and a discussion of the validity of the conclusions drawn based on the conceptual models. As part of the review of adequacy of the conceptual models, peer reviewers considered whether conceptual models reasonably represented future states of the disposal system. The NUREG–1297 requirements and the process of peer review are discussed in greater detail in the preamble for § 194.27.

DOE convened a conceptual models peer review panel to review the 24 conceptual models used in the CCA PA. During the initial review, the panel found that 11 models were not adequate and 13 models were adequate for use in PA. The panel initially found the 11 conceptual models to be inadequate for a variety of reasons, mostly related to the adequacy of assumptions incorporated in the conceptual models and the amount of supporting data or analyses for certain features of the conceptual models. Based on additional information provided by DOE and three subsequent review sessions, the panel found all the models to be adequate for use in PA except the spallings model. They found that the original CCA PA spallings model did not reasonably represent possible future states of the disposal system because it did not fully model all potential mechanisms that may cause pressure-driven solid releases. The panel ultimately concluded, based on substantial analytical and experimental work provided by DOE, that the spallings values used in the CCA are reasonable for use in PA. The panel found that, while the spallings model does not accurately represent the future state of the disposal system, its inaccuracies are of an overly conservative nature, and in fact, may overestimate the actual waste volumes that would be expected to be released by the spallings process.

EPA concurs with the conceptual model peer review panel's findings, based upon the results of DOE's analysis and development of an alternative model for spallings, which showed that the CCA PA spallings model overestimates spallings releases by up to ten times or more. The peer review panel's findings considered whether conceptual models reasonably represented future states of the disposal system. EPA does not propose to determine that the spallings model ''reasonably represents possible future states of the repository.'' The additional modeling conducted by DOE, and the additional data developed by DOE, however, provide a substantial basis for EPA to conclude that the results of the spallings model are adequate and useful for the purpose for which conceptual models are intended, i.e., to aid in the determination of whether the WIPP will comply with the disposal regulations during the regulatory time period. Because the spallings model produces reasonable and conservative results, EPA proposes to accept it for purposes of demonstrating compliance with § 194.23(a)(3)(i).

The information on peer review in the CCA and in supplementary information demonstrates that all conceptual models have undergone peer review consistent with the requirements of § 194.27. Therefore, the Agency proposes to find that DOE has demonstrated compliance with the requirements of § 194.23(a)(3)(v).

d. Public Comments. During the public comment period on the Advance Notice of Proposed Rulemaking (''ANPR''), EPA received numerous comments challenging various aspects of the spallings model. EPA and the conceptual models peer review panel, among others, shared concerns about the adequacy of the spallings model and on numerous occasions informed DOE of their concerns. In response to these concerns, DOE did substantial additional work, developed a mechanistically-based model and supported this model with experimental data. The peer review panel concluded that the spallings model used in the CCA PA calculated release volumes that were reasonable and probably conservative. On this basis, and as discussed above, EPA proposes that it is appropriate to accept the results from the spallings model for purposes of demonstrating compliance with § 194.23(a)(3)(i).

EPA also received public comments on the ANPR concerning modeling of fluid injection. Commenters expressed concern that the CCA PA calculations did not model possible effects of pressurized brine injection that may fracture the anhydrite beds near WIPP, enter the repository, become contaminated and flow to various release points. EPA required DOE to perform extensive supplementary analyses to evaluate the effects that brine injection could have on the repository. EPA also performed independent analyses to address concerns related to brine injection. EPA has determined that brine injection does not pose an unacceptable risk and that associated scenarios can be reliably screened from further consideration.

2. Progression From Conceptual Models to Computer Codes

Most of the requirements of § 194.23(a)(3) concern the Agency's evaluation of the progression from conceptual models to computer codes used in the CCA PA and compliance assessment. Each requirement in §§ 194.23(a)(3)(i) through (iv) is intended to ensure that DOE has correctly implemented the steps between development of the underlying conceptual models and encoding the computer software that implements the PA and compliance assessment calculations. The initial step of evaluating the fundamental conceptual models is discussed above.

a. Mathematical Models. Section 194.23(a)(3)(ii) requires the CCA to document that mathematical models incorporate equations and boundary conditions which reasonably represent the mathematical formulation of the conceptual models. This requirement is intended to ensure that PA calculations are based upon mathematical equations that truly implement the conditions in the fundamental conceptual models. Many of the mathematical equations are partial differential equations, which consider rates of change; thus, codes incorporating these mathematical models need initial and boundary conditions between which the rates of change in the equations will operate.

DOE documented the development of each computer code used in PA and compliance assessment, including the associated mathematical models and numerical models. This information was contained primarily in Users Manuals, Validation Documents, Implementation Documents, and Requirements Document & Verification and Validation Plans for each CCA PA computer code. EPA reviewed information supplemental to the CCA for each CCA PA computer code and evaluated whether the mathematical models incorporate equations and boundary conditions which reasonably represent the mathematical formulation of the conceptual models.

EPA reviewed the mathematical model equations and boundary conditions for the following codes: PANEL, BRAGFLO, NUTS, FMT, SANTOS, BRAGFLO__DBR, GRASP–INV, SECOFL2D, SECOTP2D, CCDFGF, and CUTTINGS__S. These are the codes DOE used to model the behavior of the repository and its surroundings and to compute results of the PA calculations. The codes PANEL, BRAGFLO, NUTS, FMT, and SANTOS incorporate mathematical model equations that implement the conceptual models for predicting future characteristics of the waste repository. These five codes simulate the following effects, respectively: concentrations of radioactive waste in brine within the waste-containing panels in the repository; flow of brine and gas in the repository; solubility and transport of radionuclides released from the repository; solubility of radionuclides in the repository; and collapse of the repository through salt creep closure of the Salado. The computer code BRAGFLO__DBR describes waste dissolution in brine and transport of the contaminated brine through direct brine releases. The three computer codes GRASP–INV, SECOFL2D, and SECOTP2D mathematically describe flow and transport of waste-laden brine in the Culebra dolomite. The computer code CUTTINGS__S incorporates mathematical model equations modeling releases of radioactive waste upon intrusion of a drill bit into the repository. The computer code CCDFGF computes complementary cumulative distribution functions (''CCDFs'') for the results of PA.

In general, EPA found that the descriptions of mathematical formulations were adequately explained and were reasonable. The Agency found that DOE adequately documented and described simplifications of conceptual models in the CCA. EPA also concluded that DOE provided an adequate technical basis to support the mathematical formulations. EPA tested each of the codes with functional tests to verify that each computer code would perform according to its functional requirements.[17] This analysis and testing indicated that equations and boundary conditions were properly incorporated into the mathematical models and that boundary conditions were reasonable representations of how the conceptual models should be implemented.

EPA encountered problems with the governing equations of the mathematical models and the representation of the boundary conditions in the codes CUTTINGS__S, SECOFL2D, SECOTP2D, NUTS and BRAGFLO. EPA specified that the equations in the codes be corrected and that the changes to the codes be documented. The Agency later required DOE to perform additional calculations in a Performance Assessment Verification Test (''PAVT'') in order to verify that the cumulative impact of all necessary corrections to input parameters, conceptual models, and computer codes used in PA was not significant enough to necessitate a new PA. For the PAVT, DOE used corrected versions of the BRAGFLO, NUTS and SECOTP2D computer codes. The results of the PAVT demonstrate that the cumulative impact of all these necessary corrections did not require new PA runs. DOE resolved all of EPA's questions related to the equations that make up the mathematical models and the incorporation of the boundary conditions of the various codes by correcting the codes and performing the PAVT.

Based on information contained in the CCA and supporting documentation for each code, EPA concludes that the mathematical models used to describe the conceptual models incorporate equations and boundary conditions which reasonably represent the mathematical formulation of the conceptual models. DOE resolved all issues raised by the Agency. DOE has provided an adequate technical basis to support the mathematical formulations used in the PA. Therefore, the Agency proposes to find DOE in compliance with § 194.23(a)(3)(ii).

b. Public Comments on Mathematical Models. During the public comment period on the ANPR, EPA received comments on aspects of the mathematical models. Several commenters felt that the mathematical models in the CCA PA, particularly those related to ground-water flow in the Culebra dolomite, did not account sufficiently for three-dimensional processes and boundary conditions. A DOE report provided a detailed sensitivity analysis of ground-water flow characteristics in the Culebra. This report concluded that the majority of ground-water flow through the Culebra is horizontal. (Docket A–93–02, Item II–G–1, Reference #147) From the perspective of calculating the potential consequences to repository performance, neglecting vertical leakage into and out of the Culebra is conservative. EPA believes that the two-dimensional modeling approach used in the PA for ground-water flow in the Culebra dolomite is conservative and adequate. EPA also reviewed the FEP screening analysis related to flow of brine and gas in the repository and concluded that there are only minor differences between the two-dimensional and three-dimensional computations. Therefore, EPA believes that the two-dimensional geometry used in the BRAGFLO computer code is reasonable and appropriate for the CCA PA.

EPA also received public comments on the ANPR concerning the modeling

[17] A functional requirement specifies how the code is intended to operate, including inputs and outputs.

of ground-water flow and radionuclide transport processes in the Culebra. Commenters stressed that scientific understanding of ground-water flow in fractured rock systems is still developing and that DOE requires greater documentation of processes and parameters embodied in the CCA PA. EPA notes in response to public comments that DOE conducted an extensive investigative program to improve its theories of ground-water flow and radionuclide transport through the Culebra. Although these activities have greatly improved the understanding of the geohydrologic system, EPA recognizes that a degree of uncertainty will always exist when attempting to make predictions about the performance of WIPP 10,000 years into the future. EPA required DOE to address this uncertainty in its PA by assigning ranges and distributions to uncertain variables, such as fracture spacings, distribution coefficients, porosities and transmissivity. EPA also required DOE to perform further analysis using different parameter values and distributions in the PAVT. EPA believes that this approach to handling uncertainty is appropriate because the uncertainty will be captured by the ranges and distributions assigned to parameters.

c. Numerical Models. Section 194.23(a)(3)(iii) requires documentation that numerical models provide numerical schemes which enable the mathematical models to obtain stable solutions. Although some mathematical models can be solved directly, many of the mathematical equations used in PA for the WIPP are so complex that they require the use of numerical solution methods to provide an approximate solution. It is important that solutions to the mathematical models be stable because unstable solutions may make it impossible to proceed to the next step in obtaining PA results or may call into question the results of the model.

The relevant information was contained in supplemental information from DOE, including Analysis Packages for each code and the documents described in the previous section. This documentation includes testing results for problems that are very similar to those solved by the code(s) in the CCA PA, in order to evaluate the stability of solutions from the numerical schemes used to solve the mathematical model equations. DOE also maintained a computational record of whether any of the codes experienced stability problems during the CCA PA calculations. The codes that use numerical solvers include: SANTOS, CUTTINGS__S, SECOFL2D, SECOTP2D, PANEL, BRAGFLO, BRAGFLO__DBR, NUTS, and GRASP–INV.

EPA reviewed all the relevant documentation on numerical solution schemes contained in the CCA and supplementary information about each code. EPA also executed DOE code verification tests to search for possible stability problems. EPA's review identified stability concerns related to the following codes: CUTTINGS__S, SECOFL2D, SECOTP2D, and NUTS. In the case of the NUTS and SECOTP2D codes, DOE was able to make minor changes to the codes to correct their stability problems. EPA's concerns regarding potential stability problems with CUTTINGS__S and SECOFL2D were alleviated after DOE provided results from further stability and code verification testing that showed these problems had been corrected. DOE satisfactorily resolved all EPA concerns regarding code stability issues.

Based on the CCA and supplementary information provided by DOE, the Agency determines that DOE provided sufficient technical information to document the numerical models used in the CCA. Based on verification testing, EPA determined that the numerical models produced stable solutions. DOE resolved stability problems with the BRAGFLO, NUTS, SECOFL2D and SECOTP2D computer codes by completing code revisions and supplementary testing requested by the Agency. Therefore, EPA proposes to find DOE in compliance with § 194.23(a)(3)(iii).

d. Computer Codes. Section 194.23(a)(3)(iv) requires documentation that computer models accurately implement the numerical models, such that computer codes are free of coding errors and produce stable solutions. This is the final step to ensure that the underlying conceptual models are implemented correctly in the PA calculations and to ensure that the PA calculations will yield valid results.

To ensure that PA computer codes accurately implement the numerical models and are free of coding errors, DOE adopted a number of Quality Assurance Procedures for each step in the software development process. (See also the preamble discussions of §§ 194.22 and 194.23(b).) DOE documented information on the software development process in Users Manuals, Validation Documents, Implementation Documents and Requirements Document & Verification and Validation Plans for each computer code.

EPA performed an independent review of the CCA PA computer codes used to support the PA. As part of this review, EPA executed functional tests established by DOE for each of the codes to verify that each computer code performed according to its functional requirements, and to verify that the computer codes accurately implemented the numerical models, were free of coding errors, and produced stable solutions. The codes that EPA reviewed and tested include: SANTOS, CUTTINGS__S, SECOFL2D, SECOTP2D, CCDFGF, LHS, PANEL, BRAGFLO, BRAGFLO__DBR, FMT, NUTS, GRASP–INV and ALGEBRA. EPA also reviewed all of the relevant documentation pertaining to each of the major codes described above.

EPA identified issues related to coding errors for the following codes: SECOFL2D, SECOTP2D, and NUTS. To address these concerns, EPA requested that DOE perform a number of additional analyses. In the process of responding to EPA's concerns, DOE discovered, rectified and documented several minor coding errors. Results from an impact analysis by DOE indicated that the coding errors would have very little impact on the WIPP's compliance with the disposal regulations. These issues were resolved to EPA's satisfaction.

Based on the CCA and supplementary information, the Agency determined that DOE provided sufficient technical information to document the numerical models used in the CCA. Based on verification testing, EPA determined that the computer codes accurately implement the numerical models and that the computer codes are free of coding errors and produce stable solutions. DOE resolved coding error problems that EPA initially encountered by performing code revisions and supplementary testing requested by the Agency. Therefore, the Agency proposes to conclude that DOE has demonstrated compliance with § 194.23(a)(3)(iv).

3. Quality Assurance

Section 194.23(b) requires that computer codes used in the CCA must be documented in a manner that complies with the quality assurance requirements of ASME NQA–2a–1990 addenda, part 2.7, to ASME NQA–2–1989 edition. This requirement is intended to ensure proper development and documentation of software and to identify any potential problems. Based on EPA audits and CCA review, EPA found that code documentation meets the NQA requirements, and thus proposes to find that DOE complies with § 194.23(b). See the preamble discussion of § 194.22(a)(2)(iv), Quality assurance, for further discussion of EPA's evaluation of compliance.

4. Documentation of Models and Codes

Sections 194.23(c)(1) through (6) contains a number of requirements related to documentation of models and computer codes. These requirements allow EPA to evaluate the design of the models, to evaluate the numerical values selected to describe the repository and its surroundings, and to operate the software used to perform the PA calculations.

DOE documented the development of computer software in a series of documents that supplement the CCA. The information that EPA reviewed was contained primarily in Analysis Packages, User's Manuals, Validation Documents, Implementation Documents and Requirements Document & Verification and Validation Plans for each code. DOE used these documents to track development of software codes beginning from the conceptual model stage, and continuing through derivation of the mathematical equations and their solutions, setting computational requirements for computer codes, designing the computer software, programming the software, and testing the codes after they are programmed. Among the types of information found in these documents are general descriptions of the models, descriptions of the theoretical background of models, discussions of the limits of the models, instructions for executing computer codes, information on the required input and output formats with examples, reports on testing of the computer codes, structure of the computer codes, source codes,[18] and sources of data used to support parameter values used in the models and codes.

a. Theoretical Background. Section 194.23(c)(1) requires the CCA to describe the theoretical backgrounds of each model and the method of analysis or assessment used by each model. EPA evaluated whether DOE's descriptions of the computer codes provided sufficient detail to determine if the codes are formulated on a sound theoretical foundation, and whether DOE provided clear documentation describing exactly how each of the codes was used to support the PA. The codes that EPA reviewed include: CUTTINGS__S, SECOFL2D, SECOTP2D, CCDFGF, LHS,[19] PANEL, BRAGFLO, BRAGFLO__DBR, NUTS, FMT, GRASP–INV, SANTOS and ALGEBRA.[20] These codes describe the repository, the movement of radionuclides in contaminated brine through the overlying Culebra dolomite, releases of radionuclides when a drill penetrates the repository, and calculations of releases for final results of the PA. EPA located the majority of the information in the Users Manuals and Analysis Packages for each code, found in the Sandia National Laboratories WIPP Record Center.

In a few cases, EPA initially found the theoretical description of the computer codes to be inadequate. Most notably, the mathematical description of the solution precipitation model contained in the NUTS code, which predicts radionuclide transport in the repository and in units underlying the Culebra, was absent from the documentation. DOE addressed EPA's concerns by providing supplementary reports that describe in detail those theoretical discussions that were originally deficient. With respect to the documentation pertaining to the method of analysis, EPA found the descriptions in the Analysis Packages for each code to be sufficiently complete. In several instances, EPA requested that DOE clarify the written documentation, which DOE did.

Based on information contained in the Users Manual and Analysis Packages for each code and supplementary information requested by EPA to address specific problems uncovered in the course of the compliance review, EPA found that DOE has provided sufficient documentation so that individuals knowledgeable in the subject matter have sufficient information to judge whether the codes are formulated on a sound theoretical foundation, and whether the code has been used properly in the PA. EPA also found that the level of documentation is consistent with the ASME requirements for quality assurance as well as consistent with recent standards on ground-water modeling published by the American Society for Testing and Materials (ASTM). Therefore, EPA proposes to determine that DOE has complied with the requirements of § 194.23(c)(1).

b. Descriptions of Models. Section 194.23(c)(2) requires the CCA to document the following kinds of information: general descriptions of the models; discussions of the limits of applicability of each model; detailed instructions for executing the computer codes, including hardware and software requirements; input and output formats with explanations of each input and output variable and parameter; listings of input and output files from a sample computer run; and reports on code verification, bench marking, validation,[21] and quality assurance (''QA'') procedures. Section 194.23(c)(3) requires documentation of the structure of the computer codes in detail and complete listings of the source codes.

The codes that EPA reviewed include: CUTTINGS__S, SECOFL2D, SECOTP2D, CCDFGF, LHS, PANEL, BRAGFLO, BRAGFLO__DBR, NUTS, FMT, GRASP–INV, SANTOS and ALGEBRA. The supplemental information from DOE that documented code development was described above in this section. DOE also set forth a number of objectives regarding issues that must be covered in code documentation to meet the QA criteria outlined in Sections 4 and 6 of the ASME NQA–2a–1990 addenda, part 2.7, to ASME NQA–2–1989.

EPA reviewed the supplemental documents, executed the computer codes, and evaluated the code verification, bench marking, and validation documentation. During its review, EPA identified a number of areas where the Agency initially judged the documentation to be inadequate. EPA required the Department to perform an analysis on the NUTS computer code, to develop a code requirement and test the statistical validity of certain aspects of the GRASP–INV code, to provide evidence that the GRASP–INV code was tested in a manner consistent with its implementation in the PA, and to document a sample computer run that corresponds to calculation of the CCA PA results. DOE provided this additional supporting analysis and documentation and satisfied EPA's concerns.

DOE submitted all of the source code listings and a detailed description of the structure of computer codes in the Implementation Documents for each code. With this information, a user can compile the source code and install it on a computer system identical to that used in the CCA PA calculation. EPA found that DOE submitted all of the source code listings. EPA identified no

[18] ''Source code'' means the written description of each step the computer code will follow when it is executed.

[19] LHS, or Latin Hypercube Sampling, is a code that selects or ''samples'' a numerical value from a distribution of probable values for a parameter. For more information on LHS, see the preamble discussion of the requirements of § 194.34.

[20] The ALGEBRA computer code manipulates input data and initial conditions that allow other codes to perform their calculations.

[21] Verification, bench marking and validation are steps in testing computer codes to ensure they operate as intended. Verification means that the aspect of the code being tested matches known solutions. Bench marking means that solutions from the code are compared to results from an outside reference or ''bench mark'' calculation, for more complicated situations where the solutions to a problem may not be known exactly. Validation means all aspects of the code work together properly.

problems with the detailed descriptions of the structure of the computer codes.

EPA found that the CCA and supplementary information included an adequate description of each model used in the calculations, a description of limits of applicability of each model, detailed instructions for executing the computer codes, hardware and software requirements to run these codes, input and output formats with explanations of each input and output variable and parameter, listings of input and output files from sample computer runs, and reports of code verification, bench marking, validation, and QA procedures that are adequate for use in the CCA PA. EPA also found that DOE adequately provided a detailed description of the structure of the computer codes and supplied a complete listing of the computer source code in supplementary documentation to the CCA. The documentation of computer codes describes the structure of computer codes with sufficient detail to allow EPA to understand how software subroutines are linked. The code structure documentation shows how the codes operate to provide accurate solutions of the conceptual models. Therefore, EPA proposes to determine that DOE has demonstrated compliance with §§ 194.23(c) (2) and (3).

c. Parameters. Section 194.23(c)(4) requires detailed descriptions of data collection procedures, data reduction and analysis, and code input parameter development. Parameters are numerical values or ranges of numerical values used to describe different physical and chemical aspects of the repository, the geology and geometry of the area surrounding the WIPP, and possible scenarios for human intrusion. Some parameter values are well-established physical constants, such as the Universal Gas Constant or atomic masses of radionuclides. Parameters also can be physical, chemical or geologic characteristics that DOE established by experimentation. DOE has also assigned parameters to aspects of human intrusion scenarios, such as the diameter of a drill bit used to drill a borehole that might penetrate the repository.

