



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
AIR AND RADIATION

March 1996



EPA WIPP Mailing List Members:

As part of EPA's efforts to keep you informed and involved in the Agency's WIPP program activities, we have enclosed the following informational materials developed by the staff of the Office of Radiation and Indoor Air:

1. *Federal Register Notice*, Volume 61, No. 28, pps 5223-5245 dated February 9, 1996, entitled "Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations; Final Rule."

EPA regulates the release of radioactivity from the management and disposal of radioactive waste to protect public health and the environment from radiation contamination. The criteria will be used to certify DOE's compliance with EPA's radioactive waste disposal standards specifically for the WIPP site in New Mexico. DOE must also apply to EPA for approval to dispose of radioactive wastes and, if WIPP is allowed to open, EPA must recertify compliance with the standards every five years after initial receipt of the waste.

2. Environmental Fact Sheet, EPA 402-F-95-008, dated January 1996, "Final Compliance Criteria for the Waste Isolation Pilot Plant (40 CFR Part 194)."

The Fact Sheet briefly describes the final compliance criteria rule, how the criteria will be used, and outlines future opportunities for public participation in EPA's WIPP rulemaking activities.

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We hope you find the enclosed materials informative, useful, and timely. If you would like additional copies of these publications, please call the toll-free WIPP Information Line at 1-800-331-WIPP.



Sincerely yours,

Handwritten signature of Julie Rosenberg in cursive.

Julie Rosenberg, Director  
Center for Federal Guidance  
and Air Standards  
Radiation Protection Division

Enclosures

# EPA FACT SHEET

## Final Compliance Criteria for the Waste Isolation Pilot Plant (40 CFR Part 194)

### INTRODUCTION

The U.S. Environmental Protection Agency (EPA) regulates the release of radioactivity from the management, storage and disposal of radioactive waste to protect public health and the environment from radiation contamination. This Fact Sheet describes one of the key elements in EPA's regulatory program — EPA's "Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's (WIPP) Compliance with 40 CFR Part 191 Radioactive Waste Disposal Regulations."

The WIPP, which is under development by the Department of Energy (DOE), is a potential geologic disposal facility for transuranic radioactive waste generated as by-products (e.g., contaminated rags, glassware, sludges, and equipment) from nuclear weapons production. In 1979, Congress authorized the development of the WIPP as a research and development facility to demonstrate the safe disposal of defense waste. The WIPP is located in southeastern New Mexico, near Carlsbad. If the WIPP opens, waste will be stored approximately 2,100 feet underground in excavated, natural salt formations.

Congress transferred the land for the WIPP to DOE by enacting the WIPP Land Withdrawal Act in 1992. The Act required EPA to perform several activities:

- Finalize general radioactive waste disposal standards
- Issue site-specific criteria for determining whether the WIPP complies with the radioactive waste disposal standards
- Certify whether the WIPP complies with the standards before waste disposal can begin, and, if the WIPP complies with the disposal regulations

- Determine whether the WIPP continues to be in compliance with the disposal standards every five years after initial receipt of the waste.

On December 20, 1993, EPA issued final radioactive waste disposal standards (40 CFR 191). These standards place limits on radiation releases from facilities that manage, store and dispose of radioactive waste. On January 30, 1995, EPA published and solicited comments on its Proposed WIPP Compliance Criteria (40 CFR Part 194) in the *Federal Register*. The Final Compliance Criteria reflect both the public's comments on the proposed rule and the suggestions received from EPA's WIPP Review Committee of the National Advisory Council for Environmental Policy and Technology.

### USE OF THE COMPLIANCE CRITERIA

Before DOE can dispose of waste at the WIPP, it must demonstrate that the WIPP complies with EPA's radioactive waste disposal standards. DOE must submit an application to EPA showing how the WIPP facility will meet the standards. The Compliance Criteria, which are specific to the WIPP, will be used by EPA to implement the radioactive waste disposal standards. The Criteria clarify the requirements of the standards and require DOE to provide EPA with specific types of information in its compliance application. The Compliance Criteria implement the following provisions of the radioactive waste disposal standards:

a) The containment requirements dictate that the disposal systems be designed to limit releases of radionuclides to specified levels for 10,000 years after the facility accepts its final waste for disposal.

b) The assurance requirements complement the containment requirements and further reduce the likelihood of any radiation being released. For example, DOE must design

both passive and active institutional controls. These controls will provide confidence that the likelihood of future intrusion into the repository by drilling for resources will be minimized. Passive institutional controls are permanent site markers and record keeping and/or archiving systems to assure that relevant information is passed on to future generations. Active institutional controls include guards patrolling the site.

c) The individual protection provisions require that the WIPP be designed to limit the amount of radiation to which any individual can be exposed. They require that disposal systems be designed to provide a reasonable expectation that for 10,000 years after disposal, the annual radiation dose to any individual does not exceed 15 millirems per year; the equivalent to receiving approximately two chest x-rays per year.

d) The ground water protection provisions state that disposal systems must be designed to provide the same level of protection as provided by the Safe Drinking Water Act.

In addition, the Compliance Criteria contain general requirements, which include: the extent to which the waste needs to be analyzed to determine its contents prior to being disposed in the WIPP; guidance on computer models and codes that simulate the performance of the WIPP; the appropriate use of expert judgment in obtaining data that support the application; and demonstrations that data and assumptions developed by DOE have been adequately peer reviewed. The Criteria also provide procedures for the Agency to modify, suspend or revoke DOE's certification of the WIPP, if necessary.

## **FUTURE OPPORTUNITIES FOR PUBLIC PARTICIPATION**

When DOE submits its WIPP Compliance Certification Application to EPA, the Agency will use the Compliance Criteria as the basis for making a decision on whether or not the facility will be certified as meeting EPA's radioactive waste disposal standards. This decision will be made through a public rulemaking process which is described in the Compliance Criteria. A proposed decision on whether or not the WIPP should open will be available for public comment. Hearings will be held in New Mexico and all input from the public will be considered before the Agency makes its final decision.

If EPA decides that the WIPP meets its standards, then DOE will proceed with the opening of the WIPP. Following the opening of

the facility and throughout its operational phase, DOE will be required to submit a re-certification application to EPA every five years. The Agency will review this application and determine whether the WIPP remains in compliance with the disposal standards. The public will be permitted to inspect and comment on any re-certification application. By law, all public comments must be considered by the Agency prior to making a final decision on WIPP's continued operation.

## **SUPPORTING DOCUMENTS**

In addition to the publication of the Compliance Criteria, EPA developed a Background Information Document describing the technical basis for developing the criteria; an Economic Impact Analysis, estimating any economic impact of the criteria that is not already imposed by existing regulations or requirements; and a Response-to-Comments Document, outlining the Agency's response to public comments on the proposed Compliance Criteria. This information can be obtained from any of EPA's four dockets. Three dockets are located in libraries in Albuquerque, Carlsbad and Santa Fe, New Mexico. The remaining docket is located at EPA Headquarters in Washington, D.C.

## **FOR MORE INFORMATION**

For the latest information on upcoming public hearings and meetings, as well as the status of EPA efforts regarding the WIPP, please call EPA's recorded WIPP Information Line at 1-800-331-WIPP. Members of the public can also leave a request for a publication, a question for EPA WIPP staff, or request to be added to EPA's WIPP Mailing List.

Federal Register

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Friday  
February 9, 1996

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**Part VI**

**Environmental  
Protection Agency**

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**40 CFR Part 194**

**Criteria for the Certification and Re-  
Certification of the Waste Isolation Pilot  
Plant's Compliance With the 40 CFR Part  
191 Disposal Regulations; Final Rule**

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 194**

[FRL-5418-5]

RIN 2060-AE30

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

**AGENCY:** Environmental Protection Agency.

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is promulgating criteria for determining if the Waste Isolation Pilot Plant (WIPP) will comply with EPA's environmental radiation protection standards for the disposal of radioactive waste. If the Administrator of EPA determines that the WIPP will comply with the standards for disposal, then the Administrator will issue to the Secretary of Energy a certification of compliance which will allow the emplacement of transuranic waste in the WIPP to begin, provided that all other statutory requirements have been met. If a certification is issued, EPA will also use this final rule to determine if the WIPP has remained in compliance with EPA's environmental radiation protection standards, once every five years after the initial receipt of waste for disposal at the WIPP. This rulemaking was mandated by the WIPP Land Withdrawal Act of 1992.

**EFFECTIVE DATE:** These regulations are effective April 9, 1996. The incorporation of certain publications listed in the regulations is approved by the Director of the Office of the Federal Register as of April 9, 1996. A petition for judicial review of this final action must be filed no later than April 9, 1996 pursuant to section 18 of the WIPP Land Withdrawal Act of 1992 (Pub. L. 102-579).

**FOR FURTHER INFORMATION CONTACT:** Betsy Forinash, Mary Kruger or Martin Offutt; telephone number (202)-233-9310; address: Radiation Protection Division, Mail Code 6602J, U.S. Environmental Protection Agency, Washington, DC 20460. Copies of the Background Information Document and Economic Impact Analysis which accompany today's action may be obtained at this address. The Agency has also published a document, accompanying today's action, which responds in detail to significant public comments that were received on the proposed rule. This document, entitled

"Response to Comments" may be obtained by contacting Betsy Forinash.

**SUPPLEMENTARY INFORMATION:**

## Introduction

*Purpose of Today's Action*

Today's action implements the Environmental Protection Agency's (EPA) environmental radiation protection standards, 40 CFR part 191, by applying them to the proposed disposal of transuranic radioactive waste in the Waste Isolation Pilot Plant (WIPP). The EPA previously promulgated 40 CFR part 191, "Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes," to provide standards that will apply to all sites (except Yucca Mountain) for the deep geologic disposal of highly radioactive waste. Complete descriptions of 40 CFR part 191 were published in the Federal Register in 1985 (50 FR 38066-38089, Sep. 19, 1985) and 1993 (58 Fed. Reg. 66398-66416, Dec. 20, 1993). The WIPP is subject to 40 CFR part 191, and is being constructed by the Department of Energy (DOE) near Carlsbad, New Mexico, as a potential repository for the safe disposal of transuranic radioactive waste. The EPA is required by the WIPP Land Withdrawal Act of 1992 (Pub. L. 102-579) to evaluate whether the WIPP will comply with subparts B and C of 40 CFR Part 191—known as the "disposal regulations"—and to issue or deny a certification of compliance. The Department of Energy is required to submit an application to EPA that will be the basis of EPA's evaluation of whether a certification of the WIPP's compliance with the disposal regulations should be issued. The Department of Energy may not begin to emplace transuranic waste underground for disposal at the WIPP until such time as a certification of compliance has been issued and all other requirements of section 7(b) of the WIPP Land Withdrawal Act have been satisfied. With today's rulemaking, the Agency establishes criteria by which to judge whether the WIPP is in compliance with the "disposal regulations" and sets forth procedural requirements for this determination.

Today's action, 40 CFR part 194, also applies to the periodic re-certification of the WIPP's compliance with the disposal regulations. The process of periodic re-certification, established by section 8(f) of the WIPP Land Withdrawal Act, calls for EPA to determine whether the WIPP continues to be in compliance with the disposal

regulations, assuming that an initial certification of compliance has been issued. The Secretary of Energy must submit to the Administrator of EPA documentation of the WIPP's continued compliance with the disposal regulations, every five years after the initial receipt of transuranic waste for disposal at the WIPP, until the end of the decommissioning phase. The Agency will use the criteria set forth in today's rulemaking in determining whether or not the WIPP will have continued to be in compliance.

The WIPP was authorized in 1980, under section 213 of the Department of Energy National Security and Military Applications of the Nuclear Energy Authorization Act of 1980 (Pub. L. 96-164, 93 Stat. 1259, 1265), "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." The waste proposed for disposal in the WIPP, transuranic radioactive waste (TRU waste), is waste consisting of materials such as rags, equipment, tools, protective gear and sludges which have become contaminated during atomic energy defense activities. The WIPP Land Withdrawal Act defines transuranic waste to be waste containing more than 100 nano-curies per gram of alpha-emitting radio-isotopes, with half-lives greater than twenty years and atomic number greater than 92, per gram of waste. The Act further stipulates that radioactive waste shall not be transuranic waste if such waste also meets the definition of high-level radioactive waste, has been specifically exempted from the disposal regulations with the concurrence of the Administrator, or has been approved for an alternate method of disposal by the Nuclear Regulatory Commission. The radioactive component of transuranic waste consists of man-made elements created during the process of nuclear fission, chiefly isotopes of plutonium.

*Statutory and Regulatory Basis*

Today's action, 40 CFR part 194, was mandated by Congress in section 8(c) of the WIPP Land Withdrawal Act. The criteria promulgated in this action implement only those subparts of 40 CFR part 191 that apply to the disposal of transuranic radioactive waste. As stated in the Code of Federal Regulations, Appendix C of 40 CFR part 191 is guidance for the implementation of the regulations contained in 40 CFR part 191 that is not binding on the implementing agency, which is EPA with respect to the WIPP. Appendix C was designed to apply to all geologic

repositories for the disposal of highly radioactive wastes, not necessarily to the specific site characteristics of the WIPP and not only to transuranic waste. As a result, the Agency found in developing today's action that only some of the guidance contained in Appendix C had specific relevance to the WIPP. Today's action has been guided by only those aspects of Appendix C that the Agency has determined, based on technical and policy considerations, to be applicable to the WIPP.

Today's action, 40 CFR part 194, does not amend 40 CFR part 191. With the Energy Policy Act of 1992, Congress mandated the development of regulations to replace 40 CFR part 191 for the Yucca Mountain site only, but the entire standard, 40 CFR part 191, remains applicable to the WIPP. See 106 Stat. 2921, section 801(a)(1). Subpart A of 40 CFR part 191 applies to the management of spent nuclear fuel, high-level and transuranic radioactive wastes at sites designated for the disposal of these wastes. Section 9(a) of the WIPP Land Withdrawal Act stipulates that the Secretary of Energy shall comply with respect to the WIPP with Subpart A of 40 CFR part 191. The Agency has not implemented these requirements in today's action, 40 CFR part 194, but intends to issue guidance for their application to the WIPP at a future date.

