TITLE 40 - PROTECTION OF ENVIRONMENT

Part 194 - Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance With the 40 CFR Part 191 Disposal Regulations

Table of Contents:

Authority:
Pub. L. 102-579, 106 Stat. 4777, as amended by Pub. L. 104-201,110 Stat. 2422; Reorganization Plan No. 3 of 1970, 35 FR 15623, Oct. 6, 1970, 5 U.S.C. app. 1; Atomic Energy Act of 1954, as amended, 42 U.S.C. 2011-2296 and 10101-10270.

Source:
61 FR 5235, Feb. 9, 1996, unless otherwise noted.

Subpart A - General Provisions

§1. Purpose, scope, and applicability

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

§2. Definitions

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

Acceptable knowledge means any information about the process used to generate waste, material inputs to the process, and the time period during which the waste was generated, as well as data resulting from the analysis of waste, conducted prior to or separate from the waste certification process authorized by EPA's Certification Decision, to show compliance with Condition 3 of the certification decision (appendix A of this part).

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

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

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

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

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

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

Department means the United States Department of Energy.

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

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

Minor alternative provision means an alternative provision to the Compliance Criteria that only clarifies an existing regulatory provision, or does not substantively alter the existing regulatory requirements.

Modification means action(s) taken by the Administrator that alters the terms or conditions of certification pursuant to section 8(d)(1) of the WIPP LWA. Modification of any certification shall comply with this part and part 191 of this chapter.

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

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

Quality assurance means those planned and systematic actions necessary to provide

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

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

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

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

Secretary means the Secretary of Energy.

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

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

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

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

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

WIPP means the Waste Isolation Pilot Plant, as authorized pursuant to section 213 of the Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1980 (Pub.L. 96-164; 93 Stat. 1259, 1265).

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

[61 FR 5235, Feb. 9, 1996, as amended at 63 FR 27404, May 18, 1998; 69 FR 42580, July 16, 2004]

§3. Communications

(a) Compliance application(s) shall be:

(1) Addressed to the Administrator; and

(2) Signed by the Secretary.

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

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

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

§4. Conditions of compliance certification

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

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

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

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

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

(i) The Department shall inform the Administrator, in writing, prior to making such a planned change in activity or disposal system condition.

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

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

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

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

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

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

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

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

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

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

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

(v) If the Department discovers a condition or activity that differs significantly from what is indicated in the most recent compliance application, but does not involve conditions or activities listed in paragraph (b)(3)(ii) of this section, then the difference shall be reported, in writing, to the Administrator within 10 calendar days of its discovery.

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

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

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

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

§5. Publications incorporated by reference

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

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

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

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

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

(b) The publications listed in paragraph (a) of this section were approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected or obtained from the Air Docket, Docket No. A-92-56, room M1500 (LE131), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, or copies may be inspected at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

or copies may be obtained from the following addresses:

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

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

[61 FR 5235, Feb. 9, 1996, as amended at 65 FR 47325, Aug. 2, 2000; 69 FR 18803, Apr. 9, 2004]

§6. Alternative provisions

The Administrator may, by rule pursuant to 5 U.S.C. 553, substitute for any of the provisions of this part alternative provisions, or minor alternative provisions, in accordance with the following procedures:

(a) Alternative provisions may be substituted after:

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

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

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

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

(b) Minor alternative provisions may be substituted after:

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

(2) A public comment period of at least 30 days has been completed for the minor alternative provisions and the public comments received have been fully considered;

(3) A notice of final rulemaking is published in the Federal Register for the minor alternative provisions.

[69 FR 42581, July 16, 2004]

§7. Effective date

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

§8. Approval process for waste shipment from waste generator sites for disposal at the WIPP

(a) *Quality Assurance Programs at Waste Generator Sites.* The Agency will determine compliance with requirements for site-specific quality assurance programs as set forth below:

(1) Upon submission by the Department of a site-specific quality assurance program plan the Agency will evaluate the plan to determine whether it establishes the applicable Nuclear Quality Assurance (NQA) requirements of §194.22(a)(1) for the items and activities of §§194.22(a)(2)(i), 194.24(c)(3) and 194.24(c)(5). The program plan and other documentation submitted by the Department will be placed in the dockets described in §194.67.