DOE discussed information supporting parameter development in the CCA and in parameter records located in the SNL WIPP Record Center. The records at SNL Record Center include WIPP parameter entry forms, Parameter Records Packages, Principal Investigator Records Packages, Data Records Packages, and Analysis Packages. DOE uses all of these documents to explain the full development of parameter values used as inputs to the CCA PA calculations.

The Agency reviewed the CCA, parameter documentation and record packages for approximately 1,600 parameters used as input values to the CCA PA calculations. EPA further reviewed parameters record packages and documentation in detail for 465 parameters important to performance of the disposal system. The Agency selected parameters to review in depth based on the following criteria: parameters that were likely to contribute significantly to releases or seemed to be poorly justified; parameters that control various functions of the CCA PA computer codes that were likely to be important to calculations of releases and important to compliance with the containment requirements of § 191.13; and other parameters the Agency used to evaluate the overall quality of SNL's documentation traceability. The Agency examined DOE's parameter documentation to see if the following elements were present: detailed listings of code input parameters and the parameters that were sampled; codes in which the parameters were used and the computer code names of the sampled parameters; descriptions of the sources of data; descriptions of the parameters, data collection procedures, data reduction and analysis, and code input parameter development; discussions of the linkage between input parameter information and data used to develop the input information; discussions of the importance of the sampled parameters relative to final calculations of releases, correlations among sampled parameters, and how these are addressed in PA; a listing of the sources of data used to establish parameters; and data reduction methodologies used for CCA PA parameters, including an explanation of QA activities.

After its initial review, the Agency found that DOE had a great deal of documentation available in the SNL Records Center supporting most of the parameters used in the CCA PA. However, EPA had some concerns about the completeness of the list of CCA PA parameters, the description and justification to support the development of some code input parameters, and the traceability of data reduction and analysis of parameter-related records. The Agency did not agree with the technical justification of some parameter values and probability distributions. The Agency did not find adequate documentation to support one of DOE's professional judgement parameters, the waste particle size value (expressed as a particle diameter). Other parameters such as professional judgment parameters and some parameters that were used in DOE's 1992 PA calculations were found to have adequate documentation to support the value used in the CCA PA calculations.

During its review, EPA found that the following types of documentation were necessary to improve DOE's records: a comprehensive database of all parameters used in the CCA PA, a database of all parameters based on experimental data, ''roadmaps'' that document and link CCA PA parameters to their sources, complete record packages in the SNL Record Center, background documentation on the development of those parameters that were originally used in DOE's 1992 PA calculations and again were used in the CCA PA calculation, and adequate explanations of why the 149 professional judgment parameters in the comprehensive parameter database did not need expert elicitation. DOE provided all of these pieces of documentation, primarily by improving the quality of the records stored in the SNL WIPP Records Center. The Agency did not accept the use of professional judgement to derive the waste particle size parameter, and thus required DOE to use the process of expert elicitation to develop the value for this parameter. (See also the preamble discussion for § 194.26 regarding expert elicitation for the waste particle size.) After subsequent review and evaluation of the SNL WIPP Record Center records and after completion of expert elicitation, EPA was satisfied with the additional documentation provided by DOE for these areas of concern.

The Agency requested further documentation from DOE, expressing concern about information supporting 58 parameters. EPA divided these parameters into those parameters lacking supporting evidence, those parameters that have records supporting values other than those selected by DOE, and those parameters that are not explicitly supported by the relevant data or information. DOE provided additional information supporting some of the parameters of concern to EPA. The Agency also performed its own sensitivity analyses for the parameters to determine if changes to some parameters have a significant impact on the final computer calculations. The Agency's concerns were resolved for thirty-four of these parameters, either by DOE's submission of additional documentation or by the results of sensitivity analyses conducted by EPA that indicated that changes to certain parameter values would not

significantly impact results of computer calculations.

The Agency later required DOE to perform additional calculations in a Performance Assessment Verification Test (''PAVT'') in order to verify that the cumulative impact of all required and other corrections to input parameters, conceptual models, and computer codes used in PA was not significant enough to necessitate a new PA. EPA directed DOE to incorporate modified values or distributions for twenty-four parameters in the PAVT. The PAVT showed that the calculated releases may increase by up to three times from those in the original CCA PA, but that the WIPP is still an order of magnitude below the containment requirements in § 191.13. For further information about results of the PAVT, see the preamble for § 194.34, ''Results of PA.'' DOE satisfied EPA's concerns about the parameters by incorporating EPA's changes to the parameter values and parameter distributions in the PAVT.

Upon subsequent review and evaluation, EPA determined that DOE, after additional work and improvement of records in the SNL Record Center, adequately provided a detailed listing of the code input parameters; listed sampled input parameters; provided a description of parameters and the codes in which they are used; discussed parameters important to releases; described data collection procedures, sources of data, data reduction and analysis; and described code input parameter development, including an explanation of QA activities. Therefore, the Agency proposes to determine that the CCA complies with § 194.23(c)(4).

d. Public Comments on Parameter Values. During the public comment period for the ANPR, EPA received comments on specific parameter values. After the end of the ANPR public comment period, EPA also received comments on parameter distribution values that the Agency mandated DOE include in the PAVT.

The Agency performed a thorough review of the parameters and the parameter development process, as discussed in the previous section. In its initial review, the Agency found that DOE had a great deal of documentation supporting most of the parameters used in the CCA PA available in the SNL Records Center. EPA specifically requested DOE to perform the PAVT in order to determine the effects of different parameter distributions for those parameters that concerned EPA and that appeared to have a significant impact on the results of PA.

e. Software Licenses. Section 194.23(c)(5) requires the CCA to document any licenses necessary for software used in the PA. DOE stated that it did not use any software requiring licenses, since software was developed by DOE or its contractors. EPA concurs with DOE's statement, and thus proposes to find that the CCA complies with § 194.23(c)(5).

f. Parameter Correlation. Section 194.23(c)(6) requires the CCA to provide an explanation of the manner in which models and computer codes incorporate the effects of parameter correlation. Parameters are correlated if they are not completely independent of each other. For example, if two parameters are programmed into computer codes so that both increase or decrease under the same conditions, the two parameters are correlated. Such a correlation can be directly programmed as an explicit correlation specified by the computer user. A parameter correlation also can be programmed into computer codes indirectly through an induced correlation when one parameter is used to derive a second parameter in the code. EPA evaluated parameter correlation in the CCA because an improper parameter correlation may call into question some parameter values and may even call into question the validity of the results from PA, depending on how significant the correlated parameters are.

User-specified (explicit) parameter correlations are introduced into the CCA PA calculations using a correlation matrix or table in the Latin Hypercube Sampling (LHS) computer program. Of all the parameters, only rock compressibility and permeability are explicitly correlated in the LHS computer code input file. When values that are sampled using the LHS computer code are used to calculate other values in the CCA PA calculations, an induced correlation parameter relationship is created through mathematical formulas used in subsequent computer codes. This is the prevalent method of correlation used in DOE's PA.

EPA reviewed the documentation in the LHS Users Manual that explains how parameter correlation is included in the parameter sample process. EPA also reviewed information in the CCA which discussed the mathematical methods used to incorporate parameter correlation into the CCA PA calculations. EPA also reviewed DOE's sensitivity analysis of the parameters sampled in the CCA PA, which includes a discussion of the impacts of parameter correlations.

Based on its review of CCA documentation and supplementary information, EPA determined that DOE has adequately demonstrated the manner in which the models and computer codes incorporate the effects of parameter correlation. Specifically, the CCA contains adequate: (1) Discussions that explain how the effects of parameter correlation are incorporated; (2) explanations of the mathematical functions that describe these relationships; and (3) descriptions of the potential impacts on the sampling of uncertain parameters. The CCA also adequately documented the effects of parameter correlation for both conceptual models and the formulation of computer codes, and appropriately incorporated these correlations in the PA. Thus, the Agency proposes to find that DOE has demonstrated compliance with the requirements of § 194.23(c)(6).

5. EPA's Independent Testing

Section 194.23(d) allows EPA to verify the results of computer simulations used in the CCA by performing independent simulations. This requirement also requires DOE to provide EPA with data files, source codes, executable versions of computer software for each model, other material or information needed to permit EPA to perform independent simulations, and to access necessary hardware to perform such simulations within 30 days of a request from EPA. This requirement ensures that EPA can verify calculations in the CCA and analyze the potential impact of changes to the PA calculations if changes are made to computer codes or parameters.

DOE provided EPA with unrestricted access to computer hardware required to perform simulations related to the CCA. DOE also provided EPA with access to data files, source codes, and executable computer codes for each model used in the CCA. DOE provided staff to assist EPA in executing various verification tests and sensitivity analyses with DOE hardware and software. EPA performed code verification tests on all CCA PA computer codes using CCA hardware and software. In some cases, EPA required DOE to perform additional verification tests. EPA conducted extensive parameter sensitivity tests using the same system of CCA PA computer codes. The PAVT was an independent computer simulation of the WIPP's performance conducted under EPA's authority to require independent verification computer simulations under § 194.23(d). DOE provided assistance in all of this work on a timely basis. Because DOE provided EPA with ready access to the necessary tools to permit EPA to perform independent simulations using computer software and hardware employed in the CCA,

EPA proposes to find DOE in compliance with § 194.23(d). For further information on EPA's evaluation of compliance for § 194.23, see CARD 23.

C. Section 194.24, Waste Characterization

Section 194.24, waste characterization, generally requires DOE to identify and describe quantitative information on the chemical, radiological and physical characteristics of the waste proposed for disposal at the WIPP that can influence disposal system performance. The DOE has not demonstrated compliance with all the requirements of § 194.24 as they pertain to waste characterization activities at generator sites. Therefore, EPA is proposing certification of compliance with these requirements, with the condition that DOE must submit additional information to demonstrate full compliance for waste generator sites. The proposed conditions of certification are addressed under EPA's discussion of the requirements at §§ 194.24(c)(3) through (5).

Section 194.24(a) requires DOE to describe the chemical, radiological and physical composition of all existing and to-be-generated waste, including a list of waste components and their approximate quantities in the waste. DOE described the existing waste by combining like waste streams into eleven final waste forms and waste stream profiles. A waste stream is defined by DOE as waste material generated from a single process or activity that is similar in material, physical form, isotopic make-up, and hazardous constituents. The waste stream profiles contained information on the waste material parameters, or components, that could affect repository performance. DOE extrapolated information from the existing waste streams to determine the amount of to-be-generated waste. DOE's waste profiles contained appropriate specific information on the components and their approximate quantities in the waste. Therefore, EPA proposes to find DOE in compliance with § 194.24(a).

Sections 194.24(b)(1) through (3) require DOE to analyze waste characteristics and waste components for their impact on disposal system performance. Waste components affect waste characteristics and are integral to disposal system performance. For example, the waste characteristic gas generation is controlled, in part, by the type and amount of waste components such as metal waste containers and plastic material. DOE identified waste-related elements pertinent to the WIPP as part of its screening for features, events, and processes (''FEPs''). The FEPs used in the performance assessment (''PA'') served as the basis from which characteristics and associated components were identified and further analyzed. (Refer to the preamble discussion of § 194.32, ''Scope of PA,'' for additional information pertaining to FEPs.)

DOE concluded that six characteristics were expected to have a significant effect on disposal system performance and were used in PA (i.e., parameters were identified for each): solubility, formation of colloidal suspensions containing radionuclides, gas generation, shear strength of waste, radioactivity of specific isotopes, and TRU activity at disposal. DOE identified eight waste components influencing the six significant waste characteristics: Ferrous metals, cellulose, radionuclide identification, radioactivity of isotopes, TRU activity of waste, solid waste components, sulfates, and nitrates. Finally, DOE provided a list of waste characteristics and components assessed, but determined not to be significant for various reasons such as negligible impact on PA. EPA found that DOE used a reasonable methodology to identify and assess waste characteristics and components. The analysis appropriately accounted for uncertainty and the quality of available information. Therefore, EPA proposes to find DOE in compliance with requirements in §§ 194.24(b)(1) through (3).

Section 194.24(c)(1) requires DOE to specify numeric limits on significant waste components and demonstrate that, for those limits, the WIPP complies with the numeric requirements of §§ 194.34 and 194.55. Either upper or lower limits were established for components that must be controlled to ensure that the PA results comply with the containment requirements. DOE explicitly included numeric limits, identified as fixed values with no associated uncertainty, for four waste components. Lower limits were established for ferrous and non-ferrous metals; upper limits were established for cellulosics and free water. The three components related to radioactivity and radionuclides were effectively limited by the inventory estimates used in the PA. The fixed-value limits and radionuclide inventory estimates were included in the PA calculations through parameters closely related to these components, and the results demonstrated compliance with EPA's standards. EPA concurred with DOE that it was not necessary to provide estimates of uncertainty for waste limits, so long as the PA demonstrated compliance at the fixed limits.

Explicit limits were not identified for solid waste, sulfates, and nitrates, even though DOE identified these as components significant to performance. For solid waste, EPA determined that in the PA, DOE took no credit for the potential gas-reducing effects of solid waste (i.e, assumed a lower limit of zero) and demonstrated that the WIPP would still comply. For nitrates and sulfates, EPA determined that these components would not significantly affect the behavior of the disposal system as long as cellulosics were limited. Thus, EPA concurred that it is unnecessary to specify limits for nitrates, sulfates, and solid waste. Therefore, EPA proposes to find DOE in compliance with § 194.24(c)(1).

Section 194.24(c)(2) requires DOE to identify and describe the methods used to quantify the limits of important waste components identified in § 194.24(b)(2). DOE proposed to use non-destructive assay (''NDA'') (e.g., passive active neutron assay), non-destructive examination (''NDE'') (e.g., radiography), and visual examination (''VE'') as the methods used to quantify various waste components. The CCA described numerous NDA instrument systems and described the equipment and instrumentation found in NDE and VE facilities. DOE also provided information about performance demonstration programs intended to show that data obtained by each method could meet data quality objectives established by DOE. EPA found that these methods, when implemented appropriately, would be adequate to characterize the important waste components. Therefore, EPA proposes to find that DOE has demonstrated compliance with § 194.24(c)(2). (Implementation of measurement programs at waste generator sites is addressed below for the requirements at §§ 194.24(c)(4) and (5).)

Section 194.24(c)(3) requires DOE to demonstrate that the use of process knowledge to quantify components in waste for disposal conforms with the quality assurance (''QA'') requirements found in § 194.22. EPA expected DOE to submit specific information on the process knowledge to be used at waste generator sites as part of DOE's certification application. EPA requires such information to conduct proper regulatory review of whether use of the process knowledge is appropriate and reliable. DOE provided some information on its overall plans for using process knowledge in the CCA. DOE did not, however, provide specific information on the use of process knowledge at any waste generator site in the CCA, nor did it provide information

demonstrating establishment of the required QA programs.

After submission of the CCA, EPA subsequently received information regarding process knowledge to be used at the Los Alamos National Laboratory (''LANL''). EPA determines DOE to have adequately described the use of process knowledge for retrievably stored (legacy) debris waste streams at LANL. EPA has confirmed establishment and execution of the required QA programs at that waste generator site through inspections. (See the preamble discussion of § 194.22, ''Quality Assurance,'' for further information on inspections.) Therefore, the Agency determines that DOE has demonstrated compliance with the § 194.24(c)(3) QA requirement for LANL. EPA does not find, however, that DOE has adequately described the use of process knowledge for any other waste streams at LANL (other than the retrievably-stored (legacy) debris waste streams discussed above). Furthermore, DOE has not demonstrated compliance with § 194.24(c)(3) for any other waste generator site.

Sections 194.24(c)(4) and (5) require DOE to demonstrate that a system of controls has been and will continue to be implemented to confirm that the waste components emplaced in the WIPP will not exceed the upper limit or fall below the lower limit calculated in accordance with § 194.24(c)(1). The system of controls must conform to the QA requirements specified in § 194.22 DOE described a system of controls over waste characterization activities, such as the requirements of the TRU QA Program Plan (''TRU QAPP'') and the Waste Acceptance Criteria (''WAC''). EPA found that the TRU QAPP established appropriate technical quality control and performance standards for sites to use in developing site-specific sampling plans. Further, DOE outlined two phases in waste characterization controls: waste stream screening/verification (pre-shipment) and waste shipment screening/verification (pre-receipt of waste at the WIPP). The tracking system for waste components against their upper and/or lower limits is found in the WIPP Waste Information System (''WWIS''). If implemented as proposed, EPA believes that the TRU QAPP, WAC, and WWIS are adequate to control important components of waste emplaced in the WIPP. EPA audited DOE's QA programs at CAO, SNL and WID and determined that DOE properly adhered to QA programs that implement the applicable NQA standards and requirements. (See the preamble discussion of § 194.22 for further information.) However, in the CCA, DOE did not demonstrate that the WWIS is fully functional and did not provide information regarding the specific system of controls to be used at individual waste generator sites.

After submission of the CCA, EPA subsequently received information regarding the system of controls to be used at LANL. The Agency confirmed through inspections that the system of controls is adequate to characterize waste and ensure compliance with the limits on waste components, and also confirmed that a QA program had been established and executed at LANL in conformance with NQA requirements. Moreover, DOE demonstrated that the WWIS is functional with respect to LANL—i.e., that procedures are in place at LANL for adding information to the WWIS system, that information can be transmitted from LANL and incorporated into the central database, and that data in the WWIS database can be compiled to produce the types of reports described in the CCA for tracking compliance with the waste limits. Therefore, EPA determines DOE to have demonstrated compliance with §§ 194.24(c)(4) and (5) for several waste streams in the category of retrievably stored (legacy) debris waste at LANL. EPA's proposed determination of compliance is limited to those retrievably stored (legacy) debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at LANL.[22] EPA does not find, however, that DOE has demonstrated compliance with § 194.24(c)(4) for any other waste stream at LANL, or with §§ 194.24(c)(4) and (5) at any other waste generator site.

In order to ship transuranic waste from other waste generator sites for emplacement at the WIPP, DOE will have to demonstrate compliance with the § 194.24(c)(3) through (5) requirements. Compliance with the requirements as they relate to QA programs will be evaluated and approved for each generator site in accordance with the language in Condition 2 (''Quality Assurance'') of the proposed Appendix A to 40 CFR Part 194. To fully comply with these requirements, DOE must also submit—and EPA must approve—for each waste stream or group of waste streams, information on how process knowledge will be incorporated into waste characterization activities, and on the system of controls proposed for (a) given waste stream(s). A waste stream is defined by DOE as waste material generated from a single process or activity that is similar in material, physical form, isotopic make-up, and hazardous constituents. EPA expects that this information will be contained in site-specific documents including, for example, site certification quality assurance plans (''QAPs'') and quality assurance project plans (''QAPjPs''). All such documentation submitted by DOE regarding plans for waste characterization of specific waste streams will be placed in EPA's dockets for public inspection.

As waste generator sites establish waste characterization programs for new waste streams (or groups of waste streams), EPA will assess their compliance with the §§ 194.24(c)(3) and (4) requirements. EPA will conduct an audit or inspection of a DOE audit at each site to evaluate the use of process knowledge and the establishment of a system of controls for each waste stream or group of waste streams. In order for a site to demonstrate the implementation of a system of controls, the WWIS must be demonstrated to be functional at any waste generator site before any waste stream(s) may be shipped from that site for disposal at the WIPP. By this, EPA means that a waste generator site must demonstrate that it has procedures in place for entering data into the WWIS tracking system, and that such data can be transmitted to the WWIS database so that it is available for compilation and reporting. In order for EPA to confirm that a system of controls has been adequately executed in accordance with § 194.24(c)(4), DOE must demonstrate that measurement techniques and control methods can be implemented for each waste stream or streams which DOE plans to emplace in the WIPP.

As described in the proposed certification condition, EPA's decision to approve site-specific plans for the use of process knowledge and the system of controls—and thus to approve a site to transport a waste stream for disposal at the WIPP—would be made only after public comment has been solicited and after EPA has conducted an audit or an inspection of a DOE audit of the waste generator site. Therefore, before making any determination to approve the use of process knowledge or the system of controls, EPA would publish a notice in the **Federal Register** announcing its intent to evaluate waste characterization programs for a given waste stream (or waste streams) at one or more sites. There would be allowed at least a 30-day comment period on DOE's proposed programs for process knowledge and a

[22] See Docket A–93–02, Item II–I–70 for a list of these systems and processes. They include characterization methodologies and relevant procedures, such as that used for entering data into the WWIS database.

system of controls for one or more specific waste streams.

EPA believes that approval of site specific QA programs is required by, and that this proposed procedure is consistent with the provisions of Section 194.24(c)(3)–(5) because it requires DOE to (1) demonstrate application of established and executed quality assurance programs to use of process knowledge; (2) demonstrate implementation of the required system of controls; and (3) demonstrate application of established and executed quality assurance programs to the system of controls, at the individual waste generator sites prior to shipment of wastes from such sites. EPA requests comment on whether the Agency should place a condition on its certification of compliance at WIPP consisting of future demonstrations by DOE that the §§ 194.24(c)(3)–(5) requirements have been met, prior to shipment of TRU waste to WIPP from such sites. In particular, EPA requests comment on its preliminary conclusion that the proposed procedures for determining whether adequate quality assurance programs have been established and executed by DOE are consistent with 40 CFR Part 194. However, if, based upon public comment on today's proposed action, EPA concludes that it would be appropriate to make clarifying changes to 40 CFR Part 194 that specifically set forth these procedures, EPA may do so as part of its final action on today's proposal.