#### *Compliance With Other Environmental Laws and Regulations*

The WIPP is regulated under the Resource Conservation and Recovery Act (RCRA) and is subject to both the Part B licensing requirements and the land disposal restrictions of that statute. The WIPP must comply with other environmental laws, including, among other statutes, the Clean Air Act (40 U.S.C. 7401 *et seq.*), the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*) and the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601 *et seq.*). This action does not affect the need for DOE to comply with these and all other applicable environmental laws with respect to the WIPP.

#### *Public Involvement in Today's Rulemaking*

The Agency has taken significant steps to involve the public in the rulemaking for today's action. The EPA published an Advanced Notice of Proposed Rulemaking (ANPR) in February, 1993 (58 FR 8029) which solicited public comment on eight issues central to the development of this final rule. The EPA again solicited

public comment on a preliminary draft of the proposed rule, in January, 1994. The Agency published a notice of proposed rule on January 30, 1995, which announced the start of a public comment period of 90 days (60 FR 5766). The Agency convened a technical workshop in February, 1995, for the express purpose of soliciting the views of both scientific experts and the public on issues germane to the rulemaking. In March, 1995, the Agency held public hearings in three cities in New Mexico to solicit public input on the notice of proposed rule. On August 1, 1995, the Agency re-opened the comment period on the notice of proposed rule for an additional 45 days (60 FR 39131). During the entire comment period on the proposed rule, the Agency received over 100 written public comments. The Agency has responded to significant comments received on the notice of proposed rule from both written submissions and from testimony at the public hearings, including late written comments received soon after the close of the second part of the comment period, in a document published concurrently with today's action. In September, 1995, EPA conducted a public meeting of the WIPP Review Committee of the National Advisory Council for Environmental Policy and Technology (NACEPT) on three issues relevant to today's action. During this meeting, members of the public provided formal presentations and oral comments to the committee. See 60 FR 43470-43471 (Aug. 21, 1995).

#### *Summary of the Final Rule*

The supporting rationale for today's action, found in the following summary and discussion of principal changes, is further explained in the Background Information Document and the Response to Comments which accompany today's action, copies of which may be obtained as described in the start of this notice. Those sections of the final rule which have remained unchanged since the rule's proposal are also further explained in the notice of proposed rule (60 FR 5766-5791).

#### *Subpart A: General Provisions*

Subpart A of the final rule establishes provisions related to the structure of the final rule itself, including: Purpose, scope and applicability; definitions; substitution of alternative provisions for those promulgated in today's final rule; and procedures which shall be followed in communications and written reports submitted by the Secretary of Energy to the Administrator. Further provisions are set forth which incorporate by reference several publications.

Publications so incorporated shall have the same legal force and effect as the other requirements of the final rule.

Section 194.4 of subpart A permits the Agency to specify conditions on the issuance of a certification and to issue a modification, suspension or revocation of a certification. The Agency would, for example, specify conditions in the event that the necessary confidence in the WIPP's compliance could be achieved by the implementation of additional measures, or if EPA determines that the WIPP will comply with the disposal regulations if certain terms of the application were to be changed.

The Agency would consider issuing a modification, suspension or revocation whenever the disposal activities or disposal system change such that significant information contained in the most recent compliance application were no longer to remain true. Such a situation may occur if (1) DOE plans to make a significant change to the disposal system or disposal activities, or (2) DOE discovers that a significant change has occurred in the disposal system or disposal activities; in either case DOE must inform the Administrator in writing. If DOE finds the latter condition to be true, then DOE must determine if a release of waste from the disposal system has occurred or is expected to occur that would cause the numerical requirements of the disposal regulations to be exceeded. Releases which might occur during management operations, covered under subpart A of 40 CFR part 191, which do not relate to compliance with the disposal regulations would not necessitate this investigation. However, if DOE conducts this investigation and determines that such a release has occurred or is likely to occur, then DOE shall notify the Administrator of this fact and immediately cease emplacing waste in the WIPP. In such situations, the Administrator will determine which of three actions—modification, suspension or revocation—will be appropriate. Any modifications and revocations issued by EPA would affect the certification issued pursuant to section 8(d)(1) of the WIPP Land Withdrawal Act and must be conducted by rulemaking under section 553 of the Administrative Procedure Act. See 5 U.S.C. 553. A suspension may be issued at any time at the Administrator's discretion so as to promptly address any potential threat to public health. A suspension shall remain in place until such time as DOE shall have effected remediations as necessary to re-establish the WIPP's compliance with the disposal regulations or until EPA will

have modified or revoked the certification. DOE shall not restart emplacing waste in the WIPP until the Administrator notifies DOE in writing that the suspension has been lifted.

#### *Subpart B: Compliance Certification and Re-certification Applications*

Subpart B of the final rule sets forth requirements for the format and content of compliance applications. Section 194.11 of the final rule stipulates that DOE must submit a complete compliance application before the one-year, statutory review period shall commence. See Pub. L. 102-579, section 8(d)(1). Should DOE's initial submission be incomplete, the Administrator will explain the nature of the deficiency and will request DOE to submit further information until the Administrator has notified the Secretary that all materials necessary for a complete application have been received. This process will ensure that the Agency's one-year period will be devoted exclusively to a substantive, meaningful review. This provision applies as well to the compliance applications periodically submitted by DOE for re-certification of compliance. Once the Administrator has notified the Secretary of Energy that a complete compliance application for re-certification has been received, the Agency will commence the six month review period as provided for in section 8(f) of the WIPP Land Withdrawal Act. Section 194.12 requires that 30 copies of the compliance applications and any accompanying materials shall be submitted to the Administrator. Section 194.13 requires that compliance applications be accompanied by any referenced materials, unless such materials are generally available.

Section 194.14 of the final rule lists 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 the final rule. The Agency intends to publish the final version of the Compliance Application Guidance (CAG) at a later date to provide detailed guidance on the submission of a complete compliance application.

Section 194.15 of the final rule specifies that DOE must submit any additional information that will have been gathered during the elapsed five-year period and that is relevant to compliance with the disposal regulations. To facilitate the Agency's review of compliance applications for re-certification, today's final rule stipulates that DOE will not have to re-submit information that will have been

included in previous compliance applications, provided that the information will have remained true and accurate. The current compliance application should clearly reference such information so that the Agency's review of the section in question can be accomplished expeditiously.

#### *Subpart C: Compliance Certification and Re-certification*

Subpart C establishes the requirements that apply to the performance assessments and compliance assessments that will be used to demonstrate compliance with the numerical requirements of the disposal regulations. In addition, subpart C implements the six assurance requirements of the disposal regulations and also establishes seven general requirements in §§ 194.21 through 194.27 which must be met by all portions of and all activities associated with compliance applications.

Section 194.21, inspections, provides EPA with right of inspection of all activities at the WIPP and all activities located off-site which provide information included in compliance applications. The Agency will conduct periodic inspections, both announced and unannounced, to verify the adequacy of information included in the compliance applications. The Agency may conduct its own laboratory tests, in parallel with those conducted by DOE, so as to confirm the adequacy of the techniques employed at those facilities. The Agency may also inspect any relevant records kept by DOE, including those records required to be generated pursuant to today's action.

Section 194.22, quality assurance (QA), sets requirements that apply to data and information collected as part of the WIPP program. The Agency requires quality assurance programs to be implemented, as soon as practicable after April 9, 1996, that meet the requirements of the American Society of Mechanical Engineers (ASME) "Quality Assurance Program Requirements for Nuclear Facilities" (NQA-1-1989), ASME's "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications" (part 2.7 of NQA-2a-1990 addendum to ASME NQA-2-1989), and ASME's "Quality Assurance Requirements for the Collection of Scientific and Technical Information on Site Characterization of High-Level Nuclear Waste Repositories," (NQA-3-1989 edition), excluding sections 2.1(b), 2.1(c) and 17.1. Section 194.5 of the final rule incorporates these three publications by reference. The Agency believes that ASME's standards offer the most

comprehensive and specific set of requirements for nuclear facilities and has therefore used these standards in place of establishing new requirements. Paragraph (a)(2) of § 194.22 requires that DOE must implement a quality assurance program that meets the above three sets of ASME's requirements for seven specific program elements of the WIPP and for any other system, structure, component, or activity important to the containment of waste in the disposal system.

Data that were collected prior to the implementation of the above programs must also satisfy quality assurance requirements. Any compliance application must demonstrate, subject to the approval of the Administrator or the Administrator's authorized representative, that such data were qualified using one or more of the following four methodologies: (1) Use of a methodology that is substantially equivalent in effect to the three sets of ASME's requirements; (2) peer review that is compatible with NUREG-1297; (3) corroborating data; or (4) confirmatory testing. The Agency believes that each of these latter three methods provides a means of inferring the quality of the existing data by subjecting some aspect of that data to additional scrutiny. Peer review involves a critical evaluation by an independent review group of the adequacy with which the experiments used to acquire this data were planned and conducted. The use of corroborating data evaluates the degree to which the existing data agree with data generated from similar work that has already been published in scientific journals, along with an appraisal of the latter's quality. Confirmatory testing involves repeating a small portion of the experiments, using quality assurance methods that meet the requirements of ASME's standards, and comparing the resulting data to the data in question. In the last two alternate methodologies, the level of agreement between the existing data and the corroborating or confirmatory data provides an objective measure to assess the quality of the existing data, if only in part. All quality assurance programs, both for existing data and data that has yet to be collected, must assess the accuracy, precision, representativeness, completeness and comparability of data. To verify that the quality assurance programs satisfy the requirements of this section, the Administrator will conduct inspections which may include surveillance, audits and management systems reviews.

Section 194.23, models and computer codes, sets requirements for the models and computer codes used in



performance assessments and compliance assessments. Compliance applications must demonstrate that performance assessments and compliance assessments make a logical progression from conceptual models to mathematical models to numerical models and finally to computer models and codes. Compliance applications must provide information on and descriptions of models and computer codes which will permit the Agency to conduct a review of the modeling approach, theoretical bases, and the methodology employed in developing the list of processes and events used to support the compliance application. Compliance applications must include evidence that all computer codes comply with the requirements of part 2.7 of ASME's NQA-2a-1990 addendum.

The Agency intends to conduct detailed reviews of the computer codes used in performance and compliance assessments, since it is the results of computer codes themselves that will be compared to the numerical requirements found at section 13 of 40 CFR part 191. Compliance applications must provide: Descriptions of the theoretical backgrounds for each model and the method of analysis or assessment; a line-by-line listing of codes, which may be submitted in electronic format; a discussion of the treatment of correlation between parameters; and other information necessary to permit the Agency to conduct its review. Upon request, DOE must provide the Agency with the means to conduct its own simulations. The final rule requires that any computer files and hardware that will be necessary for performing simulations shall be made available within 30 days of a request from the Administrator or the Administrator's authorized representative.

Section 194.24, waste characterization, has been revised in the final rule. A discussion of the rationale for the changes is contained below in the section of the supplementary information, "Principal changes in the final rule." The final rule requires DOE to identify and describe quantitative information on those physical, chemical and radiologic characteristics of the waste that can influence disposal system performance. The Agency does not expect or require that every drum of transuranic waste be opened in an effort to provide an exhaustive characterization of the contents. Rather, the Agency expects that DOE will sample drums of waste to the extent necessary and will combine the results with other information such as process

knowledge to determine the waste characteristics. The level of accuracy needed in waste characterization is determined by the degree of accuracy assumed in the compliance application. A waste characteristic, as defined in the final rule, is a physical or chemical parameter that serves as a quantitative input to performance assessments or compliance assessments, examples of which are solubility and compactibility. DOE must conduct an analysis to identify and assess the impact on long-term performance of those waste characteristics which influence the containment of waste in the disposal system. This section of the final rule lists specific characteristics which must, at a minimum, be included in the analysis.

The final rule requires DOE to establish limits on the quantities of different "waste components," such as cellulose, metals or activity in curies, that may be proposed for disposal and emplaced in the WIPP. A waste component is distinguished from a waste characteristic in that the former is an amount of a type of waste present in the total inventory—expressed as a volume, mass or weight (or curies, in the case of activity)—whereas the latter is any parameter that describes the physical, chemical or radiologic properties and behavior of some or all of the containers of waste. For example, a container of waste might contain a given quantity of chelating agents, which are a waste component. An example of a corresponding waste characteristic is the solubility in brine of the radionuclides in a container. The final rule requires that DOE establish upper or lower limits, as appropriate, on the total amount of each waste component that may be emplaced for disposal in the WIPP. A lower limit might be specified for gas-gettering waste components, and an upper limit might be specified for cellulose. The final rule requires that these upper and lower limits be established based on the total inventory proposed for disposal such that the results of a performance assessment will comply with the containment requirements of 40 CFR 191.13 when these values are used.

Performance assessments and compliance assessments must use the values for each waste characteristic as each would exist in the disposal system assuming that an amount of each waste component, equal to that component's upper or lower limit, as appropriate, were emplaced in the WIPP. As waste is emplaced in the WIPP, a running total must be kept of each waste component. The final rule requires that the quantity of each waste component that has been

emplaced in the repository shall not cause the upper limits to be exceeded or, as appropriate, shall not preclude the total emplaced quantity of any waste component from eventually reaching its lower limit. Compliance with the lower limits shall be demonstrated by DOE using information on the waste loading scheme, the total amount of that waste component that has been emplaced in the disposal system to date, the total amount of that waste component listed in the total waste inventory described in the current compliance application, and the amount of that waste component that still has yet to be generated. DOE must establish a system of controls to verify that this requirement will be met and shall submit documentation demonstrating this with any compliance application.

Section 194.24 also requires that performance assessments and compliance assessments shall be conducted in accordance with the waste loading procedures and schemes that will be employed. If a waste loading scheme is not included in the compliance application, the performance assessments and compliance assessments must assume that the containers of waste are randomly emplaced in the WIPP. Thus, for example, DOE shall not assume that the waste components and characteristics are evenly distributed throughout the repository unless a proposed loading scheme that would cause this to occur has been included in the current compliance application.

