

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 194

[FRL-5142-4]

RIN 2060-AE30

Criteria for the Certification and Determination of the Waste Isolation Pilot Plant's Compliance With Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing criteria for certifying and determining whether the Department of Energy's Waste Isolation Pilot Plant (WIPP) complies with disposal standards set forth in 40 CFR part 191 (Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes). EPA is required to promulgate these criteria under the 1992 Waste Isolation Pilot Plant Land Withdrawal Act (WIPP LWA). These criteria will be used by the Agency in ascertaining whether the WIPP disposal system complies with the disposal standards.

DATES: Comments on today's proposal must be received by May 1, 1995. Public hearings on today's proposal will be held in New Mexico. A separate announcement will be published in the **Federal Register** to provide public hearing information.

ADDRESSES: Comments should be submitted, in duplicate, to: Docket No. A-92-56, Air Docket, room M-1500 (LE-131), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. See additional docket information in the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Mary Kruger or Martin Offutt; telephone number (202) 233-9310; address: Criteria and Standards Division, Mail Code 6602J, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. An addendum to the supplementary information provided in today's notice is located in Docket No. A-92-56. For copies of this addendum and the Background Information Document and Economic Impact Analysis prepared for this proposed rule, contact Mary Kruger at the above phone number and address.

SUPPLEMENTARY INFORMATION: As discussed below, the scope of today's

proposal is limited to proposed criteria for certifying and determining whether the Waste Isolation Pilot Plant (WIPP) in New Mexico complies with the disposal standards set forth in 40 CFR part 191. Accordingly, comments should be similarly limited in scope; e.g., comments should not address the Agency's recently promulgated radioactive waste disposal standards—40 CFR part 191 (58 FR 66398, December 20, 1993)—or whether WIPP should be used as a disposal facility.

The U.S. Department of Energy (DOE) is developing the Waste Isolation Pilot Plant (WIPP) near Carlsbad in southeastern New Mexico as a potential deep geologic repository for the disposal of defense transuranic (TRU) radioactive waste currently being stored on Federal reservations in Washington, Ohio, Idaho, New Mexico, Tennessee, South Carolina, Nevada and Colorado. TRU waste consists of materials containing one or more elements having atomic numbers greater than 92, in concentrations greater than 100 nanocuries of alpha-emitting TRU isotopes per gram of waste, with half-lives greater than 20 years. Most TRU waste consists of items that have become contaminated as a result of activities associated with the production of nuclear weapons, e.g., rags, equipment, tools, and organic and inorganic sludges. TRU waste is often mixed with hazardous chemical constituents.

Before beginning disposal of radioactive waste at the WIPP, DOE must demonstrate that the WIPP complies with the Environmental Protection Agency's (EPA) radioactive waste standards at 40 CFR part 191 (Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes).

On October 30, 1992, the Waste Isolation Pilot Plant Land Withdrawal Act (WIPP LWA) was enacted (Pub. L. 102-579). The WIPP LWA contains numerous provisions pertaining to EPA's role in overseeing DOE's activities at the WIPP, including requirements for the development and implementation of the 40 CFR part 191 disposal standards as they are applied to the WIPP. Specifically, section 8(a) of the WIPP LWA reinstated all of the remanded disposal standards except those aspects of the individual and ground-water protection requirements which the court found problematic in *NRDC v. U.S. EPA*. The WIPP LWA requires EPA to certify and determine whether or not the WIPP will comply with the Agency's final radioactive waste disposal standards.

"Certification" refers to any initial certification of compliance of DOE's application for the WIPP with subparts B and C of 40 CFR part 191 (see section 8(d) of the WIPP LWA).

"Determination" refers to any subsequent decisions by the Agency (required every 5 years by the WIPP LWA) of whether the WIPP continues to be in compliance with subparts B and C of 40 CFR part 191 (see section 8(f) of the WIPP LWA). In order to certify or determine compliance, the Agency will be issuing criteria for assessing compliance with the final disposal standards, as required by section 8(c) of the WIPP LWA. On February 11, 1993, as a first step in the development of compliance criteria, EPA issued an Advance Notice of Proposed Rulemaking (ANPR) soliciting comments on issues associated with the development of compliance criteria. (58 FR 8029.) The next step in the evolution of these criteria is occurring today with the issuance of proposed compliance criteria.

Objective and Implementation of Today's Proposed Criteria

Under authority of the WIPP LWA, the Agency is proposing criteria for certifying and determining whether the Department of Energy's (DOE) Waste Isolation Pilot Plant (WIPP) will comply with the Agency's radioactive waste disposal standards set forth in 40 CFR part 191. The WIPP LWA specifies that underground emplacement of transuranic wastes for disposal at the WIPP may not commence unless and until EPA certifies that the WIPP facility will comply with 40 CFR part 191, subparts B and C. If the Agency certifies compliance, the WIPP LWA requires EPA to subsequently conduct periodic determinations of continued compliance throughout waste disposal operations at the WIPP. Criteria contained in today's notice address any initial certification of compliance as well as any subsequent determinations of continued compliance. When final compliance criteria are promulgated as Agency regulations, EPA will be responsible for assuring that the requirements are properly implemented.

Importantly, today's proposal is limited to consideration of the WIPP's compliance with the disposal regulations found in subparts B and C of 40 CFR part 191 (which include containment requirements, assurance requirements, individual protection requirements, and ground-water protection requirements). These compliance criteria do not address compliance with the management and storage regulations found in subpart A

of 40 CFR part 191. The Agency plans to issue guidance addressing implementation of subpart A at a later date.

The Agency also wishes to make clear that today's proposal does not address compliance with all of the requirements of the WIPP LWA. Rather, today's proposal is limited to those requirements of the WIPP LWA which pertain to the WIPP's compliance with the disposal standards in 40 CFR part 191. For example, today's proposal does not address the WIPP's compliance with EPA regulations developed pursuant to the Resource Conservation and Recovery Act (RCRA) or any other environmental laws or regulations. EPA intends to address compliance with the balance of these additional laws and regulations through compliance plans being developed by EPA's Region VI. For more information regarding the Region's activities, please write to EPA Region VI, 1445 Ross Avenue, Dallas, Texas 75202-2733; Attn: Chuck Byrum.

EPA has prepared a document entitled "Implementation Strategy for the Waste Isolation Pilot Plant Land Withdrawal Act of 1992" (EPA 402-R-93-002, March 1993) which explains in more detail the Agency's roles and responsibilities under the WIPP LWA. For more information concerning the Implementation Strategy Document, please write to the Policy and Public Information Section, Office of Radiation and Indoor Air, U.S. EPA, Mail Code 6602J, 401 M St., S.W., Washington, D.C. 20460 or call the EPA WIPP Information Line at 1-800-331-WIPP.

Additional Docket Information

The Agency is currently maintaining the following public information dockets: (1) Docket No. A-92-56, located in room 1500 (first floor in Waterside Mall near the Washington Information Center), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460 (open from 8:00 a.m. to 4:00 p.m. on weekdays); (2) EPA's docket in the Government Publications Department of the Zimmerman Library of the University of New Mexico located in Albuquerque, New Mexico (open from 8:00 a.m. to 9:00 p.m. on Monday through Thursday, 8:00 a.m. to 5:00 p.m. on Friday, 9:00 a.m. to 5:00 p.m. on Saturday, and 1:00 p.m. to 9:00 p.m. on Sunday); (3) EPA's docket in the Fogelson Library of the College of Santa Fe in Santa Fe, New Mexico located at 1600 St. Michaels Drive (open from 8:00 a.m. to 12:00 midnight on Monday through Thursday, 8:00 a.m. to 5:00 p.m. on Friday, 9:00 a.m. to 5:00 p.m. on Saturday, 1:00 p.m. to 9:00 p.m. on Sunday); and (4) EPA's

docket in the Municipal Library of Carlsbad, New Mexico located at 101 S. Halegueno (open from 10:00 a.m. to 9:00 p.m. on Monday through Thursday, 10:00 a.m. to 6:00 p.m. on Friday and Saturday, and 1:00 p.m. to 5:00 p.m. on Sunday). As provided in 40 CFR part 2, a reasonable fee may be charged for photocopying docket materials.

Description of Proposed Criteria

The proposed criteria consist of four subparts. Each of these subparts is discussed in more detail below.

Subpart A—General Provisions

Subpart A is chiefly concerned with identifying the purpose, scope and applicability of the criteria, defining terms, setting forth requirements regarding communications, addressing conditions of compliance certification and determinations, incorporating publications by reference, and providing for alternative provisions if future information indicates a need to modify the criteria. The specific provisions of Subpart A are discussed below.

Purpose, Scope, and Applicability

Under Section 7(b) of the WIPP LWA, the DOE cannot dispose of transuranic waste at the WIPP until the EPA certifies that the WIPP is in compliance with the Agency's radioactive waste disposal standards set forth in 40 CFR part 191. In addition, under Section 8(f) of the WIPP LWA, not later than five years after initial receipt of waste for disposal at the WIPP, and every five years thereafter until the end of the decommissioning phase (as defined in section 2 of the WIPP LWA), DOE is required to submit to the Administrator documentation of continued compliance with the Agency's disposal standards. EPA is proposing to specify that these criteria will apply to any certification of compliance or determination of continued compliance under these sections of the WIPP LWA. The Administrator will review any compliance applications (hereinafter, the term "compliance applications" refers to applications for certification of compliance under section 8(d) of the WIPP LWA as well as applications for determinations of continued compliance under section 8(f) of the WIPP LWA) and will utilize these criteria to ascertain whether such applications demonstrate compliance with subparts B and C of 40 CFR part 191. The Administrator's certification or determination of compliance for the WIPP facility will depend on satisfying the specific requirements of each section of these criteria.

Definitions

In an effort to be consistent with the disposal standards set forth in 40 CFR part 191, the Agency is proposing that, unless otherwise indicated, all terms in the criteria have the same meaning as terms found in the disposal regulations.

Communications

The Agency is proposing to specify that any compliance applications shall be addressed to the Administrator and shall be signed by the Secretary. Any other communications concerning compliance applications for the WIPP shall, likewise, be addressed to the Administrator and shall be signed by the Secretary or the Secretary's authorized representative.

Conditions of Compliance Certification and Determination

EPA is proposing that any certification or determination issued by the Agency pursuant to the WIPP LWA may include any conditions that the Administrator finds necessary to support a compliance certification or determination. In addition, EPA is proposing that any certification or determination of compliance be potentially subject to modification, suspension, or revocation for cause. The Agency believes that such conditions are necessary in order to guard against the possibility that the disposal system does not perform as expected (i.e., according to predictions contained in compliance applications).

Any certification or determination of the WIPP's compliance will be based upon the information contained in any compliance application submitted to the Administrator and upon other available information relevant to the application. So long as the contents of the application remain valid, the current certification or determination will remain valid. However, if the information contained in the application becomes invalid due to unanticipated developments, then the basis for the certification or determination may no longer be valid, and modification, suspension, or revocation of the certification or determination may be in order. Any modification, suspension, or revocation of a compliance certification will be subject to Agency rulemaking.

EPA is proposing to include these conditions because the Agency believes it is important to have a mechanism which enables a certification or determination to be modified, suspended, or revoked if new information comes to light which suggests that the WIPP is no longer

performing or may no longer perform as predicted. It would not be prudent to wait until submission of documentation of continued compliance (potentially up to five years later) before taking steps to mitigate against potential malfunctioning of the disposal system. Delay would allow a situation which could result in a violation continuing to exist or, perhaps, worsen. Hence, EPA is proposing these conditions in order to be able to take action quickly to address serious issues raised as to whether the WIPP is in compliance with the disposal regulations.

The Agency is not specifying, in today's proposal, the particular actions which may be required to be undertaken if modification or suspension were invoked. EPA has not done so because the Agency believes that it is inappropriate to specify particular actions prior to knowing the precise circumstances in which the actions would be undertaken. Since all of the scenarios in which the conditions might be invoked would be difficult to predict, specification of the actions necessary to mitigate against the consequences of all such scenarios becomes even more difficult. EPA, therefore, is proposing that decisions about the appropriate actions shall be based upon the nature and gravity of the given scenario at the time it occurs. In some cases this might entail instituting remedial actions or even removal of waste, while in other cases it might simply involve temporarily halting waste emplacement. Thus, actions will be evaluated on a case by case basis. The Agency solicits comment on this approach.

While the Agency is not specifying the particular actions which may be required in the event of a modification or suspension, the Agency is proposing that, in the event of a revocation (where presumably all attempts at remedial action have failed), the Department shall retrieve, to the extent practicable, any waste emplaced in the disposal system. The Agency solicits comment on this proposal.

The Agency is proposing that upon written request of the Administrator (after any certification or determination of compliance has been issued), the Department shall submit information to enable the Administrator to determine whether cause exists to modify, revoke, or suspend any certification or determination. Moreover, the EPA is proposing that the Department shall provide the requested information to the Administrator within 30 days of receipt of the Administrator's request. By requiring such a quick response time, the Agency can be assured that if circumstances arise which warrant

suspension, modification, or revocation, the potential consequences of such circumstances can be mitigated early and safety can, therefore, be increased. As an additional measure to ensure that the Administrator is kept apprised of any developments at the WIPP which might warrant modification, suspension, or revocation of any certification or determination of compliance, the Agency is proposing that the Department report, within ten days of discovery, any significant changes in conditions pertaining to the disposal system that depart from the application and which formed the basis of any certification or determination. Moreover, the Agency is requiring that a written report of all changes in conditions and/or activities pertaining to the disposal system that depart from the application and which formed the basis of any certification or determination be submitted to the Agency at least once every six months. If the Department plans to intentionally make any significant changes in conditions or activities pertaining to the disposal system, all such changes must be approved by the Administrator prior to being made. The Administrator will consider whether the planned change will invalidate the terms of the certification or determination in assessing whether approval should be given.