EPA's written determination that DOE has demonstrated compliance with these requirements, as well as the results of any audits or inspections, would be placed in the public dockets. EPA will confirm ongoing compliance with these requirements through unfettered access to waste generator sites for the purpose of conducting inspections under its authority at §§ 194.21 and 194.24(h).

Section 194.24(d) requires DOE either to include a waste loading scheme which conforms to the waste loading conditions used in the PA and in compliance assessments, or to assume random placement of waste in the disposal system. DOE elected to assume that radioactive waste would be emplaced in the WIPP in a random fashion. DOE examined the possible effects of waste loading configurations on repository performance (specifically, releases from human intrusion scenarios) and concluded that the waste loading scheme would not affect releases. DOE incorporated the assumption of random waste loading in its performance and compliance assessments (pursuant to §§ 194.32 and 194.54, respectively).

The EPA determined that, because DOE had assumed random waste loading and also had found that potential non-random loading of waste would not affect releases, a final waste loading plan was unnecessary. EPA determined that DOE cross-referenced the resultant waste distribution assumptions from the waste loading plan with the waste distribution assumptions used in PA, and accurately modeled random placement of waste in the disposal system. Since EPA concurred with DOE that a final waste loading plan was unnecessary, DOE does not have to further comply with § 194.24(f), requiring DOE to conform with the waste loading conditions, if any, used in the PA and compliance assessment. EPA proposes to find that DOE complies with §§ 194.24(d) and (f).

Section 194.24(e) prohibits DOE from emplacing waste in the WIPP if its disposal would cause the waste component limits to be exceeded. Section 194.24(g) requires DOE to demonstrate that the total inventory emplaced in the WIPP will not exceed limitations on TRU waste described in the LWA. Specifically, the LWA defines limits for: surface dose rate for remote-handled (''RH'') TRU waste, total amount (in curies) of RH–TRU waste, and total capacity (by volume) of TRU waste to be disposed. (LWA, Section (7)(a)) In order to meet the §§ 194.24(e) and (g) limits, DOE intends to rely on the TRU QAPP, WAC, and two-phase waste characterization (pre-shipment at generator sites, and pre-receipt at the WIPP). The CCA stated that the WWIS will be used to track specific data related to each of the LWA limits; by generating routine WWIS reports, DOE will be able to determine compliance with the imposed limits. The WWIS will also be used to track information on each of the important waste components for which limits were established. EPA finds that the WWIS is adequate to track adherence to the limits, and that the WWIS has been demonstrated to be fully functional at the WIPP facility; as discussed above, waste generator sites will demonstrate WWIS procedures before they can ship waste for disposal at the WIPP. Therefore, EPA proposes to find DOE in compliance with §§ 194.24(e) and (g).

Section 194.24(h) allows EPA to conduct inspections and record reviews to verify compliance with the waste characterization requirements. As discussed above, EPA intends to monitor execution of waste characterization and QA programs at waste generator sites through inspections and record reviews.

In summary, EPA proposes to find that DOE is in compliance with § 194.24, and that LANL has demonstrated compliance with §§ 194.24(c)(3) through (5) for certain retrievably stored (legacy) debris waste streams and may therefore ship TRU waste for disposal at the WIPP (as such shipments relate solely to compliance with EPA's disposal regulations; other applicable requirements or regulations still may need to be fulfilled before disposal may commence). EPA's proposed determination of compliance is limited to those retrievably stored (legacy) debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at LANL.

The Agency also proposes to certify compliance subject to the condition that DOE may not ship other waste streams for emplacement at the WIPP until EPA determines that (1) DOE has provided adequate information on how process knowledge will be incorporated into waste characterization activities for a particular waste stream at a generator site, and (2) DOE has demonstrated that the system of controls described in § 194.24(c)(4) has been established for the site. In particular, DOE must demonstrate that the WWIS system is functional for any waste generator site before waste may be shipped, and that the system of controls can be implemented for each waste stream which DOE plans to dispose in the WIPP. As discussed in the preamble for § 194.22 (and in Condition 2 of the proposed Appendix A to 40 CFR Part 194), DOE must also demonstrate that sites have established and executed the requisite QA programs described in §§ 194.22(a)(2)(i) and 194.24(c)(3) and (5).

The Agency proposes that the decision to allow a waste generator site to dispose of a waste stream at the WIPP will be made only after public comments have been solicited on DOE's proposed site-specific programs and after EPA has conducted an audit or an inspection of a DOE audit of the waste generator site. EPA will make available, in its public docket, the site-specific program documents being considered by the Agency, and will publish a notice in the **Federal Register** announcing its intent to evaluate such plans. There will be allowed at least a 30-day public comment period for interested parties to comment on DOE's proposed programs for process knowledge and a system of controls for one or more specific waste streams. EPA also plans to conduct an

audit or an inspection of a DOE audit at each site to evaluate the execution of such plans for pertinent waste streams.

EPA's approval of the plans relevant to compliance with §§ 194.24(c)(3) and (4) will be indicated in a letter from the Administrator's authorized representative to the Department. EPA is proposing to define the Administrator's authorized representative as ''the director in charge of radiation programs at the Agency'' to clarify the delegation of responsibilities described in the Compliance Criteria and in the proposed conditions of certification. A copy of the approval letter, as well as the results of any inspections, will be placed in the public dockets. After approval of the site-specific plans for characterization of (a) waste stream(s), EPA will confirm the execution of the programs at each waste generator site and continued compliance with the requirements of §§ 194.24(c)(3) through (5) through inspections and audits under its authority at §§ 194.21, 194.22(e) and 194.24(h). Results of such inspections will be made available to the public through the Agency's public dockets, as described in § 194.67.

For specific language on the waste characterization conditions of certification, see Condition 3 of the proposed Appendix A to 40 CFR Part 194; for specific language on the quality assurance requirements that relate to waste characterization, see Condition 2 of the proposed appendix. For further information on EPA's evaluation of compliance for § 194.24, refer to CARD 24.

D. Section 194.25, Future State Assumptions

Section 194.25 stipulates that performance assessments (''PA'') and compliance assessments (''CA'') ''shall assume that characteristics of the future remain what they are at the time the compliance application is prepared, provided that such characteristics are not related to hydrogeologic, geologic or climatic conditions.'' The purpose of the future state assumptions is to avoid unverifiable and unbounded speculation about possible future states of society, science, languages, or other characteristics of mankind. The Agency has found no acceptable methodology that could make predictions of the future state of society, science, languages, or other characteristics of mankind. However, the Agency does believe that established scientific methods can make plausible predictions regarding the future state of geologic, hydrogeologic, and climatic conditions. Therefore, § 194.25 focuses PA and CA on the more predictable significant features of disposal system performance, instead of allowing unbounded speculation on all developments over the 10,000-year regulatory time frame.

EPA required DOE to identify and document all future state characteristics and conditions that are used in the PA and CA. For all elements of the PA and CA that do not relate to hydrogeologic, geologic or climatic conditions, DOE was required to assume that characteristics of the future remain what they are at the time the compliance application was prepared. DOE was required to document the effects of potential changes to hydrogeologic, geologic and climatic conditions on the disposal system. For geologic conditions, EPA required DOE to address dissolution, near surface geomorphic features and processes, and subsidence in the geologic units of the disposal system. For climatic conditions, EPA required DOE use current climatic conditions for comparison and to consider cycles of increased precipitation.

In accordance with § 194.25(a), DOE provided a description of the future state assumptions for the features, events and processes (''FEPs'') used in the PA and CA. Except where specified otherwise (i.e., §§ 194.32 and 194.33), DOE assumed that current characteristics for the FEPS not related to hydrogeology, geology and climatic conditions will remain constant throughout the 10,000-year regulatory time frame. EPA reviewed the information in the CCA and agrees with the future state assumptions that DOE has made. EPA found this information to be inclusive of all relevant elements of the PA and CA.

To fulfill the requirements of § 194.25(b)(1), DOE predicted the potential future hydrogeologic conditions at the WIPP. DOE developed several future state assumptions about the hydrogeological conditions of the WIPP, such as increased precipitation impacts on recharge location and capacity, hydraulic gradient, and transmissivity in the Culebra member of the Rustler and Dewey Lake formations. In a few cases, DOE found that hydrogeologic conditions can change with time and can possibly affect the PA. DOE addressed these potential changes in the PA. EPA reviewed the adequacy of the uncertainty of key parameter assumptions, such as the impacts of mining subsidence on Culebra transmissivity. EPA found that DOE adequately addressed the effects of mining-induced subsidence on Culebra hydrogeologic conditions. EPA reviewed the future state assumptions DOE made about hydrogeologic conditions and concludes that DOE has accurately characterized and modeled the potential changes from current conditions. EPA found that DOE's incorporation of these changes into the PA was adequate. Other potential changes to hydrogeologic conditions, notably those associated with climate change, are addressed in the discussion of § 194.25(b)(3).

Section 194.25(b)(2) requires DOE to consider the effects of potential changes to geologic conditions on the disposal system. DOE predicted potential future geologic conditions at the WIPP. DOE analyzed the stratigraphy and physiography of undistributed geologic conditions, salt creep and excavation-induced stress changes, geochemistry, seismic activity, disturbed rock zone, dissolution, and mining in the McNutt potash zone above the repository. DOE also analyzed the geologic effects of existing boreholes, brine reservoirs, and drilling intrusions. EPA found DOE's assumptions of the future geologic conditions to cover the significant geologic units and conditions that affect PA and determined that the screening arguments adequately justify the exclusion of the majority of the geological FEPs from the PA and CA. For additional information on the FEPs included in the PA and CA, see § 194.32. EPA evaluated the CCA and additional information provided by DOE at EPA's request regarding the uncertainty associated with deep dissolution and considers DOE's analysis adequate. For additional information on both geologic and hydrogeologic conditions of the WIPP, see § 194.14(a).

Section 194.25(b)(3) requires DOE to consider the effects of potential changes to climatic conditions on the disposal system. At the WIPP, availability of water for recharge is the primary concern related to global climate change. Future global warming would be expected to continue the trend to less precipitation in the vicinity of the WIPP (which would be beneficial to disposal system performance). DOE concluded that global cooling—and increased precipitation—is the worst case scenario for the WIPP. In accordance with § 194.25(b)(3), DOE identified and described the effects of increased precipitation in future cooler climate cycles on the repository. DOE considered potential increased participation over the next 10,000 years and incorporated the uncertainty of the effects of this climate change in the PA through modeling of dissolution, groundwater flow, and potential radionuclide transport in groundwater. DOE described climate change due to

potential natural causes and the resulting changes in recharge rates, groundwater flow velocity, and flow direction. DOE included models of the impact of potential climate changes on groundwater flow in the Culebra over the regulatory time period.

EPA found that the CCA included adequate discussions of the current and previous climate at the WIPP site and found that DOE addressed the impacts of potential climate change over the regulatory time frame. EPA concludes that DOE appropriately considered climate-related factors such as precipitation, temperature, and evapotranspiration that might affect groundwater flow in the regional three-dimensional groundwater basin model. EPA also examined DOE's descriptions of recharge associated with potential climate change effects and found that DOE adequately described the uncertainties associated with potential change to the future climate cycles. For additional information on climate change ground water flow, see §§ 194.14(a) and (i).

In addition, EPA evaluated potential hydrogeologic changes related to climate change, including: groundwater recharge, Culebra flow rate variations, and water table elevation. EPA evaluated the additional information DOE provided at EPA's request regarding vertical inflow to the Dewey Lake Formation and three-dimensional groundwater flow modeling, and concluded that DOE provided adequate documentation to sufficiently address the issues. EPA verified that the CCA acknowledges and quantifies uncertainties in hydrogeologic conditions found in the site characterization data descriptions and modeling assumptions. EPA also found that DOE modeled the effects of climate changes during the next 10,000 years on the groundwater flow in the Culebra. After reviewing the CCA and the additional information provided by DOE at EPA's request, EPA concluded that DOE's explanation of uncertainty associated with the potential wetter climate impacts on Culebra transmissivities resulting from potential dissolution of fracture infillings is acceptable.

EPA determined that the overall CCA approach to dealing with uncertainty, and the examples of conservative assumptions used to compensate for uncertainty, is consistent with the FEPs list, screening arguments, and model descriptions. EPA proposes to find DOE in compliance with § 194.25. For further information on EPA's evaluation of compliance with § 194.35, refer to CARD 25.

E. Section 194.26, Expert Judgment

The requirements of § 194.26 apply to expert judgment elicitation. Expert judgment is typically used to elicit two types of information: numerical values for parameters (variables) that are measurable only by experiments that cannot be conducted due to limitations of time, money, and physical situation; and essentially unknowable information, such as which features should be incorporated into passive institutional controls to deter human intrusion into the repository. (61 FR 5228) Quality assurance (''QA'') requirements in accordance with § 194.22(a)(2)(v) must be applied to any expert judgment to verify that the procedures for conducting and documenting the expert elicitation have been followed.

The requirements of § 194.26(a) prohibit expert judgment from being used in place of experimental data, unless DOE can justify that the necessary experiments cannot be conducted. Expert judgment may substitute for experimental data only in those instances in which limitations of time, resources, or physical setting preclude the successful and timely collection of data.

The CCA submitted on October 29, 1996, did not identify any expert elicitation activities. During the Agency's review of PA parameters, EPA found that inadequate explanation and information was provided on the derivation of 149 parameters identified in the CCA as resulting from professional judgment (e.g., code control parameters, physical constants). The Compliance Criteria do not provide for utilization of ''professional judgment.'' Input parameters are to be derived from data collection, experimentation, or expert elicitation. EPA requested in letters to DOE dated March 19, April 17, and April 25, 1997, that DOE provide additional information on the derivation of the 149 parameters. (Docket A–93–02, Items II–I–17, II–I–25, and II–I–27) In the absence of data collection or experimentation, EPA expected DOE to derive these input parameters through expert elicitation.

DOE responded to EPA's requests by adding information to and improving the quality of the records stored in the Sandia National Laboratory (''SNL'') Records Center to enhance the traceability of parameter values. EPA deemed the documentation provided by DOE adequate to demonstrate proper derivation of all but one of the so-called professional judgment parameters—the waste particle size distribution parameter. The remaining parameters questioned by EPA were found to have adequate documentation to support the values used in the CCA PA calculations. For further discussion of the technical review of PA parameters, see the preamble for § 194.23. EPA required DOE to use the process of expert elicitation to develop the value distribution for the waste particle size parameter. (Docket A–93–02, Item II–I–27)

The waste particle size parameter is important in the PA because it affects the quantity of radioactive materials released in spallings from inadvertent human intrusion. Because particle diameters are uncertain and cannot be estimated either directly from available data or from data collection or experimentation, the waste particle size parameter had to be based on an elicitation of expert judgment.

DOE conducted the expert judgment elicitation on May 5 through May 9, 1997. The process included: definition of technical issues; public notification; selection of experts; general orientation and elicitation training; presentation and review of issues; preparation of expert analysis by elicitor; discussion of analysis by panel members; elicitation; recomposition; review and approval of dissenting opinions provided by experts; and documentation of the process and results. The results of the expert elicitation consisted of a model for predicting waste particle size distribution as a function of the processes occurring within the repository, as predicted by the PA. This particle size distribution was incorporated in the PAVT calculations; for a detailed discussion on the sampling of uncertain parameter distributions, refer to the preamble discussion of § 194.34, ''Results of PA.'' DOE completed a final report entitled, ''Expert Elicitation on WIPP Waste Particle Size Distributions(s) During the 10,000-Year Regulatory Post-closure Period.'' (Docket A–93–02, Item II–I–34) EPA proposes to find that DOE complies with § 194.26(a) because the Agency found adequate support for the derivation of all parameter values with the exception of the waste particle size parameter, for which DOE undertook an expert elicitation.

EPA's review of DOE's compliance with the requirements of § 194.26 principally focused on the conduct of the elicitation process. Sections 194.26 (b) and (c) set specific criteria for the performance of an expert judgment elicitation. DOE must: identify the expert judgments used to support the compliance application; identify the experts involved in the process; describe the process of eliciting expert

judgment; document the results; document that the experts have the necessary independence and qualifications for addressing the questions and issues presented; explain the connection between the questions posed to the expert panel and the manner in which the final report of the panel is used in the compliance application; adhere to requirements on the composition of the expert panel, including the fraction of the panel members who are employed by DOE; assure the public be given the opportunity to present their views in the expert judgment process; and document the elicitation process so as to demonstrate a logical progression from the first statement of issue given to the panel to the combination and presentation in the final report.

EPA observed DOE's elicitation process and conducted an audit of the documentation prepared in support of DOE's compliance with § 194.26. The scope of the audit covered all aspects of the expert judgment elicitation process, including: panel meetings, management and team procedures, curriculum vitae of panel members, background documents, and presentation materials. EPA also assessed compliance with the QA requirements of § 194.22. EPA found that the documentation provided by DOE addressed the requirements of § 194.26(b)(2).

In accordance with § 194.26(b)(1), DOE identified the individual experts on the panel. EPA found that the expert panel was composed of six experts, including four from consulting firms and two associated with universities. Two of the six panel members were DOE contractors at the time of the elicitation.

Therefore, in accordance with § 194.26(b)(7), the panel included at least five individuals, two-thirds of whom were not employed by DOE or DOE contractors. In accordance with § 194.26(b)(3), the panel did not include individuals who will use the judgments or who maintain, at any organizational level, a supervisory role or who are supervised by those who will utilize the judgment. EPA found DOE's documentation to demonstrate compliance with these requirements.

Based on its review of curriculum vitaes and completed organizational conflict of interest forms, EPA determined that the experts on the panel demonstrated the required independence and level of knowledge required by the questions or issues presented. (§ 194.26(b)(4)) EPA found the background and orientation materials addressed the relationship among information and issues as well as the purpose and intent of the judgment, in accordance with § 194.26(b)(5). The Agency determined that the expert elicitation met the requirement at § 194.26(b)(6) since the result of the process was a parameter distribution that could be implemented directly in the PA. EPA also found that DOE afforded the public an opportunity to present scientific and technical views to the expert panel. (§ 194.26(c))

Based on the review of expert elicitation supporting documentation developed by DOE and its contractors, as well as the results of the EPA audit to verify compliance, EPA proposes to determine that DOE complies with the requirements of § 194.26 in conducting the required expert elicitation.

Numerous public comments were received on DOE's statement that it did not conduct any expert judgement activities in developing the CCA. As many commenters correctly pointed out, the CCA did not contain adequate information to allow a reviewer to ascertain whether a large number of the input parameters were properly derived in accordance with the explicit requirements of the Compliance Criteria. DOE subsequently provided additional information, and substantially improved the quality of the records at the SNL Records Center to make it possible to confirm that all but one of the suspect input parameters were adequately supported. For further discussion of EPA's evaluation of compliance with § 194.26 and related public comments, see CARD 26.

F. Section 194.27, Peer Review

Section 194.27(a) requires DOE to conduct peer review evaluations related to conceptual models, waste characterization analyses, and the evaluation of engineered barriers. This section, at §§ 194.27(b) and (c)(1), also requires DOE to submit documentation showing that the required peer reviews were conducted in a manner compatible with NUREG–1297, ''Peer Review for High-Level Nuclear Waste Repositories.'' (Docket A–92–56, Item III–B–1h) NUREG–1297 is incorporated by reference in the Compliance Criteria. As stated in NUREG–1297, the purpose of peer review is to provide confidence in the validity of technical and programmatic judgments involving scientific uncertainty or ambiguity by subjecting those judgments to the evaluation of qualified, independent specialists. (NUREG–1297, p. 2)

DOE completed the required peer reviews and included a description of the peer review process in the CCA. EPA's CAG indicates the types of documentation necessary for § 194.27(b) to demonstrate that peer reviews were conducted in accordance with the NUREG–1297 guidance. For example, the CCA should show the process by which peer review panels deliberated, should present the conclusions they reached, and should show that panel members were qualified and free of conflicts of interest. EPA reviewed the CCA to determine whether DOE's procedures and plans for the required peer reviews were consistent with the CAG and whether the required peer reviews had actually been conducted in accordance with those procedures and plans.

Many of the documents detailing DOE's implementation of NUREG–1297 are kept by DOE as quality assurance (''QA'') records and were not included in the CCA but were made available to EPA. EPA first reviewed the CCA and supplementary reports and confirmed that the required peer reviews had been conducted. To evaluate the peer review process further, EPA conducted an audit of DOE's QA records for peer review in February 1997. The audit consisted of an extensive review of DOE's records and interviews with DOE staff and contractors who managed the required peer reviews. The audit raised several isolated findings, but none of these was sufficient to lead EPA to conclude that any of the peer reviews had been conducted in a manner incompatible with NUREG–1297.

EPA proposes to find DOE in compliance with §§ 194.27(a) and (b). DOE submitted documentation in the CCA showing that the required peer reviews had been conducted. DOE's procedures for the conduct of peer review satisfactorily incorporated the essential elements of NUREG–1297, as identified in the CAG. The audit conducted by EPA verified that DOE properly followed its procedures for peer review.

Section 194.27(c)(1) requires DOE to show that the three required peer reviews, if conducted prior to promulgation of 40 CFR Part 194, were conducted in accordance with an alternative process substantially equivalent to NUREG–1297. Because DOE conducted the required peer reviews after the promulgation of 40 CFR Part 194, this requirement is not applicable.

Section 194.27(c)(2) requires DOE to document any peer reviews conducted by DOE other than those required by § 194.27(a). The additional peer reviews were not required to be compatible with the guidance in NUREG–1297, but EPA recommended in the CAG that they be documented in a manner similar to the required peer reviews. EPA expected

that documentation would be sufficient to identify the purpose, scope, membership, and findings of a given peer review.