The final rule extends the requirements of § 194.22, on quality assurance, to process knowledge acquired and used during waste characterization activities. The final rule specifies that the total inventory of waste proposed for disposal in the WIPP must comply with the limitations on transuranic waste found in the WIPP Land Withdrawal Act. The final rule enables the Administrator to use audits and inspections to verify compliance with the waste characterization section.

Section 194.25 of the final rule specifies requirements on future state assumptions. The Agency recognizes the inherently conjectural nature of specifications on future states and wishes to minimize such speculation in compliance applications. The Agency has found no acceptable methodology that could make reliable predictions of the future state of society, science, languages or other characteristics of future mankind. The Agency does believe that established scientific methods could make plausible predictions regarding the future state of three classes of natural processes,

namely geologic, hydrogeologic and climatic conditions. Hence, the final rule requires that performance assessments and compliance assessments shall include dynamic analyses of geologic, hydrogeologic and climatic processes and events that will evolve over the 10,000-year regulatory time frame. DOE shall assume that all other present day conditions will exist in their present state for the entire 10,000-year regulatory time frame.

Section 194.26 sets requirements that apply to expert judgment. Typically, expert judgment is used to elicit two types of information: (1) Numerical values for parameters (variables) which are measurable only by experiments that cannot be conducted due to limitations of time, money and physical situation; and (2) essentially unknowable information, such as which features should be incorporated into passive institutional controls that will deter human intrusion into the repository. Quality assurance must be applied to expert judgment to verify that the procedures for conducting and documenting the expert elicitation have been followed. The final rule prohibits expert judgment from being used in place of experimental data unless DOE can provide a justification explaining why the necessary experiments could not be conducted. Expert judgment may substitute for experimental data in those instances where limitations of time, resources or physical setting would have precluded the successful and timely collection of data.

The compliance application must provide documentation which demonstrates that the experts have the necessary qualifications for addressing the questions and issues put before them. Compliance applications must explain the connection between the question posed to the expert panel and the manner in which the final report of the panel is used in the compliance application. These requirements have been included to prevent any misuse of expert judgment as might result from the use of the results of one elicitation process in answer to a new and separate question that was not posed to the experts and for which, if asked, the experts might have provided a different answer.

The final rule places requirements on the composition of the expert panel, including the fraction of panel members who are not employed by DOE. At least two-thirds of the experts sitting on an expert panel shall not be employed directly by DOE or its contractors. University professors with grants from DOE for research not related to the WIPP will not be considered employees

or contractors of DOE, nor will the New Mexico Environmental Evaluation Group and the National Academy of Sciences' Board on Radioactive Waste Management and WIPP Panel. In exceptional instances, DOE may use as few as one-third non-DOE employees if a sufficient number of non-DOE employees cannot be found. DOE must submit documentation which demonstrates that a sufficient number of non-DOE experts were not available. In the proposed rule, the Agency had set this minimum at one-half of the expert panel's membership. However, because of the pervasive effort of DOE in the fields of highly radioactive waste disposal and actinide chemistry, the Agency has lessened this requirement in the final rule in striving to balance the importance of technical expertise with the need for the advice to be impartial.

The section on expert judgment requires that the public be given the opportunity to present information to the expert panel to allow the public's views to be incorporated in the expert judgment process. This requirement will help prevent an inappropriately narrow spectrum of background information from being presented to the experts which might have slanted the outcome of the elicitation process. This section also requires that the elicitation process be well documented so as to demonstrate a logical progression from the first statement of the issue given to the panel members to the combination and presentation in the final report of the elicited results.

Section 194.27, peer review, has been revised in the final rule. The rationale for these changes is discussed in the section of the **SUPPLEMENTARY INFORMATION**, "Principal changes in the final rule." Given that decisions in the field of highly radioactive waste disposal are inherently first-of-a-kind, the Agency is requiring peer review so that others working in the field can confirm the adequacy of these decisions and interpretations. The final rule requires DOE to conduct peer review of three specific elements of the WIPP program. In specific, the Agency has required peer review of the conceptual models that DOE selects and develops, waste characterization assessments and the study of engineered barriers. The requirement for peer review of conceptual models will enrich DOE's process of selecting and developing conceptual models with a broad spectrum of scientific viewpoints. Waste characterization is a field in which many new and precedent-setting techniques will be employed in areas in which no standardized practice exists. Peer review of waste characterization is

indicated due to the importance of a knowledge of the physical, chemical and radiological state of the waste in predictions of the long term performance of the disposal system. This section, § 194.27, requires peer review to be conducted of the study of engineered barriers so as to ensure that the best possible information is provided to DOE on the selection of engineered barriers. Additionally, this section requires compliance applications to include documentation of any peer review activities that DOE may have conducted apart from those required by this rule, including those activities which are similar to peer review, such as the reviews conducted by the WIPP Panel of the National Academy of Sciences.

The Agency is requiring that peer review which occurs subsequent to the promulgation of today's action must be conducted according to the guidelines of NUREG-1297. The final rule incorporates this publication by reference, as specified in § 194.5. The specific requirements in NUREG-1297 that discuss for which activities peer review should be conducted do not apply, nor do they supersede the requirements of the final rule. Peer review which has been conducted prior to today's action must be documented in compliance applications. Such past peer review activities must conform to either NUREG-1297 or to an alternate set of criterion which are substantially equivalent in effect to NUREG-1297 and which have been approved by the Administrator.

Sections 194.31 through 194.34 of the final rule implement the numerical containment requirements of 40 CFR 191.13. Section 194.31, which provides instructions for setting the release limits of appendix A of 40 CFR part 191, has been revised from the proposed rule. The rationale for this change is explained in the section, "Principal changes in the final rule." Section 194.31 now specifies that the release limits are to be determined based on the total activity, in curies, of transuranic waste present at the time of disposal (as defined in 40 CFR 191.2). If the activity of a waste container is assayed prior to this time, then the known rates of decay for the radionuclides in the container should be used to calculate the activity of the waste as it will exist at the anticipated time of disposal.

Section 194.32 stipulates that performance assessments shall include both natural and man-made processes and events which can have an effect on the disposal system. Performance assessments need not include those processes and events which have a

probability of less than 1 in 10,000 of occurring during the 10,000-year regulatory time frame. For the purposes of this screening requirement, processes and events must be analyzed in the most general formulation possible; for example, the probability of dissolution must be set equal to the probability of all types of dissolution occurring anywhere in the Delaware Basin during the regulatory time frame. Performance assessments should, however, conduct separate analyses of the different dissolution fronts which occur in the Delaware Basin so as to account for the different hydrogeologic characteristics of each.

With respect to man-made processes and events, performance assessments must include the effects of drilling events and excavation mining. Some natural resources in the vicinity of the WIPP can be extracted by mining. These natural resources lie within the geologic formations found at shallower depths than the tunnels and shafts of the repository and do not lie vertically above the repository. Were mining of these resources to occur, this could alter the hydrologic properties of overlying formations—including the most transmissive layer in the disposal system, the Culebra dolomite—so as to either increase or decrease ground-water travel times to the accessible environment. For the purposes of modeling these hydrologic properties, this change can be well represented by making corresponding changes in the values for the hydraulic conductivity. The Agency has conducted a review of the data and scientific literature discussing the effects mining can induce in the hydrologic properties of a formation. Based on its review of available information, the Agency expects that mining can, in some instances, increase the hydraulic conductivity of overlying formations by as much as a factor of 1,000, although smaller or even negligible changes can also be expected to occur. Thus, the final rule requires DOE to consider the effects of mining in performance assessments. In order to consider the effects of mining in performance assessments, DOE may use the location-specific values of hydraulic conductivity, established for the different spatial locations within the Culebra dolomite, and treat them as sampled parameters with each having a range of values varying between unchanged and increased 1,000-fold relative to the value that would exist in the absence of mining.

The Agency recognizes that other numerical changes to the hydraulic conductivity values may be more

appropriate for use in representing the effects of mining. Compliance applications must include a discussion of the rationale and experimental data which support the hydraulic conductivity values chosen and the effects of mining on the range of these values. The Agency further recognizes that some parameter other than hydraulic conductivity might be demonstrated to incorporate, equally or perhaps better, the potential effects of mining in performance assessments. DOE may elect to use another parameter, provided that DOE can demonstrate that the use of this other parameter is equally or more appropriate than hydraulic conductivity in reflecting the potential effects of mining on the disposal system. Pursuant to § 194.34 of the final rule, performance assessments must randomly sample across the full range of values that have been established for all uncertain variables, including the hydraulic conductivity of the Culebra dolomite established as discussed above.

The final rule specifies those assumptions and methods that shall be used in performance assessments to account for the effects of mining. As with drilling, the historical record of the past 100 years' mining activity in the Delaware Basin provides a reasonable basis for predicting the nature of future mining activity. Accordingly, the Agency examined the records of past mining of mineral resources in the Delaware Basin, using data supplied by the U.S. Bureau of Land Management. The Agency found that the areal extent of mining in the immediate vicinity of WIPP over the past 100 years covered roughly one percent of the land area of the entire Delaware Basin and used this information to predict the likelihood that a mining event would occur in succeeding centuries. Accordingly, the final rule requires performance assessments to assume that, in each century after closure of the repository, there will be a 1 in 100 chance that a single mining event will occur within the controlled area. As explained later in this section, the assumed mining event would remove all of the existing mineral deposits lying within the controlled area that are of similar quality and type to those minerals currently extracted in the Delaware Basin. For each century during the regulatory time frame, performance assessments should determine whether this mining event will occur, based on the 1 in 100 probability, proceeding one century at a time from the start of the 10,000-year period. If a positive determination is made, then

performance assessments must assume that the single mining event occurs at the start of that century and further assume that no mining will occur thereafter. The Department may elect to use an alternate method for calculating the point in time at which mining will occur, provided that such method would not, on average, predict that mining will occur at times later than those calculated using the method in the final rule.

The final rule specifies that mining should be assumed to occur within the controlled area, with the size and shape of the mine conforming to existing mineral deposits that are similar in type and quality to those extracted in the Delaware Basin. The Agency based this requirement on a consideration of the physical nature of mining activities. First, the Agency assumed that the size and shape of a mine will be dictated by the size and shape of the mineral deposits that are to be extracted with no two mines being alike. The mineral deposits that will be mined in the future may consist of minerals of current economic interest, or of materials not useful or valuable in present-day terms. Without knowledge of what these future resources might be, any attempt to predict the size and shape of the associated mineral deposits would be speculative, as would any attempt to determine the size and shape of the mines used to extract them. The Agency further recognized that individual mines are of highly irregular shape and there is every reason to believe that deposits of minerals that are mined in the future will also vary in size and be highly irregular in shape. The Agency believes that no logical mathematical scheme exists that could be used to predict the potentially wide variety of sizes and highly irregular shapes. In light of the speculativeness and mathematical difficulty, the Agency has chosen to use existing mineral deposits as "stand-ins" to be used to determine the size and shape of the unknown mineral deposits that might be mined in the future. Thus, the final rule requires performance assessments to assume that all the presently known mineral resources lying within the controlled area will be extracted at the single point in time determined by the method in the final rule, discussed above. No further mining will be assumed to occur, since the available mineral deposits will have been depleted. The type of minerals that shall be assumed to be extracted are those mineral deposits that are similar in quality and type to those that are currently extracted in the Delaware Basin.

Performance assessments may assume that the likelihood of mining may be decreased by PICs and active institutional controls, to the extent that can be justified in the compliance application and to a degree identical to that assumed for drilling. The requirements of sections 41 and 43 of the final rule therefore will apply to the consideration of mining in performance assessments.

Section 194.33, consideration of drilling events, has been revised since the proposed rule. The rationale for the new provisions is explained in the section below, entitled "Principle changes in the final rule." Section 194.2 includes two definitions relevant to the consideration of drilling events. "Deep drilling" denotes those drilling events that reach or exceed a depth 2150 feet below the surface where such drilling occurred. "Shallow drilling" denotes those drilling events that do not reach to a depth 2150 feet below the surface where such drilling occurred. Sections 194.32 and 194.33 of the final rule require that performance assessments include the effects of both deep drilling and shallow drilling, whether such drilling has occurred prior to the time at which the compliance application is prepared, can be reasonably expected to occur in the near future based on existing leases, or can be expected to occur in the future during the 10,000-year regulatory time frame.

The future rates of both deep drilling and shallow drilling shall each be set equal to the rate at which deep drilling and shallow drilling, respectively, have occurred in the Delaware Basin during the 100-year period immediately prior to the time the current compliance application is prepared. The Delaware Basin is defined, in § 194.2, to be the surface and subsurface features which lie inside the innermost edge of the Capitan Reef and, where the Capitan Reef is absent to the south, the features which lie to the north of a straight line connecting the southeastern point of the Davis Mountains and the southwestern point of the Glass Mountains.

Performance assessments must add together all releases of radionuclides which are predicted to occur during the 10,000-year regulatory time frame to arrive at the cumulative releases from the disposal systems; the containment requirements of 40 CFR 191.13 apply to cumulative releases of waste and not the individual events which cause the releases. Further, boreholes drilled after closure of the repository shall be assumed to affect the properties of the disposal system for the remainder of the 10,000-year regulatory time frame. When analyzing the effects of all later

boreholes, performance assessments must account for the effect that these existing boreholes will have had on the hydrogeologic properties of the disposal system and on the creation of new pathways for releases. In today's final rule, the Agency requires that performance assessments and compliance assessments must include—among other processes and events—the effects on the disposal system of drilling and all types of resource extraction activities, including *inter alia* solution mining and fluid injection, that will have occurred prior to the time at which the compliance application is prepared or that may be expected to occur soon afterward based on existing plans and leases for drilling.

In the case of shallow drilling only, DOE may, if justified, derive the drilling rate from the historical rates of shallow drilling for only those resources in the Delaware Basin which are of similar quality and type to those found in the controlled area. For example, if only non-potable water can be found within the controlled area, then the rate of drilling for water may be set equal to the historical rate of drilling for non-potable water in the Delaware Basin over the past 100 years.

Section 194.33 requires performance assessments to make several specific assumptions about future deep drilling and shallow drilling. These assumptions include that drilling will occur randomly in space and time and may occur at different rates for each resource, and that drilling practices will remain as those of today and may vary depending on the resource. Performance assessments should assume that the permeability of sealed boreholes will be affected by natural processes, and should assume that the fraction of boreholes that will be sealed by man equals the fraction of boreholes which are currently sealed in the Delaware Basin.