EPA is proposing to require the reporting of changes in WIPP conditions or activities once every six months to assure that the Agency is kept apprised of such changes but in a manner which is not overly burdensome to the Department in submitting the information or to the Agency in reviewing it.

EPA is also proposing to require that if the Department determines that a release of waste from the disposal system in excess of what is permitted under the disposal regulations has occurred or is likely to occur, the Department shall immediately suspend emplacement of waste in the disposal system and notify the Administrator within 24 hours of discovery of such a release. Following such notification, the Administrator may request additional information and will determine whether to modify, suspend, or revoke any previously issued certification or determination of compliance. The EPA is proposing this requirement to ensure that the Administrator is quickly apprised of any changes in the disposal system's performance from the projections included in any compliance applications.

Publications Incorporated by Reference

EPA is proposing that the following four documents be incorporated by reference: (1) The Nuclear Regulatory Commission's NUREG 1297 "Peer Review for High-Level Nuclear Waste Repositories"; (2) The American Society of Mechanical Engineers' (ASME) NQA-1-1989 edition "Quality Assurance Program Requirements for Nuclear Facilities"; (3) ASME NQA-2a-1990 addenda (part 2.7) to ASME NQA-2-1989 edition "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications"; and (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." The Agency is proposing to incorporate all of these documents because EPA believes that each is appropriate for use at the WIPP. More detailed information about the contents of each document is provided below in the sections dedicated to the particular topic covered by the various documents. Documents incorporated by reference are also available for inspection in the Office of the Federal Register.

Alternative Provisions

Although the Agency believes that the criteria being proposed today are appropriate based upon current knowledge and information, the possibility that future information may indicate necessary modifications to the criteria can not be ruled out.

In recognition of this possibility, today's proposed criteria set forth procedures under which the Administrator may develop modifications to this part, should the need arise. Any such modifications would proceed through the notice-and-comment rulemaking process under the Administrative Procedure Act (5 U.S.C. 553). The proposed criteria stipulate that such a rulemaking would require a public comment period of at least 120 days, including public hearings in New Mexico.

Subpart B—Compliance Certification and Determination Applications

Subpart B of the proposed compliance criteria addresses: (1) The completeness and accuracy of compliance applications; (2) the filing and distribution requirements for such applications and any associated reference materials; (3) the contents of a complete application; and (4) the criteria for updating certification

applications. Each of these sections is discussed below.

Completeness and Accuracy of Compliance Applications

The Agency proposes to require that any applications submitted to the Administrator for a certification or determination of compliance be complete and accurate. Since the statutory review period for applications is only one year for certification and six months for determinations, it is essential that all of that time be devoted to substantive evaluation of the information contained in the applications. Therefore, the Agency is proposing that the statutory review periods not begin until the Administrator has determined that the application is complete, accurate, and in accordance with the compliance criteria. The Administrator will notify the Secretary in writing once this determination is made.

Submission of Compliance Applications

In order to meet EPA's needs for reviewing and docketing any compliance applications, the Agency proposes to require that 30 paper copies of applications be filed with the Administrator (one original and 29 printed copies), unless otherwise specified by the Administrator. This number of copies is necessary because the Agency plans to place copies of compliance applications in various public dockets and the complexity of the application material will require multiple reviewers. The phrase "unless otherwise specified by the Administrator" is meant to allow for the possibility of alternative requirements for submission of compliance applications in the event that new submission methods are developed; e.g., electronic submission requirements.

Submission of Reference Materials

The Agency recognizes that compliance applications will likely include references to other sources of information. Accordingly, today's proposal requires submission to the Administrator of ten paper copies of any referenced material unless otherwise specified by the Administrator. This is necessary due to the limited time period for review and due to the needs of multiple reviewers, including the public. Again, the phrase "unless otherwise specified by the Administrator" signals that the Administrator may require an alternative method for submission of reference materials if a more appropriate system (e.g., an electronic submission system) is developed. Regardless of

what system is ultimately used, submissions need not include referenced material from standard textbooks (e.g., physics or chemical handbooks).

Content of Compliance Certification Applications

The Agency is proposing to specify information which must be included in any compliance certification application. The proposed criteria require descriptions of the WIPP disposal system and surrounding environment, and the components and results of long-term compliance assessments. The items listed, however, are not intended to be an exhaustive identification of the necessary elements of a complete application. Rather, the proposed criteria identify what the Agency considers to be major elements of a complete compliance application. Note that other major submission requirements are discussed elsewhere in the criteria and are too numerous to list here (such as documentation requirements for use of expert judgment and for waste characterization).

In the future, the Agency will be issuing a detailed guide as a supplement to the 40 CFR part 194 compliance criteria. This guide will provide additional detailed information on the expected format and content of a complete compliance application. The Agency is not including such a detailed itemization in today's proposal because EPA needs more information about factors important to the disposal system's ability to contain waste before such detailed submission requirements can be identified.

As an example of the type of information which may be necessary for inclusion in a complete application, but which EPA is not specifying in today's proposal due to the fact that there is currently an incomplete understanding of its effect on the disposal system, is an analysis and identification of higher permeability marker beds in the host rock. (Marker beds are stratified units with distinctive characteristics making them an easily recognized geologic horizon.) At present, there is some information about the existence of these marker beds in the host rock, but little knowledge about how they may affect the transport of radionuclides and the flow of ground water. As further study is done of these marker beds, it is possible that they may be discovered to have a great impact on the WIPP's ability to comply with the disposal standards of 40 CFR part 191. It is also possible that they will be discovered to have little or no impact. Depending on the results of further study, then, EPA

will decide whether information about the higher permeability beds needs to be included in compliance applications and if so, how much information. EPA solicits comment on this approach.

Content of Compliance Determination Application(s)

As required by section 8(f) of the WIPP Land Withdrawal Act, DOE must submit documentation of continued compliance every five years after any initial certification is granted for the WIPP until the end of the decommissioning phase, when all shafts and rooms at the WIPP are backfilled and sealed. To avoid duplication of information already submitted to the Administrator as part of any previous compliance applications, EPA proposes to require that only relevant new information be submitted as documentation of continued compliance. This documentation must update the information contained in previous applications and apprise the Agency of new developments regarding the WIPP disposal system and its performance. Information included in previous applications may be summarized and referenced.

Subpart C—Compliance Certification and Determination

Subpart C sets forth general and specific requirements for certifying and determining compliance with the provisions of the disposal regulations found in subparts B and C of 40 CFR part 191. The provisions of Subpart C are discussed in detail below.

General Requirements

Inspections

Today's proposal provides for EPA inspections to help ensure that WIPP-related activities and pertinent records described in any compliance applications are implemented as described. Inspections, including, random, unannounced inspections of WIPP-related activities and records, will assist EPA in assuring the validity of information used to support compliance applications. In conducting such inspections, EPA will comply with applicable access control measures for security, radiological protection and personal safety, but shall otherwise have unfettered access to WIPP-related activities and records.

To facilitate EPA's ability to inspect as warranted, EPA is proposing that, upon request, the Department provide the Administrator's inspectors with rent-free office space convenient to the WIPP disposal system. Additionally, records shall be made immediately

available to Agency inspectors where possible, and in no circumstances shall the furnishing of records be extended beyond 30 days from the initial request.

As an additional matter, the Agency believes that on occasion, EPA personnel may need to conduct sampling and analysis or monitoring of the disposal system. Such sampling may include split sampling, in which portions of samples taken by the DOE shall be furnished to EPA for analysis. Through split sampling, EPA can independently verify the results of DOE analyses. Moreover, by taking such samples, EPA will be better equipped to evaluate the quality of data being produced, as well as gain a better understanding of the disposal system.

EPA proposes that its inspection privileges be broad enough to allow the Agency to inspect activities that may provide information used to support compliance application(s) and are deemed by the Administrator or the Administrator's authorized representative to be relevant to a compliance certification or determination. This may include, but is not necessarily limited to, examination of quality assurance procedures, waste characterization activities, experimental programs, computer operations, and data collection activities, insofar as all of these items may affect the WIPP's ability to comply with the 40 CFR part 191 disposal regulations. Significantly, under today's proposal, EPA inspections would be limited to locations to which the Department has rights of access but would not be limited to activities which occur at the WIPP facility. As discussed above, if an activity can potentially affect the WIPP's ability to comply with the Agency's disposal regulations, it shall be subject to potential inspection by EPA personnel. For instance, EPA may inspect WIPP-destined waste generation and storage sites because waste characterization activities often occur at these sites.

Quality Assurance

To help assure that calculations of compliance with 40 CFR part 191, subparts B and C, are based upon sound data and information, the Agency proposes to include compliance criteria addressing quality assurance (QA). EPA is proposing that the Department implement a QA program that meets the requirements of the American Society of Mechanical Engineer's (ASME) "Quality Assurance Program Requirements for Nuclear Facilities" (NQA-1-1989 Edition), ASME's "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications" (NQA-2a-1990 addenda, part 2.7 to ASME

NQA-2-1989 edition), and ASME's "Quality Assurance Program Requirements for the Collection of Scientific and Technical Information on Site Characterization of High-Level Nuclear Waste Repositories" (NQA-3-1989 edition—excluding Section 2.1 (b) and (c)). EPA is proposing to use the ASME standards referenced above because it appears they offer the most comprehensive and specific set of QA requirements for all compliance-related elements of the disposal system. EPA solicits comment on whether these standards are the most appropriate to use for this purpose.

With respect to data collected prior to the implementation of the ASME standards, EPA is proposing that such data be acceptable for the purpose of supporting any applications for compliance certification if it can be demonstrated to have been collected: (1) Under a QA program that is equivalent in scope and implementation to the NQA series, or (2) through a method otherwise approved by the Administrator for use at the WIPP. Today's proposal does not include any specific criteria identifying how such equivalence should be demonstrated, nor is there any specification about what the Agency will consider in approving QA plans. The Agency intends to issue guidance on this topic in the future.

The Agency is proposing to allow a flexible approach on quality assurance for data collected prior to implementation of the ASME NQA series because the Agency recognizes that unless a method exists for qualifying such "old data," the efforts in collecting such "old data" will be wasted. It is likely that a large portion of the data submitted in support of an application for certification of compliance will be "old data." To prohibit the inclusion of such data if the data can be demonstrated to be of equivalent quality to "new data," or is sufficiently reliable for approval by the Administrator, would be unreasonable because data that are sufficiently reliable should be included in the analysis. The Agency solicits comment on this approach.

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

The NQA-2(a)-1990 addenda (part 2.7) to ASME NQA-2-1989 edition standard is directed toward establishing requirements for "the development, procurement, maintenance, and use of computer software, as applied to the

design, construction, operation, modification, repair, and maintenance of nuclear facilities." More specifically, it applies to computer software "used to produce or manipulate data which is used directly in the design, analysis, and operation of structures, systems, and components."

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

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

As a final matter, the Agency is proposing to conduct its own examination of DOE QA programs and plans through select inspections, management system reviews, and audits. This is to help assure that QA plans are implemented appropriately.

Models and Computer Codes

Computer models are needed to assess whether the WIPP disposal system will comply with the 40 CFR part 191 disposal regulations. In order for these computer models to perform their

functions with acceptable accuracy, they must be based upon appropriate conceptual, mathematical, and numerical models.

In order to ensure that the conceptual, mathematical, numerical, and computer models used to support compliance applications are appropriate for use in certifying whether the WIPP complies with the disposal regulations, EPA proposes to require that detailed information about these models be submitted to the Agency as part of any compliance certification applications. EPA proposes to assess the appropriateness of the models and any computer codes used to represent them based on the following factors: Whether conceptual models reasonably represent the disposal system; whether mathematical models incorporate equations and boundary conditions which reasonably represent mathematical formulations of the conceptual models; whether numerical models provide numerical schemes which enable mathematical models to obtain stable solutions; whether computer models accurately implement the numerical models (i.e., are free of coding errors and produce stable and accurate solutions); and whether the models, data, and computer codes have been properly peer reviewed. EPA solicits comment on these factors and whether other factors should be included. For instance, should EPA require information which demonstrates that there is agreement between the model results and any measured and observed data? Or, if it can be demonstrated that models and computer codes are sufficiently conservative, is such demonstration unnecessary?

In addition, EPA is proposing to require that the American Society of Mechanical Engineer's NQA-2a-1990 addenda (part 2.7 to ASME NQA-2-1989 edition) be used to help ensure that models and codes are fully and clearly documented.

In order to determine whether the conceptual models used to support a compliance certification application offer the best representation of the disposal system, EPA is proposing to require a complete listing and description of conceptual models considered but not used to support such application. In addition, EPA is proposing to require a complete listing of conceptual model(s) considered but not used to support compliance certification applications, a description of such model(s), and an explanation of the reason(s) why such model(s) was/were not used. An examination of conceptual models requires an assessment as to whether the theories

represented in conceptual models are appropriate and whether other theories may be more or equally appropriate. For this reason, EPA is proposing that the DOE identify and describe all conceptual models that the Department considered and provide justification why some were selected and others were not. The Agency solicits comments on this approach and on whether any particular theories should be represented in conceptual models used to support compliance certification applications.

EPA is proposing to require that documentation include such items as: Descriptions of the theoretical backgrounds of each model, the method of analysis and assessment, scenario construction, data collection procedures, and code structures and source codes. In addition, the Agency is proposing that user's manuals be submitted that include the following information: discussions of the limits of applicability of each model; detailed instructions for running the codes including hardware and software requirements; input and output formats with detailed explanations of each input and output variable and parameter; listings of input and output files with a sample computer run; reports on code verification, benchmarking, validation and quality assurance procedures. The Agency is also proposing to require the submission of programmer's manuals and any necessary licenses. Programmer's manuals typically include such things as the mathematical formulations included in the model, computational algorithms and modeling structures.