DOE developed a list of criteria, based principally on guidance in NUREG–1297, to determine whether a review activity conducted prior to promulgation of the Compliance Criteria constituted a peer review. DOE then identified past activities that met the criteria and incorporated relevant documentation in the CCA. EPA reviewed the materials provided and found that sixteen peer reviews were properly included in the CCA. EPA also found that the CCA contained sufficient documentation to allow EPA to identify the purpose, scope, membership, and findings of those sixteen peer review activities. Therefore, EPA proposes to find DOE in compliance with § 194.27(c)(2).

Comments received in regard to peer review expressed mainly two concerns. First, commenters considered the CCA incomplete because some peer reviews were reopened after the CCA was sent to EPA in October 1996. EPA requested, received, and docketed pertinent documentation resulting from the reopened peer reviews prior to determining that the CCA was complete.

Second, commenters questioned the findings of some peer reviews. EPA's compliance review for § 194.27(b) focused on the extent to which the required peer reviews were conducted in a manner compatible with NUREG–1297. The Agency believes that the critical evaluation of peer review findings is necessary but not directly relevant to DOE's compliance with § 194.27. EPA carefully examined the findings of all peer reviews conducted after the promulgation of 40 CFR Part 194 and discusses them under the relevant technical sections: quality assurance (§ 194.22), conceptual models (§ 194.23), waste characterization (§ 194.24), passive institutional controls (§ 194.43), and engineered barriers (§ 194.44). For further information of EPA's evaluation of compliance for § 194.27, see CARD 27.

XI. Containment Requirements

The disposal regulations include requirements for containment of radionuclides. The containment requirements at 40 CFR 191.13 specify that release of radionuclides to the accessible environment shall not exceed specific limits, which are based on the amount of waste in the WIPP at the time of disposal. (§ 194.31) Assessment of the likelihood that the WIPP will meet these release limits is conducted through use of a process known as performance assessment (''PA''). The WIPP PA essentially consists of a series of computer simulations that attempt to describe the physical attributes of the disposal system (site, geology, waste forms and quantities, engineered features) in a manner that captures the behaviors and interactions among its various components. The computer simulations require the use of conceptual models that represent physical attributes of the repository. The conceptual models are then expressed as mathematical relationships, which are then translated into computer code. The results of the simulations show the potential releases of radioactive materials from the disposal system to the accessible environment over the 10,000-year regulatory time frame. (Models and computer codes are addressed in more detail in the preamble for § 194.23 of the general requirements.)

The PA must include both natural and man-made processes and events which have an effect on the disposal system. It must consider all reasonable potential release mechanisms from the disposal system and must be structured and conducted in a way that demonstrates an adequate understanding of the physical conditions in the disposal system. The PA must evaluate both human-initiated releases (e.g., via drilling intrusions) and releases by natural processes that would occur independently of human activities. The requirements at §§ 194.32 and 194.33 address the scope of PA and the types of human intrusion which must be considered in PA.

The results of PA are used to demonstrate compliance with the containment requirements in 40 CFR 191.13. The containment requirements are expressed in terms of ''normalized releases'' (discussed in more depth in subsequent sections of this preamble). The results of PA are assembled into complementary cumulative distribution functions (''CCDFs'') which indicate the probability of exceeding various levels of normalized releases. Section 194.34 of the WIPP Compliance Criteria imposes specific statistical requirements on the results of PA and on the single curve used to judge compliance with the containment requirements.

A. Section 194.31, Application of Release Limits

Section 194.31 indicates that DOE is to quantify releases of radionuclides from the WIPP in terms of ''cumulative releases,'' which are calculated from ''release limits.'' Release limits for radionuclides at a radioactive waste disposal facility must be calculated in accordance with 40 CFR Part 191, Appendix A. There, a ''release limit'' for a radionuclide is introduced as a measure of the cumulative amount of radioactivity, measured in curies, that is allowed to reach the accessible environment (that is, land surface, the atmosphere, surface waters, oceans, and all the land beyond the boundary of the WIPP land withdrawal area) over the 10,000 years after the disposal[23] of radioactive waste. Release limits are to be calculated using the activity from radioactive waste, in curies, that will exist in the WIPP at the time of disposal.

To calculate normalized releases and release limits, DOE must first identify all the radionuclides that are present in the waste that it plans to put in the WIPP (e.g., plutonium-238). Next, the Department projects which radionuclides will be present in the waste at the time of disposal, including those isotopes created by radioactive decay between the time of the waste inventory (approximately 1995) and the time of disposal (estimated to be the year 2033). DOE then determines which of these radionuclides emit alpha-particles, have an atomic number greater than that of uranium (transuranic), and have half-lives greater than twenty years. These radionuclides comprise the ''TRU component'' of the waste. The total activity of the TRU component of the waste, in curies, divided by one million curies, is called the ''waste unit factor.'' For the WIPP, Table 1 of Appendix A of 40 CFR Part 191 presents values of release limits (in curies) per unit of this ''waste unit factor.''

To obtain the release limit for a radionuclide, DOE must multiply each release limit value in Table 1 by the numerical value of the waste unit factor. Finally, to obtain the normalized release for a scenario, DOE must divide the projected estimated release (obtained from PA modeling), in curies, for every radionuclide (whether TRU or non-TRU) by its respective release limit, and sum these quotients.

In the CCA, the Department provided an inventory of the various radionuclides in the waste expected at the time of disposal, including those radionuclides in the waste inventory that are currently stored at different DOE sites, those radionuclides that are projected to be generated at different DOE sites between 1995 and the time of

[23] ''Disposal'' is defined as ''[P]ermanent isolation of . . . radioactive waste from the accessible environment with no intent of recovery whether or not such isolation permits the recovery of such fuel or waste. For example, disposal of waste in a mined geologic repository occurs when all of the shafts to the repository are backfilled and sealed.'' 40 CFR 191.02(l)

disposal, and those radionuclides that would be created by radioactive decay between the time of the waste inventory in 1995 and the time of disposal, approximately in the year 2033. The waste inventory showed that plutonium and americium produce almost all of the radioactivity from waste that would be in the WIPP at the time of disposal. Based on the fifteen radionuclides in the inventory that were transuranic, alpha-emitting, and had half-lives greater than twenty years, DOE calculated that the relevant total activity at the time of disposal would be 3.44 million curies and that the waste unit factor would be 3.44.

DOE used the waste unit factor to obtain the release limit for each radionuclide found in Table 1 in Appendix A of 40 CFR Part 191. These release limits were then used in the calculation of cumulative releases. The Department designated six transuranic radionuclides that contributed more than 99.9 percent of the activity as ''major radionuclides.'' The Department calculated the release limits and relative contributions to releases for the six major radionuclides using a computer program called EPAUNI. The Department verified the computer calculations with sample hand calculations.

EPA reviewed DOE's description of the procedure used to estimate the activity of waste proposed for disposal, examined DOE's hand calculations, and verified the computer code and output to determine whether DOE correctly calculated the waste unit factor, including radioactive decay up to the year 2033. EPA also evaluated whether DOE appropriately calculated release limits for each major radionuclide and identified the relative contribution of each major radionuclide.

EPA found DOE's simplification of using the six transuranic radionuclides that contribute the greatest activity in computer calculations to be appropriate. Because these six radionuclides would make up more than 99.9 percent of the activity from the transuranic waste, DOE's simplification could contribute at most an error of 0.1 percent to its calculations of the contribution to releases from individual radionuclides, which would not have a significant impact upon the calculation of release limits or the contribution to releases from individual radionuclides.

EPA found that the TRU waste component used to calculate the waste unit factor of 3.44 omitted some waste stored at an off-site facility at Savannah River. DOE corrected this error by recalculating the waste unit factor based on a TRU inventory that included the Savannah River waste; the revised waste unit factor was 3.59. EPA did not require DOE to recalculate the release limits based on the new value for the waste unit factor, because using the larger revised factor would have resulted in higher release limits (and thus, lower normalized releases). That is, the use of the incorrect value in the CCA is more conservative than using the correct value of 3.59. The correction of the error would only show that the WIPP will comply with the disposal regulations by a wider margin than had been previously demonstrated.

The Agency confirmed that the Department calculated the waste unit factor of 3.44 and the release limits at the time of disposal in accordance with the requirements of Appendix A of 40 CFR Part 191. In addition, the Agency found that the Department correctly identified the relative contribution of each major radionuclide to releases. Finally, the Agency confirmed that the computer codes, model results, and hand calculations were consistent and thus supported the use of the computer codes. Because the Agency's review concluded that the Department calculated release limits for the WIPP using an appropriate methodology and conservative waste inventory estimates, the Agency proposes that the requirements of § 194.31 have been met. For further information on EPA's evaluation of compliance for § 194.31, see CARD 31.

B. Section 194.32, Scope of Performance Assessments (PA)

Section 194.32 requires DOE to consider, in the performance assessment (''PA''), both natural and man-made processes and events which can have an effect on the disposal system. EPA expected DOE to consider all features, events and processes (''FEPs'') that may have an effect on the disposal system. In particular, EPA expected DOE to consider mining effects on hydraulic conductivity, fluid injection, future development of leases and existing boreholes in the scope of the PA. The CCA was also expected to document which FEPs (or sequences or combinations of FEPs) are included in the PA. DOE is required to document the decision not to include any feature, event, or process in the PA. Deep and shallow drilling, over the regulatory time frame, are addressed in more detail in the preamble discussion of § 194.33.

To fulfill the requirements of §§ 194.32(a), (d) and (e), DOE developed and followed a process for considering FEPs in the PA. DOE initially identified 1,200 FEPs from a list of FEPs developed by the Swedish Nuclear Power Inspectorate (''SKI''). This list was compiled and categorized based on location of occurrence and cause by nine organizations world wide. DOE modified this list to make it relevant to WIPP. DOE's final list of FEPs was then classified and screened for consideration in the PA. DOE screened FEPs from consideration in the PA based on regulatory exemption, low probability and low consequence. FEPs were then combined to form scenarios. Scenarios were also screened based on regulations, probability or consequence. The remaining scenarios were retained for implementation in the PA. The CCA documents DOE's decision not to include specific FEPs in the PA.

Approximately 237 FEPs were retained for screening. DOE concluded that 17 of 72 initial natural FEPs should be retained for the PA, including stratigraphy, shallow dissolution, saturated groundwater, infiltration, precipitation, and climate change. Of 108 waste and repository-induced FEPs, DOE concluded that 51 of these should be retained for the PA, including disposal geometry, waste inventory, salt creep, backfill chemical composition, actinide solubility, spallings, and cavings. DOE concluded that 15 of the 57 human-initiated events and processes should be retained for the PA, including oil and gas exploration. Examples of FEPs screened from use in the PA include: lateral dissolution, regional tectonics, salt deformation, mechanical effects of backfill, liquid waste disposal and groundwater extraction.

EPA concluded that the initial FEP list assembled by DOE was sufficiently comprehensive, in accordance with §§ 194.32(a) and (e)(1). In compiling this list, DOE appropriately screened out events and processes on the basis of probability, consequence or regulatory requirements. DOE considered and incorporated into the PA numerous natural processes and events, mining, and deep drilling. DOE considered shallow drilling and appropriately screened it out on the basis of low consequence. (See preamble for § 194.33.)

Based on quantitative and qualitative assessments provided in the CCA and supporting documents, EPA concluded that DOE appropriately rejected those FEPs that exhibit low probability of occurrence during the regulatory period, in accordance with § 194.32(d).

Review of the CCA and the submitted supporting documents confirms that DOE used a thorough process to identify all the appropriate FEPs as well as the related combinations and sequences that can potentially occur within the

regulatory time frame and affect disposal system performance. EPA determined that the process is sufficiently documented and that DOE justified the retention and elimination of FEPs. In addition, EPA found DOE's inclusion of various scenarios in the PA to be reasonable and justified, and meets the requirement of § 194.32(e)(2). DOE provided documentation and justification for eliminating those FEPs that were not included in the PA. In some cases (e.g., fluid injection and dissolution), the CCA did not provide adequate justification or convincing arguments to eliminate FEPs from consideration in PA. (Fluid injection is discussed in more detail below, relative to compliance with § 194.32(c).) However, DOE provided supplemental information and analyses to demonstrate compliance with § 194.32(e)(3). EPA found this supplementary information to be adequate in fulfilling the requirements to justify FEP exclusion from the PA.

For disturbed scenarios (i.e., human activities), DOE discussed how mining was incorporated into the PA. DOE identified potash as the only natural resource currently being mined near the WIPP. DOE, in accordance with § 194.32(b), used the EPA-specified mining probability and considered changes in hydraulic conductivity up to 1000 times the base hydraulic conductivity of the Culebra. In its calculation of the potash area to be mined, DOE considered minable reserves inside and outside of the controlled area. The Compliance Criteria require DOE to examine only currently extractable resources, not to speculate on what other resources may become economically viable.

EPA verified, through review of the CCA and supporting documents, that DOE included, in the PA, appropriate changes in the hydraulic conductivity values for the areas affected by mining. These values for hydraulic conductivity considered the impact of institutional controls on mining, mining practices and mineral resources. The area considered to be mined for potash in the controlled area is consistent with the requirement of § 194.32(b), that the mined area be based on mineral deposits of those resources currently extracted from the Delaware Basin. EPA proposes to find that DOE complies with § 194.32(b).

EPA's review of the CCA raised questions regarding DOE's analysis, in accordance with § 194.32(c), of human-initiated activities, including fluid injection. The fluid injection scenario has been of particular concern to the public because of events that occurred in the Rhodes-Yates oil field, about 40 miles east of WIPP but outside the Delaware Basin. An oil well operator, Mr. Hartman, drilling in the Salado Formation in the Rhodes-Yates Field, encountered a salt water blowout in an oil development well. In subsequent litigation, the court found that the source of the water flow was injection water from a long-term waterflood borehole located more than a mile away.

DOE addressed the fluid injection scenario in the CCA with an analysis of waterflooding (for enhanced oil recovery) and brine disposal activities. (Docket A–93–02, Item II–G–1, Reference #611) In accordance with § 194.32(c), DOE determined that these two activities were the only fluid injection scenarios that were currently occurring or could be initiated in the near future in the vicinity of the WIPP. DOE identified the Bell Canyon Formation under the Salado and Castile Formations as the primary target for fluid injection for brine disposal. DOE stated that this scenario had the potential to produce more brine inflow to the WIPP. DOE modeled the fluid injection scenario using WIPP geology, and again using the geology identified in the Rhodes-Yates Field. The two sites differ significantly because the Castile Formation, which underlies the Salado at the WIPP, is absent in the Rhodes-Yates Field. DOE assumed that fluid injection activities would occur continuously for 50 years, and evaluated the subsequent effects of such injection activities over the entire 10,000-year regulatory time frame. The modeling results indicated that some brine could potentially get into the WIPP from fluid injection activities. However, the amount of brine from the worst case scenario (the ''Rhodes-Yates'' scenario) was low compared to the amount of brine expected to enter the waste area naturally. DOE thus screened out the fluid injection scenario on the basis of low consequence.

EPA's review of the CCA raised additional questions regarding DOE's screening analysis of fluid injection. EPA believes that 50 years is an accurate estimate for the life of a single oil field, but that it does not account for the possibility of multiple fields. Because drilling restrictions currently applicable to potash areas in the Delaware Basin could be lifted, it is possible that multiple oil fields could be developed in the foreseeable future near the WIPP. Based on the current resources and leases in the vicinity of the WIPP, EPA estimated that oil could still be drilled up to 150 years from now. EPA thus required DOE to extend the 50-year time frame in its models to 150 years. EPA also required DOE to use modified values for some input parameters, and to model the behavior of the disturbed rock zone consistent with assumptions used in the PA. (Docket A–93–02, Item II–I–17) Finally, EPA required DOE to provide additional information on the frequency of fluid injection well failures.

In supplemental work on fluid injection, DOE addressed all the issues identified by EPA. DOE modified the computer model grid configuration and added a new model to address concerns raised by both EPA and stakeholders. DOE researched injection well operating practices and construction in the Delaware and identified significant differences between those in the vicinity of the WIPP and the Rhodes-Yates Field. For example, wells near the WIPP are typically less than ten years old and are constructed to much higher mechanical standards than the older, less robust wells found in the Rhodes-Yates Field. DOE identified a range of well failure scenarios, from undetectable brine flow to catastrophic well failure. DOE's data indicated that the probability of a catastrophic well failure in the vicinity of the WIPP is extremely low. DOE confirmed that the presence of the Castile at the WIPP also substantially inhibits injected brine movement into the Salado anhydrite markerbeds.

Public comments on this issue included a detailed report that contradicted the DOE fluid injection modeling and indicated that fluid injection activities could overwhelm the WIPP with brine. (Docket A–93–02, Item II–H–28) EPA has reviewed the report and considers it to model conditions that are highly unrealistic for the WIPP. For example, all modeled scenarios assumed that the entire volume of brine was injected directly into the anhydrite marker beds in the Salado Formation. In addition, the report modeled the occurrence of fluid injection well beyond the time frame contemplated by § 194.32(c). The report also ignored current well construction and fluid injection operating practices, which are more robust than that used in the 45-year-old Rhodes-Yates Field.

EPA agreed with commenters that the original fluid injection screening was not adequate. Thus EPA required DOE to provide additional information and to do additional modeling. The additional modeling showed rates of brine inflow (and thus effects on the disposal system) even smaller than those estimated by the original CCA screening analysis. DOE provided documented evidence that the well construction and operating practices near the WIPP are much more robust than that in the Rhodes-Yates

well. Both DOE's research and EPA's own review of fluid injection, indicated that the probability of a long-term fluid injection well failure is below the regulatory cutoff of 1 in 10,000 over 10,000 years. Based on DOE's modeling and examination of fluid injection practices, EPA believes that a salt water blowout situation in the Rhodes-Yates Field is extremely unlikely to occur and affect WIPP's ability to contain radionuclides. Thus, EPA concurs with DOE that fluid injection is a low-probability scenario that can be screened out of the PA based on low consequence.

DOE, in accordance with § 194.32(c), also identified oil and gas exploration and exploitation, and water and potash exploration as the only near future human-initiated activities that need to be considered in the PA. DOE included and assessed the potential effects of existing boreholes as part of its FEPs screening analysis. DOE concluded that natural borehole fluid flow through abandoned boreholes would be of little consequence during current and operational phase activities. In addition, DOE screened out the occurrence of flow through undetected boreholes based on low probability.

To further address § 194.32(c), DOE assessed scenarios ranging from the effects of deep and shallow drilling and mining to undisturbed disposal system performance. DOE retained the FEPs describing both undisturbed and disturbed system performance. DOE identified the specific locations in the CCA that related to modeling of the individual FEPs. These discussions focused on conceptual model development, but often linked the conceptualizations with associated computational (computer) models.

EPA's review of the CCA and supporting documents referenced in the CCA with respect to § 194.32(c), indicated that DOE adequately analyzed the possible effects of current and future potential activities on the disposal system. However, DOE inadequately analyzed in the application some future activities in the vicinity of the disposal system, including injection of drilling fluids for brine disposal and enhanced oil recovery, solution mining, and full extraction potential of the leaseholds (in the vicinity of WIPP). In response to the concerns expressed by EPA and stakeholders, DOE conducted additional analyses and submitted follow-up information. This information was adequate and EPA concurred with the conclusions, concluding that DOE's analysis met the requirements of § 194.32(c).

In summary, EPA proposes to find DOE in compliance with § 194.32. For further information on EPA's evaluation of compliance for § 194.32, refer to CARD 32.

C. Section 194.33, Consideration of Drilling Events in PA

Section 194.33 requires DOE to make specific assumptions about future deep and shallow drilling in the Delaware Basin. Section 194.33 requires that the following assumptions be incorporated into the PA: drilling will occur randomly in space and time; the drilling rate may vary with the resources; drilling practices will remain constant for a single resource but may be different for others; and plugging practices will remain constant, but the permeability of a borehole may change with time. Deep and shallow drilling practices and related activities can directly impact the cumulative potential for contaminant release to ground, surface or geologic units.

For this requirement, EPA required DOE to discuss the resources for which deep and shallow drilling occur in the Delaware Basin. DOE was also required to describe the techniques and rates for deep and shallow drilling for each resource. In these analyses, DOE was required to document assumptions and sources of information. EPA also required DOE to document assumptions that DOE made in analyzing the consequences of drilling events in PA. Finally, DOE was required to evaluate the effects of boreholes on the properties of the disposal system.

To fulfill the requirements of § 194.33(a), DOE identified several deep and shallow drilling activities as being present in the Delaware Basin. DOE identified oil and gas exploration and exploitation, and water and potash exploration, as the principal drilling activities to be considered in the PA. The shallow drilling components of these activities were screened from inclusion in the PA because DOE considered these activities to be of low consequence to PA calculations. DOE considered three scenarios in PA for deep drilling: (1) One or more boreholes penetrate(s) the Castile brine reservoir and also intersect(s) a repository panel, (2) one or more boreholes intersect(s) a repository panel, and (3) multiple penetrations of waste panels, by boreholes of the first or second type, at many possible combinations of intrusion times, locations and combinations of borehole types. EPA found that the PA incorporated deep and shallow drilling events, in accordance with § 194.33(a).

To comply with the requirements of § 194.33(b), DOE incorporated assumptions into the PA about the severity, frequency and randomness of human intrusion. DOE considered intermittent and inadvertent drilling, including exploratory and developmental drilling, as the most severe human intrusion scenarios and used them to calculate cumulative radionuclide releases. The drilling rate is one of the most important parameters affecting compliance with the containment requirements. Using a publicly available petroleum database, DOE established the rate of future deep drilling to be 46.8 boreholes per square kilometer per 10,000 years. EPA found that DOE identified the number of deep drilling events for each resource, and that sources of information used to do so were thorough and appropriate. (The rate of shallow drilling in the Delaware Basin was not needed because, as noted above, shallow drilling was screened from inclusion in the PA based on low consequence.) DOE applied the deep drilling rate in the PA by randomly sampling with respect to: (1) The location of a borehole in the repository footprint, and (2) the time of occurrence during the regulatory time frame. EPA therefore proposes to find DOE in compliance with § 194.33(b).