The Agency recognizes that drill operators currently employ different techniques in the exploration and development of each resource. Hence, performance assessments shall conduct a separate analysis of the effects that future drilling for each different resource—the act creating a borehole—will have on the disposal system. Each separate analysis should set the future rate of drilling for the particular resource equal to the historical rate at which that resource has been drilled for in the Delaware Basin during the past 100 years. The analyses of the consequences of each type of drilling might remain conceptually similar, but vary with regard to assumptions made on size and depth of boreholes, quantity

of drilling fluid used, or any other characteristic specific to that type of resource. Analyses of the consequences of future drilling events may be confined only to the drilling activity and the subsequent effect of the borehole's presence and need not include an analysis of extraction and recovery activities which would occur subsequently.

In determining the drilling rate or the amount of waste released from such drilling, performance assessments should not assume that drill operators would detect the waste and then cease the current drilling operations or otherwise mitigate the consequences of their actions. Similarly, drill operators should not be assumed to cease further exploration and development of resources as a result of the driller's detecting the waste.

Section 194.34 requires that the results of performance assessments be expressed as complementary, cumulative distributions functions (CCDFs). The CCDFs shall be generated using random sampling techniques which draw upon the full range of values established for each uncertain parameter, which may include physical and chemical waste characteristics. Parameters of lesser sensitivity in performance assessments may be held constant, provided that such constant values can be justified as sufficiently conservative. The quantitative requirements of this section state that there must be a 0.95 probability that, at values of cumulative release of 1 and 10, the maximum CCDF generated exceeds the 99th percentile of the population of CCDFs. The values of cumulative release are calculated according to Note 6 of Table 1, Appendix A of 40 CFR part 191. Additionally, the mean of the population of CCDFs must meet the requirements of section 13 of 40 CFR part 191 with at least a 95 percent level of statistical confidence. In demonstrating compliance with these standards, the infinite number of CCDFs denoted by the term, population of CCDFs, need not be generated. By generating only a finite number of CCDFs and applying statistical theory, the relationships between the finite group of computer-generated CCDFs, the population of CCDFs and the numerical requirements of this section can be established.

Subpart C of today's action also implements the six assurance requirements of section 14 of 40 CFR part 191. The assurance requirements were included in the disposal regulations to provide the confidence needed for long-term compliance with

the containment requirements of section 13 of 40 CFR part 191.

Section 194.41 of today's final rule requires a description of the active institutional controls that will be implemented at the WIPP. This description shall be sufficient to support any assumptions made on their effectiveness in performance assessments and compliance assessments. However, in no case shall active institutional controls be assumed to be in effect for more than 100 years after the time of disposal.

Section 194.42 of the final rule, monitoring, has been revised from the proposed rule. The rationale for these changes is provided below, in "Principal changes in the final rule." Any unpredicted detection of movement of radionuclides toward the accessible environment would be cause for concern that a release of waste in excess of what is permitted under the disposal regulations is likely to occur. This section specifies requirements for monitoring in both the pre-closure and post-closure periods, as necessary to verify that the WIPP complies with the disposal regulations. In the event that an initial certification has been granted, the results of monitoring during the pre-closure period will be used by the Agency to verify that the information contained in the initial compliance application has remained true and accurate; this information would be used by the Agency during both the initial five-year period after the start of emplacement of waste and during the reviews made for the periodic re-certifications of compliance. The final rule has included a provision which requires DOE to conduct an analysis of parameters that will be used in the development of pre-closure and post-closure monitoring plans. The analysis should consider the importance of the parameter with respect to both the containment of waste in the disposal system and the practicability of performing such monitoring, including its technical feasibility and the cost.

Section 194.43 implements the assurance requirements on passive institutional controls (PICs). The final rule specifies that DOE must include a detailed description of the PICs that will be employed and lists the information that the PICs are required, at a minimum, to convey. Additionally, the final rule allows the Department to reduce the likelihood of future human intrusion that is used in performance assessments by a proposed amount corresponding to the predicted effect of PICs. See generally 47 FR 58196, 58201 (Dec. 29, 1982); 50 FR 38066, 38080 (Sept. 19, 1985). Thus, DOE may

propose in its compliance application to reduce the rate of human intrusion by a fractional amount, extending over a technically supportable period of time, and must justify this using the plans for the implementation for PICs and associated evidence of their effectiveness. This credit may take the form of a constant reduction in the rate of human intrusion lasting several hundred years or may be a reduction in the rate which tapers off in size over several hundred years. Such credit cannot be assumed to eliminate completely the possibility of human intrusion, even for a short period of time after the active institutional controls at the WIPP are assumed to be ineffective. During the rulemaking on certification, the Agency could determine that the description of the PICs does not adequately justify the degree of proposed credit assumed by DOE and therefore disallow some or all of the credit proposed by DOE in the compliance application.

Having considered the public comments regarding PICs, the Agency believes that such credit could be no more than approximately 700 years past the time of disposal. Thus, the final rule limits to several hundred years the amount of credit that EPA may grant for PICs. Any determination that a specific numerical credit would be appropriate for a much longer period of time would be unduly speculative and therefore inappropriate.

Today's action should not be construed to approve or award any amount of credit for PICs, as such a determination cannot be made in advance of the rulemaking on certification of compliance. The Agency is deferring any decisions on credit for PICs planned for the WIPP until such time as the compliance application has been received and a rulemaking for certification has been completed. This restates the Agency's prior assertion, made in the promulgation of the final disposal regulations in 1985:

Specific judgments about the chances and consequences of intrusion should be made by the implementing agencies (EPA for the WIPP) when more information about particular disposal sites and passive control systems is available. See 50 FR 38080.

In developing this section of the final rule, 40 CFR 194.43, the Agency considered the treatment of PICs in the disposal regulations, the input received in public forums and the public comments received on the proposed rule. The disposal regulations established the foundation of today's action on the role of passive institutional controls. Section 191.14(c) of the disposal regulations require that

disposal sites be designated by the most permanent markers, records, and other passive institutional controls practicable to indicate the dangers of the wastes and their location. In adopting these provisions of the disposal regulations, the Agency expressly assumed that passive institutional controls "should reduce the chance of inadvertent intrusion compared to the likelihood if no markers and records were in place." See 50 FR 38080. With respect to performance assessments, the Agency examined whether PICs should be taken into account to some degree when estimating the likelihood of inadvertent human intrusion and concluded that "a limited role for passive institutional controls would be appropriate when projecting the long-term performance of mined geologic repositories to judge compliance with (the containment requirements of 40 CFR part 191)." At the same time, the Agency explicitly determined that PICs should not be assumed to completely prevent the possibility of inadvertent human intrusion. See 50 FR 38080.

In the proposed rule, 40 CFR part 194, the Agency specifically requested comment on the requirements on PICs. The Agency conducted a public discussion of PICs in a technical workshop in Washington, DC, in February, 1995. In September, 1995, EPA consulted the WIPP Review Committee of the National Advisory Council for Environmental Policy and Technology (NACEPT) on three issues, including PICs, in a public meeting in New Mexico. See 60 FR 43470-43471 (Aug. 21, 1995). The Committee agreed that PICs would be likely to decrease the likelihood of inadvertent intrusion into the WIPP but expressed concern about the availability of a rigorous method by which to determine the appropriate reduction due to PICs in the future likelihood of inadvertent intrusion. Some members of the Committee stated that, if credit were to be approved, the size of the credit should not reflect that PICs would be effective for more than a small fraction of the 10,000 year regulatory time frame.

Many public comments received on the proposed rule expressed skepticism about whether PICs would be effective for the entire 10,000 year regulatory time frame or for even a fraction thereof. Other comments stated the belief that civilizations living 1,000 to 10,000 years from now would, in fact, be capable of understanding the records and markers that were left behind at the WIPP. Still other comments asserted that, in allowing for the possibility of credit, the Agency had revised the intent of the

assurance requirements, one of which being the requirement for the implementation of PICs. Specifically, comments stated that the assurance requirements were not intended to be considered when determining compliance with the numerical containment requirements found at 40 CFR 191.13.

The provisions of the final rule entertaining possible credit for PICs are within EPA's authority. In adopting the assurance requirements in 40 CFR part 191, EPA expressly limited the credit for active institutional controls. EPA prohibited performance assessments from considering any contributions from active institutional controls for more than 100 years after disposal. See 40 CFR 191.14(a). EPA declined to similarly limit the effect of PICs in reducing the likelihood of human intrusion. 50 FR 38080. By contrast, EPA contemplated that PICs may discourage the likelihood of human intrusion for some period of time longer than active institutional controls. However, EPA indicated that it generally believed it was inappropriate to rely on PICs for extended periods of time. See 50 FR 38080. Based on the public comments and consistent with EPA's general view that it is inappropriate to rely on PICs for very long periods of time, EPA is constraining in the final rule the length of time that EPA could consider granting credit for PICs to several hundred years. EPA's decision about the actual efficacy of PICs proposed for the WIPP will be based on DOE's compliance application but may not exceed this limit.

Further, the degree to which PICs might reduce the future drilling rate can be reliably determined only through informed judgment. The Agency agrees with the NACEPT Committee that no rigorous and non-speculative method is available to determine the appropriate amount of credit for PICs. Thus, DOE's proposed reduction in the likelihood of human intrusion due to PICs would probably be conducted through an expert judgment process that considers the specific PICs to be implemented at the WIPP by DOE. The expert judgment performed specifically to determine the effect of PICs must satisfy the requirements of section 26 of today's action, on expert judgment. For example, this section requires that the range of professions represented on the expert panel must cover the complete spectrum of knowledge that will be necessary to address the question given to the experts. In the case of PICs, the Agency would expect that experts would be selected not only from

professions such as archeology, but from professions which are concerned with the exploration and development of natural resources such as oil and natural gas.

Section 194.44 of the final rule implements the assurance requirement on engineered barriers. This section 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 requirement, found at 40 CFR 191.13, that DOE analyze the performance of the complete disposal system, any engineered barriers that are ultimately implemented at the WIPP must be considered by the Department and, ultimately, EPA when evaluating compliance with both the containment requirements of 40 CFR 191.13 and the assurance requirement of 40 CFR 191.14(d).

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 of the disposal system resulting from exploration and development of nearby natural resources. This assurance requirement will be met if performance assessments comply with the numerical containment requirements of section 13 of 40 CFR part 191, provided that the potential effects of human intrusion at the WIPP will have been appropriately considered.

Section 194.46 implements the assurance requirement that the removal of waste remain possible for a reasonable period of time after disposal. The final rule has eliminated the requirement for the development of a plan for the removal of waste which had been contained in the proposed rule. In place of the requirement for a removal plan, EPA is including in the final rule a requirement that DOE perform an evaluation to demonstrate that the removal of waste will remain feasible for a reasonable period of time after disposal.

Sections 194.51 through 194.55 provide the criteria that must be met in order to demonstrate that the WIPP will comply with the ground-water requirements of subpart C of 40 CFR part 191 and the individual protection requirements of section 15 of 40 CFR part 191. Section 194.51 and 194.52 specify the assumptions that must be incorporated into compliance assessments in the analyses of annual committed effective dose equivalent received by individuals, used in determining compliance with the

individual protection requirements. Compliance assessments should separately analyze the doses received by individuals from each pathway. Compliance assessments should assume that the protected individual resides at the single geographic point where the maximum dose would be received, calculated by the sum of all pathways.

Section 194.53 lists the assumptions that compliance assessments must include when analyzing the doses received through underground sources of drinking water (USDWs), used in determining compliance with subpart C of 40 CFR part 191. Doses can be received from any USDW outside of the controlled area, provided that a connective pathway could be expected to be established via ground-water travel between the disposal system and that USDW. The Agency expects that USDWs which lie closer to the disposal system will have a greater chance of being affected by releases of waste. The Agency therefore does not intend for DOE to expend resources analyzing doses received from USDWs located large distances from the disposal system. The calculations of doses received from USDWs should assume that drinking water is withdrawn directly from the contaminated USDW and consumed at a rate of two liters per day.

Section 194.54 defines the scope of compliance assessments. Compliance assessments should be conducted of the undisturbed performance of the disposal system, which, by the definition in section 12 of 40 CFR part 191, denotes that the disposal system is not disrupted by human intrusion or the occurrence of unlikely natural events. Section 194.55 requires that compliance assessments include calculations or "estimates" of three quantities: (1) The annual committed effective dose received from all pathways, an analysis which corresponds to the requirements of section 15 of 40 CFR part 191; (2) dose equivalents received from USDWs; and (3) concentrations of radionuclides present in USDWs, the latter two of which correspond to subpart C of 40 CFR part 191. To generate a "range" of estimates, compliance assessments must make repeated calculations, with each iteration employing a different set of randomly selected values for each uncertain parameter. Parameters of lesser sensitivity in compliance assessments may be held constant, provided that these values can be justified as being sufficiently conservative. The final rule requires that there be a 0.95 probability that the maximum estimate of each set so generated exceeds the 99th percentile of

the population of estimates. The mean and the median of the population of each set of estimates must meet the requirements of section 15 and subpart C of 40 CFR part 191, as applicable, with at least a 95 percent level of statistical confidence.

#### *Subpart D: Public Participation*

Subpart D of today's action establishes procedures that EPA will use to involve the public in the decisions on certification and re-certification and requires EPA to publish notices of its actions in the Federal Register. Subpart D includes new provisions which require the Agency to involve the public in decisions to modify or revoke a certification. Section 194.65 requires that EPA publish a notice in the Federal Register announcing the Agency's proposed decision on the modification or revocation of the certification. The notice of proposed rulemaking must solicit comment on the proposed decision. Section 194.66 requires the Administrator to publish a notice of final rulemaking in the Federal Register, announcing whether the Agency has revoked, modified or taken no action to change the certification. Section 194.67 requires that EPA maintain a public docket with all information used in making the decisions on certification, re-certification, and modification and revocation of the certification.

#### *Principal Changes in the Final Rule*

In addition to the principal changes described below, today's action contains other minor modifications to the proposed rule. Further discussion of the rationale and information supporting significant changes found in today's action is contained in the Background Information Document and the Response to Comments, which may be obtained as explained in the start of this notice.