In addition, because the WIPP disposal system is very complex, it is likely that some of its characteristics correlate to one another. If this correlation is not reflected in modeling efforts, then the models may fail to portray the realities of the system and significant errors in performance assessment results can occur. Covariance, a measurement of the tendency of random variables to vary together, is used to evaluate this possibility. Therefore, EPA is proposing that information be provided which indicates whether and how models and codes handle covariance of model input parameters. If models do not consider covariance, EPA would expect to be provided with an explanation of why covariance was not considered and the potential impact of instead treating variables independently. EPA solicits comments on this approach and on the alternatives of (1) requiring covariance to be included in models and codes and, (2) requiring covariance to be included

unless justification can be provided that the independent treatment of variables would cause models to predict greater releases than if covariance is taken into account.

Finally, EPA proposes that copies of the models and software, data files, source codes, licenses, or other materials necessary to run the models on EPA's own computers (or on DOE computers if EPA computers are unable to run the models) be provided to the Agency within 30 days of a request by the Administrator or the Administrator's authorized representative. Additional requirements for models are covered in the quality assurance and peer review sections of today's proposal.

Waste Characterization

In order to make meaningful predictions about the performance of the WIPP over long periods of time, it is necessary to have a good understanding of the characteristics of the waste proposed to be emplaced in the disposal system. The potential for releasing radionuclides from the disposal system can be directly affected by the chemical, radiological, and physical composition of the waste. These factors, therefore, can affect the ability of the WIPP to comply with the 40 CFR part 191 disposal standards and, consequently, must be examined as part of any certification or determination of compliance.

Currently, the waste inventory to be potentially disposed of at the WIPP consists of: (1) A large volume of stored ("existing") waste with varying degrees of adequacy of accompanying documentation regarding its composition and properties; and (2) an estimated larger volume of "to-be-generated" waste about which there is uncertain knowledge of its expected composition and properties.

For the purpose of gaining a complete understanding of the waste proposed for disposal at the WIPP, EPA is proposing to require submittal of a detailed description of the waste's chemical, physical, and radiological contents including a description of the activity in curies of each radionuclide contained in such waste. Such description shall be used in assessing compliance with subparts B and C of 40 CFR part 191.

To identify waste characteristics important to the containment of waste in the disposal system, EPA is proposing that DOE undertake a study to determine the effect of various characteristics on the performance of the disposal system. The characteristics studied shall include, but need not be limited to: (1) waste form; (2) free liquid content and liquid saturation; (3)

pyrophoric and explosive material content, and (4) characteristics affecting the solubilization and mobilization of radionuclides, formation of colloidal suspensions containing radionuclides, production of gas from the waste, nuclear criticality, and generation of heat in the disposal system. The impact of non-radioactive hazardous components of the waste should also be assessed as such components have the capacity to influence radionuclide transport. The results of this study shall be provided to EPA along with documentation of the methodology and information describing the importance of particular characteristics of the waste. These results shall dictate the breadth of characterization to be performed.

Once the waste characteristics that are important to the disposal system's ability to isolate radionuclides have been identified, the waste shall be categorized based on those characteristics that would be expected to make all waste within a particular category behave similarly in the disposal system. For example, if the curie content of a given radionuclide in the waste is determined to be important to the disposal system's ability to contain radionuclides, it might be used as part of a system of categorization. Waste having a high curie content of that nuclide could comprise one category, while waste having a low curie content of that nuclide could comprise another category. Similarly, if a given waste form is found to be important, categories could be made for various waste forms such as sludges and solids. EPA proposes that a detailed description shall be provided which identifies the characteristics of each category of waste established.

A variety of methods for characterizing waste exists including sampling and analysis, radioassay, and examination of waste generation documentation and associated records (often referred to as "process knowledge"). Today's proposal does not specify any particular method for characterizing the waste. Nevertheless, regardless of which method or combination of methods is selected for waste characterization activities, the Agency is proposing to require that each method be identified and described. Moreover, the uncertainty associated with each method shall be identified, and if information about the processes and materials that generated the waste is used as a basis for waste characterization, the DOE shall be required to substantiate such characterization.

The manner in which the Agency proposes that waste characterization

shall be accomplished is explained below. The DOE will examine each important characteristic of the waste and determine a value or range of values for that characteristic. Since DOE must demonstrate that the WIPP complies with the containment, individual, and ground-water protection requirements of 40 CFR part 191 for the whole range of values for each waste characteristic, the larger the range, the greater the uncertainty associated with a claim that WIPP complies. DOE can reduce the range of values for each characteristic through enhanced information gathering until the range is small enough such that DOE is reasonably confident that the resulting probability for compliance will meet the containment, individual, and ground-water protection requirements of 40 CFR part 191. Thus, DOE has a great deal of flexibility in the amount of characterization required. However, whatever value or range of values DOE selects for each characteristic must be considered in compliance assessments of the WIPP. In assessing compliance, DOE shall consider all combinations of waste characteristics and the resulting impact on the disposal system's behavior.

EPA is proposing that waste not be emplaced in the repository unless its characteristics fall within the ranges of values for those characteristics used in compliance assessments. To assure that only waste whose characteristics fall within the given range of values is emplaced, the Agency is proposing that a system of controls be established, including measurements, sampling, and recordkeeping for the waste, such that the actual characteristics of waste will be identified before the waste is emplaced in the WIPP. Compliance applications shall provide an identification and description of these controls along with an analysis of the uncertainty associated with them.

As a final measure to assure proper waste characterization, the Agency is proposing that EPA audits and inspections will be used to verify the waste characterization requirements of this part.

Future State Assumptions

Demonstrating compliance with 40 CFR part 191, subparts B and C, involves the use of computer models based on conceptual models which project, over an extended period of time, the transport of radionuclides from the disposal system to the accessible environment and resulting radiation doses to individual members of the public. Because of the long-term nature of these evaluations, uncertainty of values for many parameters important to

the analysis may be very large. Environmental conditions and living habits of future populations and individuals may change in significant and unforeseeable ways over the lengthy timeframes that will be analyzed for compliance.

In light of the difficulty of assigning appropriate values with confidence, the Agency is proposing to specify certain assumptions about the future for use in long-term modeling. The Agency is proposing that, unless otherwise specified, any certification of compliance shall assume that characteristics of the future remain what they are today. EPA believes such an approach will enable compliance assessment to focus on more predictable and more significant features of disposal system performance. For instance, EPA is proposing that such an approach not be used to characterize the long-term geologic, hydrologic, or climatologic conditions of the system and its vicinity.

With regard to consideration of climatic conditions, the Agency is proposing to require predictions about climate, but within a specified framework. Specifically, EPA is proposing to limit the consideration of climate effects to the effects of increased and decreased precipitation on the disposal system. This would include predictions of temperature, which affects evapotranspiration, and other factors.

With respect to human technology and behavior, EPA has tentatively concluded that it would be fruitless to attempt any predictions about the future that would be useful over 10,000 years. The one constant in human history is change—in social organization, economic activity, and technology. Thus, at first glance it seems highly anomalous to assume that future states will be like the present. However, as noted, EPA believes that there is no reasonable way to predict in any definitive way what changes will take place in the future. In effect, then, EPA is proposing to employ present conditions as default values for future states because it has no better choices, and because this approach at least has the advantage of providing readily ascertainable and verifiable values.

The Agency solicits comment on its approach to future states assumptions and the Agency's treatment of geology, hydrology, and climate considerations. Suggestions of alternatives to the proposed approach are also solicited.

Expert Judgment

EPA recognizes that expert judgment may be used to support disposal system

compliance analyses. EPA is proposing that use of expert judgment be limited to those situations where data is not reasonably attainable through data collection or experimentation.

To assure that the Agency is aware of all cases in which expert judgment is used, EPA is proposing that any compliance certification application clearly identify all instances in which such judgment is used and the names and professional affiliations of experts involved. Moreover, documentation shall be included which describes the process for expert judgment elicitation, the results of expert elicitation, and the reasoning behind those results. Documentation shall also be provided of interviews used to elicit judgments from experts, deliberations and formal interactions among experts, background information provided to experts, and the questions or issues presented for elicitation of expert judgment. Access to this information will help the Agency assess the quality and appropriateness of expert judgment as well as DOE's interpretation and use of that judgment.

Although EPA has not specified any particular methods for expert judgment elicitation in today's proposal, the Agency does believe that some restrictions and guidelines for the selection of individuals for expert judgment are appropriate. The restrictions which EPA is proposing today include prohibitions on: selecting individuals who are members of the team of investigators requesting the judgment or the team of investigators who will use the judgment; selecting individuals who maintain a supervisory role or who are supervised by (directly or indirectly) those who will utilize the judgment; and selecting a membership of which no more than one-third consists of individuals who are employed directly by the Department or its contractors (unless it can be shown that this is impracticable because of a lack or unavailability of qualified independent experts, in which case at least one-half of the membership must be non-DOE personnel). University professors with grants from the Department not related to work on the WIPP and the New Mexico Environmental Evaluation Group are not considered employees or contractors of the Department for purposes of this part. Additionally, compliance applications shall provide information which demonstrates that the expertise of any individuals involved in expert judgment is consistent with the level of knowledge required by the question or issue presented to that individual.

Furthermore, the Agency is requiring that at least five individuals be used in

any expert elicitation process, unless a lack or unavailability of experts can be demonstrated. Also, any compliance certification application shall include a discussion explaining the relationship between the information presented, the questions asked, the judgment of any expert panel or individual, and the purpose for which the expert judgment is being used. The Agency is proposing all of the above requirements to assure that expert judgment is elicited in a manner that is as objective and informed as possible.

As a final means of helping to assure the appropriateness of expert judgment, EPA is proposing that the elicitation process afford an opportunity for presentation to the experts of the scientific and technical views of outside groups and individuals. This provision is being proposed in today's notice because the Agency believes it will help to provide experts involved in elicitation with a fuller range of information and view points upon which to base their judgments.

The Agency considered several different approaches to the use of expert elicitation and concluded that though each was appropriate for a specific type of situation, none were appropriate for all types of situations. For example, one approach identified would require that the average of all values elicited by an expert panel be used as the final judgment. This may be appropriate if the issue presented to an expert panel lends itself to meaningful averaging of values. For instance, if an expert panel is asked to determine the rate of rainfall in the Delaware Basin over 10,000 years, the range of answers that would be obtained from the various experts would be expressed in numbers that could be meaningfully averaged. However, if an expert panel is asked to determine whether the possibility of a meteor hitting the WIPP site is likely, the answers would be expressed in terms of yes or no, which cannot be meaningfully averaged. Hence, depending on the situation, this approach may not be appropriate.

Given the above, EPA believes that it may not be useful to specify a particular method. However, the Agency solicits comments on alternative approaches to incorporating the results of expert judgment elicitation into compliance assessment.

Peer Review

Peer review is widely used as a means of validating technical data, processes and assumptions. Peer review involves a group of experts who are convened to review work conducted by their peers to determine whether the work was

performed appropriately and in keeping with the purpose intended.

Since a large part of compliance applications will consist of data and descriptions of methods for producing data, EPA believes that peer review can be helpful as a means of validating the information contained in such applications. Therefore, the Agency proposes that peer review be used to support compliance applications. Specifically, EPA proposes to require peer review of any information contained in any compliance certification application regarding the evaluation of engineered barriers, consideration of processes and events that may affect the disposal system's performance, quality assurance programs and plans, models and computer codes and including data used to support them, and waste characterization activities. Peer review can build additional confidence in the soundness of these important aspects of a compliance certification.

EPA proposes that peer review be conducted in a manner which is compatible with the Nuclear Regulatory Commission's NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories," which is incorporated by reference in today's proposal. This document provides guidance on the definition of peer review, the acceptability of peers, and the conduct and documentation of peer review.

Containment Requirements

The Agency's disposal regulations found in 40 CFR part 191 include requirements for containment of radionuclides. These containment requirements specify numerical requirements limiting the cumulative release of radionuclides over 10,000 years. The specific release limits are found in Appendix A of the disposal regulations. The containment requirements specify that there be less than one chance in ten of cumulative releases exceeding the limits specified in Appendix A and less than one chance in 1,000 of cumulative releases exceeding ten times those limits.

Application of Release Limits

The containment requirements of 40 CFR part 191 specify that releases from a disposal system to the accessible environment can not exceed release limits set forth in Appendix A, Table 1. Information about the curie content will be needed for calculation of the release limits. However, because the curie content of the waste inventory will vary over time due to natural ingrowth and decay of radionuclides, a question arises concerning when the curie content of

the waste should be fixed for purposes of calculating the release limits.

The EPA is proposing that the expected curie activity 100 years after disposal of the waste in the WIPP be used in calculating applicable release limits. The Agency is proposing this approach because EPA believes that 100 years represents a long enough period of time for most of the radioactive material with short half-lives to decay to low levels. The remaining activity after the 100-year period will largely be the result of radioactivity from waste with long half-lives. Such waste may pose the most danger to human health and the environment and, therefore, should be the focus of attention.

The Agency solicits comment on the appropriateness of the above-mentioned approach and on alternative time frames for fixing the curie content.

Scope of Performance Assessments

In today's notice, the Agency is proposing criteria which indicate that performance assessments shall consider both natural and human-initiated processes and events that may affect the disposal system. However, EPA is also proposing that performance assessments need not consider processes, events, or sequences of processes and events (sometimes referred to as "scenarios") that have less than one chance in 10,000 of occurring over 10,000 years.

EPA is proposing the above requirements because section 13 of 40 CFR part 191 requires the implementing agencies to evaluate compliance through performance assessments. One method of displaying results of performance assessments required under section 13 of 40 CFR part 191 is to assemble "complementary cumulative distribution functions" (CCDF). CCDFs are assembled by first calculating the probability of each release scenario and associating a consequence (e.g., release of radionuclides) with each probability. Once the paired probability and consequence estimates are made, they are combined into the CCDF by ranking them in the order of decreasing consequences. The first point on the curve would represent the large consequence of a low probability scenario. The second point on the curve would represent the probability of the first scenario added to the probability of a second scenario. Since the probability of scenarios occurring is cumulative, scenarios with probabilities lower than one chance in 1,000 must be incorporated into probability distributions assembled under section 13 of 40 CFR part 191 to see if the results are significant with regard to compliance assessment.