DOE evaluated, in accordance with § 194.33(c), the consequences of drilling events assuming that drilling practices and technology remain consistent with practices in the Delaware Basin at the time the certification application was prepared. DOE evaluated borehole drilling and borehole seal degradation for their effects on properties of the disposal system and their impact on radionuclide migration and transport. DOE determined that boreholes can impact radionuclide migration and transport through cuttings, cavings, spallings and direct brine releases. In addition, DOE considered the effects of borehole degradation and its impact on the permeability of borehole plugs.

EPA and public commenters disagreed with the constant value DOE used in the PA for the short-term (up to 200 years after disposal) borehole plug permeability. EPA therefore directed DOE to use a range of borehole plug permeabilities when conducting the EPA-mandated Performance Assessment Verification Test (''PAVT''). While EPA's sensitivity analysis indicated that the short-term plug permeability affected some performance measures, the results of the PAVT demonstrated that the range of short-term plug permeability values, compared to the long-term borehole permeability, had little impact on the results of modeling.

EPA and public commenters also disagreed with DOE's use of a small range of values for the long-term borehole plug permeability. (Docket A–93–02, Item II–I–17) For example, one commenter asserted that DOE should evaluate both ''perfect plugs'' (i.e., low permeability) and plugs that ''fail'' (i.e, very high permeability). (Docket A–93–02, Item II–E–34, comment #113) In the PAVT, the long-term borehole plug permeability was changed so that the sampled parameter range included both low and high permeability values to simulate perfect plugs and borehole plug failure, respectively. Low permeability plugs did increase releases by increasing repository pressure and allowing more spallings and direct brine releases. However, the PAVT results indicated that changing the long-term borehole permeability, in combination with several other changes requested in public comments (notably those related to pressurized brine pockets), still would not cause predicted releases to violate the containment requirements; this indicates that the original CCA parameter values were acceptable for comparison to the containment requirements. (See preamble discussion of § 194.34 for further information on the PAVT.)

EPA reviewed the information contained in the CCA and concluded that DOE demonstrated that the effects of drilling events have been adequately considered. EPA found that the documentation in the CCA demonstrated that DOE thoroughly considered deep and shallow drilling activities and rates within the Delaware Basin. EPA found that DOE appropriately screened out shallow drilling from consideration in the PA. EPA also found that DOE appropriately incorporated the assumptions and calculations for drilling into the PA as stipulated in §§ 194.33(b) and (c). EPA determined that the PA models did not incorporate the effects of techniques used for resource recovery, in accordance with § 194.33(d). EPA further concludes that the information in the CCA is consistent with available data. EPA proposes to find DOE in compliance with the requirements of § 194.33. For further information on EPA's evaluation of compliance for § 194.33, see CARD 33.

D. Section 194.34, Results of PA

The containment requirements at § 191.13 indicate that a disposal system is to be tested through a PA that predicts the likelihood of occurrence of all significant processes and events that may disturb the disposal system and affect its performance, and that predicts the ability of the disposal system to contain radionuclides. Section 194.34 of the Compliance Criteria provides specific requirements for presenting the results of the PA for the WIPP.

The restriction on releases of radioactive material is expressed in terms of ''normalized releases'' or ''cumulative releases.'' Normalized releases refer to amounts of radioactivity projected (by means of the mathematical models of the PA) to be released from the repository over 10,000 years under various physical conditions and intrusion scenarios. To calculate the normalized release for a given intrusion scenario, one first obtains the normalized release separately for each individual radionuclide; this involves dividing the amount projected to be released, in curies, by its radionuclide-specific release limit, as calculated in accordance with Appendix A of 40 CFR Part 191. (See the discussion of release limits for § 194.31 in today's preamble.) One then adds together the normalized releases for all radionuclides to determine the overall normalized release for the scenario. Section 191.13 requires that a disposal system be designed so that there is reasonable assurance that cumulative releases (1) have a probability of less than one in ten (0.1) of exceeding the calculated release limits, and (2) have no more than a one in one thousand (0.001) chance of exceeding ten times the calculated release limits.

Section 194.34 requires DOE to use complementary cumulative distribution functions (''CCDFs'') to express the results of the PA. The Department also must document the development of probability distributions, and the computational techniques used for drawing random samples from these probability distributions, for any uncertain parameters used in PA. The PA must include a statistically sufficient number of CCDFs; in particular, the number of CCDFs must be large enough to ensure that the maximum CCDF curve exceeds the 99th percentile of the population of CCDFs, with at least a 95 percent probability, at the specific values of 1 and 10 for normalized releases. The CCA must display the full range of CCDFs generated. Finally, the CCA must demonstrate that the mean of the population of CCDFs meets the containment requirements of § 191.13 with at least a 95 percent level of statistical confidence.

EPA found that the CCA PA demonstrated that the WIPP meets the containment requirements of § 191.13 by more than an order of magnitude in probability. The largest release at any point on the mean CCDF curve was a normalized release of only 0.3. The PA calculations indicated no cases where cumulative releases would be ten times greater than the release limits.

In the process of reviewing the CCA, the Agency and public commenters raised concerns about certain assumptions and specific parameter values incorporated into the PA. Also, DOE found some coding problems in the PA computer software. The Agency therefore directed the Department to conduct additional modeling that included corrections to computer coding problems and modifications to parameter values and distributions. The PAVT also excluded the assumption of credit for passive institutional controls. EPA required this additional modeling in the PAVT in order to determine whether the cumulative impact of the changes in the PA codes and parameters would be small enough that the WIPP would still meet the containment requirements of § 191.13. (For further discussion of parameter values, see the discussion of parameters in the preamble for § 194.23.) The results of the PAVT showed somewhat higher cumulative release values than the original CCA PA. However, even these higher cumulative release values were more than an order of magnitude lower than the containment requirements, at the probability levels prescribed by § 191.13. Based upon the results of the CCA PA and the PAVT, EPA proposes to find that the WIPP meets the containment requirements of § 191.13.

Further discussion of the specific compliance criteria of § 194.34 follows.

1. Complementary Cumulative Distribution Functions (CCDFs)

Section 194.34(a) requires DOE to report the results of the PA in the form of ''complementary, cumulative distribution functions'' (''CCDFs''), which may be presented graphically as a set of curves. A CCDF curve presents the probability that releases from the repository, caused by all significant processes and events, might exceed any particular level of cumulative (normalized) release. That is, a point on a CCDF curve displays, on the vertical axis, the relative number of release scenarios or ''futures'' that could result in calculated releases larger than the corresponding normalized release value found on the horizontal axis. Each CCDF curve starts with a maximum probability of one on the left side of the graph (i.e., there is a 100% probability that cumulative releases from the disposal system will be either zero or greater, and will not take on negative values); and then decreases toward the right as the normalized release becomes

larger, and as relatively fewer simulations yield releases that exceed the corresponding normalized release value.

Each CCDF curve in the CCA is calculated using 10,000 simulations or ''futures,'' each of which models a ten-thousand year period in which a series of human intrusion events may occur. (For further information about how the possible effects of human intrusion are included in the PA, see the preamble discussions of §§ 194.32 and 194.33.) A single CCDF curve uses a fixed set of uncertain physical, chemical and geologic characteristics at the WIPP and its surroundings, but uses 10,000 different, randomly-determined sequences of intrusion events. Different CCDF curves are developed by using different information about the uncertain physical, chemical and geologic characteristics of the WIPP and its surroundings. The CCA PA included 300 different CCDF curves so that, in all, it calculated normalized releases for three million different possible futures.

EPA reviewed features, events and processes, scenarios, conceptual models and computer codes that support CCDF generation. EPA found that all significant features, events and processes and scenarios were included in the generation of CCDFs. (See preamble discussions of §§ 194.32 and 194.33 for more detailed information on EPA's evaluation of PA scenarios.) DOE used the same approach in calculating and presenting results of the Performance Assessment Verification Test (''PAVT'').

The Agency found that DOE assembled the results of the CCA PA and the PAVT into CCDFs incorporating all significant processes and events. Therefore, the Agency proposes to find DOE in compliance with the requirements of § 194.34(a).

2. Generation of the Full Range of CCDFs

Section 194.34(e) requires the CCA to display the full range of CCDFs generated. The CCA included all three hundred CCDFs. These were presented in three graphs, one for each replicate of one hundred CCDF curves. In addition, DOE provided summary CCDF curves for descriptive statistics. DOE generated a mean CCDF curve, 95th-percentile confidence bound curves for the mean, a 10th percentile curve, a median curve, and a 90th percentile curve for each replicate, and generated a mean curve and 95th-percentile confidence bound curves for the mean of all three replicates. The Department also provided the same information for the PAVT.

EPA determined that the CCA displayed the full range of CCDF curves over the full range of CCDF values and displays normalized releases relevant to the determination of DOE's compliance with § 194.34(e). EPA also concluded that DOE applied the same methodology to the PAVT for displaying the full range CCDF curves over the full range of probabilities and normalized releases. Therefore, EPA proposes to find that DOE has demonstrated compliance with § 194.34(e).

3. Probability Distributions and Random Sampling of Uncertain Parameters

Section 194.34(b) requires DOE to develop and document probability distributions for uncertain disposal system parameter values used in PA. Section 194.34(c) requires DOE to use and to document computational techniques which draw random samples from across the entire range of these probability distributions to generate CCDFs.

Parameters are numerical values or ranges of numerical values used to describe different physical and chemical aspects of the repository, the geology and geometry of the area surrounding the WIPP, and possible scenarios for human intrusion. Some parameters are well-established chemical and physical constants, such as Avogadro's Number or the Universal Gas Constant. Other parameters describe characteristics unique to the WIPP, such as the solubility and mobility of specific actinides in brines in the WIPP. It is not possible to determine a single, constant value to describe particular characteristics of the WIPP, in which case one must consider a range of values. The relative probabilities of occurrence of different uncertain parameter values within that range can be presented as a mathematical expression known as a probability distribution. A probability distribution may be described in terms of statistical parameters such as the average (mean), median, maximum and minimum values of the parameter, or standard deviation. Section 194.34(b) requires development and documentation of these probability distributions.

DOE selected 57 uncertain parameters whose values were to be obtained through random sampling in the PA. DOE also performed a sensitivity analysis to show if changes to some parameter values would affect the results of PA.

The uncertainty in the value of a parameter is built into PA computer codes by programs that ''sample,'' or select, numeric values from within the probability distribution for that parameter. Section 194.34(c) requires these sampling techniques to draw random samples from across the entire range of each probability distribution. This requirement ensures that PA calculations fully consider the possible extremes of calculated releases of radioactivity without systematically underestimating or overestimating releases.

The Department used the Latin Hypercube Sampling (''LHS'') code to sample the parameter distributions related to physical, chemical and geologic conditions of the repository and its surroundings. DOE used Monte Carlo-type random sampling to determine the effects of human intrusion through drilling or mining. Both codes select values from across the entire range of the probability distributions. The LHS code requires fewer samples to cover the entire range of the distribution because it samples randomly within divisions spread across the entire probability distribution.

EPA reviewed the parameters used in the modeling, the probability distributions for the sampled parameters and DOE's sensitivity analysis. As a result of its review, the Agency found that 58 parameter values and distributions were not well supported by the data available. (See the preamble discussion of § 194.23 for further details on EPA's review of parameters.) EPA performed its own sensitivity analysis on some parameters to determine if uncertainties in the parameter values of concern would have a significant impact on the PA. The Agency concluded that many of the parameters of concern had little impact, but twenty-four parameters could significantly affect the PA results, either individually or in combination with other parameters.

As a result of the parameter review, EPA requested that DOE perform additional modeling. This additional modeling, the PAVT, included, among other things, parameter value and distribution modifications to twenty-four parameters that the Agency believed might have a significant impact on the results of PA. DOE conducted the PAVT using the same computer codes and the same sampling methodologies as for the CCA PA, but changed the 24 parameters in accordance with EPA's direction and modified some of the computer codes in response to EPA's questions about the codes. DOE conducted 300 simulations for the PAVT, resulting in 300 CCDF curves, just as for the CCA PA. The results of the PAVT showed higher normalized releases than those in the CCA PA, but were still more than an order of

magnitude below the containment requirements at § 191.13. Thus, the PAVT incorporated changes that addressed EPA's concerns about PA, and showed that the resulting releases were still within the containment requirements. Because the PAVT used identical technical methods to the CCA PA, EPA concludes that the PAVT results are numerically equivalent to those that would be obtained by performing a new PA incorporating the changes required in the PAVT. EPA believes that the PAVT verifies that the original CCA PA was adequate for comparison against the radioactive waste containment requirements.

Because DOE has developed and documented the probability distributions for uncertain disposal system parameter values used in the PA, EPA proposes to find the DOE to be in compliance with § 194.34(b). After reviewing the results of sensitivity analyses and of the PAVT, the Agency concludes that the probability distributions are adequate. The Agency found that the LHS and Monte Carlo sampling techniques draw random samples from across the entire ranges of the probability distributions used for the uncertain disposal system parameters in the PA. The use of these computational techniques are documented in the CCA. Therefore, EPA proposes to find that DOE has demonstrated compliance with § 194.34(c).

4. Sufficient Number of CCDFs Generated

Section 194.34(d) requires DOE to generate a sufficiently large number of CCDF curves to ensure that, at cumulative releases of 1 and 10, the maximum CCDF exceeds the 99th percentile of the population of CCDFs with at least a 95-percent probability. Section 194.34(d) also requires DOE to calculate cumulative release values according to Note 6 of Table 1 in Appendix A of 40 CFR Part 191.

The PA process uses techniques based upon probability theory to calculate the potential for releases. Because of the many sources of uncertainty, a computer model could calculate results of billions of situations without exhausting every possibility. However, running billions of simulations is not feasible given the cost and time involved. Furthermore, this is not necessary in order to provide a reasonable expectation that a disposal system will contain waste and protect human health and the environment. So long as the PA includes a large enough number of randomly-produced simulations covering the full range of possible calculated release values, the results of PA will yield a valid result that shows whether or not a disposal system meets the containment requirements of § 191.13. (61 FR 5230) Section 194.34(d) provides a statistical test to determine if the CCA contains enough CCDF curves: there must be at least a 95 percent probability that the CCDF curve generated in PA with the highest cumulative release exceeds the 99th percentile of the entire population of CCDFs (that is, the full range of possible calculated release values).

As was mentioned above in this section, each CCDF is generated using a specific set of sampled values from distributions of uncertain parameters related to the physical, chemical and geologic conditions of the repository and its surroundings. In the case of the WIPP, the CCA PA included three sets or replicates of one hundred CCDF curves, for a total of 300 CCDF curves. Each of the CCDF curves is based upon a sample of 57 uncertain parameters.

DOE used the LHS code to take samples of the parameter values. The Department also presented a probabilistic analysis, based on the definition of the 99th percentile, and determined that there would be a 0.95 probability that at least one CCDF curve will exceed the 99th percentile so long as the PA includes at least 298 CCDF curves. Since the CCA PA included 300 CCDF curves, DOE concluded that this was enough CCDF curves to meet the requirements of § 194.34(d).

EPA agreed with DOE's argument based upon probability and the definition of the 99th percentile, and concluded that the CCA PA generated a sufficient number of CCDFs. As another approach to evaluating compliance with § 194.34(d), EPA also examined the statistical characteristics of the 300 CCDF curves in the CCA PA. EPA compared the CCDF curves in the CCA PA to a statistical distribution that the Agency believes is a plausible description of what the entire population of all possible CCDFs would produce. EPA found that the maximum CCDF curve in the CCA PA had a higher cumulative release than the 99th percentile predicted using the probability distribution which represents the entire population of CCDFs. Based upon this statistical analysis, the Agency concluded that there was at least a 95 percent probability that the maximum CCDF curve would exceed the 99th percentile of the population of CCDFs.

Section 194.34(d) also requires PA to calculate cumulative release values according to Note 6 of Table 1 in Appendix A of 40 CFR Part 191. DOE's approach to calculating cumulative release (or ''normalized release'') values is described in the introduction to this section of the preamble. EPA found DOE's approach to be consistent with Note 6 of Table 1 in Appendix A of 40 CFR Part 191.

EPA found that DOE generated 300 CCDF curves in the PA, using the appropriate method to calculate cumulative releases, as specified in Note 6 of Table 1 in Appendix A of 40 CFR Part 191. Because of the statistical arguments described above, EPA is satisfied that the number of CCDFs is large enough such that, at cumulative releases of 1 and 10, the maximum CCDF generated exceeds the 99th percentile of the population of CCDFs with at least a 0.95 probability. Therefore, EPA proposes to find that DOE has demonstrated compliance with § 194.34(d).

5. Compliance of the Mean CCDF

Section 194.34(f) requires the CCA to demonstrate that the mean of the population of CCDFs meets the containment requirements of § 191.13 with at least a 95 percent level of statistical confidence. This statistical demonstration allows DOE to demonstrate compliance using a finite number of CCDFs, rather than having to generate the entire (infinitely large) population of CCDFs.

In order to meet the requirements of § 194.34(f), DOE must calculate the mean CCDF curve from all 300 CCDF curves generated in the CCA PA, must compute the 95 percent confidence limits for that overall mean curve, and must compare the 95 percent upper confidence limit CCDF curve to the containment requirements of § 191.13. The DOE must show that the mean of its 300 CCDF curves, and the 95th percentile upper confidence limit on the mean, both lie below a probability of 0.1 at a cumulative release value of 1, and lie below a probability of 0.001 at a cumulative release value of 10.

In the CCA, DOE presented the steps used in its PA to generate the 300 CCDF curves. DOE also showed how it then calculated the mean of all CCDFs, by first computing the mean CCDF for each of the three replicates of 100 curves, and then averaging those three mean CCDF curves. Using the three mean CCDF curves, DOE calculated the 95 percent confidence limits for the overall mean CCDF curve. DOE identified the mean of all CCDFs generated and the 95 percent confidence limits and showed that both the mean CCDF and the CCDF for the upper confidence limit satisfy the containment requirements by more than an order of magnitude.

EPA examined DOE's calculations of the mean CCDF curve and the CCDF curve for the 95 percent confidence limit on the mean, and found that they were appropriate and were correctly executed. EPA concurred with DOE's conclusion that both the mean CCDF and the CCDF for the upper confidence limit satisfy the containment requirements by more than an order of magnitude.

As discussed above, EPA was dissatisfied with many of the parameter ranges and values used in PA and had concerns about some codes and the assumption of credit for passive institutional controls. EPA required DOE to perform the PAVT to determine whether the cumulative impact of the changes in PA codes and parameters would require additional PA runs. DOE applied the same methodology in the CCA PA and in the PAVT for calculating the mean CCDF curve and the 95 percent upper confidence limit. The PAVT results demonstrate that the level of statistical confidence is significantly greater than 95% that the mean of the CCDFs meets the § 191.13 containment requirements. Therefore, EPA concludes that the final results of the PAVT are also in compliance with the containment requirements of § 191.13 and that the results are presented in accordance with § 194.34(f).

A public comment received on EPA's Advance Notice of Proposed Rulemaking (ANPR) expressed concern about the fact that at least some of the CCDF curves in the CCA PA indicated that there would be releases into the accessible environment. EPA's containment requirements limit the likelihood of releases at specific levels, but do not require DOE to demonstrate that no releases of any magnitude will occur. EPA recognized that some parameters used in CCA PA were questionable, and required DOE to perform a PAVT that included revised parameters in order to alleviate concerns such as those raised by the commenter. Less than one percent of CCDF curves in the CCA PA exceeded normalized releases of one. EPA concludes that the probabilities of such releases are still well below the EPA release limits.

The CCA demonstrates that there is at least a 95 percent level of statistical confidence that the mean of the population of CCDFs meets the containment requirements of § 191.13. (The PAVT results indicate that PA would still demonstrate that the WIPP is in compliance with the containment requirements of § 191.13, even including substantial modifications to some of the significant uncertain parameters used in PA.) Therefore, EPA proposes that the WIPP complies with the containment requirements of § 191.13 and with § 194.34(f). EPA believes that the WIPP will safely contain radioactive waste for up to 10,000 years after disposal and will protect public health and the environment. For further information on the EPA's evaluation of compliance for § 194.34, or on the results of the PA or the PAVT, see CARD 34.

XII. Assurance Requirements

In 40 CFR 191.14, EPA included six qualitative assurance requirements to assure that the desired level of protection is achieved at disposal facilities. (60 FR 5777) The assurance requirements address active institutional controls, monitoring, passive institutional controls, engineered barriers, consideration of the presence of resources, and removal of waste. These measures are designed to compensate for the inherent uncertainty in projecting the behavior of natural and engineered components of the repository for many thousands of years. (50 FR 38072) The assurance requirements are implemented at the WIPP by §§ 194.41 through 194.46 of the WIPP Compliance Criteria.

A. Section 194.41, Active Institutional Controls

Section 194.41 implements the active institutional controls (''AICs'') assurance requirement. The disposal regulations define AICs as ''controlling access to a disposal site by any means other than passive institutional controls, performing maintenance operations or remedial actions at a site, controlling or cleaning up releases from a site, or monitoring parameters related to disposal system performance.'' (40 CFR 191.12) Section 194.41 requires AICs to be maintained for as long a period of time as is practicable after disposal; however, contributions from AICs may not be considered in the PA for more than 100 years after disposal.