#### *Scope of Performance Assessments and Consideration of Drilling Events*

In §§ 194.32 and 194.33 of the final rule, the Agency has provided further clarification on which activities fall within the scope of human intrusion. (Section 194.33 had been titled "Consideration of human initiated processes and events" in the proposed rule.) The final rule requires that the effects of deep drilling, shallow drilling and excavation mining must be included in performance assessments. In the proposed rule, the Agency had excluded excavation mining from consideration (60 FR 5774; January 30, 1995). The Agency received several public comments recommending that

performance assessments should be required to include the effects of future mining during the regulatory time frame in order to account for the presence of potash in the vicinity of the repository. The Agency has re-evaluated the proposed exclusion of mining, in light of these public comments. The Agency believes that, while there is uncertainty surrounding the potential effects of mining, mining could nonetheless alter the hydrogeologic properties of certain formations that lie at shallower depths than the mined portion of the repository. Thus, the final rule requires performance assessments to consider the possible effects of excavation mining on the disposal system. As discussed previously, DOE may address this requirement by considering the changes that mining would induce in the hydraulic conductivity of the disposal system. Additionally, the requirements of the final rule specify the method for determining the size and shape, location and point in time at which mining occurs. The Agency specified these items to provide clarification on how mining should be considered and to avoid unbounded speculation that would result from the high uncertainty regarding whether, where and how mining would occur in the Land Withdrawal area. EPA's decision was based on a desire to include mining in performance assessment in a realistic fashion without recourse to such unconstrained speculation. To this end, the final rule has specified that mining will continue at the same rate as it has over the past 100 years, that the area to be mined is the area that contains mineral deposits of similar type and quality to those that are currently extracted in the Delaware Basin, and that only the major impacts on the disposal system of mining need be considered. EPA believes this is consistent with the future states assumptions of section 25 as they apply to the future activities of man.

The Agency has added definitions of deep drilling and shallow drilling in § 194.2. Both types of drilling shall include exploratory and developmental wells. The addition of these definitions was prompted by commenters who noted that the definitions of human intrusion and "human activity" that were in the proposed rule had caused confusion by distinguishing their meanings on the basis of the depth at which drilling occurs. In the final rule, the Agency has removed these definitions from the final rule and instead makes use of the defined terms, deep drilling and shallow drilling in order to provide greater clarity.

Commenters also requested that the final rule require analysis of disposal of brine that accumulates during the extraction of oil and of secondary recovery of oil performed using water-flood injection. The Agency considered this comment in the larger context of the nature of potential human intrusions during the next 10,000 years and what assumptions might hold true during that time. The Agency believes that no one resource will last for the entire 10,000 years and therefore has concluded that the techniques for extraction of any one resource—such as water-flood injection for oil recovery—are unlikely to be in use during much of the 10,000-year regulatory time frame. With respect to drilling rates, the Agency reasoned that while the resources drilled for today may not be the same as those drilled for in the future, the present rates at which these boreholes are drilled can nonetheless provide an estimate of the future rate at which boreholes will be drilled. The Agency does expect that drilling will never completely cease; while some resources may become depleted over time and, while the rate of extraction of those resources may decrease, the increased rate of drilling for newly discovered resources will compensate for this decline. In effect, when used for the purpose of determining the future drilling rate, today's drilling activities act as surrogates for the unknown resources that will be drilled for in the future. With respect to the consequence and releases due to future drilling, present-day drilling activities provide the only available basis for making assumptions in performance assessments. Future extraction of any resource will likely necessitate drilling a hole for its recovery. However, because there is doubt as to whether the resources associated with today's specialized extraction techniques and fluid injection will remain available for 10,000 years, the final rule does not require that performance assessments assume that such extraction activities will occur during the entire regulatory time frame, but does require that the effects of the drilling events themselves be analyzed. The techniques include, for example, water-flood injection for secondary recovery of oil, solution mining and the disposal by injection of brine accumulated during recovery of oil.

The Agency recognizes, however, that resource extraction and fluid injection activities which are currently performed in the Delaware Basin can alter the hydrogeologic properties of the initial state of the disposal system. The final

rule requires that performance assessments and compliance assessments analyze the effects of all types of fluid-injection and all boreholes which can have an effect on the disposal system and which have been or will have been drilled prior to or soon after disposal. These boreholes shall be assumed to affect the properties of the disposal system for the entire 10,000-year regulatory time frame. Predictions about such future activities shall be strictly limited to the expected use of existing leases.

Today's final rule eliminates the proposed cap on the rate of deep drilling into the disposal system of 62.5 boreholes per square kilometer per 10,000 years as well as the proposed lower limit of 25 boreholes per square kilometer per 10,000 years. The Agency received numerous public comments objecting to the use of upper and lower limits on the rate of deep drilling. The Agency has concluded that the rate of drilling into the disposal system used in performance assessments covering the 10,000-year regulatory time frame should be derived solely from the historical record of drilling in the region surrounding the WIPP. In the proposed rule, the Agency had specified that the past 50 years of records on drilling shall be used to establish the rates for shallow drilling and deep drilling, the latter being subject to upper and lower caps. While developing the final rule, the Agency recognized that drilling activity has been at a maximum during the past 50 years, whereas during the past 100 years, a broader spectrum of high and low drilling rates can be found. In the long-term future, it can be expected that the drilling rate will consist of periods of high and low drilling activity, which makes the past 100 years a more appropriate period for calculating the drilling rate. In addition, more detailed examination of the available records in Texas and New Mexico since the time of the proposed rule has shown that accurate data on drilling activity dates back 100 years, rather than 50 years as was believed initially. The final rule therefore specifies that the rates of both shallow drilling and deep drilling are to be set based on data from the 100 year period ending at the time DOE prepares the compliance application.

Today's final rule includes a definition of the term "Delaware Basin," used in the regulation to be that area over which the past drilling rate is to be averaged in order to establish the rate of drilling used in performance assessments. In the proposed rule, the Agency had solicited comment on how to define the Delaware Basin. Many comments were received, with the bulk

of the discussion focusing on whether the Capitan Reef should be included in the definition. In arriving at the definition in the final rule, the Agency considered the geologic and hydrogeologic characteristics of the formations which contain the WIPP versus those of the Capitan Reef. The Capitan Reef is more permeable to the flow of water and was formed from organic material which differs from the salt formations which immediately surround the WIPP. The Agency had stated its intention to define the Delaware Basin to be the largest contiguous area that has similar geologic properties. Because of the differences, noted above, between the Capitan Reef and the interior formations, the Agency has chosen to define the Delaware Basin to be those surface and subsurface formations which lie inside the innermost edge of the Capitan Reef. Where the Capitan Reef is absent to the south, the Delaware Basin includes those features which lie to the north of a straight line connecting the southeastern point of the Davis Mountains and the southwestern point of the Glass Mountains.

#### *Waste Characterization*

Numerous public comments were received on the proposed § 194.24, waste characterization. Commenters stated that this section required greater clarity in order to be implemented effectively at the WIPP. The final rule retains the use of "waste characteristics" to provide a description of the waste. The term, waste categories, has been eliminated in the final rule. The final rule uses the term, "waste components," to denote an amount of a type of waste—expressed as a volume, mass or weight (or curies, in the case of activity)—such as chelating agents and cellulose. The waste categories in the proposed rule were to be established based on the assumption that wastes with similar waste characteristics would behave similarly in the disposal system. The Agency believes that using instead the term "waste components" provides a less abstract scheme for classifying waste which could be more easily implemented. In particular, the Agency believes that, for a given container of waste, DOE could more readily identify how much of each waste component is present rather than how much of each waste category is present. The final rule requires that these limits be established such that the results of performance assessments and compliance assessments will comply with the numerical requirements of 40 CFR Part 191 when the maximum or minimum

values for each waste component are used, as appropriate.

To assist in establishing the waste characteristics and waste components and quantitative values of each, the final rule requires that compliance applications include an analysis to identify and assess the impact on long-term performance of those waste characteristics which influence the containment of waste in the disposal system. An analysis must also be conducted of waste components to determine which of these will influence the waste characteristics identified as having an influence on containment. This section of the final rule specifies those waste characteristics and waste components which, at a minimum, the respective analyses must investigate.

#### *Peer Review*

Section 194.26, peer review, has been narrowed in scope in the final rule. The Agency received many public comments stating that the requirements on peer review were stated too broadly such that an inordinate and unmanageable number of peer reviews would be required. Additionally, commenters noted that many of the activities that the proposed rule had required to be peer reviewed were subject to specific quality assurance requirements under § 194.22. Public comments noted that, in this instance, the proposed peer review requirements would be redundant with the quality assurance requirements. Such activities would include the computer codes and the data used to support all models—conceptual, mathematical and numerical—and computer codes.

The Agency consulted the WIPP Review Committee of NACEPT at the September, 1995 meeting and sought its advice on how to address peer review. The Committee suggested that peer review of quality assurance programs would be unnecessary, since, by requiring DOE to adhere to a program that meets the requirements of three sets of ASME's standards, today's action would already be sufficient to control the quality assurance process. The Agency agrees with both the Committee and with similar public comment and has eliminated the requirement for peer review of quality assurance programs and plans. The Committee also stated that peer review could be used both to insure that analyses use the correct model of repository behavior and to evaluate the subjective uncertainty in whether the appropriate conceptual model was selected. In the case of WIPP, unanimous agreement does not exist on the nature of the conceptual models of natural processes such as dissolution



which can have an effect on the disposal system. To subject these issues to wider scrutiny, the final rule specifies that peer review must be conducted of the conceptual models selected and developed by DOE.

#### *Application of Release Limits*

Section 194.31 of the final rule specifies that the release limits of Appendix A of 40 CFR part 191 shall be determined based on the total activity, in curies, of transuranic waste present at the time of disposal. Public comment was divided between those who recommended setting release limits at 100 years, as in the proposed rule, and those who recommended the time of disposal. The Agency solicited the views of the WIPP Review Committee of NACEPT on the subject of release limits in the meeting held in September, 1995. Some committee members noted that radionuclides such as plutonium 238 would quickly decay to less than half their original number in under 100 years and thus would not pose a threat for more than a small fraction of the 10,000-year regulatory time frame. Hence, some members of the committee recommended the option of setting the release limits at later times so that the release limits would be based on longer-lived radionuclides. Doing so would more accurately reflect the long-term hazards presented by the waste.

Some committee members also recommended that the Agency should base its decision on the original intent of the disposal regulations. The Agency believes that the disposal regulations were designed to avoid the undue influence of short-lived radionuclides on the size of the release limits. The disposal regulations accomplished this purpose in Appendix A by eliminating the contribution of radionuclides having half-lives of less than twenty years. The Agency has therefore chosen in the final rule to determine release limits based on the total activity, in curies, of transuranic waste present at the time of disposal.

#### *Monitoring*

The monitoring requirements have been modified to provide clearer direction for the development of a post-closure monitoring plan. Several commenters suggested that, by requiring that post-closure monitoring be conducted in a manner "compatible" with RCRA, DOE might be forced to implement two over-lapping monitoring programs in order to comply with both RCRA hazardous waste regulations and 40 CFR part 194. Other commenters noted that, in the event that RCRA monitoring at the WIPP were to be

modified or eliminated, the requirement in 40 CFR Part 194 as proposed would be correspondingly reduced. To provide clearer direction on the performance of post-closure monitoring, the Agency has made two changes in the final rule. First, to eliminate potential overlap, the Agency is requiring that post-closure monitoring be required to be "complementary" with RCRA, so that information yielded by the one monitoring program would not be duplicated by the other. The Agency is requiring in the final rule that post-closure monitoring be conducted, to the extent practicable when considering technical feasibility and cost, of those parameters which are important to the containment of waste in the disposal system. Such parameters shall be identified in a required analysis that will assess which parameters are important to the containment of waste and which therefore should be included in post-closure (and pre-closure) monitoring.

#### *Rulemaking Analyses*

##### *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.

#### *Regulatory Flexibility Act*

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities. Today's final rule sets forth requirements which apply only to Federal agencies and the Administrator therefore certifies that no small entities will be affected.

#### *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.*)

#### *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. Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local or tribal governments or 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).

#### *List of Subjects in 40 CFR Part 194*

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

Dated: February 1, 1996.

Carol M. Browner,  
*Administrator.*

For the reasons set out in the preamble, 40 CFR part 194 is added as set forth below.

### **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**

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

#### Subpart A—General Provisions

##### § 194.1 Purpose, scope and applicability.

This part specifies criteria for the certification or any re-certification, or subsequent actions relating to the terms or conditions of certification of the Department of Energy's Waste Isolation Pilot Plant's compliance with the disposal regulations found at part 191 of this chapter and pursuant to section 8(d)(1) and section 8(f), respectively, of the WIPP LWA. The compliance certification application submitted pursuant to section 8(d)(1) of the WIPP LWA and any compliance re-certification application submitted pursuant to section 8(f) of the WIPP LWA shall comply with the requirements of this part.

##### § 194.2 Definitions.

Unless otherwise indicated in this part, all terms have the same meaning as in part 191 of this chapter.

*Certification* means any action taken by the Administrator pursuant to section 8(d)(1) of the WIPP LWA.

*Compliance application(s)* means the compliance certification application submitted to the Administrator pursuant to section 8(d)(1) of the WIPP LWA or any compliance re-certification applications submitted to the Administrator pursuant to section 8(f) of the WIPP LWA.

*Compliance assessment(s)* means the analysis conducted to determine compliance with § 191.15, and part 191, subpart C of this chapter.

*Delaware Basin* means those surface and subsurface features which lie inside the boundary formed to the north, east and west of the disposal system by the innermost edge of the Capitan Reef, and formed, to the south, by a straight line drawn from the southeastern point of the Davis Mountains to the most southwestern point of the Glass Mountains.

*Deep drilling* means those drilling events in the Delaware Basin that reach or exceed a depth of 2,150 feet below the surface relative to where such drilling occurred.

*Department* means the United States Department of Energy.

*Disposal regulations* means part 191, subparts B and C of this chapter.