Importantly, not all scenarios considered by the Department will necessarily be included in calculations of compliance with the 40 CFR part 191 disposal standards. Some scenarios may be eliminated from incorporation into performance assessments because assumptions will be made about such scenarios which indicate that the probability or consequences of such scenarios are outside of the scope of the requirements of 40 CFR part 191. In an effort to understand which scenarios were considered in performance assessments, EPA is proposing that information be provided which identifies all potential processes, events, or sequences of processes and events that may occur during the regulatory time frame and that may affect the disposal system, as well as information which identifies those processes, events, or sequences of processes and events actually included in performance assessment results.

Consideration of Human-Initiated Processes and Events

Compliance with the containment requirements of 40 CFR part 191 requires consideration of the effects of human-initiated processes and events on the disposal system. The Agency believes that the most productive consideration of inadvertent human-initiated processes and events concerns those realistic possibilities that may be usefully mitigated by disposal system design, site selection, or use of passive institutional controls. Therefore, the Agency is proposing that inadvertent and intermittent drilling for resources (other than those resources provided by the waste in the disposal system or any engineered barriers designed to isolate such waste) be the most severe scenario for human-initiated processes and events.

Further, the Agency is limiting the consideration of human-initiated processes and events to drilling events because mining events were not included in EPA's analyses that supported the final rule of 40 CFR part 191 as promulgated in 1985.

The Agency has chosen to divide human-initiated processes and events into two distinct categories, "human intrusion" and "human activity," and is proposing a separate process to establish the drilling rate for each. "Human intrusion" includes those drilling events that reach the level of the waste in the disposal system or below. Such events would include, but would not be limited to, exploration for and development of oil and natural gas resources. The second category of human-initiated processes and events,

"human activity," includes all drilling events that may affect the disposal system, but do not reach the level of the waste in the disposal system. Such drilling events may include, but would not be limited to, exploration for potash, withdrawal of water—whether for purposes of drinking, irrigating or controlling dust—and drilling for other resources. Note that a given resource may exist at levels above and below the level of the waste in the disposal system and may therefore be included in establishing the rates for both human intrusion and human activity.

EPA is proposing that consideration be given to the record of human-initiated processes and events in the Delaware Basin over the past 50 years. The Agency believes that the 50-year time frame is appropriate because it represents a period during which information regarding human-initiated processes and events in the Delaware Basin can be reasonably obtained.

Importantly, by making assumptions about the frequency of human-initiated processes and events in the vicinity of the WIPP and holding them constant throughout the future, scenarios in which such events cease because, for instance, resources eventually become depleted would no longer be considered. However, the Agency recognizes that as one resource becomes depleted, the decrease in exploratory or production operations may be compensated for by the increase in drilling operations for another. Rather than engage in speculation about which resources will become more valuable in the future, and which will become depleted, EPA believes it is preferable to assume that current rates of drilling for each individual resource will remain constant. The Agency solicits comment on this approach.

As stated above, the Delaware Basin is being proposed as the area for examination of the record of human-initiated processes and events. The Delaware Basin is an elongated depression that extends from just north of Carlsbad, New Mexico, southward into Texas. The Agency solicits comment on how, precisely, the Delaware Basin should be defined. The Agency believes that the Delaware Basin is an appropriate region because the WIPP is situated within it and, as a region, it represents the largest contiguous area which shares similar geologic and hydrologic conditions with the WIPP site. However, EPA solicits comments on whether a different area should be used (such as a subset of the Delaware Basin).

It is important to note that the Agency is proposing to require a separate

examination of each type of human-initiated process and event. The reason for this requirement is to account for the fact that each type of drilling has a distinct rate and unique properties, resulting in a different effect on the disposal system for each type of drilling. For example, oil drilling is conducted at a different depth, rate and with a different drilling technique than water drilling and is, therefore, more likely to penetrate the repository than water drilling. Accordingly, the analyses for each resource must be conducted individually.

In assessing the consequences of human-initiated processes and events, the Agency is proposing that such processes and events be assumed to occur at random intervals in time and space throughout the regulatory time frame. The consequences of each human-initiated process and event shall be calculated in terms of the projected impact on the WIPP disposal system. If more than one human-initiated process or event is predicted to occur, the consequences of any processes and events which occur subsequent to initial ones shall take into account any impacts on the disposal system from such previous disruptions. This is done to take into account the fact that every drilling event introduces potential changes to the disposal system. For example, a disposal system with man-made pathways interconnecting aquifers underlying the disposal system with ground water above the disposal system may react differently than a disposal system that has never been disturbed. In other words, the cumulative consequences of all human-initiated processes and events shall be taken into account in performance assessment results.

For the purpose of performance assessments, the Agency is proposing different criteria for establishing the frequency of "human intrusion" and the frequency of "human activity". While both are based on the historical record of resource exploration over the past 50 years in the Delaware Basin, an upper and lower limit is placed on the rate of human intrusion. The rate of human activity, however, is not limited to a set range.

Specifically, the rate of human intrusion is determined by first identifying and examining past occurrences of human intrusion in the Delaware Basin over the past 50 years for all resources.

The sum of the individual rates of human intrusion for each resource then becomes the rate of human intrusion to be used in performance assessments, provided that the sum is not less than

25 and not greater than 62.5 boreholes per square kilometer per 10,000 years. In the event that the calculated total rate is less than 25, then the rate of human intrusion to be used in performance assessments should be adjusted upward proportionally to yield a total rate of 25 boreholes per square kilometer per 10,000 years. Thus, if the oil drilling rate is 8 and the natural gas drilling rate is 2, both values are adjusted upward by a factor of 2.5 to yield a rate of 20 for oil and 5 for natural gas. Likewise, if the calculated total rate exceeds 62.5, then the rate of each type of human intrusion should be adjusted downward proportionally to yield a maximum rate of 62.5 boreholes per square kilometer per 10,000 years to be used in performance assessments.

By placing an upper and lower limit on the rate of human intrusion, the Agency is adhering to the assumptions that the Agency made in developing the technical basis used for formulating the containment requirements of the final disposal regulations as promulgated in 1985. As part of the development of the disposal regulations, the Agency estimated the range of future human intrusion and human activity for the general case of a repository in bedded salt, the geologic setting of the WIPP. Assumptions were made about the presence near a repository of different types of resources—including oil, gas, minerals and water—though it was assumed that the most significant resources present would be oil and gas. Using drilling data from the contiguous 48 states as a rough guide, the Agency estimated that a region of bedded salt would experience 25 to 62.5 boreholes per square kilometer per 10,000 years. Because the depths at which oil and gas, the only significant resources assumed to be present, are located typically exceed 10,000 feet the estimated range applies only to the rate of human intrusion. Thus, by proposing a human intrusion range of 25 to 62.5 boreholes per square kilometer per 10,000 years, the Agency is grounding the criteria on the same basis as 40 CFR part 191. Discussion of the assumptions as developed for the 1985 final rule of 40 CFR part 191 can be found in "Technical Support of Standards for High-Level Radioactive Waste Management, Volume D" (EPA 520/4-79-007D) and "Addendum to Volumes C and D" (EPA 520/4-79-007E).

The Agency is proposing that, should the Department wish to forego the process of analyzing the historical rates of human intrusion events in the Delaware Basin, the Department shall assume the maximum rate of 62.5 boreholes per square kilometer per

10,000 years. The Agency is further proposing that the rate of human intrusion may be reduced in accordance with the criteria found in § 194.41, active institutional controls, and § 194.43(c), passive institutional controls. A complete discussion of reduction of the human intrusion rate can be found in the discussion of those two portions of the criteria.

For consideration of "human activity" in performance assessments, the Agency is proposing that the historical record of drilling be examined, but without placing pre-set limits on the rates. Specifically, the rate of human activity is determined by first identifying and examining past occurrences of human activity in the Delaware Basin over the past 50 years for all resources. The sum of the individual rates for each resource then becomes the rate of human activity to be used in performance assessment.

The Agency is placing no limits on the rate of human activity, in contrast to the treatment of the rate of human intrusion. This divergent treatment is consistent with the final rule of 40 CFR part 191, which was based on an estimate of 25 to 62.5 boreholes per square kilometer per 10,000 years for the general case of a repository in bedded salt in the vicinity of few resources other than oil and natural gas. Because the depths at which oil and natural gas reserves are located typically exceed 10,000 feet, the estimated range of 25 to 62.5 boreholes per square kilometer per 10,000 years applies to the case of human intrusion only. Hence, no limit, upper or lower, is placed on the rate of human activity.

The Agency recognizes that for some resources such as water, the use of that resource may depend upon the quality of the specific reservoir of that resource that is being exploited. A given reservoir of water, for example, may not be of potable quality but may still be usefully withdrawn for controlling dust. Therefore it may be possible to show that certain resources found within the controlled area differ in quality from the same resource as found in rest of the Delaware Basin. For such resources, it could potentially be demonstrated that the resource would normally be exploited for different purposes at a different rate within the controlled area, and further that there is reason to believe that such practices would continue. The Agency is proposing that if such a case can be made in compliance applications, then when examining the historical record of human activity associated with that resource, only that human activity that has been associated with resources of quality similar to that found within the

controlled area need be considered. Consider a hypothetical example in which the water resources in the controlled area were found not to be of potable quality, and this were demonstrated and documented in the application for certification of compliance. Then, when examining the history of drilling for water in the Delaware Basin, the Department would need only consider boreholes created for water uses other than drinking, e.g., irrigation and control of dust.

The Agency is further proposing that the rate of human activity may be reduced in accordance with the criteria found in § 194.41, active institutional controls, and in § 194.43(c), passive institutional controls. A complete discussion of reduction of the human activity rate can be found under the discussion of those two portions of the criteria.

In assessing the consequences of human-initiated processes and events, the Agency is proposing that assumptions pertaining to characteristics of such processes and events be based on characteristics associated with current practice in the Delaware Basin. This approach is consistent with the approach the Agency is proposing for future state assumptions. For example, assumptions related to the type and amount of any drilling fluids, borehole depths, diameters, and seals should be assumed to remain consistent with the current practice in the Delaware Basin. For the specific case of borehole seals, EPA is further proposing that boreholes shall be assumed to be sealed at the rate boreholes have been sealed over the past 50 years in the Delaware Basin and that natural processes will degrade or otherwise affect the permeability of boreholes over the regulatory time frame.

The Agency has chosen in today's proposal to differ from the Appendix C "Guidance for Implementation" which accompanied 40 CFR part 191 because EPA believes that the approach outlined above for assessing the likelihood and consequences of human-initiated processes and events is more appropriate for the WIPP than the method discussed in the guidance. Today's proposal is specific to the WIPP; the guidance, on the other hand, is generic. Moreover, the guidance only took into account drilling frequencies for oil and gas. The Agency believes that other human activities, such as drilling for potash and drilling for water, are equally important for consideration at the WIPP, as they too have the potential to affect the disposal system. Therefore, today's proposal requires consideration

of all human actions that could affect a waste disposal system. However, the Agency solicits comment on its proposed approach and the appropriateness of differing from the Appendix C guidance.

Results of Performance Assessments

The Agency proposes to establish criteria for assessing the results of performance assessments required under the containment requirements of 40 CFR part 191. The Agency is proposing to require that the results of performance assessments be displayed as complementary cumulative distribution functions or "CCDFs." These CCDFs would display the releases of radionuclides over 10,000 years after disposal—summed and normalized according to Table 1, Note 6 of 40 CFR part 191—on the horizontal axis and the probability of releases occurring on the vertical axis.

In conducting performance assessments, there will be many parameter values that can affect the results of such assessments. For instance, gas generation by the waste, radionuclide solubilities, permeability of the host rock, and the porosity and transmissivity of surrounding aquifers entail parameter values that can affect the results of such performance assessments. These values may be difficult to quantify particularly over a 10,000-year period. Therefore, the Agency is proposing to require the development of probability distributions for parameter values in order to represent the probability of different values of the parameter occurring.

The Agency is further proposing to require that, in generating CCDFs, computational techniques be developed that sample randomly across the full range of probability distributions developed for uncertain disposal system parameter values used in performance assessments. In so doing, it is possible to convey the influence of parameter uncertainty upon the resulting CCDFs. Random sampling techniques can select a predetermined number of values from a parameter's probability distribution, the collection of which will represent the range of the distribution in successive stages of calculation.

The Agency is proposing to require that the entire range or "family" of CCDFs generated as a result of these sampling techniques be included in compliance applications. By requiring that all CCDFs be submitted, the Agency can evaluate whether given the conditions that exist at the disposal system, the disposal system could fail to comply with section 13 of 40 CFR part 191 in some of the CCDFs. By noting the

number of total CCDFs generated that fail to comply, the Agency will gain insight into the performance of the disposal system over the 10,000-year time frame.

The Agency is proposing to place statistical criteria on the number of CCDFs generated. The Agency is proposing to require that the number of CCDFs generated be large enough such that the maximum CCDF generated exceeds the 99th percentile of the population of CCDFs with at least a 0.95 probability. A 95% confidence level is commonly recognized as being a good indicator of statistical acceptability. The Agency believes that the effect of this approach will be that the number of CCDFs generated will be large enough to ensure that a full range of realizations have been generated. EPA estimates that this will require several hundred realizations, although the number submitted in compliance with this requirement may ultimately be larger or smaller.