In evaluating DOE's compliance with § 194.41, EPA sought a detailed description of DOE's proposed AICs and how those controls would be implemented. EPA reviewed this description for thoroughness, feasibility, and likely effectiveness. DOE proposed to: construct a fence and roadway around the surface footprint of the repository; post warning signs; conduct routine patrols and surveillance; and repair and/or replace physical barriers as needed. DOE also identified other measures that function as AICs, such as DOE's prevention of resource exploration at the WIPP and DOE's construction of long-term site markers. DOE stated that it would maintain the proposed AICs for at least 100 years after closure of the WIPP, and that the WIPP PA assumed that AICs would prevent human intrusion for that period.

EPA reviewed the proposed AICs in connection with the types of activities that may be expected to occur in the vicinity of the WIPP site during the first 100 years after disposal (i.e., ranching, farming, hunting, scientific activities, utilities and transportation, groundwater pumping, surface excavation, potash exploration, hydrocarbon exploration, construction, and hostile or illegal activities). EPA also examined the assumptions made by DOE to justify the assertion that AICs will be completely effective for 100 years. The assumptions were that: (1) The fence and signs will convey the message that the WIPP site is hazardous and protected; (2) legal prohibitions on resource recovery activities will be enforced; and (3) the time required to initiate a resource extraction operation will allow routine site patrols to discover and halt such activities.

EPA found the assumptions regarding longevity and efficacy of the proposed AICs to be acceptable. This finding was based on the fact that the types of inadvertent intrusion which AICs are designed to obviate are not casual activities, but require extensive resources, lengthy procedures for obtaining legal permission, and substantial time to set up at the site before beginning.

Section 194.41 prohibits the consideration of contributions from AICs in the PA for more than 100 years after disposal. Contributions from AICs in the PA are considered as a reduction in the rate of human intrusion. EPA reviewed the CCA and the parameter inputs to the PA and determined that DOE did not assume credit for the effectiveness of active institutional controls for more than 100 years after disposal.

EPA found the description of each active control measure (fence, signs, roadways, site maintenance, and security patrols) and its location to be adequate to support its intended function. Also, EPA found DOE's assumptions to be sufficient to justify DOE's assertion that AICs will completely prevent human intrusion for 100 years after closure. Because DOE adequately described the proposed AICs and the basis for their assumed effectiveness and did not assume in the PA that AICs would be effective for more than 100 years, EPA proposes to find DOE in compliance with § 194.41. For further information on EPA's

evaluation of compliance for § 194.41, refer to CARD 41.

B. Section 194.42, Monitoring

Section 194.42 implements the assurance requirement that DOE monitor the disposal system to detect deviations from expected performance. The monitoring requirement distinguishes between pre- and post-closure monitoring because of the differences in the monitoring techniques that may be used during operations (pre-closure) and once the repository has been backfilled and sealed (post-closure). Monitoring is intended to provide information about the repository that may affect the results of the PA or containment of waste.

To meet the criteria of § 194.42, EPA required DOE to conduct an analysis of the effects of disposal system parameters on the containment of waste. At a minimum, this analysis must include the seven specific parameters listed in § 194.42(a). DOE was required to present the analysis methodology, assumptions and results. DOE also was required to justify the decision not to monitor any of the parameters analyzed. (§ 194.42(b))

Section 194.42 requires that the screening of parameters be conducted to develop plans for pre- and post-closure monitoring described in §§ 194.42(c) and (d). In accordance with § 194.42(e), these monitoring plans must: (1) identify the parameters to be monitored and how the baseline data will be determined, (2) indicate how the parameters will be used to evaluate deviations from the expected performance of the disposal system, and (3) discuss the length of time over which each parameter will be monitored.

DOE conducted an analysis of disposal system parameters that included the parameters specified in § 194.42(a), along with other parameters. The analysis assigned high, medium or low significance to each parameter for its importance to the containment of waste and to the verification of predictions about disposal system performance. DOE then screened parameters out of consideration for monitoring based on the ability of the parameter to produce meaningful data during the monitoring period and on whether parameters can be monitored without violating disposal system integrity.

EPA evaluated the analysis and screening of parameters, including the methodology, assumptions, and results. EPA found that the analysis included the required parameters and adequately justified both the selection and rejection of parameters for inclusion in monitoring plans. Therefore, EPA proposes to find DOE in compliance with §§ 194.42(a) and (b).

Based on the results of its analysis, DOE submitted plans that identified ten parameters that will be monitored for pre-closure monitoring, five of which will also be monitored for post-closure monitoring. The pre-closure monitoring parameters are: (1) Culebra groundwater composition, (2) change in Culebra groundwater flow, (3) probability of encountering a Castile brine reservoir, (4) drilling rate, (5) subsidence measurements, (6) waste activity, (7) creep closure and stresses, (8) extent of deformation, (9) initiation of brittle deformation and (10) displacement of deformation features. Parameters one through five are also post-closure monitoring parameters. The parameters selected for monitoring included several of those listed in § 194.42(a), such as creep closure and stresses, extent of deformation, initiation of brittle deformation, displacement of deformation features, Culebra ground water composition and flow and Castile brine reservoir location.

The CCA described how DOE intends to implement monitoring programs for both pre-and post-closure parameters. The monitoring plans included information on establishing baseline data, how monitoring data will be used to evaluate deviations from expected performance and on the length of time each parameter will be monitored. EPA finds that DOE submitted monitoring plans in accordance with §§ 194.42(c), (d), and (e). The monitoring plans in the CCA addressed both pre-closure monitoring (planned to begin before emplacement of waste) and post-closure monitoring (using methods that would not jeopardize containment of waste in the disposal system), and included information required by the Compliance Criteria.

EPA proposes to find DOE in compliance with the requirements of § 194.42. In accordance with its authority under § 194.21, EPA intends to conduct an inspection of the pre-closure monitoring activities prior to emplacement of waste to confirm implementation of the plans detailed in the CCA. The results of this inspection will be placed in the public dockets described under § 194.67. For further information on EPA's evaluation of compliance for § 194.42, see CARD 42.

C. Section 194.43, Passive Institutional Controls

The Compliance Criteria at § 194.43 require a description of passive institutional controls (PICs) that will be implemented at the WIPP. PICs are measures that do not require human intervention in order to warn away potential intruders from disposal sites. EPA defined PICs in the disposal regulations as markers, public records and archives, government ownership of a site and restrictions on land use at the site, and any other means of preserving knowledge of a site. (50 FR 38085) PICs are intended to deter unintentional intrusions by people who otherwise might not be aware of the presence of radioactive waste at the site.

Sections 194.43(a)(1) through (3) of the Compliance Criteria implement the disposal regulations by requiring DOE to: (1) identify the controlled area by markers designed, fabricated, and emplaced to be as permanent as practicable; (2) place records in local, State, Federal, and international archives and land record systems likely to be consulted by individuals in search of resources; and (3) employ other PICs intended to indicate the location and dangers of the waste. In accordance with § 194.43(b), DOE also must indicate the period of time that PICs are expected to endure and be understood by potential intruders. Finally, DOE is permitted to propose a credit for PICs in the PA, as explained in § 194.43(c). Such credit must be based on the proposed effectiveness of PICs over time, and would take the form of reduced likelihood in the PA of human intrusion over several hundred years. The Compliance Criteria prohibit DOE from assuming that PICs could entirely eliminate the likelihood of future human intrusion.

The PICs design proposed by DOE in the CCA calls for the construction at the WIPP site of a large earthen berm, dozens of granite monuments, and three granite information rooms, two of which will be buried for their protection. DOE also proposed to bury thousands of small markers at shallow depths around the site. All markers except the berm will be engraved with warning messages in several languages and of varying complexity.

DOE plans to distribute WIPP records and other information to over one hundred archives, record centers, professional organizations, and commercial enterprises in the United States and abroad. Finally, DOE points to its ownership of the WIPP site as a measure that will identify the site as Federal property and off limits to resource exploration.

EPA evaluated whether the proposed markers are ''as permanent as practicable'' by considering the manner in which DOE accounted for potential marker failures and by confirming that

the proposed markers could be fabricated. EPA's analysis of the proposed markers suggests that they are practicable, although DOE may decide to revise the design as implementation proceeds. Any such revisions would constitute a modification of the design and would therefore require EPA approval in accordance with §§ 194.65 and 194.66. Also, the CCA showed that the proposed design incorporates features intended to promote the endurance of markers. Examples of these features are: redundant markers, highly durable materials with low intrinsic value, large dimensions, and location both above and below the surface. EPA proposes to find that the proposed markers are designed to be as permanent as practicable, in accordance with § 194.43(a)(1).

With regard to placement of records, DOE has prioritized archives and record centers in order to target those closest to the WIPP and most likely to be consulted by resource exploration industries nationally and abroad. The additional PICs proposed by DOE, which involve placement of WIPP information on maps and in various reference materials, also appear to be practicable. Therefore, EPA proposes to find that DOE complies with §§ 194.43(a)(2) and (3).

DOE estimated the amount of time that most of the proposed PICs are expected to endure by comparing them to analogues with similar properties that have survived to the present. The estimates of endurance, the lowest of which is at least 2,400 years and the greatest of which is at least 5,000 years, vary according to the age of analogues. DOE estimated the length of time that messages and records are expected to be understood (at least 1,000 years) by making assumptions about the future and then stating why those assumptions are reasonable. Because DOE based its design on sound principles, took into account likely failures of PICs, based estimates of endurance on relevant analogues, and based estimates of comprehensibility on a reasonable framework of assumptions, EPA believes that the proposed design for markers meets the criterion of ''as permanent as practicable'' and that DOE's estimates for that purpose are acceptable for compliance with § 194.43(b).

DOE proposed to take most of the steps necessary for implementing the proposed PICs, such as making arrangements with archives and record centers and refining marker messages, during the WIPP's operational period. However, DOE also plans to extend some activities, particularly testing of markers, over nearly 100 years after closure (i.e., during the proposed active institutional control period) before finalizing important aspects of the design, in the belief that future technology may improve the design. EPA cannot base a regulatory determination that DOE has demonstrated compliance with the requirements at § 194.43 on a speculative plan to finalize the required design during the active institutional control period. It would be inconsistent with Congress' intent in the LWA for EPA to allow DOE to alter the approved PICs design after EPA's regulatory function comes to an end.

Rather, EPA's determination must be based on the design proposed in the CCA. EPA acknowledges that future technological developments might improve the design of certain PICs components. Should DOE develop evidence that aspects of the proposed design can be improved during the operational period, DOE could then request modification of the approved plan in a recertification application. DOE also will not be precluded in the future from implementing other measures in addition to those comprising the final design. During the period that EPA exercises regulatory oversight over the WIPP, DOE may not alter or delete aspects of the approved plan in the CCA without notifying EPA and subjecting the certification to modification, if EPA deems it necessary.

Given that EPA considered the design proposed in the CCA to be final for the purposes of its compliance review, EPA finds that DOE has not justified sufficiently the need for additional testing of markers after closure of the repository or the need to delay implementation for many years after closure. EPA believes that PICs should be implemented as soon as possible after the WIPP facility is sealed, and that measures necessary to prepare for such implementation should be accomplished during the operational period for the WIPP, unless doing so would compromise the effectiveness of the CCA design. For example, EPA believes that it is appropriate and practicable during the operational period for DOE to establish agreements with national archives to accept and maintain records related to the WIPP. EPA therefore proposes to find DOE in compliance with the PICs requirements at §§ 194.43(a) and (b), on the condition that DOE submit additional information to EPA for approval. No later than the final re-certification application submitted prior to closure of the disposal system, DOE must provide a schedule for implementing PICs that has been revised to show that markers will be fabricated and emplaced, and other measures will be implemented, as soon as possible following closure of the disposal system. DOE also must describe how testing of any aspect of the conceptual design will be completed prior to or soon after closure, and what changes to the design may be expected to result from such testing. (See Condition 4 of the proposed Appendix A to 40 CFR Part 194.)

DOE proposed to take a credit of 99 percent over 700 years in the PA. In other words, DOE requested that the likelihood of human intrusion into the WIPP during the first 700 years after closure be reduced to one percent of the drilling rates calculated in accordance with the requirements of §§ 194.33(b)(3) and (4). The proposed credit was based largely on DOE's approach to compliance with § 194.43(b), which led DOE to conclude that all PICs are ''virtually certain'' to endure and be understood for at least 700 years. DOE identified drilling in the wrong location on a properly issued lease as the only plausible scenario whereby the proposed PICs could fail to deter an inadvertent intrusion. DOE then surveyed the Delaware Basin and other areas for such failures and determined that wells were drilled in the wrong location in 5 out of 429,000 instances, a rate of 0.001 percent. Finally, DOE bounded the failure rate (of 0.001) at 1.0 percent for the sake of conservatism.

EPA agrees with DOE that the proposed PICs appear likely to endure and be understood for hundreds of years. However, EPA proposes to deny DOE's request for PICs credit. The reasons for EPA's denial of PICs credit are discussed briefly below.

First, in promulgating its PICs credit criterion, EPA explicitly stated that ''the degree to which PICs might reduce the future drilling rate can be reliably determined only through informed judgment.'' (61 FR 5232) EPA clearly expected the proposed PICs credit to be derived through an expert elicitation conducted in accordance with the requirements at 40 CFR 194.26. DOE instead prepared a justification and submitted it to peer review. EPA regards peer review as qualitatively different from expert judgment, in which the independent panel itself prepares the justification.

Second, § 194.43(c) states, ''In no case . . . shall passive institutional controls be assumed to eliminate the likelihood of human intrusion entirely.'' DOE's rationale for the proposed credit repeatedly states that PICs are ''virtually certain'' to eliminate the likelihood of human intrusion. EPA believes that the

assertion that PICs are virtually certain (i.e, 99.9 percent) to endure and be understood is equivalent in effect to assuming that they eliminate the likelihood of human intrusion entirely. Furthermore, DOE's estimate of the effectiveness of PICs does not adequately account for the considerable uncertainty associated with quantifying the effectiveness of PICs for use in the PA. Specifically, there are potential failure scenarios that DOE did not account for in developing the proposed credit. For example, within the next 700 years, someone could drill based on an incorrect permit, permits may be mistakenly granted, records of the WIPP could be lost, or a system of permits to control drilling may be abandoned. While DOE's proposal does not account conservatively for uncertainty, EPA recognizes that any level of credit EPA would propose in place of DOE's estimate would be arbitrary. Finally, EPA found that the issue of quantitative credit for PICs is of little consequence for the purpose of evaluating the WIPP's performance, since the removal of PICs credit from computer models (in the Performance Assessment Verification Test) produced no signification effect on the WIPP's compliance with EPA's numerical standards.

EPA proposes to determine that DOE complies with § 194.43, on the condition that additional information on the final PICs design be submitted for EPA's review no later than the final re-certification application. For additional information on EPA's evaluation of compliance for § 194.43, see CARD 43.

D. Section 194.44, Engineered Barriers

Section 194.44 requires that DOE conduct a study of available options for engineered barriers at the WIPP and submit this study and evidence of its use with the compliance application. Consistent with the assurance requirement found at 40 CFR 191.14, which requires the use of one or more engineered barriers, DOE must analyze the performance of the complete disposal system, and any engineered barrier(s) that DOE ultimately implements at the WIPP must be considered in the PA and EPA's subsequent evaluation.

To comply with this requirement, EPA expected DOE to describe the engineered barrier(s) selected for implementation at the WIPP. EPA also expected the CCA to document how the engineered barrier(s) prevents or substantially delays the movement of water or radionuclides to the accessible environment, and how it reduces uncertainties in modeling performance of the disposal system. EPA expected DOE to conduct a comprehensive evaluation of engineered barrier alternatives in order to compare the benefits and detriments of various barriers and then use the results of such a comparison to justify selecting or rejecting a barrier(s).

In accordance with § 194.44(b), EPA observed DOE's scoping study and screening process during March and April 1995. The scoping effort produced a list of 111 potential barriers and combinations of barriers (including the barriers described in § 194.44(b)), of which 18 were evaluated against the factors described in § 194.44(c). Although DOE did not specifically address the waste categories in § 194.44(d), the study effectively accounted for the categories by analyzing three waste types (sludges, solid organics, and solid inorganics) and considering multiple waste processing schemes. DOE's evaluation of engineered barriers was peer reviewed in accordance with § 194.27(a)(3). See § 194.27, ''Peer Review,'' for details of EPA's evaluation of the general peer review process. On the basis of its evaluation of the benefits and detriments of eighteen engineered barrier types, DOE concluded that a chemically-buffering backfill was a high-benefit, low-cost, and practicable engineered alternative. DOE selected magnesium oxide (MgO) backfill as an engineered barrier, and proposed to emplace bags of MgO between and around waste containers in the repository. DOE stated that the backfill will serve to: (1) substantially delay movement of radionuclides by controlling chemical conditions in the underground waste panels so that the solubility of radionuclides in water is reduced, (2) delay movement of water by reacting with brine to reduce free water in the disposal system, and (3) fix pH levels within a narrow range, thereby bounding an important modeling parameter whose value might otherwise be highly uncertain.

EPA found that DOE conducted the requisite analysis of engineered barriers and selected an engineered barrier designed to prevent or substantially delay the movement of water or radionuclides toward the accessible environment. DOE provided substantial documentation in the CCA and supplementary information that MgO can effectively reduce actinide solubility in the disposal system. EPA agrees that the chemical reactions that DOE associated with MgO can occur under predicted repository conditions. DOE proposed to emplace a large amount of MgO in and around waste drums in order to provide an additional factor of safety and thus account for uncertainties in the geochemical conditions that would affect CO_2 generation and MgO reactions. (For details regarding chemical reactions of MgO, see CARD 24, ''Waste Characterization.'' For further information regarding the PA modeling of solubility and chemical conditions in the repository, see CARD 23, ''Models and Computer Codes.'')

Public comments received on EPA's Advance Notice of Proposed Rulemaking (''ANPR'') questioned two aspects of DOE's treatment of engineered barriers in the CCA. First, commenters disagreed that borehole plugs, shaft seals, and panel seals should be treated by DOE as engineered barriers for the purpose of complying with § 194.44. EPA found that DOE had treated plugs and seals as part of the baseline design of the disposal system, not as additional barriers for the purpose of assurance. The effectiveness of plugs and seals is discussed as part of EPA's evaluation of the disposal system design under § 194.14, ''Content of Compliance Certification Applications.'' Second, commenters expressed concern that the CCA did not support conclusions about the effectiveness of MgO with experimental data or other documentation. EPA shared this concern and so requested that DOE provide additional documentation showing that backfill could be emplaced in the required manner and would function in the disposal system as proposed. EPA believes that supplementary information sent by DOE adequately addressed insufficiencies in the CCA.

EPA proposes to find DOE in compliance with § 194.44. For further information on EPA's evaluation of compliance for § 194.44, see CARD 44.

E. Section 194.45, Consideration of the Presence of Resources

Section 194.45 implements the assurance requirement that the disposal system be sited such that the benefits of the natural barriers of the disposal system compensate for the increased probability of disruptions to the disposal system resulting from exploration and development of existing resources. (61 FR 5232) In promulgating this requirement, EPA determined that the performance assessment (''PA'') is the appropriate tool to weigh the advantages and disadvantages of the WIPP site because PA demonstrates whether potential human intrusion will cause unacceptably high releases of radioactive material from the disposal facility.

In accordance with the Compliance Criteria, DOE must demonstrate that PA has incorporated the potential effects of human activities near the WIPP prior to disposal, and of drilling and excavation mining over the regulatory time frame. DOE also must document that the results of the PA demonstrate compliance with the containment requirements at 40 CFR 191.13. No further demonstration of compliance is needed for § 194.45.

The Agency confirmed that PA incorporated human intrusion scenarios and met EPA's release limits in accordance with the WIPP Compliance Criteria. Based on EPA's findings that DOE complied with requirements related to scope of PA, conduct of PA, mining and drilling activities over the regulatory time frame, results of PA, and pertinent assurance requirements, EPA proposes to determine that DOE has demonstrated compliance with § 194.45. For further explanation of EPA's proposed compliance decisions for these related compliance criteria, see preceding preamble discussions for § 194.14, § 194.23, § 194.32, § 194.33, § 194.34, § 194.41, and § 194.43. For further information on EPA's evaluation of compliance for § 194.45, refer to CARD 45.

F. Section 194.46, Removal of Waste

Section 194.46 requires documentation that the removal of waste from the disposal system is feasible for a reasonable period of time after disposal. (61 FR 5244) The intent of this provision is to implement the assurance requirement at 40 CFR 191.14(f) that ''disposal systems be selected so that removal of most of the waste is not precluded for a reasonable period of time after disposal.'' To meet the criteria of § 194.46, EPA expected the CCA to provide a comprehensive strategy that showed the manner in which waste could be removed from the repository for a reasonable period of time after closure and an estimate of how long after disposal removal of waste would remain technologically feasible. Although the eventual disposition of the waste is an important environmental concern, 40 CFR Part 194 does not require DOE to speculate on the possible location or hazards of the waste once it is removed from the repository.

In the CCA, DOE presented a five-phase approach to removing waste from the WIPP repository, including: planning and permitting; initial above-ground set-up and shaft sinking; underground excavation and facility set-up; waste location and removal operations; and decontamination and decommission of the facility. The CCA included a discussion of techniques that could be used to remove the waste given the repository conditions at the time of removal, and also discussed several existing mining techniques that could be used to remove waste from the WIPP repository.

EPA reviewed the CCA to assess the completeness of the strategy for removing the waste and the justification of the proposed technology for removing the waste. EPA believes that the five phases described for waste removal provide an orderly sequence of planning and implementation procedures that could be implemented. EPA agrees that the proposed activities, techniques, and equipment that would be necessary to remove the waste are all presently feasible.