*Management systems review* means the qualitative assessment of a data collection operation or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate to ensure that the type and quality of data needed are obtained.

*Modification* means action(s) taken by the Administrator that alters the terms

or conditions of certification pursuant to section 8(d)(1) of the WIPP LWA. Modification of any certification shall comply with this part and part 191 of this chapter.

*Population of CCDFs* means all possible complementary, cumulative distribution functions (CCDFs) that can be generated from all disposal system parameter values used in performance assessments.

*Population of estimates* means all possible estimates of radiation doses and radionuclide concentrations that can be generated from all disposal system parameter values used in compliance assessments.

*Quality assurance* means those planned and systematic actions necessary to provide adequate confidence that the disposal system will comply with the disposal regulations set forth in part 191 of this chapter. Quality assurance includes quality control, which comprises those actions related to the physical characteristics of a material, structure, component, or system that provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

*Re-certification* means any action taken by the Administrator pursuant to section 8(f) of the WIPP LWA.

*Regulatory time frame* means the time period beginning at disposal and ending 10,000 years after disposal.

*Revocation* means any action taken by the Administrator to terminate the certification pursuant to section 8(d)(1) of the WIPP LWA.

*Secretary* means the Secretary of Energy.

*Shallow drilling* means those drilling events in the Delaware Basin that do not reach a depth of 2,150 feet below the surface relative to where such drilling occurred.

*Suspension* means any action taken by the Administrator to withdraw, for a limited period of time, the certification pursuant to section 8(d)(1) of the WIPP LWA.

*Waste* means the radioactive waste, radioactive material and coincidental material subject to the requirements of part 191 of this chapter.

*Waste characteristic* means a property of the waste that has an impact on the containment of waste in the disposal system.

*Waste component* means an ingredient of the total inventory of the waste that influences a waste characteristic.

*WIPP* means the Waste Isolation Pilot Plant, as authorized pursuant to section 213 of the Department of Energy National Security and Military

Applications of Nuclear Energy Authorization Act of 1980 (Pub.L. 96-164; 93 Stat. 1259, 1265).

WIPP LWA means the Waste Isolation Pilot Plant Land Withdrawal Act of 1992 (Pub.L. 102-579, 106 Stat. 4777).

**§ 194.3 Communications.**

(a) Compliance application(s) shall be:

(1) Addressed to the Administrator;

and

(2) Signed by the Secretary.

(b) Communications and reports concerning the criteria in this part shall be:

(1) Addressed to the Administrator or the Administrator's authorized representative; and

(2) Signed by the Secretary or the Secretary's authorized representative.

**§ 194.4 Conditions of compliance certification.**

(a) Any certification of compliance issued pursuant to section 8(d)(1) of the WIPP LWA may include such conditions as the Administrator finds necessary to support such certification.

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

(1) The certification shall be subject to modification, suspension or revocation by the Administrator. Any suspension of the certification shall be done at the discretion of the Administrator. Any modification or revocation of the certification shall be done by rule pursuant to 5 U.S.C. 553. If the Administrator revokes the certification, the Department shall retrieve, as soon as practicable and to the extent practicable, any waste emplaced in the disposal system.

(2) Any time after the Administrator issues a certification, the Administrator or the Administrator's authorized representative may submit a written request to the Department for information to enable the Administrator to determine whether the certification should be modified, suspended or revoked. Unless otherwise specified by the Administrator or the Administrator's authorized representative, the Department shall submit such information to the Administrator or the Administrator's authorized representative within 30 calendar days of receipt of the request.

(3) Any time after the Administrator issues a certification, the Department shall report any planned or unplanned changes in activities or conditions pertaining to the disposal system that differ significantly from the most recent compliance application.

(i) The Department shall inform the Administrator, in writing, prior to

making such a planned change in activity or disposal system condition.

(ii) In the event of an unplanned change in activity or condition, the Department shall immediately cease emplacement of waste in the disposal system if the Department determines that one or more of the following conditions is true:

(A) The containment requirements established pursuant to § 191.13 of this chapter have been or are expected to be exceeded;

(B) Releases from already-emplaced waste lead to committed effective doses that are or are expected to be in excess of those established pursuant to § 191.15 of this chapter. For purposes of this paragraph (b)(3)(ii)(B), emissions from operations covered pursuant to part 191, subpart A of this chapter are not included; or

(C) Releases have caused or are expected to cause concentrations of radionuclides or estimated doses due to radionuclides in underground sources of drinking water in the accessible environment to exceed the limits established pursuant to part 191, subpart C of this chapter.

(iii) If the Department determines that a condition described in paragraph (b)(3)(ii) of this section has occurred or is expected to occur, the Department shall notify the Administrator, in writing, within 24 hours of the determination. Such notification shall, to the extent practicable, include the following information:

(A) Identification of the location and environmental media of the release or the expected release;

(B) Identification of the type and quantity of waste (in activity in curies of each radionuclide) released or expected to be released;

(C) Time and date of the release or the estimated time of the expected release;

(D) Assessment of the hazard posed by the release or the expected release; and

(E) Additional information requested by the Administrator or the Administrator's authorized representative.

(iv) The Department may resume emplacement of waste in the disposal system upon written notification that the suspension has been lifted by the Administrator.

(v) If the Department discovers a condition or activity that differs significantly from what is indicated in the most recent compliance application, but does not involve conditions or activities listed in paragraph (b)(3)(ii) of this section, then the difference shall be reported, in writing, to the

Administrator within 10 calendar days of its discovery.

(vi) Following receipt of notification, the Administrator will notify the Secretary in writing whether any condition or activity reported pursuant to paragraph (b)(3) this section:

(A) Does not comply with the terms of the certification; and, if it does not comply,

(B) Whether the compliance certification must be modified, suspended or revoked. The Administrator or the Administrator's authorized representative may request additional information before determining whether modification, suspension or revocation of the compliance certification is required.

(4) Not later than six months after the Administrator issues a certification, and at least annually thereafter, the Department shall report to the Administrator, in writing, any changes in conditions or activities pertaining to the disposal system that were not required to be reported by paragraph (b)(3) of this section and that differ from information contained in the most recent compliance application.

**§ 194.5 Publications incorporated by reference.**

(a) The following publications are incorporated into this part by reference:

(1) U.S. Nuclear Regulatory Commission, NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories," published February 1988; incorporation by reference (IBR) approved for §§ 194.22, 194.23 and 194.27.

(2) American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard, NQA-1-1989 edition, "Quality Assurance Program Requirements for Nuclear Facilities;" IBR approved for § 194.22.

(3) ASME NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989 edition "Quality Assurance Requirements for Nuclear Facility Applications;" IBR approved for § 194.22 and § 194.23.

(4) ASME NQA-3-1989 edition, "Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories" (excluding section 2.1 (b) and (c)); IBR approved for § 194.22.

(b) The publications listed in paragraph (a) of this section were approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected or obtained from the Air Docket, Docket No. A-92-56, room M1500 (LE131),

U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, or copies may be inspected at the Office of the Federal Register, 800 N. Capitol Street NW, 7th floor, Suite 700, Washington, DC, or copies may be obtained from the following addresses:

(1) For ASME standards, contact American Society of Mechanical Engineers, 22 Law Drive, P.O. Box 2900, Fairfield, NJ 07007-2900, phone 1-800-843-2763.

(2) For Nuclear Regulatory Commission documents, contact Division of Information Support Services, Distribution Service, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or contact National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, phone 703-487-4650.

#### § 194.6 Alternative provisions.

The Administrator may, by rule pursuant to 5 U.S.C. 553, substitute for any of the provisions of this part alternative provisions chosen after:

(a) The alternative provisions have been proposed for public comment in the Federal Register together with information describing how the alternative provisions comport with the disposal regulations, the reasons why the existing provisions of this part appear inappropriate, and the costs, risks and benefits of compliance in accordance with the alternative provisions;

(b) A public comment period of at least 120 days has been completed and public hearings have been held in New Mexico;

(c) The public comments received have been fully considered; and

(d) A notice of final rulemaking is published in the Federal Register.

#### § 194.7 Effective date.

The criteria in this part shall be effective on April 9, 1996. The incorporation by reference of certain publications listed in the criteria is approved by the Director of the Federal Register as of April 9, 1996.

### Subpart B—Compliance Certification and Re-certification Applications

#### § 194.11 Completeness and accuracy of compliance applications.

Information provided to the Administrator in support of any compliance application shall be complete and accurate. The Administrator's evaluation for certification pursuant to section 8(d)(1)(B) of the WIPP LWA and evaluation for recertification pursuant to section 8(f)(2) of the WIPP LWA shall not begin until the Administrator has

notified the Secretary, in writing, that a complete application in accordance with this part has been received.

#### § 194.12 Submission of compliance applications.

Unless otherwise specified by the Administrator or the Administrator's authorized representative, 30 copies of any compliance application, any accompanying materials, and any amendments thereto shall be submitted in a printed form to the Administrator.

#### § 194.13 Submission of reference materials.

Information may be included by reference into compliance application(s), provided that the references are clear and specific and that, unless otherwise specified by the Administrator or the Administrator's authorized representative, 10 copies of the referenced information are submitted to the Administrator. Referenced materials which are widely available in standard textbooks or reference books need not be submitted.

#### § 194.14 Content of compliance certification application.

Any compliance application shall include:

(a) A current description of the natural and engineered features that may affect the performance of the disposal system. The description of the disposal system shall include, at a minimum, the following information:

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

(2) A description of the geology, geophysics, hydrogeology, hydrology, and geochemistry of the disposal system and its vicinity and how these conditions are expected to change and interact over the regulatory time frame. Such description shall include, at a minimum:

(i) Existing fluids and fluid hydraulic potential, including brine pockets, in and near the disposal system; and

(ii) Existing higher permeability anhydrite interbeds located at or near the horizon of the waste.

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

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

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

(1) Information on materials of construction including, but not limited to: Geologic media, structural materials, engineered barriers, general arrangement, and approximate dimensions; and

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

(c) Results of assessments conducted pursuant to this part.

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

(e) Documentation of measures taken to meet the assurance requirements of this part.

(f) A description of waste acceptance criteria and actions taken to assure adherence to such criteria.

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

(h) One or more topographic map(s) of the vicinity of the disposal system. The contour interval shall be sufficient to show clearly the pattern of surface water flow in the vicinity of the disposal system. The map(s) shall include standard map notations and symbols, and, in addition, shall show boundaries of the controlled area and the location of any active, inactive, and abandoned injection and withdrawal wells in the controlled area and in the vicinity of the disposal system.

(i) A description of past and current climatologic and meteorologic conditions in the vicinity of the disposal system and how these conditions are expected to change over the regulatory time frame.

(j) The information required elsewhere in this part or any additional information, analyses, tests, or records determined by the Administrator or the Administrator's authorized representative to be necessary for determining compliance with this part.

#### § 194.15 Content of compliance re-certification application(s).

(a) In submitting documentation of continued compliance pursuant to section 8(f) of the WIPP LWA, the previous compliance application shall be updated to provide sufficient information for the Administrator to determine whether or not the WIPP continues to be in compliance with the disposal regulations. Updated documentation shall include:

(1) All additional geologic, geophysical, geochemical, hydrologic, and meteorologic information;

(2) All additional monitoring data, analyses and results;

(3) All additional analyses and results of laboratory experiments conducted by the Department or its contractors as part of the WIPP program;

(4) An identification of any activities or assumptions that deviate from the most recent compliance application;

(5) A description of all waste emplaced in the disposal system since the most recent compliance certification or re-certification application. Such description shall consist of a description of the waste characteristics and waste components identified in §§ 194.24(b)(1) and 194.24(b)(2);

(6) Any significant information not previously included in a compliance certification or re-certification application related to whether the disposal system continues to be in compliance with the disposal regulations; and

(7) Any additional information requested by the Administrator or the Administrator's authorized representative.

(b) To the extent that information required for a re-certification of compliance remains valid and has been submitted in previous certification or re-certification application(s), such information need not be duplicated in subsequent applications; such information may be summarized and referenced.

### Subpart C—Compliance Certification and Re-certification

#### General Requirements

#### § 194.21 Inspections.

(a) The Administrator or the Administrator's authorized representative(s) shall, at any time:

(1) Be afforded unfettered and unannounced access to inspect any area of the WIPP, and any locations performing activities that provide information relevant to compliance application(s), to which the Department has rights of access. Such access shall be equivalent to access afforded Department employees upon presentation of credentials and other required documents.

(2) Be allowed to obtain samples, including split samples, and to monitor and measure aspects of the disposal system and the waste proposed for disposal in the disposal system.

(b) Records (including data and other information in any form) kept by the Department pertaining to the WIPP shall be made available to the Administrator or the Administrator's authorized representative upon request. If

requested records are not immediately available, they shall be delivered within 30 calendar days of the request.

(c) The Department shall, upon request by the Administrator or the Administrator's authorized representative, provide permanent, private office space that is accessible to the disposal system. The office space shall be for the exclusive use of the Administrator or the Administrator's authorized representative(s).

(d) The Administrator or the Administrator's authorized representative(s) shall comply with applicable access control measures for security, radiological protection, and personal safety when conducting activities pursuant to this section.

#### § 194.22 Quality assurance.

(a)(1) As soon as practicable after April 9, 1996, the Department shall adhere to a quality assurance program that implements the requirements of ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c), and Section 17.1). (Incorporation by reference as specified in § 194.5.)

(2) Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been established and executed for:

(i) Waste characterization activities and assumptions;

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

(iii) Field measurements of geologic factors, ground water, meteorologic, and topographic characteristics;

(iv) Computations, computer codes, models and methods used to demonstrate compliance with the disposal regulations in accordance with the provisions of this part;

(v) Procedures for implementation of expert judgment elicitation used to support applications for certification or re-certification of compliance;

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

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

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

(b) Any compliance application shall include information which demonstrates that data and information

collected prior to the implementation of the quality assurance program required pursuant to paragraph (a)(1) of this section 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, conducted in a manner that is compatible with NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories," published February 1988 (incorporation by reference as specified in § 194.5); corroborating data; confirmatory testing; or a quality assurance 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). (Incorporation by reference as specified in § 194.5.)