The Agency is proposing to require that the mean CCDF of the population of CCDFs meets the requirements of section 13(a) of 40 CFR part 191 with at least a 95 percent level of statistical confidence. The mean CCDF is calculated from a "family" of CCDFs whose parameters have an associated uncertainty to them, as discussed above. As a result, the mean will have its own associated uncertainty. This uncertainty around the location of the mean reduces the level of assurance with which we can state that the mean CCDF is in compliance with section 13 of 40 CFR part 191. One way of attaining statistical confidence in the mean is to determine how reproducible the mean is if recalculated. For example, first generate an ensemble of a certain number of CCDFs and calculate the mean. Next, generate an entirely new ensemble of the same number of CCDFs and compare the mean calculated for this new set to that of the first set. If the number of CCDFs generated is a statistically representative portion of the infinite population of CCDFs, then the two calculated means will likely agree. By placing a statistical confidence requirement on the mean of the CCDFs, the Agency hopes to ensure that a mean that is in compliance would upon recalculation from a new ensemble of CCDFs, still be in compliance. The Agency is proposing to require a 95 percent level of statistical confidence that the mean meets the requirements but solicits comment on other levels of confidence which may be more appropriate.

Before selecting the mean as the compliance indicator, the Agency

examined three options. The first option, the mean CCDF or expected value, was selected because of its ability to convey a sense of the whole ensemble of CCDFs generated. In calculating the mean, all CCDFs—those representing best case results, those representing worst case results, and everything in between—are included. Since it cannot be known which CCDF represents actual performance over the 10,000 year regulatory period, it is deemed wise to include the influence of all generated CCDFs.

The Agency also examined the median CCDF. The median CCDF would be indicative of the central tendency of the majority of the CCDFs and would not exhibit the influence of high or low consequence CCDFs as strongly as the mean CCDF. Specifically, the influence of high consequence CCDFs that do not meet the requirements of section 13(a) of 40 CFR part 191 would be discounted by the median. In the Agency's view, this makes the median CCDF less suitable as a compliance indicator.

The Agency also examined the possibility of using a percentile value as a compliance indicator. The Agency has considered and rejected percentile values at or below 50 on grounds that such values would not provide adequate confidence of achieving the desired protection of public health. As for higher values, the Agency believes that it would be extremely difficult to justify any specific higher value.

The Agency solicits comment on the appropriateness of the mean or some other CCDF as a basis for compliance. The Agency solicits comments on using some possible combination of CCDFs as a basis for compliance; e.g., requiring that the mean and the median meet the requirements of section 13(a) of 40 CFR part 191.

Another issue upon which the Agency solicits comment is on the alternative of basing compliance on one single realization, rather than on a multitude of them as discussed above and then using that realization to determine compliance with the containment requirements. Instead of sampling from a given range of variables for each parameter and generating a new realization curve each time this is done, it has been suggested that all possible values for each parameter should be selected in creating a single curve. In this way, all the information is folded into one realization which either complies or does not. The advantage in this technique is that the issue of the appropriateness of the mean, median, or other percentile is obviated. The disadvantage is that it is difficult to see

exactly which parameters caused the curve to behave in a particular way.

Regardless of the method ultimately used to determine compliance with the numerical requirements of section 13 of 40 CFR part 191, a "reasonable expectation of compliance" with the containment requirements cannot be achieved until a demonstration has been made that the qualitative requirements set forth in sections 21 through 27 of today's proposal have also been met. A "reasonable expectation of compliance" with the containment requirements shall not be based solely upon a statistical estimate of radionuclide releases to the accessible environment. Instead, the Agency will consider the full record of information submitted in compliance applications and will examine the methods and assumptions which were used to support the development of radionuclide release estimates. For example, the EPA will consider such factors as the reasonableness of the processes and events incorporated into performance assessments, the appropriateness of any expert elicitation used to provide input to models, the adequacy of peer review, and the quality of other data inputs. Only after a demonstration has been made that all of the requirements set forth in sections 21 through 27 of today's proposal have been met and that the numerical requirements of section 13 of 40 CFR part 191 have been satisfied, will a "reasonable expectation" of compliance with the containment requirements be achieved.

Assurance Requirements

In addition to the numerical requirements set forth in the Agency's radioactive waste disposal standards, section 14 of the standards contains a set of qualitative requirements to help assure that the desired level of protection is achieved. These assurance requirements address: (1) Active institutional controls; (2) monitoring; (3) passive institutional controls; (4) engineered barriers; (5) consideration of the presence of resources; and (6) removal of waste.

Active Institutional Controls

According to the disposal standards:

Active institutional controls over disposal sites should be maintained for as long a period of time as is practicable after disposal; however, performance assessments that assess the isolation of the wastes from the accessible environment shall not consider any contributions from active institutional controls for more than 100 years after disposal.

As defined in 40 CFR part 191, "active institutional control" means:

"(1) Controlling access to a disposal site by any means other than passive institutional controls; (2) performing maintenance operations or remedial actions at a site; (3) controlling or cleaning up releases from a site; or (4) monitoring parameters related to disposal system performance."

With the above requirements in mind, today's proposal requires that any application for certification of compliance contain detailed descriptions of proposed active institutional controls, their location and the period of time they are proposed to remain active. Any credit assumed for reduced human activity in the vicinity of the WIPP or reduced releases of radionuclides must be supported by such descriptions but, as indicated in the disposal standards, in no case shall it be assumed that active institutional controls will be effective in preventing or reducing releases beyond 100 years after disposal.

Monitoring

Since the predictions associated with long-term compliance with the disposal standards of 40 CFR part 191 are inherently uncertain, final disposal standards issued in 1985 included a provision requiring monitoring of disposal systems to help assure that they are performing as predicted. The proposed disposal standards issued in 1982 had not included such a requirement. However, several commenters (including most of the States) urged addition of a requirement for long-term monitoring of a repository after disposal to guard against unexpected failures. Accordingly, further information was sought on this idea. The Agency surveyed the capabilities and expectations of long-term monitoring approaches. As explained in the preamble to the 1985 disposal standards (50 FR 38081, September 19, 1985):

Evaluating this information led the Agency to several conclusions:

(1) Perhaps most importantly, the techniques used for monitoring after disposal must not jeopardize the long-term isolation capabilities of the disposal system. Furthermore, plans to conduct monitoring after disposal should never become an excuse to relax the care with which systems to isolate these wastes must be selected, designed, constructed, and operated.

(2) Monitoring for radionuclide releases to the accessible environment is not likely to be productive. Even a poorly performing geologic repository is very unlikely to allow measurable releases to the accessible environment for several hundreds of years or more, particularly in view of the engineered controls needed to comply with 10 CFR Part 60. A monitoring system based only on

detecting radionuclide releases—a system which would almost certainly not be detecting anything for several times the history of the United States—is not likely to be maintained for long enough to be of much use.

(3) Within the above constraints, however, there are likely to be monitoring approaches which may, in a relatively short time, significantly improve confidence that a repository is performing as intended. Two examples are of particular interest. One involves the concept of monitoring ground-water sources at a variety of distances for benign tracers intentionally released to the ground water in the repository; this approach can evaluate the delay involved in ground-water movement from the repository to the environment and can serve to validate expectations of the performance expected from the system's natural barriers. Another concept involves monitoring the small uplift of the land surface over the repository in order to validate predictions of the system's thermal behavior. Both of these approaches can be carried out without enhancing pathways for the wastes to escape from the repository.

Based on these conclusions and the public comments on this question, the Agency included a provision (in the assurance requirements of the final disposal standards) for long-term monitoring after disposal: "Disposal systems shall be monitored after disposal to detect substantial and detrimental deviations from expected performance. This monitoring shall be done with techniques that do not jeopardize the isolation of the wastes and shall be conducted until there are no significant concerns to be addressed by further monitoring."

Accordingly, EPA is proposing criteria for complying with the monitoring requirements in the disposal standards. EPA is proposing that monitoring programs be designed to detect the movement of radionuclides toward the accessible environment at the earliest practicable time. Such monitoring programs shall be consistent with monitoring required under applicable federal hazardous waste regulations and shall be done with techniques that do not jeopardize the containment of waste in the disposal system. Due to the long-term nature of the potential hazard associated with disposal of transuranic radioactive waste, any unpredicted detection of movement of radionuclides away from the disposal system and toward the accessible environment would be cause for concern that an exceedance of what is permitted under the disposal regulations is likely to occur. If releases are detected early enough, remedial action can be implemented before radionuclides reach the accessible environment.

EPA is proposing in today's criteria that any compliance certification application include a detailed plan for monitoring the performance of the WIPP after disposal. At a minimum, this plan shall: Identify parameters that will be monitored and how baseline states will be determined; indicate how each parameter will be used to evaluate the performance of the disposal system; and discuss the length of time over which each parameter will be monitored to detect deviations from expected performance. Radionuclide monitoring programs should be consistent with applicable federal hazardous waste monitoring programs in order to minimize duplication of monitoring efforts. The Agency solicits comments on this approach.

In addition to monitoring after closure of the disposal system (i.e., when all of the shafts to the repository are backfilled and sealed), EPA proposes that, to the extent practicable, pre-closure monitoring of parameters which may affect the long-term performance of the disposal system after closure shall also be conducted. The Agency believes that such monitoring can provide important information about the disposal system and that such information can contribute to a better understanding of how the disposal system is likely to perform after closure. Furthermore, such information can be used to verify assumptions (about the disposal system) which form the basis of a compliance assessment.

The Agency is proposing to require that, as a part of the pre-closure monitoring plan for the WIPP, monitoring of parameters which can affect the containment of waste in the disposal system shall be conducted to the extent practicable. The Agency believes that the following parameters can affect the containment capability of the WIPP: Brine quantity, flux, composition, and spatial distribution; gas quantity and composition; and temperature distribution. Since there may be additional disposal system parameters important to the containment of waste, EPA is proposing that DOE undertake a study to determine the effect of various disposal system parameters on the performance of the disposal system. Such study shall consider whether a disposal system parameter should be monitored because the parameter either provides information regarding the disposal system's ability to contain waste or regarding the ability to predict the future performance of the disposal system. The parameters studied shall include, but need not be limited to: Backfilled mechanical state including

porosity, permeability, and degree of compaction and reconsolidation; extent of deformation of the surrounding roof, walls, and floor of the disposal room; and initiation or displacement of major brittle deformation features in the roof or surrounding rock. The results of the study shall be provided to EPA along with documentation of the methodology and information describing the importance of each disposal system parameter studied. The results of such study shall dictate the breadth of monitoring of disposal system parameters.

The parameters specifically mentioned above and in the proposed criteria were identified as important to the containment capability of the WIPP by the Agency in its comments to the Department (dated October 19, 1989) regarding the Test Phase Plan for the WIPP. In those comments, EPA recommended that the Department implement monitoring systems in disposal rooms that would be "indicative of waste system performance" (Recommendation 7). In response to EPA's comments, the DOE agreed to conduct a feasibility study on underground monitoring of the WIPP.

EPA solicits comment on whether monitoring should be required for the specific parameters listed above, on whether additional or other parameters should be specified, and on the feasibility of continuing such monitoring after disposal (i.e., after the repository has been backfilled and sealed). Additionally, the Agency solicits comment on whether EPA should require the use of specific monitoring methods.

Passive Institutional Controls

The assurance requirements of 40 CFR part 191 require that "disposal systems shall be designated by the most permanent markers, records, and other passive institutional controls practicable to indicate the dangers of the wastes and their location." Section 14(c) of 40 CFR part 191. The standards define "passive institutional controls" as "(1) permanent markers placed at a disposal site, (2) public records and archives, (3) government ownership and regulations regarding land or resource use, and (4) other methods of preserving knowledge about the location, design and contents of a disposal system."

In light of the requirement for use of passive institutional controls set forth in 40 CFR part 191, the Agency is proposing that any application for certification of compliance include detailed descriptions of the measures that will be employed to preserve knowledge about the location, design,

and contents of the disposal system. At a minimum, it is proposed that such measures will include: (1) Identification of the controlled area by markers that have been designed, fabricated and emplaced to be as permanent as practicable; and (2) placement of records in the archives and land record systems of local, state, and Federal Government agencies, and international archives, that would be likely to be consulted by individuals in search of unexploited resources.

The Agency proposes that the type of information contained in records shall include: The location of the controlled area and the disposal system; the design of the disposal system; the nature and hazard of the waste; geologic, geochemical, hydrologic, other site data pertinent to the containment of waste in the disposal system, and the results of tests, experiments, and other analyses relating to backfill of excavated areas, shaft sealing, waste interaction with the disposal system, and any other tests, experiments, or analyses pertinent to the containment of waste in the disposal system. EPA solicits comments on the appropriateness of this list and on whether additional or other items should be specified. Any application for certification of compliance shall include detailed descriptions of the proposed controls as well as information regarding the period of time those controls are expected to endure and be understood.

A question arises with regard to the extent to which the Agency should allow performance assessments to consider contributions from passive institutional controls in reducing the likelihood of human-initiated processes and events that may affect the disposal system. While the disposal regulations address contributions from active institutional controls (see above discussion of active institutional controls), they do not specifically address contributions from passive institutional controls. The Agency may be willing to consider such contributions if a persuasive case can be made that the passive institutional controls can be expected to endure and act as a deterrent to potential intruders. In no instance, however, will passive institutional controls be assumed to eliminate the likelihood of human-initiated processes and events entirely. Furthermore, contributions from passive institutional controls may vary over time. For example, the effectiveness of passive institutional controls may decrease over the regulatory time frame. The Agency solicits comment on the extent—if any—to which contributions from passive institutional controls

should be considered in performance assessments.

Because of the uncertainty concerning the effectiveness of passive institutional controls in terms of influencing human activity, EPA must carefully scrutinize information about such controls. The Agency has considered the fact that markers exist in the world today that are thousands of years old. This would tend to support the view that passive institutional controls can survive for very long periods of time. Nevertheless, it is possible that markers have been created in the past and were destroyed or disintegrated. The actual percentage of surviving markers is thus unknown. It could be very small, meaning that an unrealistically large number of markers would have to be placed at the WIPP in order to assure survival. Further uncertainty in the effectiveness of markers derives from the possibility that even if markers survive, it does not mean they will necessarily be understood by future generations.