EPA reviewed the CCA for an estimate of how long after disposal it would remain technologically feasible to remove the waste. DOE stated that, using the system and equipment proposed in the CCA, it would be feasible to remove the waste any time after emplacement. Thus, DOE appeared to conclude that no features of the disposal system (such as salt creep) will prevent the removal of waste from the repository as long as the technology described in the CCA remains available. The CCA did not address how long the technology might remain available.

EPA agrees that waste removal would be feasible as long as current technology remains available, but does not believe it is reasonable to assume that the technology will remain available over the entire regulatory time frame. To estimate the length of time for which waste removal would be feasible, EPA considered how long the technology described in the CCA might remain available. The Agency concluded that, as long as our present society remains stable, it is reasonable to conclude that there will likely be a continuity or advancement of technology which would allow waste removal to occur. In the disposal regulations, EPA identified 100 years after disposal as a realistic but conservative limit on how long active controls could be assumed to be effective—i.e., how long present institutions would remain in place continuously to enforce such controls. (50 FR 38080) Based on this same rationale, EPA believes it is reasonable to assume that current technology will remain available for the 100-year period after disposal, and therefore that waste removal will remain feasible for that time. EPA believes that 100 years constitutes a reasonable period of time after disposal, in accordance with § 194.46. Therefore, EPA concludes that DOE has met the regulatory requirements for the removal of waste, and proposes to find DOE in compliance with § 194.46. For further information on EPA's evaluation of compliance for § 194.46, see CARD 46.

XIII. Individual and Ground-water Protection Requirements

Sections 194.51 through 194.55 of the Compliance Criteria implement the individual protection requirements of 40 CFR 191.15 and the ground-water protection requirements of Subpart C of 40 CFR Part 191. Assessment of the likelihood that the WIPP will meet the individual radiation dose limits and radionuclide concentration limits for ground water is conducted through use of a process known as compliance assessment (''CA''). Compliance assessments use methods similar to those of PA (for the containment requirements) but are required to address only undisturbed performance of the disposal system. Sections 194.51 and 194.52 specify the requirements which must be incorporated into CA in the analyses of individual radiation doses to protected individuals. Section 194.53 addresses underground sources of drinking water. Finally, the criteria specify the scope of CA and establish statistical requirements on the results of CA in demonstrating compliance with the individual and ground-water protection requirements (§§ 194.54 and 194.55).

A. Section 194.51, Consideration of Protected Individual

Section 194.51 requires DOE to assume in compliance assessments (''CA'') that an individual resides at the point on the surface where the dose from radionuclide releases from the WIPP would be greatest. EPA required that the CCA identify the maximum annual committed effective dose and the location where it occurs, and explain how DOE arrived at those results.

DOE's analysis of the WIPP's compliance with § 194.51 and related sections of the Compliance Criteria was contained in the CCA and in supplementary information. DOE described its analysis as a ''bounding analysis'' because it assumed that the maximum concentration of radionuclides was available in underground sources of drinking water (''USDWs'') and that humans using that water would therefore receive the maximum dose possible from that pathway.

The bounding analysis was derived from the performance assessment for the undisturbed scenario. DOE analyzed all potential routes of release of radioactive

waste from the repository that could lead to exposure of an individual and determined that the only release to the accessible environment would be passage of contaminated water through the interbeds in the Salado Formation, where the WIPP is situated. In the analysis, DOE demonstrated that radionuclides migrated horizontally to the accessible environment in only nine out of 300 realizations.

DOE then assumed that the highest concentration of radionuclides from the nine realizations was present at the subsurface boundary of the accessible environment, and that individuals would take water for consumption or agricultural use directly from this location in the Salado. DOE stated that it was not necessary to identify a single point of maximum dose because the analysis assumed that the maximum radionuclide concentration was available to individuals in brine taken from the Salado Formation; therefore, the dose from various pathways would be maximized regardless of an individual's location on the surface of the accessible environment. For more discussion of DOE's consideration of pathways in the bounding analysis, see § 194.52, ''Consideration of Exposure Pathways.''

EPA agrees that it was conservative for DOE to base its calculations of individual dose on the maximum predicted radionuclide concentrations. EPA also accepts as technically sound DOE's rationale for not identifying a single geographic point at which individual committed effective dose is greatest, since under DOE's assumptions, all points on the surface would result in the same maximum dose. Therefore, EPA proposes to find DOE in compliance with § 194.51. EPA discusses whether the results of DOE's dose calculations comply with the individual protection requirements at 40 CFR 191.15 under the evaluation for § 194.55, ''Results of CA.'' Due to the relatedness of the requirements, EPA combined the discussion of DOE's compliance for §§ 194.51 and 194.52 (''Consideration of Exposure Pathways'') in a single Compliance Application Review Document (CARD 51/52).

B. Section 194.52, Consideration of Exposure Pathways

The individual protection requirements focus on the annual radiation dose of a hypothetical maximally-exposed person living on the surface just outside the boundary to the accessible environment. Section 194.52 requires DOE's compliance assessments for the individual protection requirements to consider all potential exposure pathways for radioactive contaminants from the WIPP. DOE must assume that an individual consumes 2 liters per day of drinking water from any underground source of drinking water in the accessible environment. EPA expected that DOE would postulate several release pathways and calculate the dose resulting from each pathway. In the CAG, EPA stated that DOE could employ simplified exposure models provided that DOE showed them to be more conservative than more detailed models. (CAG, pp. 67–68)

DOE's modeling identified only one possible release of radionuclides to the accessible environment for the undisturbed performance scenario, resulting from contaminated brine flowing through the Salado Formation interbeds. DOE's modeling indicated that this release could occur if there were a significant buildup of gas and fluid pressure within the WIPP's waste panels.

To assess this potential exposure pathway, DOE conservatively assumed that Salado brine would be available for human use once it reached the subsurface boundary of the accessible environment. Water in the Salado interbeds is actually a highly concentrated brine unsuitable for drinking; DOE has measured the average concentration of total dissolved (non-radioactive) solids (''TDS'') in Salado brine as 324,000 milligrams per liter (mg/L). DOE therefore assumed that brine would have to be diluted with pure water in order to bring the concentration of TDS down to the highest allowable amount under the standard for potable water (10,000 mg/L TDS). DOE assumed that this diluted Salado brine would be consumed at the rate of two liters per day and then calculated the dose resulting from this single pathway of water ingestion.

EPA required DOE to expand its analysis to include additional pathways. This expanded analysis is described in supplementary information sent by DOE. (Docket A–93–02, Item II-I–10) DOE examined pathways whereby humans either inhale dust from soil irrigated with contaminated water or consume agricultural products irrigated with contaminated water. In the latter case, pathways included plants eaten directly by humans and milk or beef from cattle whose stock pond contained contaminated water.

Based on the CCA and the supplementary information described above, EPA found that DOE assumed in its analysis of pathways that individuals consume 2 liters per day of water from underground sources. EPA also conducted independent calculations and concluded that DOE had reliably reported the doses expected to result from all pathways considered. EPA discusses whether the results of DOE's dose calculations comply with the specific requirements of 40 CFR 191.15 under 194.55, ''Results of Compliance Assessments.''

EPA found that the simplified ''bounding analysis'' employed by DOE (described under § 194.51 above) was sufficiently conservative not to require the use of more detailed models. The bounding analysis was conservative because it assumed unrealistically that brine in the Salado Formation would be used as a source of water for drinking and irrigation. In fact, brine in the Salado is not likely to be used as an underground source of drinking water because it has an extremely high concentration of TDS. Salado brine would require considerable dilution in order to meet the criteria for potable water, and dilution would serve to reduce radionuclide concentrations. There are other, more likely sources of water than the Salado in the vicinity of the WIPP (see § 194.53 below), but DOE's modeling demonstrated that radionuclides from the WIPP would not reach these sources in the undisturbed scenario.

EPA therefore proposes to find the WIPP in compliance with § 194.52. Due to the relatedness of the requirements, EPA combined the discussion of DOE's compliance with §§ 194.51 (''Consideration of the Protected Individual'') and 194.52 in a single Compliance Application Review Document (CARD 51/52).

C. Section 194.53, Consideration of Underground Sources of Drinking Water

Section 194.53 requires that compliance assessments of the undisturbed performance scenario consider underground sources of drinking water (''USDWs'') near the WIPP and their interconnections. The undisturbed scenario assumes that the disposal system will not be disturbed by human activities such as drilling or mining. A USDW is defined at 40 CFR 191.22 as ''an aquifer or its portion that supplies a public water system, or contains a sufficient quantity of ground water to do so and (i) supplies drinking water for human consumption or (ii) contains fewer than 10,000 mg per liter of total dissolved solids.''

DOE identified three potential USDWs near the WIPP—the Culebra Member of the Rustler Formation, the Dewey Lake Red Beds, and the Santa Rosa Sandstone of the Dockum Group—despite incomplete data showing that

they in fact meet the regulatory definition of a USDW. However, DOE did not identify a plausible release scenario in undisturbed conditions in which radionuclides from the WIPP reached these potential USDWs. DOE found instead that the only plausible release scenario in undisturbed conditions involved transport of radionuclides by brine laterally through the Salado Formation (where the WIPP is situated) to the subsurface boundary of the accessible environment. The concentration of radionuclides at the subsurface boundary in this scenario represents the maximum level possible in the accessible environment.

DOE assumed that brine at the subsurface boundary would be directly available to a hypothetical individual on the surface for use as drinking water. In other words, DOE assumed that people would draw water directly from the Salado, thereby bypassing other potential USDWs, and would thus be exposed to the maximum concentration of radionuclides. Because DOE assumed the worst-case scenario and did not attempt to demonstrate in the analysis that transport of radionuclides through geological formations in the accessible environment would lower their concentrations, DOE concluded that it was not necessary to analyze underground interconnections among water bodies.

EPA agrees that the Culebra, Santa Rosa, and Dewey Lake Formations are the most likely potential USDWs. Also, EPA agrees that it was not necessary to identify USDW interconnections because of DOE's conservative assumption that individuals, regardless of their location on the surface of the accessible environment, would be exposed to the maximum available concentration of radionuclides in drinking water.

Based on information provided in the CCA, EPA concluded that DOE adequately considered USDWs in compliance assessments. EPA therefore proposes to find that DOE complies with § 194.53. EPA discusses whether the results of DOE's calculations comply with the requirements of § 191.15 and Subpart C of 40 CFR Part 191 in § 194.55, ''Results of CA.'' For further discussion of EPA's evaluation of compliance for § 194.53, see CARD 53.

D. Section 194.54, Scope of Compliance Assessments (CA)

Section 194.54 addresses the scope of compliance assessments (''CA'') conducted to determine compliance with the individual dose and ground-water protection requirements of the disposal regulations. The CA must account for the undisturbed performance of the disposal system; that is, the predicted behavior of the disposal system if it is not disrupted by human intrusion or the occurrence of unlikely natural events (§ 191.12). As with performance assessment, the CA must consider features, events, and processes (''FEPs'') and associated uncertainties. The CA can be considered a ''subset'' of performance assessment, as CA considers only natural/undisturbed conditions and past/near-future human induced activities, but does not include long-term future human-induced activities that are included in performance assessment.

EPA required DOE to consider FEPs that relate to undisturbed performance of the disposal system. EPA required DOE to identify how these FEPs were screened, combined, and used in the CA. DOE was required to document why any undisturbed scenario FEPs were not included in the CA. EPA also required the CA to consider activities that occur in the vicinity of the WIPP and their effect on radionuclide migration from the site. Specifically, DOE was required to consider existing boreholes and near future lease development.

To fulfill the requirements of § 194.54(a), DOE developed and followed a process for considering FEPs in the CA. Out of the initial list of approximately 72 natural FEPs, DOE eventually included 17 in the CA. This is the same process that was used in identifying FEPs for PA; EPA's evaluation of the process is addressed in the preamble discussion of § 194.32. EPA concluded that the initial FEP list assembled by DOE was sufficiently comprehensive, in accordance with the requirements of § 194.54(a). This list appropriately screened out events and processes on the basis of probability, consequence or regulatory requirements. DOE considered and incorporated into CA numerous natural processes and events. DOE adequately documented the decision not to include FEPs in the CA. (See preamble discussion for § 194.32.)

DOE, in accordance with the requirements of § 194.54(b), conducted an analysis of the activities that are expected to occur in the vicinity of the WIPP in the near future. DOE's assessment of existing boreholes indicated that natural fluid flow through abandoned boreholes would be of very little consequence in the near future and was therefore not included in the CA. In addition to existing boreholes, DOE addressed a number of activities that could occur in the vicinity of the WIPP in the near future. These activities were: oil and gas exploration, exploitation and extraction; potash exploration and exploitation; fluid injection related to oil and gas production; sulfur coreholes; hydrocarbon/gas storage; brine wells for solution mining; and water supply wells. DOE determined that none of these activities will have an impact on the disposal system in the near future and therefore did not include them in the CA. DOE examined fluid injection for inclusion in the CA, but screened it out based on low consequences to the disposal system if it happened. DOE also provided information on leases in the WIPP area.

EPA reviewed the CCA analysis of existing boreholes in the vicinity of the WIPP and their potential impact on radionuclide migration and agrees with DOE's conclusion that existing boreholes will not affect the disposal system. EPA and public commenters disagreed with DOE's initial analysis of the effects of fluid injection and salt water mining. Upon reviewing supplemental modeling of these scenarios, conducted by DOE and also independently by EPA, EPA agrees that these activities were correctly omitted from the CA. (See the preamble for § 194.32 for further discussion of this additional modeling.) DOE satisfactorily identified leases near the WIPP and appropriately estimated the life of the leases for consideration in the CA.

EPA proposes to find DOE in compliance with the requirements of § 194.54. For further information on EPA's evaluation of compliance for § 194.54, see CARD 54.

E. Section 194.55, Results of CA

Section 194.55 establishes requirements for analyzing the WIPP's compliance with the individual and the ground-water protection requirements of the disposal regulations. These requirements: (1) limit the possible radiation dose from the WIPP to individuals in the accessible environment, and (2) limit the degree of radioactive contamination of groundwater for which the WIPP might be responsible. Both limitations are required to be analyzed for undisturbed performance of the disposal system for 10,000 years. (See the discussion for § 194.54 in today's preamble.)

40 CFR 191.15, the individual protection requirements, requires that there must be a reasonable expectation that undisturbed performance of the WIPP disposal system will not cause the annual committed effective dose equivalent to exceed 15 millirems (150 microsieverts) to any member of the public in the accessible environment. Subpart C of 40 CFR Part 191, the ground-water protection requirements, sets requirements on the radiation levels

in underground sources of drinking water (''USDWs'') by referencing the standards of the Safe Drinking Water Act at 40 CFR Part 141. In order to determine compliance with these requirements, DOE must calculate the maximum individual radiation dose from all pathways, the maximum concentrations of specific radionuclides in any USDW, and the maximum annual dose equivalents from radioactivity in any USDW.

Section 194.55 establishes six requirements for computing, presenting, and evaluating the results of compliance assessments (''CA''). The requirements of §§ 194.55(b) through (f) are analogous to the requirements of §§ 194.34(b) through (f) for the results of performance assessment (''PA''). As a result, DOE has been able to use the same computational techniques and the same computer codes to perform both PA and CA. The major differences between the analyses for PA and CA are that: (1) CA considers only undisturbed performance of the WIPP, and thus does not consider scenarios of human intrusion; (2) CA requires calculations of doses and radioactivity concentrations in USDWs, as well as cumulative releases; and (3) CA results are expressed as a set of dose and concentration values, while PA results are expressed as a series of complementary cumulative distribution function (''CCDF'') curves.

1. Uncertainty of CA

Section 194.55(a) requires the CA to consider and to document uncertainty in the performance of the disposal system. There are two general sources of such uncertainty. The first is the uncertainty associated with physical, chemical and geologic conditions within and around the repository. The CA deals with this by running 300 different undisturbed-site scenarios, with 300 independent sets of sampled values for the most important uncertain parameters (i.e., parameters either that vary from place to place or that simply are not known with precision, but which have been determined to have a significant effect on the WIPP's ability to contain radionuclides). The second source of uncertainty is the lack of detailed knowledge of the ways in which contaminated ground water might be pumped out and utilized by persons living near the site in the future. DOE handles this uncertainty through a conservative bounding calculation on individual doses, which is intended to demonstrate compliance regardless of any uncertainties. The bounding calculation is discussed in further detail in the discussions of §§ 194.51 and 194.52 in this preamble.

DOE evaluated uncertainty in the amount of contaminants transported underground using the same method as in the PA, except that uncertainty from human intrusion scenarios was not considered. For further information on the treatment of uncertainty in PA, see the discussion of § 194.34 in today's preamble. EPA found that the conservative bounding calculation is appropriate, in lieu of further uncertainty analysis, and that DOE's treatment of uncertainty in CA is sufficient. Therefore, the Agency proposes to find that WIPP complies with § 194.55(a).

2. Probability Distributions for Uncertain Parameters

Section 194.55(b) requires DOE to develop and document probability distributions for uncertain disposal system parameter values used in CA. This is similar to the requirement for parameter values used in the PA. DOE uses the same probability distributions for uncertain disposal system parameter values in both PA and CA calculations. This involves performing calculations with 300 independent sets of sampled parameter values for each of the 57 important parameters associated with uncertain physical, chemical and geological conditions in the repository and its surroundings. EPA conducted the same evaluation of probability distributions for CA as for PA.

Upon reviewing DOE's models and computer codes, the Agency questioned a number of important input parameter values and distributions used in the PA and in CA. EPA determined that corrections were necessary for certain input parameters and conceptual models. Because of concerns that the necessary corrections to these parameters and conceptual models could have significant effects on the actual results of modeling, EPA required DOE to demonstrate that the combined effect of all the parameter and computer code changes required by EPA was not significant enough to necessitate a new PA. EPA required DOE to perform 300 simulations in additional PA and CA calculations as a Performance Assessment Verification Test (''PAVT''). The PAVT implemented DOE's PA modeling, using the same sampling methods as the CCA PA, but incorporating parameter values that were selected by EPA. CA results of the PAVT are discussed below for requirement § 194.55(f) and PA results of the PAVT are discussed above in § 194.34 of this preamble. The PAVT results confirmed that the original PA is sufficiently conservative and indicated that further PA and CA analysis is not required.

After considerable analyses, including the PAVT, EPA was satisfied that the parameter values and distributions were adequate for determining compliance. See the discussion of the requirements of § 194.34 of this preamble. For the reasons discussed in that section, EPA also proposes to find the CCA in compliance with § 194.55(b).

3. Sampling of Uncertain Parameters

Section 194.55(c) requires CA to use computational techniques which draw random samples from across the entire range of probability distributions of uncertain parameters. These computational techniques then must be used to calculate the ranges of estimated radiation doses to individuals received from all pathways; radionuclide concentrations in USDWs; and radiation doses received from USDWs. This requirement is parallel to § 194.34(c), which requires techniques for random sampling from parameter distributions in the computation of CCDF curves for the results of PA.

The statistical technique that DOE used in selecting parameter values in PA, Latin Hypercube Sampling (''LHS''), is also employed in the calculations of radionuclide concentrations in ground water (which are then used to calculate individual doses) for the CA. The CA generated 300 values of contaminant concentrations in ground water (at the boundary to the accessible environment) and individual annual radiation doses to assess compliance with § 194.55.

EPA found the LHS technique for drawing samples randomly from probability distributions of uncertain parameters to be sufficient, as discussed in this preamble for § 194.34. In addition, EPA determined that DOE's conceptual model for determining maximum individual exposure and the GENII-A computer code used to calculate radiation doses were adequate. The Agency found that DOE has used an appropriate computational technique, LHS, for sampling widely from the parameter distributions described in § 194.55(b), and has used it to generate ranges of radionuclide concentrations in USDWs, doses from the ingestion of water from USDWs, and all-pathways doses. Therefore, EPA proposes to find that DOE has demonstrated compliance with § 194.55(c).

4. Sufficient Number of Estimates Generated

Section 194.55(d) requires that the number of estimates of radionuclide concentrations in USDWs, doses from

the ingestion of water from USDWs, and all-pathways doses must be large enough such that the maximum estimates of doses and concentrations generated exceed the 99th percentile of the population of estimates with at least 0.95 probability. This requirement is similar to the requirement of § 194.34(d) for determining if there is a sufficient number of CCDF curves in PA analysis. Both requirements have the purpose of ensuring that enough simulations are generated so that conclusions drawn from their analyses are statistically justified.

DOE produced 300 CA calculations and used the same statistical arguments to justify both the number of calculations for CA and the number of CCDF curves. See the discussion for § 194.34 in this preamble for a further explanation of DOE's justification and EPA's review. EPA found that, for random sampling, 300 individual estimates will provide 0.95 probability that at least one of them will exceed the population 99th percentile value. Thus, EPA proposes to determine that the CCA satisfies the requirement of § 194.55(d).

5. Display full range of CA results

Section 194.55(e) requires the CCA to display the full range of estimated radiation doses and radionuclide concentrations. Section 194.34(e) has a parallel requirement for displaying the full range of CCDFs generated.