(c) Any compliance application shall provide, to the extent practicable, information which describes how all data used to support the compliance application have been assessed for their quality characteristics, including:

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

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

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

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

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

(d) Any compliance application shall provide information which demonstrates how all data are qualified for use in the demonstration of compliance.

(e) The Administrator will verify appropriate execution of quality assurance programs through inspections, record reviews and record keeping requirements, which may include, but may not be limited to, surveillance, audits and management systems reviews.

#### § 194.23 Models and computer codes.

(a) Any compliance application shall include:

(1) A description of the conceptual models and scenario construction used to support any compliance application.

(2) A description of plausible, alternative conceptual model(s) seriously considered but not used to support such application, and an explanation of the reason(s) why such model(s) was not deemed to accurately portray performance of the disposal system.

(3) Documentation that:

(i) Conceptual models and scenarios reasonably represent possible future states of the disposal system;

(ii) Mathematical models incorporate equations and boundary conditions which reasonably represent the mathematical formulation of the conceptual models;

(iii) Numerical models provide numerical schemes which enable the mathematical models to obtain stable solutions;

(iv) Computer models accurately implement the numerical models; i.e., computer codes are free of coding errors and produce stable solutions;

(v) Conceptual models have undergone peer review according to § 194.27.

(b) Computer codes used to support any compliance application shall be documented in a manner that complies with the requirements of ASME NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989 edition. (Incorporation by reference as specified in § 194.5.)

(c) Documentation of all models and computer codes included as part of any compliance application performance assessment calculation shall be provided. Such documentation shall include, but shall not be limited to:

(1) Descriptions of the theoretical backgrounds of each model and the method of analysis or assessment;

(2) 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 (e.g., parameter name and units); listings of input and output files from a sample computer run; and reports on code verification, benchmarking, validation, and quality assurance procedures;

(3) Detailed descriptions of the structure of computer codes and complete listings of the source codes;

(4) Detailed descriptions of data collection procedures, sources of data, data reduction and analysis, and code input parameter development;

(5) Any necessary licenses; and

(6) An explanation of the manner in which models and computer codes incorporate the effects of parameter correlation.

(d) The Administrator or the Administrator's authorized representative may verify the results of computer simulations used to support any compliance application by performing independent simulations. Data files, source codes, executable versions of computer software for each model, other material or information needed to permit the Administrator or the Administrator's authorized representative to perform independent simulations, and access to necessary hardware to perform such simulations, shall be provided within 30 calendar days of a request by the Administrator or the Administrator's authorized representative.

#### § 194.24 Waste characterization.

(a) Any compliance application shall describe the chemical, radiological and physical composition of all existing waste proposed for disposal in the disposal system. To the extent practicable, any compliance application shall also describe the chemical, radiological and physical composition of to-be-generated waste proposed for disposal in the disposal system. These descriptions shall include a list of waste components and their approximate quantities in the waste. This list may be derived from process knowledge, current non-destructive examination/ assay, or other information and methods.

(b) The Department shall submit in the compliance certification application the results of an analysis which substantiates:

(1) That all waste characteristics influencing containment of waste in the disposal system have been identified and assessed for their impact on disposal system performance. The characteristics to be analyzed shall include, but shall not be limited to: Solubility; formation of colloidal suspensions containing radionuclides; production of gas from the waste; shear strength; compactability; and other waste-related inputs into the computer models that are used in the performance assessment.

(2) That all waste components influencing the waste characteristics identified in paragraph (b)(1) of this section have been identified and assessed for their impact on disposal system performance. The components to be analyzed shall include, but shall not be limited to: metals; cellulose; chelating agents; water and other

liquids; and activity in curies of each isotope of the radionuclides present.

(3) Any decision to exclude consideration of any waste characteristic or waste component because such characteristic or component is not expected to significantly influence the containment of the waste in the disposal system.

(c) For each waste component identified and assessed pursuant to paragraph (b) of this section, the Department shall specify the limiting value (expressed as an upper or lower limit of mass, volume, curies, concentration, etc.), and the associated uncertainty (i.e., margin of error) for each limiting value, of the total inventory of such waste proposed for disposal in the disposal system. Any compliance application shall:

(1) Demonstrate that, for the total inventory of waste proposed for disposal in the disposal system, WIPP complies with the numeric requirements of § 194.34 and § 194.55 for the upper or lower limits (including the associated uncertainties), as appropriate, for each waste component identified in paragraph (b)(2) of this section, and for the plausible combinations of upper and lower limits of such waste components that would result in the greatest estimated release.

(2) Identify and describe the method(s) used to quantify the limits of waste components identified in paragraph (b)(2) of this section.

(3) Provide information which demonstrates that the use of process knowledge to quantify components in waste for disposal conforms with the quality assurance requirements found in § 194.22.

(4) Provide information which demonstrates that a system of controls has been and will continue to be implemented 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 this section. The system of controls shall include, but shall not be limited to: Measurement; sampling; chain of custody records; record keeping systems; waste loading schemes used; and other documentation.

(5) Identify and describe such controls delineated in paragraph (c)(4) of this section and confirm that they are applied in accordance with the quality assurance requirements found in § 194.22.

(d) The Department shall include a waste loading scheme in any compliance application, or else performance assessments conducted

pursuant to § 194.32 and compliance assessments conducted pursuant to § 194.54 shall assume random placement of waste in the disposal system.

(e) Waste may be emplaced in the disposal system only if the emplaced components of such waste will not cause:

(1) The total quantity of waste in the disposal system to exceed the upper limiting value, including the associated uncertainty, described in the introductory text to paragraph (c) of this section; or

(2) The total quantity of waste that will have been emplaced in the disposal system, prior to closure, to fall below the lower limiting value, including the associated uncertainty, described in the introductory text to paragraph (c) of this section.

(f) Waste emplacement shall conform to the assumed waste loading conditions, if any, used in performance assessments conducted pursuant to § 194.32 and compliance assessments conducted pursuant to § 194.54.

(g) The Department shall demonstrate in any compliance application that the total inventory of waste emplaced in the disposal system complies with the limitations on transuranic waste disposal described in the WIPP LWA.

(h) The Administrator will use inspections and records reviews, such as audits, to verify compliance with this section.

#### § 194.25 Future state assumptions.

(a) Unless otherwise specified in this part or in the disposal regulations, performance assessments and compliance assessments conducted pursuant the provisions of this part to demonstrate compliance with § 191.13, § 191.15 and part 191, subpart C 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.

(b) In considering future states pursuant to this section, the Department shall document in any compliance application, to the extent practicable, effects of potential future hydrogeologic, geologic and climatic conditions on the disposal system over the regulatory time frame. Such documentation shall be part of the activities undertaken pursuant to § 194.14, Content of compliance certification application; § 194.32, Scope of performance assessments; and § 194.54, Scope of compliance assessments.

(1) In considering the effects of hydrogeologic conditions on the

disposal system, the Department shall document in any compliance application, to the extent practicable, the effects of potential changes to hydrogeologic conditions.

(2) In considering the effects of geologic conditions on the disposal system, the Department shall document in any compliance application, to the extent practicable, the effects of potential changes to geologic conditions, including, but not limited to: Dissolution; near surface geomorphic features and processes; and related subsidence in the geologic units of the disposal system.

(3) In considering the effects of climatic conditions on the disposal system, the Department shall document in any compliance application, to the extent practicable, the effects of potential changes to future climate cycles of increased precipitation (as compared to present conditions).

#### § 194.26 Expert judgment.

(a) Expert judgment, by an individual expert or panel of experts, may be used to support any compliance application, provided that expert judgment does not substitute for information that could reasonably be obtained through data collection or experimentation.

(b) Any compliance application shall:

(1) Identify any expert judgments used to support the application and shall identify experts (by name and employer) involved in any expert judgment elicitation processes used to support the application.

(2) Describe the process of eliciting expert judgment, and document the results of expert judgment elicitation processes and the reasoning behind those results. Documentation of interviews used to elicit judgments from experts, the questions or issues presented for elicitation of expert judgment, background information provided to experts, and deliberations and formal interactions among experts shall be provided. The opinions of all experts involved in each elicitation process shall be provided whether the opinions are used to support compliance applications or not.

(3) Provide documentation that the following restrictions and guidelines have been applied to any selection of individuals used to elicit expert judgments:

(i) Individuals who are members of the team of investigators requesting the judgment or the team of investigators who will use the judgment were not selected; and

(ii) Individuals who maintain, at any organizational level, a supervisory role

or who are supervised by those who will utilize the judgment were not selected.

(4) Provide information which demonstrates that:

(i) The expertise of any individual involved in expert judgment elicitation comports with the level of knowledge required by the questions or issues presented to that individual; and

(ii) The expertise of any expert panel, as a whole, involved in expert judgment elicitation comports with the level and variety of knowledge required by the questions or issues presented to that panel.

(5) Explain the relationship among the information and issues presented to experts prior to the elicitation process, the elicited judgment of any expert panel or individual, and the purpose for which the expert judgment is being used in compliance application(s).

(6) Provide documentation that the initial purpose for which expert judgment was intended, as presented to the expert panel, is consistent with the purpose for which this judgment was used in compliance application(s).

(7) Provide documentation that the following restrictions and guidelines have been applied in eliciting expert judgment:

(i) At least five individuals shall be used in any expert elicitation process, unless there is a lack or unavailability of experts and a documented rationale is provided that explains why fewer than five individuals were selected.

(ii) At least two-thirds of the experts involved in an elicitation shall consist of individuals who are not employed directly by the Department or by the Department's contractors, unless the Department can demonstrate and document that there is a lack or unavailability of qualified independent experts. If so demonstrated, at least one-third of the experts involved in an elicitation shall consist of individuals who are not employed directly by the Department or by the Department's contractors.

(c) The public shall be afforded a reasonable opportunity to present its scientific and technical views to expert panels as input to any expert elicitation process.

#### § 194.27 Peer review.

(a) Any compliance application shall include documentation of peer review that has been conducted, in a manner required by this section, for:

- (1) Conceptual models selected and developed by the Department;
- (2) Waste characterization analyses as required in § 194.24(b); and
- (3) Engineered barrier evaluation as required in § 194.44.

(b) Peer review processes required in paragraph (a) of this section, and conducted subsequent to the promulgation of this part, shall be conducted in a manner that is compatible with NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories," published February 1988. (Incorporation by reference as specified in § 194.5.)

(c) Any compliance application shall:

(1) Include information that demonstrates that peer review processes required in paragraph (a) of this section, and conducted prior to the implementation of the promulgation of this part, were conducted in accordance with an alternate process substantially equivalent in effect to NUREG-1297 and approved by the Administrator or the Administrator's authorized representative; and

(2) Document any peer review processes conducted in addition to those required pursuant to paragraph (a) of this section. Such documentation shall include formal requests, from the Department to outside review groups or individuals, to review or comment on any information used to support compliance applications, and the responses from such groups or individuals.

#### Containment Requirements

##### § 194.31 Application of release limits.

The release limits shall be calculated according to part 191, appendix A of this chapter, using the total activity, in curies, that will exist in the disposal system at the time of disposal.

##### § 194.32 Scope of performance assessments.

(a) Performance assessments shall consider natural processes and events, mining, deep drilling, and shallow drilling that may affect the disposal system during the regulatory time frame.

(b) Assessments of mining effects may be limited to changes in the hydraulic conductivity of the hydrogeologic units of the disposal system from excavation mining for natural resources. Mining shall be assumed to occur with a one in 100 probability in each century of the regulatory time frame. Performance assessments shall assume that mineral deposits of those resources, similar in quality and type to those resources currently extracted from the Delaware Basin, will be completely removed from the controlled area during the century in which such mining is randomly calculated to occur. Complete removal of such mineral resources shall be assumed to occur only once during the regulatory time frame.

(c) Performance assessments shall include an analysis of the effects on the disposal system of any activities that occur in the vicinity of the disposal system prior to disposal and are expected to occur in the vicinity of the disposal system soon after disposal. Such activities shall include, but shall not be limited to, existing boreholes and the development of any existing leases that can be reasonably expected to be developed in the near future, including boreholes and leases that may be used for fluid injection activities.

(d) Performance assessments need not consider processes and events that have less than one chance in 10,000 of occurring over 10,000 years.

(e) Any compliance application(s) shall include information which:

(1) Identifies all potential processes, events or sequences and combinations of processes and events that may occur during the regulatory time frame and may affect the disposal system;

(2) Identifies the processes, events or sequences and combinations of processes and events included in performance assessments; and

(3) Documents why any processes, events or sequences and combinations of processes and events identified pursuant to paragraph (e)(1) of this section were not included in performance assessment results provided in any compliance application.

##### § 194.33 Consideration of drilling events in performance assessments.

(a) Performance assessments shall examine deep drilling and shallow drilling that may potentially affect the disposal system during the regulatory time frame.

(b) The following assumptions and process shall be used in assessing the likelihood and consequences of drilling events, and the results of such process shall be documented in any compliance application:

(1) Inadvertent and intermittent intrusion by drilling for resources (other than those resources provided by the waste in the disposal system or engineered barriers designed to isolate such waste) is the most severe human intrusion scenario.

(2) In performance assessments, drilling events shall be assumed to occur in the Delaware Basin at random intervals in time and space during the regulatory time frame.

(3) The frequency of deep drilling shall be calculated in the following manner:

(i) Identify deep drilling that has occurred for each resource in the Delaware Basin over the past 100 years

prior to the time at which a compliance application is prepared.

(ii) The total rate of deep drilling shall be the sum of the rates of deep drilling for each resource.

(4) The frequency of shallow drilling shall be calculated in the following manner:

(i) Identify shallow drilling that has occurred for each resource in the Delaware Basin over the past 100 years prior to the time at which a compliance application is prepared.

(ii) The total rate of shallow drilling shall be the sum of the rates of shallow drilling for each resource.

(iii) In considering the historical rate of all shallow drilling, the Department may, if justified, consider only the historical rate of shallow drilling for resources of similar type and quality to those in the controlled area.

(c) Performance assessments shall document that in analyzing the consequences of drilling events, the Department assumed that:

(1) Future drilling practices and technology will remain consistent with practices in the Delaware Basin at the time a compliance application is prepared. Such future drilling practices shall include, but shall not be limited to: The types and amounts of drilling fluids; borehole depths, diameters, and seals; and the fraction of such boreholes that are sealed by humans; and

(2) Natural processes will degrade or otherwise affect the capability of boreholes to transmit fluids over the regulatory time frame.