Institutional controls have been known to fail. The New Mexico Environmental Evaluation Group (EEG) has documented instances in the recent past where institutional controls have failed at the WIPP. According to EEG, both the DOE and the Department of the Interior's Bureau of Land Management "failed to implement the procedures described by the DOE as crucial to protecting the site from inadvertent human intrusion in twenty-two of the twenty-five applications to drill oil and gas wells filed while a Memorandum of Understanding was legally binding and the WIPP facility was in a state of full readiness to receive waste." (EEG letter to EPA dated February 23, 1994). This indicates that even today, and even with governmental entities responsible for implementation of controls, such controls are not, necessarily, reliable. The unknown nature of future societies and governmental institutions compounds the uncertainty.

Engineered Barriers

The assurance requirements of 40 CFR part 191 require that disposal systems "use different types of barriers to isolate the wastes from the accessible environment." Additionally, the disposal standards mandate that "Both engineered and natural barriers shall be used." 40 CFR part 191 defines the term "barrier" as "any material or structure that prevents or substantially delays movement of water or radionuclides toward the accessible environment. For example, a barrier may be a geologic structure, a canister, a waste form with physical and chemical characteristics that significantly decrease the mobility

of radionuclides, or a material placed over and around waste, provided that the material or structure substantially delays movement of water or radionuclides."

If selected and designed properly, engineered barriers can significantly reduce the potential for waste migration away from the disposal system. They can be an effective mechanism for improving the performance of the WIPP and for reducing the uncertainty inherent in long-term projections about the ability of the disposal system to comply with the quantitative requirements of 40 CFR part 191.

While the disposal standards require use of engineered barriers, they do not specify how many or what kinds of engineered barriers must be used. The Agency is, therefore, proposing criteria for selecting engineered barriers.

In today's notice, EPA is proposing that DOE complete a study of engineered barrier alternatives and their benefits and costs. The results of such study shall be used to justify both the selection and rejection of engineered barriers at the WIPP. Moreover, the study shall be peer reviewed. For example, EPA believes that the National Academy of Sciences may be able to provide an appropriate forum for peer review of the study envisioned in today's proposed criteria. The Agency believes that the credibility of the study of engineered barrier alternatives and resulting selection of engineered barriers for the WIPP disposal system is critically important.

The specific engineered barriers proposed to be evaluated include, but are 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. These specific engineered barriers were selected by the Agency because they have already begun to be considered by DOE's Engineered Alternatives Task Force (EATF) (see July, 1991 EATF Report on Engineered Alternatives for the WIPP, DOE/WIPP 91-007) and appear to represent potentially promising alternatives. EPA solicits comment on the appropriateness of specifying the above-mentioned engineered barriers as the subject of the study and on whether alternative barriers should be specified.

The Agency is proposing that the following factors be considered in benefit/cost analysis of the above-mentioned engineered barriers: the ability of the engineered barrier to

prevent or substantially delay the movement of water or radionuclides toward the accessible environment; the impact on worker exposures to radiation (at the WIPP and off-site) both during and after incorporation of engineered barriers; the increased ease or difficulty in removing the waste from the disposal system; the increased or reduced risk of transporting the waste to the disposal system; the increased or reduced uncertainty in compliance assessment; the increased or reduced public confidence in the performance of the disposal system; the increased or reduced total system costs; the impact, if any, on other waste disposal programs from the incorporation of engineered barriers; and the effect on mitigating the consequences of human-initiated processes and events.

It would be inappropriate to limit the study only to the impact of engineered barriers on the performance of the WIPP. If this were done, the possibility would exist that an engineered barrier may be selected, for example, which marginally improves the disposal system's performance, yet results in much higher environmental risks at treatment sites. This increase in risk would contravene the Agency's objective of protecting human health and the environment. EPA solicits comment on this approach to selecting engineered barriers and on whether an alternative list of factors should be specified for consideration.

The Agency proposes that the benefit/cost study described above include separate analyses for different categories of waste potentially destined for disposal at the WIPP. The Agency believes that benefits and costs of engineered barriers can differ depending on whether they are applied to existing waste that is already packaged, existing waste that is not yet packaged or is in need of repackaging, or to-be-generated waste. Therefore, the Agency is proposing that these different categories of waste be analyzed separately.

Finally, EPA is proposing that engineered barrier alternatives be considered both alone and in combination. In this way, assurance can be had that the full range of alternative applications of engineered barrier systems has been considered.

Importantly, today's proposal requires the results of the benefit/cost study to be included in any compliance application and for the results to be used to justify the selection or rejection of any engineered barrier. This will help the Agency understand why particular barriers were selected while others were not, as well as help the Agency to

evaluate the appropriateness of such selections.

The Agency solicits comments on other potential approaches to the treatment of engineered barriers in the WIPP compliance criteria. In particular, the Agency is interested in receiving comment on the option of specifying a performance standard for engineered barriers similar to that specified by the Nuclear Regulatory Commission in 10 CFR part 60 regulations for disposal of high-level radioactive waste. Under this approach, a maximum radionuclide release rate would be established for the engineered barrier system. Engineered barriers selected for the disposal system would have to contain radionuclide releases within the established rate.

Consideration of the Presence of Resources

Section 14 of 40 CFR part 191 includes the following requirement: "Places where there has been mining for resources, or where there is a reasonable expectation of exploration for scarce or easily accessible resources, or where there is a significant concentration of any material that is not widely available from other sources, should be avoided in selecting disposal sites. Resources to be considered shall include minerals, petroleum or natural gas, valuable geologic formations, and ground waters that are either irreplaceable because there is no alternative source of drinking water available for substantial populations or that are vital to the preservation of unique and sensitive ecosystems. Such places shall not be used for disposal of the wastes covered by this part unless the favorable characteristics of such places compensate for their greater likelihood of being disturbed in the future."

EPA is proposing that any application for certification of compliance shall include information which demonstrates that the favorable characteristics of the WIPP compensate for the presence of resources and the likelihood of human-initiated processes and events as a result of the presence of those resources. If, after full consideration of the potential effects of resource recovery activities the WIPP is still predicted to meet the requirements of 40 CFR part 191, then the Agency will assume that the requirements of this part and section 14(e) of 40 CFR part 191 have been fulfilled. The Agency solicits comment on this approach.

Removal of Waste

Another assurance requirement included in the 40 CFR part 191 disposal standards involves the removal

of waste from the disposal system. Specifically, 40 CFR part 191 mandates that: "Disposal systems shall be selected so that removal of most of the wastes is not precluded for a reasonable period of time after disposal." In order to address this requirement, EPA is proposing criteria to require a plan for removing waste from the disposal system using the best technology available at the time of application.

Individual and Ground-Water Protection Requirements

The Agency incorporated requirements in 40 CFR part 191 for the protection of individuals and ground-water. The individual protection requirements of 40 CFR part 191 limit annual committed effective doses of radiation to members of the public to no more than 15 millirem. The ground-water protection requirements limit releases to ground water to no more than the limits set by the maximum contaminant level for radionuclides (MCL) established in 40 CFR part 141 under section 1412 of the Safe Drinking Water Act (SDWA), 42 U.S.C. 300g-1. Both of these requirements are concerned with human exposure to radionuclides from disposal systems and, like the containment requirements of 40 CFR part 191, both limit such exposure for 10,000 years.

The proposed criteria address the following issues: the definition of a protected individual, the consideration of exposure pathways, the consideration of underground sources of drinking water, the scope of compliance assessments, and the basis for a determination of compliance with these requirements (results of compliance assessments).

With regard to identifying protected individuals, the Agency is proposing to require that assessments regarding individual exposures to radiation from the disposal system be based upon the assumption that individuals reside at the point on the surface of the accessible environment where they would be expected to receive the highest exposure from radionuclide releases from the disposal system. This helps ensure that the individual most likely to receive the highest exposure from the disposal system is accounted for and protected.

In assessing individual doses, the Agency proposes to require consideration of all potential pathways (associated with undisturbed performance) for radionuclide transport. The pathways which need to be considered include land-surface pathways (including direct radiation exposure), surface or ground-water pathways, and air pathways, as well as

combinations of the above. Furthermore, consistent with the Agency's approach under the Safe Drinking Water Act (42 U.S.C.A. sections 300(f) to 300j-26), it should be assumed that individuals consume two liters of water per day from any underground source of drinking water in the accessible environment.

EPA is proposing today that any underground sources of drinking water in the accessible environment which are likely to be affected by the disposal system over 10,000 years be considered in WIPP compliance applications. Such consideration should include an analysis of the interconnection and commingling of bodies of ground water with underground sources of drinking water, as well as ground-water flow rates and direction.

According to 40 CFR part 191, calculations of compliance with the individual and ground-water protection requirements must consider the undisturbed performance of the disposal system. 40 CFR part 191 defines "undisturbed performance" as: "the predicted behavior of a disposal system, including consideration of the uncertainties in predicted behavior, if the disposal system is not disrupted by human-intrusion or the occurrence of unlikely natural events." The Agency solicits comment on whether there is a need for further clarification of the analysis of undisturbed performance, e.g.; is there a need to identify what constitutes an "unlikely" natural event or what probability of occurrence renders an event "likely" or "unlikely?"

EPA is proposing that any application for certification of compliance shall include information which identifies the processes, events, or sequences of processes and events considered in compliance analyses. Moreover, EPA is proposing that documentation be provided which justifies the inclusion/non-inclusion of particular processes, events, or sequences of processes and events in compliance assessment results.

Once the processes, events, or sequences of processes and events have been identified, they shall be incorporated into compliance assessments of the disposal system. The disposal standards require compliance assessments to include consideration of the uncertainties associated with the undisturbed performance of the disposal system. To do this, it is necessary to identify all disposal system parameters that can affect the performance of the WIPP, as well as to identify the uncertainty associated with each parameter.

When the disposal system parameters and their accompanying uncertainty have been identified, EPA is proposing that probability distributions be developed for each such parameter. A probability distribution is a function which assigns a probability of occurrence to each value for a given parameter.

The Agency is proposing that, in compiling compliance assessment results, computational techniques be used which draw random samples from across the full range of probability distributions for parameter values used in compliance assessments. This will help assure that all possible values of a parameter have been considered in compiling compliance assessment results.

EPA is proposing that the range of estimated radiation doses to individuals (as generated through use of the computational techniques referred to above), and the range of estimated radionuclide concentrations in ground water must be large enough such that the maximum estimate generated exceeds the 99th percentile of the population of estimates with at least a 95% probability. The "population of estimates" refers to the set of all possible estimates that can be generated from all disposal system parameter values used in compliance assessments. A single estimate, in effect, samples this population. This is similar to the requirement for the number of CCDFs which must be generated for purposes of compliance with the containment requirements. The Agency is proposing to include this provision for the purpose of ensuring that there is a 95% probability that 99% of all possible values have been exceeded by the maximum estimate generated.

In order to assure that all pertinent information is provided to the Agency, EPA is proposing to require that compliance applications display the full range of estimated radiation doses and the full range of estimated radionuclide concentrations.

Finally, the Agency is proposing to require that any compliance certification application provide information which demonstrates that there is at least a 95% level of statistical confidence that the mean and the median of the full range of estimated radiation doses and of the full range of estimated radionuclide concentrations meet the requirements set forth in sections 15 and 16 of 40 CFR part 191. The mean estimate provides a measure of compliance that expresses the average impacts of the disposal system on individuals and ground water as well as the probabilities of uncertain disposal

system parameter values. The median estimate provides a measure of compliance that expresses the central tendency of a population of estimates. Specifically, the median represents the point that a calculated estimate would be equally likely to fall above or below. Insofar as both statistics contain useful information, the Agency is proposing an approach that assures that both meet the limits of the individual and ground-water protection requirements.

The Agency solicits comments on the above approach for evaluating the results of compliance assessment.

Subpart D—Public Participation

The Agency intends to involve the public throughout the Agency's regulatory oversight at the WIPP. Accordingly, today's proposal contains a set of criteria for public participation in any compliance certification or determination.

In today's proposal, the Agency is proposing to continue to maintain the four public information dockets listed in the Supplementary Information section of this part. All materials relevant to any compliance certification or determination or to any decision regarding modifications, suspensions, or revocations of such compliance certifications and determinations will be placed in the proposed dockets.

The Agency believes that maintaining dockets is useful because they can greatly increase communication between EPA and all interested parties. The Agency intends to maintain all dockets in conformance with EPA's "Uniform Rulemaking Docket Guidance" to the extent practicable. This guidance is widely used within the Agency and helps to ensure that public participation in Agency rulemakings is optimized.

The Agency also proposes to hold public hearings on proposed compliance criteria within the State of New Mexico. These hearings will provide an opportunity for members of the public, beyond submission of written comments, to express their views to EPA in the rulemaking process.

With respect to applications for compliance certification, the Agency is proposing that, upon receipt of an application for certification of compliance, it will publish a notice in the **Federal Register** announcing that an application for certification of compliance has been received and soliciting comment on that application. This notice in the **Federal Register** will be an Advance Notice of Proposed Rulemaking (ANPR), as it will also announce the Agency's intent to conduct a rulemaking to certify whether

the WIPP will comply with the disposal regulations. The Agency is proposing this approach in order to afford the public an opportunity for early input into EPA's certification decision. The alternative might have been simply putting the application in the docket and receiving comments from the public through a more informal means. However, the Agency believes that this approach would not necessarily lead to as much public input relevant to its decision. Hence, the more formal approach is proposed.

Upon completion of a review of the application for certification of compliance, the Agency also proposes to publish in the **Federal Register** a Notice of Proposed Rulemaking announcing the Administrator's proposed decision on whether the WIPP facility will comply with the disposal regulations and soliciting comment on such proposal. The notice will provide a comment period of at least 120 days and will announce the opportunity for public hearings in New Mexico (including times and procedures for registering to testify).