DOE's CA analysis of individual doses started with the findings of the PA of contamination that has migrated to the accessible environment in the anhydrite interbeds immediately surrounding the repository in the case of an undisturbed repository. This analysis generated a full range of radionuclide concentrations in the ground water. DOE found that only nine of the three hundred estimates were not negligibly small (that is, less than 10^{-18} curies/liter)[24]. Starting with the concentrations in the interbeds, DOE conducted bounding calculations on individual dose, both from the ingestion of drinking water and from all exposure pathways combined. These calculations adopted assumptions that resulted in upper-bound estimates of dose that are much greater than what any individual might reasonably be expected to receive. DOE performed this bounding calculation in lieu of providing descriptive statistics for the estimates such as mean, median and standard deviation, as stated in EPA's ''Compliance Application Guidance for the WIPP'' (''CAG''). The criteria and the CAG allow the use of a bounding calculation as long as the simplified model is more conservative than more detailed and more complex modes. (CAG, p. 68)

EPA reviewed the CCA and found that DOE performed a full range of the necessary calculations to demonstrate compliance with § 191.15 and Subpart C of 40 CFR Part 191. EPA independently estimated and tabulated the all-pathway and USDW doses in a dose verification analysis. EPA's results generally agreed with those of the DOE analysis, although EPA found DOE's calculations to be conservative. EPA calculated descriptive statistics such as the mean and the 95 percent confidence interval for doses and concentrations to provide added assurance of the adequacy of DOE's methodology. Because the CCA presents specific estimates for each of the non-zero simulations or the upper bound estimate for those simulations and presents the full ranges of radionuclide concentrations and radiation doses, EPA proposes to find that DOE has demonstrated compliance with § 194.55(e).

6. Compliance With Radiation Dose and Radionuclide Concentration Limits

Section 194.55(f) requires the CCA to document that there is at least a 95 percent level of statistical confidence that the mean and the median of the range of estimated radiation doses and the range of estimated radionuclide concentrations meet the requirements of § 191.15 and Subpart C of 40 CFR Part 191. This requirement is analogous to § 194.34(f), which requires at least a 95 percent level of statistical confidence that the mean of the population of CCDFs meets the containment requirements of § 191.13. In order to meet this requirement, it is necessary to calculate the lower and upper limits of the range, the mean, and the median of the estimated doses and of the radionuclide concentrations.

The limit for individual doses in § 191.15 is an annual committed effective dose, from all pathways, of 15 mrem/year. The limits for doses and radionuclide concentrations in USDWs under Subpart C of 40 CFR Part 191 are a total radioactivity concentration for radium-226 and radium-228 in any USDW of 5 picocuries per liter of water (pCi/L); a gross alpha particle radioactivity (including radium-226 but excluding radon and uranium) in any USDW of 15 pCi/L; and an annual dose equivalent to the total body or any internal organ from beta particle and photon radioactivity in any USDW of 4 mrem/year. DOE calculated a maximum annual committed effective dose equivalent from exposure through all pathways of 0.93 mrem/year. The CCA reported that the maximum estimated radium concentration in ground water is 2.0 pCi/L. The CCA contained the 300 estimated concentrations for the five radionuclides ^{241}Am, ^{239}Pu, ^{238}Pu, ^{234}U, and ^{230}Th, and only nine of these were not negligibly small. The CCA reported the maximum gross alpha particle concentration as 7.81 pCi/L from ^{241}Am, ^{239}Pu, ^{238}Pu, ^{230}Th and all isotopes of Ra. DOE used its bounding calculation for dose due to all radionuclides from drinking USDWs to show that the annual dose equivalent to the whole body from beta particle and photon radioactivity would be no more than 0.47 mrem/year. Supplemental analyses conducted by DOE also showed that the maximum beta particle and photon dose equivalent to any internal organ was well below the 4 mrem/year regulatory limit; bone surface was identified as the critical organ for that calculation. The maximum estimate concentration or dose for each of these is less than the standard. Because the maximum value for each of these values was less than the applicable standard, and because the bounding analysis accounted for sources of uncertainty, DOE concluded that the mean, median and 95 percent confidence interval values also met the standards of § 191.15 and Subpart C of 40 CFR Part 191.

EPA commissioned an independent analysis to verify DOE's dose calculations. In general, EPA's analysis calculated values similar to those calculated by DOE. EPA also calculated the mean, median and 95 percent confidence intervals of concentrations and doses. EPA's analysis confirmed that the mean and median values are in compliance with the requirements of § 191.15 and Subpart C of Part 191.

The PAVT computed thirteen simulations with non-negligible concentrations of radionuclides in ground water, compared with nine in the CCA CA. All of these thirteen simulations computed doses of less than 1 mrem/year, compared to the standard of 15 mrem/year for individuals. PAVT calculations also demonstrated that the doses to internal organs and from beta particle and photon radiation in ground water were several orders of magnitude less than the standard. Thus, PAVT results indicated that the mean and median dose values and ground-water concentrations will meet the requirements of § 191.15 and Subpart C of Part 191.

[24] The Agency agrees with DOE that concentrations of less than 10^{-18} curies per liter are negligibly small. Such small concentrations found in the analysis could be due to calculational error rather than true indicators of radioactive contamination of USDWs.

Based on the CCA, supplementary documentation provided by DOE, and the Agency's independent studies, EPA has determined that there is at least a 95 percent level of statistical confidence that the mean and the median of the range of estimated radiation doses and the range of estimated radionuclide concentrations meet the requirements of § 191.15 and Subpart C of 40 CFR Part 191. Therefore, EPA proposes to find that DOE has demonstrated compliance with § 194.55(f). For further information on EPA's evaluation of compliance for § 194.55, see CARD 55.

XIV. Land Withdrawal Act Section 4(b)(5)(B) Leases

The 1992 WIPP Land Withdrawal Act (''LWA'') (Public Law 102–579) withdrew the geographical area containing the WIPP facility from all forms of entry, appropriation, and disposal under public land laws. The LWA transferred jurisdiction of the land to the Secretary of Energy explicitly for the use of constructing, operating, and conducting other authorized activities related to the WIPP. Further, the LWA established responsibilities for DOE to manage the land withdrawal area and required submittal of a management plan for that purpose. Under DOE's management plan, all surface or subsurface mining or oil or gas production is prohibited at all times on lands on or under the withdrawal area. (LWA, section 4(b)(5)(A)) However, the LWA exempted, from the prohibition on oil and gas production, two leases already in existence. Section 4(b)(5)(B) states that the existing rights under the two oil and gas leases (Nos. NMNM 02953 and 02953C) (hereafter, ''the section 4(b)(5)(B) leases'') shall not be affected unless the Administrator determines, after consultation with DOE and the Department of Interior, that the acquisition of such leases by DOE is required to comply with EPA's final disposal regulations at 40 CFR Part 191, Subparts B and C. Before DOE can emplace waste in the WIPP, DOE must either acquire the leases or the EPA must determine that such acquisition is not required. (LWA, section 7(b)(2))

In 1977, DOE purchased the leases in the land withdrawal area between the surface and 6,000 feet (1829 meters) below the surface. Since DOE owns all land rights down to 6,000 feet, no drilling is permitted from the surface of the LWA leases. Any drilling that takes place on the LWA section 4(b)(5)(B) leases must therefore be slant drilling that is initiated from outside the land withdrawal area. Oil and gas resources in the southwest area of the site, where the section 4(b)(5)(B) leases are located, are expected to occur below 6000 feet down to approximately 16,000 feet.

The EPA's determination of whether the section 4(b)(5)(B) leases must be acquired by DOE depends on an evaluation of drilling activities very similar to that conducted by DOE for performance assessment (''PA'') related to the containment requirements at 40 CFR 191.13. In fact, § 194.32(c) of the WIPP Compliance Criteria requires DOE to analyze the effects of any activities that occur in the vicinity of the disposal system prior to or soon after disposal, including the ''development of any existing leases.'' Therefore, in its examination of the effects of the section 4(b)(5)(B) leases, EPA relied on the closely related PA analyses conducted by DOE for the purpose of compliance with § 194.32(c).

For an oil or gas well, the potential life cycle may consist of: drilling; resource recovery (production); fluid injection for enhanced secondary production (either by waterflooding techniques or injection to maintain oil reservoir pressure); reinjection of waste fluids for disposal; and abandonment. In the PA for the compliance certification application (''CCA''), DOE conducted several analyses to identify the potential effects of these activities on the disposal system, with the exception of production, which is exempted from consideration by regulation (§ 194.33(d)). EPA examined each of DOE's analyses in its evaluation for the section 4(b)(5)(B) leases.

In its analyses for the PA, DOE concluded that the drilling of a deep well would adversely affect the disposal system only if the borehole intersected a waste panel in the underground portion of the WIPP. Drilling is of concern if the borehole penetrates the waste, and forces it to the surface, or allows a pathway for long-term transport of radionuclides. EPA agrees that the effects of drilling a borehole—and similarly, the effects of resource recovery (oil or gas production)—would be highly localized, for several reasons. Current oil and gas production drilling in the area near the WIPP site includes well casing procedures and borehole plugging practices that would mitigate the potential impact of future drilling activities. Wells drilled in the Delaware Basin (which encompasses the entire land withdrawal area) include at least two sets of steel casing lining the borehole (deeper wells use three sets of steel casing). Also, production and injection wells contain an additional set of tubing used to produce the oil or gas, or to inject fluid into the well. Present day practice would require multiple failures in these steel casings and tubings to cause any flow from the oil- or gas-producing zone towards the disposal system.

Borehole plugging practices near the WIPP site also employ multiple levels of protection that mitigate the potential impact of oil and gas operations in the immediate area. The State of New Mexico regulates borehole plugging practices with a robust series of requirements that control the flow of fluid in the subsurface (New Mexico Oil Conservation Division, Order R–III–P). The use of these measures reduce the chance of any fluid flow toward or into the repository using current methods and technology.

Fluid injection for brine disposal, waterflood, or pressure maintenance could affect the disposal system if the injected brine were to reach the waste area by way of migration through Salado anhydrites (calcium sulfate rock) (markerbeds 138 or 139). DOE analyzed this scenario in two different modeling studies (Docket A–93–02, Item II–G–1, Reference #611, and Item II–I–36) as well as in a study that identified well construction and operating practices in the vicinity of WIPP. The results of the modeling studies showed that little or no brine would be expected to reach the WIPP waste area through the anhydrite interbeds. The amount of brine that is modeled to reach the repository in the initial study (Docket A–93–02, Item II–G–1, Reference #611) is within the amount that is already accounted for in PA, and does not cause the WIPP to violate the disposal regulations.

An examination of current practice for fluid injection techniques confirms that the effects of fluid injection can also be expected to be highly localized. All injection operations in the vicinity of the WIPP site are controlled by the underground injection control requirements of the EPA. (40 CFR Parts 144 and 146) The requirements limit the flow rates of injection fluids and the maximum pressures that can be used in all injection wells. In addition, the injection well operator is required to evaluate the area of influence of any injection well before injection operations can be approved, and the State of New Mexico monitors the performance of injection operations periodically by requiring stringent reporting procedures.

Regarding abandonment, DOE indicated (Appendix SCR.3.3.1.4.2 of the CCA) that abandoned deep boreholes that do not intersect waste panels have been eliminated from the PA calculations on the basis of low consequence to the performance of the disposal system. This is because the rate of fluid flow through a borehole located

more than a meter away from the waste panels is so small that it would have an insignificant impact on releases.

EPA's review of DOE's modeling studies and analyses of well construction and operating practices found that the parameterization (e.g., injection rate and volumes) and model representation (e.g., incorporation of stratigraphy) used in DOE's modeling are consistent with those characteristics identified independently by EPA for the region in the southwest part of the land withdrawal area (the location of the section 4(b)(5)(B) leases). (Docket A–93–02, Item III–B–27) DOE's analysis of drilling for the PA indicated that deep wells drilled into the controlled area, but away from the waste disposal rooms and panels, will not adversely affect the disposal system's capability to contain radionuclides. A slant-drilled borehole from outside the land withdrawal area, into the section 4(b)(5)(B) lease area, at least 6000 feet below the surface, would be at least 2400 meters (8000 feet) away from the WIPP disposal rooms, and would thus have an insignificant effect on releases from the disposal system (and in turn, on compliance with the disposal regulations). Based on EPA's findings that DOE adequately modeled human intrusion scenarios in PA, and on the additional analyses described above, EPA concludes that potential activities at the section 4(b)(5)(B) leases do not cause the WIPP to violate the disposal regulations. Therefore, EPA determines that it is not necessary for the Secretary of Energy to acquire the Federal Oil and Gas Leases No. NMNM 02953 and No. NMNM 02953C.

XV. Administrative Requirements

A. Executive Order 12866

Under Executive Order 12866, (58 FR 51,735; October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a ''significant regulatory action'' because it raises novel policy issues which arise from legal mandates. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Regulatory Flexibility

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This proposed rule would not have a significant impact on a substantial number of small entities because it sets forth requirements which apply only to Federal agencies. Therefore, I certify that this action will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The EPA has determined that this proposed rule contains no information collection requirements as defined by the Paperwork Reduction Act (44 U.S.C. 3501 *et seq*).

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments and the private sector. Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4), EPA has determined that this regulatory action is not subject to the requirements of sections 202 and 205, because this action does not contain any ''federal mandates'' for State, local, or tribal governments or for the private sector. The rule implements requirements specifically set forth by the Congress in the Waste Isolation Pilot Plant Land Withdrawal Act (Pub. L. 102–579).

E. Executive Order 12898

Pursuant to Executive Order 12898 (59 FR 7629, February 16, 1994), entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' the Agency has considered environmental justice related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income and minority communities. EPA has complied with this mandate. EPA involved minority and low-income populations early in the rulemaking process. In 1993 EPA representatives met with New Mexico residents and government officials to identify the key issues that concern them, the types of information they wanted from EPA, and the best ways to communicate with different sectors of the New Mexico public. The feedback provided by this group of citizens formed the basis for EPA's WIPP communications and consultation plan.

To assist citizens, including a significant Hispanic population in Carlsbad and the nearby Mescalero Indian Reservation, stay abreast of EPA's WIPP-related activities, the Agency developed many informational products and services. EPA translated into Spanish many documents regarding WIPP including educational materials and fact sheets describing EPA's WIPP oversight role and the radioactive waste disposal standards. EPA also established a toll-free WIPP Information Line, recorded in both English and Spanish, providing the latest information on upcoming public meetings, publications, and other WIPP-related activities. EPA also developed a vast mailing list, which includes many low-income and minority groups, to systematically provide interested parties with copies of EPA's public information documents and other materials. EPA will continue its efforts toward open communication and outreach during the development of the final rule.

List of Subjects in 40 CFR Part 194

Environmental protection, Administrative practice and procedure, Nuclear materials, Radionuclides, Plutonium, Radiation protection, Uranium, Transuranics, Waste treatment and disposal.

Dated: October 23, 1997.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, 40 CFR Part 194 is proposed to be amended as follows.

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

1. The authority citation for part 194 is revised to read as follows:

Authority: The Waste Isolation Pilot Plant Land Withdrawal Act of 1992, Pub. L. 102–579, 106 Stat. 4777, as amended by the 1996 LWA Amendments, Pub. L. 104–201; Reorganization Plan No. 3 of 1970, 5 U.S.C. app. 1; Atomic Energy Act of 1954, as amended, and Nuclear Waste Policy Act of 1982, as amended, 42 U.S.C. 2011–2296 and 10101–10270.

2. In § 194.2, a definition is added in alphabetical order to read as follows:

§ 194.2 Definitions.

* * * * *

Administrator's authorized representative means the director in charge of radiation programs at the Agency.

* * * * *

3. Appendix A to Part 194 is added to read as follows:

Appendix A to Part 194—Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations and the 40 CFR Part 194 Compliance Criteria

In accordance with the provisions of the WIPP Compliance Criteria of this part, the Agency finds that the Waste Isolation Pilot Plant (''WIPP'') will comply with the radioactive waste disposal regulations at part 191, subparts B and C, of this chapter. Therefore, pursuant to Section 8(d)(2) of the WIPP Land Withdrawal Act (''WIPP LWA''), as amended, the Administrator certifies that the WIPP facility will comply with the disposal regulations. In accordance with the Agency's authority under § 194.4(a), the certification of compliance is subject to the following conditions:

Condition 1: § 194.14(b), Disposal System Design, Panel Seal System. The Department shall implement the panel seal design designated as Option D in Docket A–93–02, Item II–G–1 (October 29, 1996, Compliance Certification Application submitted to the Agency). The Option D design shall be implemented as described in Appendix PCS of Docket Item II–G–1, with the exception that the Department shall use Salado mass concrete (consistent with that proposed for the shaft seal system, and as described in Appendix SEAL of Docket Item II–G–1) instead of fresh water concrete.

Condition 2: § 194.22, Quality Assurance. (a) The Secretary shall not allow any waste generator site other than the Los Alamos National Laboratory to ship waste for disposal at the WIPP until the Agency determines that the site has established and executed a quality assurance program, in accordance with §§ 194.22(a)(2)(i), 194.24(c)(3) and 194.24(c)(5) for waste characterization activities and assumptions.

(b) Upon submission by DOE of site-specific quality assurance program plans, EPA will evaluate the relevant quality assurance program at the relevant waste generator site by conducting a quality assurance audit or an inspection of a DOE quality assurance audit. EPA will publish a notice in the **Federal Register** announcing its intent to evaluate the relevant quality assurance program, and soliciting public comment on the quality assurance program plans and appropriate audit documentation. A public comment period of at least 30 days will be allowed.

(c) EPA's written approval that the requisite quality assurance requirements have been met at a waste generator site will be conveyed in a letter from the Administrator's authorized representative to the Department. No such approval shall be granted until after the end of the public comment period described in paragraph (b) of this condition. A copy of EPA's approval letter will be placed in the public dockets in accordance with § 194.67. The results of any audits or inspections conducted by the Agency to evaluate the quality assurance programs described in paragraph (a) of this condition will also be placed in the dockets described in § 194.67.

(d) EPA will conduct inspections, in accordance with §§ 194.21 and 194.22(e), to confirm the continued compliance of the programs approved under paragraphs (2)(b) and (c) of this condition. The results of such inspections will be made available to the public through the Agency's public dockets, as described in § 194.67.

Condition 3: § 194.24, Waste Characterization. (a) The Secretary may allow shipment for disposal at the WIPP of retrievably stored (legacy) debris waste streams, at the Los Alamos National Laboratory (''LANL''), that can be characterized using the systems and processes documented in Docket A–93–02, Item II–I–70. The Secretary shall not allow shipment of any waste from any other LANL waste streams or from any other waste generator site for disposal at the WIPP until the Agency determines that the site has:

(1) provided information on how process knowledge will be used for waste characterization of the waste stream(s) proposed for disposal at the WIPP,

(2) implemented a system of controls at the site, in accordance with § 194.24(c)(4), to confirm that the total amount of each waste component that will be emplaced in the disposal system will not exceed the upper limiting value or fall below the lower limiting value described in the introductory text of paragraph (c) of § 194.24. The implementation of such a system of controls shall include a demonstration that the site has procedures in place for adding data to the WIPP Waste Information System (''WWIS''), and that such information can be transmitted from that site to the WWIS database; and a demonstration that measurement techniques and control methods can be implemented in accordance with § 194.24(c)(4) for the waste stream(s) proposed for disposal at the WIPP.

(b) The Agency will conduct an audit or an inspection of a DOE audit for the purpose of evaluating the use of process knowledge and the implementation of a system of controls for each waste stream or group of waste streams at a waste generator site. The Agency will announce a scheduled audit or inspection in the **Federal Register**. In that notice, the Agency will also solicit public comment on all appropriate audit documentation, which will be placed in the dockets described in § 194.67. A public comment period of at least 30 days will be allowed.

(c) EPA's written approval of the waste characterization programs described in paragraph (a) of this condition for one or more waste streams from a waste generator site will be conveyed in a letter from the Administrator's authorized representative to the Department. No such approval shall be granted until after the end of the public comment period described in paragraph (b) of this condition. A copy of EPA's approval letter will be placed in the public dockets in accordance with § 194.67. The results of any inspections or audits conducted by the Agency to evaluate the plans described in paragraph (a)(1) and (2) of this condition will also be placed in the dockets described in § 194.67.

(d) The Administrator's authorized representative(s) will conduct inspections, in accordance with §§ 194.21 and 194.24(h), to confirm the continued compliance of the plans approved under paragraphs (b) and (c) of this condition. The results of such inspections will be made available to

the public through the Agency's public dockets, as described in § 194.67.

Condition 4: § 194.43, Passive Institutional Controls. (a) Not later than the final re-certification application submitted prior to closure of the disposal system, the Department shall provide, to the Administrator or the Administrator's authorized representative:

(1) a schedule for implementing passive institutional controls that has been revised to show that markers will be fabricated and emplaced, and other measures will be implemented, as soon as possible following closure of the WIPP. Such a schedule should describe how testing of any aspect of the conceptual design will be completed prior to or soon after closure, and what changes to the design of passive institutional controls may be expected to result from such testing.

(2) documentation showing that the granite pieces for the proposed monuments and information rooms described in Docket A–93–02, Item II–G–1, and supplementary information may be: quarried (cut and removed from the ground) without cracking due to tensile stresses from handling or isostatic rebound; engraved on the scale required by the design; transported to the site, given the weight and dimensions of the granite pieces and the capacity of existing rail cars and rail lines; loaded, unloaded, and erected without cracking based on the capacity of available equipment; and successfully joined.

(3) documentation showing that archives and record centers will accept the documents identified and will maintain them in the manner identified in Docket A–93–02, Item II–G–1.

(4) documentation showing that proposed recipients of WIPP information other than archives and record centers will accept the information and make use of it in the manner indicated by DOE in Docket A–93–02, Item II–G–1 and supplementary information.

(b) Upon receipt of the information required under paragraph (a) of this condition, EPA will place such documentation in the public dockets identified in § 194.67. The Agency will determine if a modification to the compliance certification in effect is necessary. Any such modification will be conducted in accordance with the requirements at §§ 194.65 and 194.66.

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