(d) With respect to future drilling events, performance assessments need not analyze the effects of techniques used for resource recovery subsequent to the drilling of the borehole.

##### § 194.34 Results of performance assessments.

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

(b) Probability distributions for uncertain disposal system parameter values used in performance assessments shall be developed and documented in any compliance application.

(c) Computational techniques, which draw random samples from across the entire range of the probability distributions developed pursuant to paragraph (b) of this section, shall be used in generating CCDFs and shall be documented in any compliance application.



(d) The number of CCDFs generated shall be 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. Values of cumulative release shall be calculated according to Note 6 of Table 1, Appendix A of Part 191 of this chapter.

(e) Any compliance application shall display the full range of CCDFs generated.

(f) Any compliance application shall provide information which 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 of this chapter.

#### Assurance Requirements

##### § 194.41 Active institutional controls.

(a) Any compliance application shall include detailed descriptions of proposed active institutional controls, the controls' location, and the period of time the controls are proposed to remain active. Assumptions pertaining to active institutional controls and their effectiveness in terms of preventing or reducing radionuclide releases shall be supported by such descriptions.

(b) Performance assessments shall not consider any contributions from active institutional controls for more than 100 years after disposal.

##### § 194.42 Monitoring.

(a) The Department shall conduct an analysis of the effects of disposal system parameters on the containment of waste in the disposal system and shall include the results of such analysis in any compliance application. The results of the analysis shall be used in developing plans for pre-closure and post-closure monitoring required pursuant to paragraphs (c) and (d) of this section. The disposal system parameters analyzed shall include, at a minimum:

(1) Properties of backfilled material, including porosity, permeability, and degree of compaction and reconsolidation;

(2) Stresses and extent of deformation of the surrounding roof, walls, and floor of the waste disposal room;

(3) Initiation or displacement of major brittle deformation features in the roof or surrounding rock;

(4) Ground water flow and other effects of human intrusion in the vicinity of the disposal system;

(5) Brine quantity, flux, composition, and spatial distribution;

(6) Gas quantity and composition; and

(7) Temperature distribution.

(b) For all disposal system parameters analyzed pursuant to paragraph (a) of this section, any compliance application shall document and substantiate the decision not to monitor a particular disposal system parameter because that parameter is considered to be insignificant to the containment of waste in the disposal system or to the verification of predictions about the future performance of the disposal system.

(c) Pre-closure monitoring. To the extent practicable, pre-closure monitoring shall be conducted of significant disposal system parameter(s) as identified by the analysis conducted pursuant to paragraph (a) of this section. A disposal system parameter shall be considered significant if it affects the system's ability to contain waste or the ability to verify predictions about the future performance of the disposal system. Such monitoring shall begin as soon as practicable; however, in no case shall waste be emplaced in the disposal system prior to the implementation of pre-closure monitoring. Pre-closure monitoring shall end at the time at which the shafts of the disposal system are backfilled and sealed.

(d) Post-closure monitoring. The disposal system shall, to the extent practicable, be monitored as soon as practicable after the shafts of the disposal system are backfilled and sealed to detect substantial and detrimental deviations from expected performance and shall end when the Department can demonstrate to the satisfaction of the Administrator that there are no significant concerns to be addressed by further monitoring. Post-closure monitoring shall be complementary to monitoring required pursuant to applicable federal hazardous waste regulations at parts 264, 265, 268, and 270 of this chapter and shall be conducted with techniques that do not jeopardize the containment of waste in the disposal system.

(e) Any compliance application shall include detailed pre-closure and post-closure monitoring plans for monitoring the performance of the disposal system. At a minimum, such plans shall:

(1) Identify the parameters that will be monitored and how baseline values will be determined;

(2) Indicate how each parameter will be used to evaluate any deviations from the expected performance of the disposal system; and

(3) Discuss the length of time over which each parameter will be monitored to detect deviations from expected performance.

##### § 194.43 Passive institutional controls.

(a) Any compliance application shall include detailed descriptions of the measures that will be employed to preserve knowledge about the location, design, and contents of the disposal system. Such measures shall include:

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

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

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

(ii) The design of the disposal system;

(iii) The nature and hazard of the waste;

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

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

(3) Other passive institutional controls practicable to indicate the dangers of the waste and its location.

(b) Any compliance application shall include the period of time passive institutional controls are expected to endure and be understood.

(c) The Administrator may allow the Department to assume passive institutional control credit, in the form of reduced likelihood of human intrusion, if the Department demonstrates in the compliance application that such credit is justified because the passive institutional controls are expected to endure and be understood by potential intruders for the time period approved by the Administrator. Such credit, or a smaller credit as determined by the Administrator, cannot be used for more than several hundred years and may decrease over time. In no case, however, shall passive institutional controls be assumed to eliminate the likelihood of human intrusion entirely.

##### § 194.44 Engineered barriers.

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

(b) In selecting any engineered barrier(s) for the disposal system, the Department shall evaluate the benefit and detriment of engineered barrier alternatives, including but not limited to: Cementation, shredding, supercompaction, incineration, vitrification, improved waste canisters, grout and bentonite backfill, melting of metals, alternative configurations of waste placements in the disposal system, and alternative disposal system dimensions. The results of this evaluation shall be included in any compliance application and shall be used to justify the selection and rejection of each engineered barrier evaluated.

(c)(1) In conducting the evaluation of engineered barrier alternatives, the following shall be considered, to the extent practicable:

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

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

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

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

(v) The increased or reduced uncertainty in compliance assessment;

(vi) Public comments requesting specific engineered barriers;

(vii) The increased or reduced total system costs;

(viii) The impact, if any, on other waste disposal programs from the incorporation of engineered barriers (e.g., the extent to which the incorporation of engineered barriers affects the volume of waste);

(ix) The effects on mitigating the consequences of human intrusion.

(2) If, after consideration of one or more of the factors in paragraph (c)(1) of this section, the Department concludes that an engineered barrier considered within the scope of the evaluation should be rejected without evaluating the remaining factors in paragraph (c)(1) of this section, then any compliance application shall provide a justification for this rejection explaining why the evaluation of the remaining factors would not alter the conclusion.

(d) In considering the ability of engineered barriers to prevent or substantially delay the movement of water or radionuclides toward the accessible environment, the benefit and detriment of engineered barriers for existing waste already packaged, existing waste not yet packaged, existing

waste in need of re-packaging, and to-be-generated waste shall be considered separately and described.

(e) The evaluation described in paragraphs (b), (c) and (d) of this section shall consider engineered barriers alone and in combination.

**§ 194.45 Consideration of the presence of resources.**

Any compliance application shall include information that demonstrates that the favorable characteristics of the disposal system compensate for the presence of resources in the vicinity of the disposal system and the likelihood of the disposal system being disturbed as a result of the presence of those resources. If performance assessments predict that the disposal system meets the containment requirements of § 191.13 of this chapter, then the Agency will assume that the requirements of this section and § 191.14(e) of this chapter have been fulfilled.

**§ 194.46 Removal of waste.**

Any compliance application shall include documentation which demonstrates that removal of waste from the disposal system is feasible for a reasonable period of time after disposal. Such documentation shall include an analysis of the technological feasibility of mining the sealed disposal system, given technology levels at the time a compliance application is prepared.

Individual and Ground-water Protection Requirements

**§ 194.51 Consideration of protected individual.**

Compliance assessments that analyze compliance with § 191.15 of this chapter shall assume that an individual resides at the single geographic point on the surface of the accessible environment where that individual would be expected to receive the highest dose from radionuclide releases from the disposal system.

**§ 194.52 Consideration of exposure pathways.**

In compliance assessments that analyze compliance with § 191.15 of this chapter, all potential exposure pathways from the disposal system to individuals shall be considered. Compliance assessments with part 191, subpart C and § 191.15 of this chapter shall assume that individuals consume 2 liters per day of drinking water from any underground source of drinking water in the accessible environment.

**§ 194.53 Consideration of underground sources of drinking water.**

In compliance assessments that analyze compliance with part 191, subpart C of this chapter, all underground sources of drinking water in the accessible environment that are expected to be affected by the disposal system over the regulatory time frame shall be considered. In determining whether underground sources of drinking water are expected to be affected by the disposal system, underground interconnections among bodies of surface water, ground water, and underground sources of drinking water shall be considered.

**§ 194.54 Scope of compliance assessments.**

(a) Any compliance application shall contain compliance assessments required pursuant to this part. Compliance assessments shall include information which:

(1) Identifies potential processes, events, or sequences of processes and events that may occur over the regulatory time frame;

(2) Identifies the processes, events, or sequences of processes and events included in compliance assessment results provided in any compliance application; and

(3) Documents why any processes, events, or sequences of processes and events identified pursuant to paragraph (a)(1) of this section were not included in compliance assessment results provided in any compliance application.

(b) Compliance assessments of undisturbed performance shall include the effects on the disposal system of:

(1) Existing boreholes in the vicinity of the disposal system, with attention to the pathways they provide for migration of radionuclides from the site; and

(2) Any activities that occur in the vicinity of the disposal system prior to or soon after disposal. Such activities shall include, but shall not be limited to: Existing boreholes and the development of any existing leases that can be reasonably expected to be developed in the near future, including boreholes and leases that may be used for fluid injection activities.

**§ 194.55 Results of compliance assessments.**

(a) Compliance assessments shall consider and document uncertainty in the performance of the disposal system.

(b) Probability distributions for uncertain disposal system parameter values used in compliance assessments shall be developed and documented in any compliance application.

(c) Computational techniques which draw random samples from across the entire range of values of each probability distribution developed pursuant to paragraph (b) of this section shall be used to generate a range of:

(1) Estimated committed effective doses received from all pathways pursuant to § 194.51 and § 194.52;

(2) Estimated radionuclide concentrations in USDWs pursuant to § 194.53; and

(3) Estimated dose equivalent received from USDWs pursuant to § 194.52 and § 194.53.

(d) The number of estimates generated pursuant to paragraph (c) of this section shall 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 a 0.95 probability.

(e) Any compliance application shall display:

(1) The full range of estimated radiation doses; and

(2) The full range of estimated radionuclide concentrations.

(f) Any compliance application shall 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 part 191, subpart C of this chapter, respectively.

#### Subpart D—Public Participation

##### § 194.61 Advance notice of proposed rulemaking for certification.

(a) Upon receipt of a compliance application submitted pursuant to section 8(d)(1) of the WIPP LWA and § 194.11, the Agency will publish in the Federal Register an Advance Notice of Proposed Rulemaking announcing that a compliance application has been received, soliciting comment on such application, and announcing the Agency's intent to conduct a rulemaking to certify whether the WIPP facility will comply with the disposal regulations.

(b) A copy of the compliance application will be made available for inspection in Agency docket established pursuant to § 194.67.

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

(d) A public hearing concerning the notice will be held if a written request is received by the Administrator or the Administrator's authorized representative within 30 calendar days of the date of publication pursuant to paragraph (a) of this section.

(e) Any comments received on the notice will be made available for

inspection in the dockets established pursuant to § 194.67.

(f) Any comments received on the notice will be provided to the Department and the Department may submit to the Agency written responses to the comments.

##### § 194.62 Notice of proposed rulemaking for certification.

(a) The Administrator will publish a Notice of Proposed Rulemaking in the Federal Register announcing the Administrator's proposed decision, pursuant to section 8(d)(1) of the WIPP LWA, whether to issue a certification that the WIPP facility will comply with the disposal regulations and soliciting comment on the proposal.

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

(c) The notice will announce public hearings in New Mexico.

(d) Any comments received on the notice will be made available for inspection in the dockets established pursuant to § 194.67.

##### § 194.63 Final rule for certification.

(a) The Administrator will publish a Final Rule in the Federal Register announcing the Administrator's decision, pursuant to section 8(d)(1) of the WIPP LWA, whether to issue a certification that the WIPP facility will comply with the disposal regulations.

(b) A document summarizing significant comments and issues arising from comments received on the 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 the dockets established pursuant to § 194.67.

##### § 194.64 Documentation of continued compliance.

(a) Upon receipt of documentation of continued compliance with the disposal regulations pursuant to section 8(f) of the WIPP LWA and § 194.11, the Administrator will publish a notice in the Federal Register announcing that such documentation has been received, soliciting comment on such documentation, and announcing the Administrator's intent to determine whether or not the WIPP facility continues to be in compliance with the disposal regulations.

(b) Copies of documentation of continued compliance received by the Administrator will be made available for inspection in the dockets established pursuant to § 194.67.

(c) The notice will provide a public comment period of at least 30 days after publication pursuant to paragraph (a) of this section.

(d) Any comments received on such notice will be made available for public inspection in the dockets established pursuant to § 194.67.

(e) Upon completion of review of the documentation of continued compliance with the disposal regulations, the Administrator will publish a notice in the Federal Register announcing the Administrator's decision whether or not to re-certify the WIPP facility.

##### § 194.65 Notice of proposed rulemaking for modification or revocation.

(a) If the Administrator determines that any changes in activities or conditions pertaining to the disposal system depart significantly from the most recent compliance application, the Agency will publish a Notice of Proposed Rulemaking in the Federal Register announcing the Administrator's proposed decision on modification or revocation, and soliciting comment on the proposal.

(b) Any comments received on the notice will be made available for inspection in the dockets established pursuant to § 194.67.

##### § 194.66 Final rule for modification or revocation.

(a) The Administrator will publish a Final Rule in the Federal Register announcing the Administrator's decision on modification or revocation.

(b) A document summarizing significant comments and issues arising from comments received on the 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 the dockets established pursuant to § 194.67.

##### § 194.67 Dockets.

The Agency will establish and maintain dockets in the State of New Mexico and Washington, DC. The dockets will consist of all relevant, significant information received from outside parties and all significant information considered by the Administrator in certifying whether the WIPP facility will comply with the disposal regulations, in certifying whether or not the WIPP facility continues to be in compliance with the disposal regulations, and in determining whether compliance certification should be modified, suspended or revoked.

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