The Agency will publish a Notice of Final Rule in the **Federal Register** announcing the Administrator's decision on certifying whether the WIPP facility will comply with the disposal regulations. Additionally, a document summarizing major comments and issues arising from comments received on the Notice of Proposed Rulemaking, as well as the Administrator's response to such comments and issues, will be prepared and made available for inspection in Agency dockets.

Similar to the process outlined above for applications for compliance certification (and for the same reasons), when EPA receives documentation of continued compliance as required under 8(f) of the WIPP LWA, the Agency will publish a notice in the **Federal Register** announcing the Administrator's intent to determine whether the WIPP facility continues to be in compliance with the disposal regulations. Copies of any documentation received will be made available for inspection in Agency dockets and comments will be solicited for at least 30 days after receipt. Once the Agency has considered all comments received, the Administrator will make a determination regarding WIPP's continued compliance and publish that decision in the **Federal Register**.

Questions for Comment

The Agency is requesting comment on today's proposed criteria for the certification and determination of the WIPP's compliance with the 40 CFR

part 191 disposal standards and on the proposed approaches taken. EPA generally invites comment on whether today's proposal addresses all issues related to any EPA certification or determination of WIPP's compliance with the disposal regulations in 40 CFR part 191.

Effective Date

The effective date of these compliance criteria, once finalized, will be 30 calendar days after date of publication of the final rule in the **Federal Register**.

Regulatory Analyses

Executive Order 12866

Under Executive Order 12866 (58 FR 51735 (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 arising out of 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

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires each Federal agency to consider the effects of their regulations on small entities and to examine alternatives that may reduce these effects. The nature of this action is to propose criteria for the certification of compliance of the WIPP with the Agency's radioactive waste disposal standards set forth in 40 CFR Part 191. Since the preparation of applications for compliance will only be conducted by DOE, and since any ensuing disposal

and information gathering activities will only be carried out by DOE, the Agency certifies that this regulation will not have a significant impact on a substantial number of small entities.

Paperwork Reduction Act

The EPA has determined that this proposed rule contains no information requirements as defined by the Paperwork Reduction Act (42 U.S.C. 3501 et seq.).

List of Subjects in 40 CFR Part 194

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

Dated: January 11, 1995.

Carol M. Browner,
Administrator.

A new part 194 is hereby proposed to be added to title 40, Code of Federal Regulations, as follows:

PART 194—CRITERIA FOR THE CERTIFICATION AND DETERMINATION OF THE WASTE ISOLATION PILOT PLANT'S COMPLIANCE WITH ENVIRONMENTAL STANDARDS FOR THE MANAGEMENT AND DISPOSAL OF SPENT NUCLEAR FUEL, HIGH-LEVEL AND TRANSURANIC RADIOACTIVE WASTES

Subpart A—General Provisions

Sec.

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Subpart C—Compliance Certification and Determination

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- 194.21 Inspections.
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- 194.31 Application of release limits.
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- 194.41 Active institutional controls.
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- 194.43 Passive institutional controls.
- 194.44 Engineered barriers.
- 194.45 Consideration of the presence of resources.
- 194.46 Removal of waste.

Individual and Ground-Water Protection Requirements

- 194.51 Consideration of protected individual.
- 194.52 Consideration of exposure pathways.
- 194.53 Consideration of underground sources of drinking water.
- 194.54 Scope of compliance assessments.
- 194.55 Results of compliance assessments.

Subpart D—Public Participation

- 194.61 Advance notice of proposed rulemaking.
- 194.62 Notice of proposed rulemaking.
- 194.63 Final rule.
- 194.64 Documentation of continued compliance.
- 194.65 Dockets.

Authority: The Waste Isolation Pilot Plant Land Withdrawal Act of 1992, Pub.L. 102-579, 106 Stat. 4777; 5 U.S.C.app.1; 42 U.S.C. 2011-2296; 42 U.S.C. 10101-10270.

Subpart A—General Provisions**§ 194.1 Purpose, scope and applicability.**

This part specifies criteria for any certification or determination of compliance, under section 8(d) and section 8(f) of the Waste Isolation Pilot Plant Land Withdrawal Act of 1992 (WIPP LWA), with the disposal regulations at 40 CFR part 191. Any compliance application submitted under section 8(d) of the WIPP LWA and any compliance application submitted under section 8(f) of the WIPP LWA must comply with the requirements of this part.

§ 194.2 Definitions.

Unless otherwise indicated in this part, all terms have the same meaning as in 40 CFR part 191.

Certification means any action taken by the Administrator under section 8(d) of the WIPP LWA.

Compliance application(s) means any application submitted to the Administrator under section 8(d) of the WIPP LWA or any application(s) submitted to the Administrator under section 8(f) of the WIPP LWA.

Compliance assessment(s) means the analysis conducted to determine

compliance with section 15 and subpart C of 40 CFR part 191.

Determination means any action taken by the Administrator pursuant to 8(f) of the WIPP LWA.

Disposal regulations means subparts B and C of 40 CFR part 191.

Human activity means those drilling events that may affect the disposal system, but do not necessarily reach the level of the waste in the disposal system.

Human intrusion means those drilling events that reach the level of the waste in the disposal system.

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 for ensuring that the type and quality of data needed are obtained.

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

Population of CCDFs means all possible CCDFs that can be generated from all disposal system parameter values used in performance assessments.

Population of estimates means all possible estimates that can be generated from all disposal system parameter values used in compliance assessments.

Quality assurance means all those planned and systematic actions necessary to provide adequate confidence that the disposal system will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

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 or withdraw the effectiveness of a certification under section 8(d) of the WIPP LWA or to terminate or withdraw the effectiveness of a determination under section 8(f) of the WIPP LWA.

Secretary means the Secretary of the Department of Energy.

Suspension means any action taken by the Administrator to withdraw, for a limited period of time, the effectiveness of certification under section 8(d) of the

WIPP LWA or to withdraw, for a limited period of time, the effectiveness of a determination under section 8(f) of the WIPP LWA.

Waste means the radioactive waste and radioactive material subject to the requirements of 40 CFR part 191.

WIPP means the Waste Isolation Pilot Plant project authorized under 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 (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, where indicated, the Administrator's authorized representative; and

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

§ 194.4 Conditions of compliance certification and determination.

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

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

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

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

(3) Not later than six months after the Administrator has issued any

certification or determination of compliance, and at least every six months thereafter, the Department shall report to the Administrator, in writing, any changes in conditions or activities pertaining to the disposal system that depart from the application and that formed the basis of such certification or determination of compliance.

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

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

(6) If the Department determines that a release of waste from the disposal system to the accessible environment in excess of what is permitted under the disposal regulations has occurred or is likely to occur, the Department shall:

(i) Immediately suspend emplacement of waste in the disposal system, and

(ii) Notify the Administrator, in writing, within 24 hours of the determination that such a release has occurred or is likely to occur. Such notification shall include, but need not be limited to, the following information to the extent possible:

(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 approximate 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 and deemed by the Administrator or the Administrator's authorized representative to be relevant to a modification, suspension or revocation of a certification or determination of compliance.

(iii) Following receipt of the notification, the Administrator:

(A) May request additional information; and

(B) Will determine whether emplacement of waste in the disposal system may continue and whether to modify, suspend, or revoke any previously issued certification or determination of compliance.

§ 194.5 Publications incorporated by reference.

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

(1) NUREG 1297 "Peer Review for High-Level Nuclear Waste Repositories."

(2) ASME NQA-1-1989 edition "Quality Assurance Program Requirements for Nuclear Facilities."

(3) ASME NQA-2a-1990 addenda (part 2.7) to ASME NQA-2-1989 edition "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications."

(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."

(b) The publications listed in paragraph (a) of this section were approved 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.

§ 194.6 Alternative provisions.

The Administrator may, by rule, 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 compliance with the existing provisions of this part appears inappropriate, 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, during which an opportunity for public hearings in New Mexico has been provided; and

(c) The public comments received have been fully considered in developing the final version of alternative provisions.

Subpart B—Compliance Certification and Determination Applications

§ 194.11 Completeness and accuracy of compliance applications.

Information provided to the Administrator in support of any compliance application(s) shall be complete and accurate. The Administrator's evaluation for certification under section 8(d)(1)(B) of the WIPP LWA and evaluation for determination under section 8(f)(2) of the WIPP LWA shall not begin until the Administrator has notified the Secretary, in writing, that a complete application in accordance with this Part has been received.

§ 194.12 Submission of compliance applications.

Unless otherwise specified by the Administrator, 30 copies of any compliance application(s), 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 referenced in compliance application(s): Provided, That the references are clear and specific and that 10 copies of the referenced information are submitted to the Administrator. Referenced materials which are widely available in standard textbooks need not be submitted.

§ 194.14 Content of compliance certification application.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Scale and date;

(2) Floodplain area;

(3) Surface waters including intermittent streams;

(4) Surrounding land uses, i.e., residential, commercial, industrial, agricultural, recreational;

(5) A wind rose, i.e., wind speeds and directions;

(6) Orientation of the map, i.e., north arrow;

(7) Boundaries of the controlled area;

(8) Location of proposed active and passive institutional controls;

(9) Location of any active, inactive, and abandoned injection and withdrawal wells in the controlled area and in the vicinity of the disposal system; and

(10) Location of proposed monitoring stations or wells.

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

(j) Any additional information required elsewhere in this part or determined by the Administrator or the Administrator's authorized representative to be necessary for a decision whether to certify or determine compliance.

§ 194.15 Content of compliance determination application(s).

(a) In submitting documentation of continued compliance pursuant to section 8(f) of the WIPP LWA, the most recent previous application(s) for compliance certification or determination shall be updated so as 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) Additional geologic, geophysical, geochemical, hydrologic, and meteorologic information.

(2) Monitoring results.

(3) An evaluation of the conformance of the disposal system components with design.

(4) A description of any waste emplaced in the disposal system since the most recent previous compliance certification or determination application. Such description shall consist of a description of the waste characteristics identified in § 194.24(a)(ii).

(5) Any additional information that the Administrator or the Administrator's authorized representative identifies as necessary to determine whether or not the disposal system continues to be in compliance with the disposal regulations.

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

Subpart C—Compliance Certification and Determination

General Requirements

§ 194.21 Inspections.

(a)(1) The Administrator or the Administrator's authorized representative(s) shall be afforded unfettered and unannounced access to inspect any area of the WIPP and locations performing activities that may provide information used to support any compliance application(s) to which the Department has rights of access.

(2) The Administrator or the Administrator's authorized representative(s) shall be afforded access, pursuant to paragraph (a)(1) of this section, equivalent to access afforded Department employees upon presentation of credentials and other documents as may be required by law.

(b) Records kept by the Department pertaining to aspects of the disposal system that could affect the containment of waste in the disposal system shall be made available to the Administrator or the Administrator's authorized representative(s) upon request. If requested records are not immediately available, they shall be made available to the Administrator or the Administrator's authorized representative(s) within 30 calendar days of a request from the Administrator or the Administrator's authorized representative(s).

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

(d) The Administrator or the Administrator's authorized representative(s) shall 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 and deemed by the Administrator or the Administrator's authorized representative to be relevant to a compliance certification or determination.

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

§ 194.22 Quality assurance.

(a)(1) The Department shall implement a quality assurance program

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

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

- (i) Waste characterization activities and assumptions;
- (ii) Environmental monitoring, monitoring the performance of the disposal system, sampling, and analysis activities;
- (iii) Field measurements of geological factors, ground water, meteorology, and topography;
- (iv) Computations, codes, models and methods used to demonstrate compliance with the disposal regulations;
- (v) Expert judgment elicitation used to support applications for certification or determination of compliance;
- (vi) Design of the disposal system and actions taken to ensure compliance with design specifications;
- (vii) The collection of data and information used to support compliance application(s); and
- (viii) Other systems, structures, components, and activities important to the containment of waste in the disposal system.

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

(1) A quality assurance program equivalent in scope and implementation 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)); or

(2) An alternative method approved by the Administrator for use at the WIPP.

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

- (1) Data accuracy, i.e., the degree to which data agree with an accepted reference or true value;
- (2) Data precision, i.e., a measure of the mutual agreement between comparable data gathered or developed

under similar conditions expressed in terms of a standard deviation;

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

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

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

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

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

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

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

§ 194.23 Models and computer codes.

(a) Any application for certification of compliance shall include:

(1) A complete listing and description of the models used to support such application. The description shall be sufficiently complete to permit technical review of the purpose of modeling, the modeling approach, method of analysis and the assumptions underlying such analyses.

(2) A complete listing of conceptual model(s) considered but not used to support such application, a description of such model(s), and an explanation of the reason(s) why such model(s) was/were not used to support such application.

(3) Information which demonstrates that:

- (i) Conceptual models reasonably represent 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 and accurate solutions; and

(v) Models, computer codes, and observed and measured data used to confirm models and computer codes have undergone peer review according to § 194.27.

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

(c) Documentation for models and computer codes shall include:

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

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

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

(4) Programmers' manuals;

(5) Any necessary licenses; and

(6) An explanation of how models and computer codes handle covariance.

(d) The Administrator or the Administrator's authorized representative may verify the results of computer simulations used to support any application for certification of compliance 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)(1) Any application for certification of compliance shall identify, in detail, the chemical, radiological and physical characteristics of all waste proposed for disposal in the disposal system. Such identification shall provide information about waste characteristics as they exist or, in the case of to-be-generated waste, as they are expected to exist upon emplacement in the disposal system.

(2) Information about the following characteristics of waste proposed for disposal in the disposal system shall be provided:

(i) Activity in curies of each radionuclide; and

(ii) Any other characteristic(s) important to the containment of waste in the disposal system as identified by the study conducted under paragraph (a)(3) of this section.

(3) The Department shall conduct a study of the effects of waste characteristics on the containment of waste in the disposal system and shall include the results of such study in any application for certification of compliance. The characteristics studied shall include, but need not be limited to:

(i) Waste form;

(ii) Free liquid content and liquid saturation;

(iii) Pyrophoric and explosive materials; and

(iv) Characteristics affecting the solubilization and mobilization of radionuclides, formation of colloidal suspensions containing radionuclides, production of gas from the waste, nuclear criticality, and generation of heat in the disposal system.

(4) For all waste characteristics studied pursuant to paragraph (a)(3) of this section, any application for certification of compliance shall document and substantiate any decision not to provide information on a particular waste characteristic because that characteristic is considered to be unimportant to the containment of waste in the disposal system.

(5) Categories of waste shall be established, by the Department, based on characteristics of the waste that would be expected to behave similarly in the disposal system.

(b) The information provided under paragraph (a) of this section:

(1) Shall consist of a value or range of values for characteristics listed under paragraph (a)(2) of this section; and

(2) Shall consist of a value or range of values for characteristics identified as important to the containment of waste in the disposal system by the study required under paragraph (a)(3) of this section; and

(3) Shall describe in detail the characteristics of each category of waste established under paragraph (a)(5) of this section; and

(4) May specify the maximum amount of each category of waste that will be placed in any waste container or location in the disposal system.

(c)(1) Any application for certification of compliance shall identify and describe the method(s) used to

determine waste characteristics and the uncertainty associated with such method(s).

(2) Any application for certification of compliance shall provide information which substantiates any determination of waste characteristics based on knowledge of the processes and materials that generated the waste.

(d) Any application for certification of compliance shall provide information which demonstrates that the disposal system complies with the disposal regulations for all combinations of waste whose contents fall within the range of characteristics provided pursuant to paragraph (b) of this section.

(e)(1) Waste may only be emplaced in the disposal system if the characteristics of such waste fall within the range of values provided under paragraph (b) of this section and if the amount of each category of waste placed in any waste container or location in the disposal system does not exceed any maximum specified under paragraph (b)(4) of this section.

(2) Any application for certification of compliance shall provide information which demonstrates that a system of controls which includes but is not necessarily limited to measurements, sampling, chain of custody records and other record-keeping is and will continue to be implemented to assure that only waste containers whose contents fall within the range of characteristics provided under paragraph (b) of this section are emplaced in the disposal system. Any application for certification of compliance shall identify and describe such controls and the uncertainty associated with them.

(f) The Administrator will use audits and inspections to verify the waste characterization requirements of this part.

§ 194.25 Future state assumptions.

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

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

§ 194.26 Expert judgment.

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

(b) Any application for certification of compliance shall identify any expert judgments used to support the application and shall identify experts (by name and by professional affiliation) involved in any expert judgment elicitation processes used to support the application.

(c) Any application for certification of compliance shall describe the process of eliciting expert judgment, and shall 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.

(d) Any application for certification of compliance shall provide information which demonstrates that the following restrictions and guidelines have been applied to any selection of individuals used to elicit expert judgments:

(1) Individuals who are members of the team of investigators requesting the judgment or the team of investigators who will use the judgment shall not be selected; and

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

(e) Any application for certification of compliance shall provide information which demonstrates that 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.

(f) Any application for certification of compliance shall include an explanation of the relationship between the information presented, the questions or issues presented, the judgment of any expert panel or individual, and the purpose for which the expert judgment is being used.

(g) Any application for certification of compliance shall provide information which demonstrates that the following restrictions and guidelines have been applied in eliciting expert judgment:

(1) 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 which explains why fewer than five individuals were selected.

(2) 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; however, in no case shall more than one-half of the experts involved in an elicitation consist of individuals employed directly by the Department or by the Department's contractors.

(h) Groups and individuals (including those not directly employed by the Department or by the Department's contractors) shall be afforded an opportunity to present their scientific and technical views as input to any expert elicitation process.

§ 194.27 Peer review.

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

(1) The evaluation, required under this part, of engineered barriers for the disposal system;

(2) Consideration of processes and events that may affect the disposal system;

(3) Quality assurance programs and plans;

(4) Models and computer codes;

(5) Data used to support models and computer codes; and

(6) Waste characterization.

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

Containment Requirements

§ 194.31 Application of release limits.

The expected curie activity 100 years after disposal of the waste proposed for disposal in the disposal system shall be used in calculating applicable release limits under Appendix A of 40 CFR part 191, Table 1, Note 1(e).

§ 194.32 Scope of performance assessments.

(a) Performance assessments shall consider both natural and human-initiated processes and events that may affect the disposal system.

(b) Performance assessments need not consider processes, events, or sequences of processes and events that have less

than one chance in 10,000 of occurring over 10,000 years.

(c) Any application for certification of compliance shall include information which:

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

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

(3) Documents why any processes, events or sequences of processes and events identified under paragraph (c)(1) of this section were not included in performance assessment results provided in any application for certification of compliance.

§ 194.33 Consideration of human-initiated processes and events.

(a) A separate examination of each type of human-initiated process and event shall be conducted. Analyses shall be limited to those types of human-initiated processes and events that may potentially affect the disposal system.

(b) The following process shall be used in assessing the likelihood and consequences of human-initiated processes and events and the results of such process shall be documented in any application for certification of compliance:

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

(2) Human-initiated processes and events occur at random intervals in time and space throughout the regulatory time frame.

(3) Two categories of human-initiated processes and events shall be considered:

(i) Human intrusion, which shall include those drilling events that reach the level of the waste in the disposal system, and

(ii) Human activity, which shall include those drilling events that may affect the disposal system, but do not necessarily reach the level of the waste in the disposal system.

(4) The frequency of human intrusion shall be calculated in the following manner:

(i) Identify each type of human intrusion in the Delaware Basin over the past 50 years.

(ii) The total rate of human intrusion shall be the sum of the rates of each type

of human intrusion. However, in no event shall the total rate of human intrusion be less than 25/km²/10,000 yrs or more than 62.5/km²/10,000 yrs.

(iii) In lieu of conducting the analysis in paragraphs (b)(4)(i) and (b)(4)(ii) of historical rates, a rate of 62.5 may be assumed.

(iv) The rate may then be reduced in accordance with § 194.41 and § 194.43(c).

(5) The frequency of human activity shall be calculated in the following manner:

(i) Identify each type of human activity in the Delaware Basin over the past 50 years.

(ii) The total rate of human activity shall be the sum of the rates of each type of human activity.

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

(iv) The rate may then be reduced in accordance with § 194.41 and § 194.43(c).

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

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

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

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

§ 194.34 Results of performance assessments.

(a)(1) 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.

(2) Probability distributions for uncertain disposal system parameter values used in performance assessments shall be developed.

(3) Computational techniques which draw random samples from across all of the probability distributions developed under paragraph (a)(2) of this section shall be used in generating CCDFs.

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

(c) Any application for certification of compliance shall display the full range of CCDFs generated.

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

Assurance Requirements

§ 194.41 Active institutional controls.

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

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

§ 194.42 Monitoring.

(a)(1) Disposal systems shall be monitored after disposal to detect substantial and detrimental deviations from expected performance at the earliest practicable time and shall be consistent with monitoring required under applicable federal hazardous waste regulations at 40 CFR parts 264, 265, 268, and 270. These monitoring programs shall be done with techniques that do not jeopardize the containment of waste in the disposal system.

(2) Any application for certification of compliance shall include a detailed plan for monitoring the performance of the disposal system. At a minimum, such plan shall:

(i) Identify parameters that will be monitored and how baseline states will be determined;

(ii) Indicate how each parameter will be used to evaluate the performance of the disposal system; and

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

(b)(1) To the extent practicable, pre-closure monitoring of the following disposal system parameters shall be conducted:

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

(ii) Gas quantity and composition;

(iii) Temperature distribution; and

(iv) Any other disposal system parameter(s) important to the containment of waste in the disposal system as identified by the study conducted under paragraph (b)(2) of this section. A disposal system parameter shall be considered important 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 after the Administrator's certification of compliance; however, in no case shall waste be emplaced in the disposal system prior to the implementation of such monitoring. Monitoring shall end when the last container of waste is emplaced in the disposal system but before shafts of the disposal system are backfilled and sealed.

(2) The Department shall conduct a study of the effects of disposal system parameters on the containment of waste in the disposal system and shall include the results of such study in any application for certification of compliance. The disposal system parameters studied shall include, but need not be limited to:

(i) Backfilled mechanical state including porosity, permeability, and degree of compaction and reconsolidation;

(ii) Extent of deformation of the surrounding roof, walls, and floor of the waste disposal room;

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

(iv) Subsidence and other effects of human activity in the vicinity of the disposal system.

(3) For all disposal system parameters studied pursuant to paragraph (b)(2) of this section, any application for certification of compliance shall document and substantiate the decision not to monitor a particular disposal system parameter because that parameter is considered to be unimportant to the containment of waste in the disposal system and to the verification of predictions about the future performance of the disposal system.

§ 194.43 Passive institutional controls.

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

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

(2) Placement of records in the archives and land record systems of local, State, and Federal governments, and international archives, that 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; and

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

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

(c) Any application for certification of compliance may include a proposed credit (which may vary over the regulatory time frame) for reducing the rate of human-initiated processes and events calculated using the procedures enumerated in § 194.33. The Administrator shall allow such credit, or a smaller credit, to be taken if the Department demonstrates that such credit is justified because the passive institutional controls can be expected to endure, be understood, and act as a deterrent to potential intruders throughout the regulatory time frame. In no case, however, shall passive institutional controls be assumed to eliminate the likelihood of human-initiated processes and events entirely.

§ 194.44 Engineered barriers.

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

(b) In selecting engineered barriers for the disposal system, the Department shall evaluate the benefit and detriment of engineered barrier alternatives including but not limited to such engineered barriers as cementation, shredding, supercompaction, incineration, vitrification, improved waste canisters, grout and bentonite backfill, melting of metals, alternative

configurations of waste placements in the disposal system, and alternative disposal system dimensions. The results of this evaluation shall be included in any application for certification of compliance 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:

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

(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-initiated processes and events.

(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 should be rejected without evaluating the remaining factors in paragraph (c)(1) of this section, then any application for certification of compliance shall provide a justification for this rejection explaining why the evaluation of the remaining factors would not alter the conclusion.

(d) In considering the benefit and detriment of incorporation of engineered barriers, 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 shall consider engineered barriers alone and in combination.

§ 194.45 Consideration of the presence of resources.

Any application for certification of compliance shall include information

that demonstrates that the favorable characteristics of the disposal system compensate for the presence of resources in the vicinity of the disposal system and the likelihood of future human-initiated processes and events as a result of the presence of those resources.

§ 194.46 Removal of waste.

Any application for certification of compliance shall include a plan for removal of waste from the disposal system. The plan shall incorporate the best technology available, at the time of application, for removing such waste.

Individual and Ground-Water Protection Requirements

§ 194.51 Consideration of protected individual.

Certifications or determinations of compliance with section 15 and subpart C of 40 CFR part 191 shall assume that an individual resides at the location in the accessible environment where that individual would be expected to receive the highest exposure from radionuclide releases from the disposal system.

§ 194.52 Consideration of exposure pathways.

In certifying or determining compliance with section 15 and subpart C of 40 CFR part 191, all potential exposure pathways, associated with undisturbed performance, from the disposal system to individuals shall be considered. Certifications or determinations of compliance with section 15 and subpart C of 40 CFR part 191 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 certifying or determining compliance with subpart C of 40 CFR part 191, all underground sources of drinking water in the accessible environment likely to be affected by the disposal system over the regulatory time frame shall be considered. In determining whether underground sources of drinking water are likely to be affected by the disposal system, interconnections between bodies of surface water, ground water, and underground sources of drinking water shall be considered.

§ 194.54 Scope of compliance assessments.

Any application for certification of compliance shall include information which:

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

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

(c) Documents why any processes, events or sequences of processes and events identified under paragraph (a) of this section were not included in compliance assessment results provided in any application for certification of compliance.

§ 194.55 Results of compliance assessments.

(a)(1) Compliance assessments shall consider uncertainty in the undisturbed performance of a disposal system.

(2) Probability distributions for uncertain disposal system parameter values used in compliance assessments shall be developed.

(3) Computational techniques which draw random samples from across all of the probability distributions developed under paragraph (a)(2) of this section shall be used to generate a range of:

(i) Estimated radiation doses; and

(ii) Estimated radionuclide concentrations.

(b) Each of the ranges generated under paragraph (a)(3) of this section must be large enough such that the maximum estimate generated exceeds the 99th percentile of the population of estimates with at least a 0.95 probability.

(c) Any application for certification of compliance shall display:

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

(2) The full range of estimated radionuclide concentrations.

(d) Any application for certification of compliance shall provide information which demonstrates that there is at least a 95% 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 sections 15 and 16 of 40 CFR part 191.

Subpart D—Public Participation

§ 194.61 Advance notice of proposed rulemaking.

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

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

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

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

(d) A public hearing concerning the notice will be held if a written request for a hearing is received within 30 calendar days of the date of publication under paragraph (a) of this section. Written requests shall be directed to the Administrator and the Administrator's authorized representative.

(e) Any comments received on the notice will be made available for inspection in the dockets established under section 65 of this part.

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

§ 194.62 Notice of proposed rulemaking.

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

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

(c) The notice will announce the opportunity for public hearings in New

Mexico and provide information on the timing and location of such hearings and procedures for registering to testify.

(d) Any comments received on the notice will be made available for inspection in the dockets established under section 65 of this part.

§ 194.63 Final rule.

(a) The Administrator will publish a Final Rule in the **Federal Register** announcing the Administrator's decision on certifying whether the WIPP facility will comply with the disposal regulations.

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

§ 194.64 Documentation of continued compliance.

(a) Upon receipt of documentation of continued compliance with the disposal regulations pursuant to section 8(f) of the WIPP LWA, the Administrator will publish a notice in the **Federal Register** announcing that such documentation has been received, soliciting comment on such documentation, and announcing the Administrator's intent to determine whether 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 under section 65 of this part.

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

(d) Any comments received on such notice will be made available for public inspection in the dockets established under § 194.65.

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

§ 194.65 Dockets.

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

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