(2) The Agency will conduct a quality assurance audit or an inspection of a Department quality assurance audit at the relevant site for the purpose of verifying proper execution of the site-specific quality assurance program plan. The Agency will publish a notice in the Federal Register announcing a scheduled inspection or audit. In that or another notice, the Agency will also solicit public comment on the quality assurance program plan and appropriate Department documentation described in paragraph (a)(1) of this section. A public comment period of at least 30 days will be allowed.

(3) The Agency's written decision regarding compliance with the requisite quality assurance requirements at a waste generator site will be conveyed in a letter from the Administrator's authorized representative to the Department. No

such compliance determination shall be granted until after the end of the public comment period described in paragraph (a)(2) of this section. A copy of the Agency's compliance determination letter will be placed in the public dockets in accordance with §194.67. The results of any inspections or audits conducted by the Agency to evaluate the quality assurance programs described in paragraph (a)(1) of this section will also be placed in the dockets described in §194.67.

(4) Subsequent to any positive determination of compliance as described in paragraph (a)(3) of this section, the Agency intends to conduct inspections, in accordance with §§194.21 and 194.22(e), to confirm the continued compliance of the programs approved under paragraphs (a)(2) and (a)(3) of this section. The results of such inspections will be made available to the public through the Agency's public dockets, as described in §194.67.

(b) *Waste characterization programs at transuranic waste sites.* The Agency will establish compliance with Condition 3 of the certification using the following process:

(1) DOE will implement waste characterization programs and processes in accordance with §194.24(c)(4) to confirm that the total amount of each waste component that will be emplaced in the disposal system will not exceed the upper limiting value or fall below the lower limiting value described in the introductory text of §194.24(c). Waste characterization processes will include the collection and use of acceptable knowledge; destructive and/or nondestructive techniques for identifying and measuring waste components; and the validation, control, and transmittal to the WIPP Waste Information System database of waste characterization data, in accordance with §194.24(c)(4).

(2) The Agency will verify the compliance of waste characterization programs and processes identified in paragraph (b)(1) of this section at sites without EPA approval prior to October 14, 2004, using the following process:

(i) DOE will notify EPA by letter that a transuranic waste site is prepared to ship waste to the WIPP and has established adequate waste characterization processes and programs. DOE also will provide the relevant waste characterization program plans and documentation. EPA may request additional information from DOE.

(ii) EPA will conduct a baseline compliance inspection at the site to verify that adequate waste characterization program plans and technical procedures have been established, and that those plans and procedures are effectively implemented. The inspection will include a demonstration or test by the site of the waste characterization processes identified in paragraph (b)(1) of this section. If an inspection does not lead to approval, we will send an inspection report to DOE identifying deficiencies and place the report in the public docket described in §194.67. More than one inspection may be necessary to resolve compliance issues.

(iii) The Agency will announce in the Federal Register a proposed Baseline Compliance Decision to accept the site's compliance with §194.24(c)(4). We will place the inspection report(s) and any supporting documentation in the public docket described in §194.67. The site inspection report supporting the proposal will describe any limitations on approved waste streams or waste characterization processes. It will also identify (through tier designations in accordance with paragraph (b)(4) of this section) what changes to the approved waste characterization processes must be reported to and approved by EPA before they can be implemented. In the notice, we will solicit public comment (for a minimum of 45 days) on the proposed Baseline Compliance Decision, including any limitations and the tier designations for future changes or expansions to the site's waste characterization program.

(iv) Our written decision regarding compliance with the requirements for waste characterization programs and processes described in paragraph (b)(1) of this section will be conveyed in a letter from the Administrator's authorized representative to DOE. EPA will not issue a compliance decision until after the end of the public comment period described in paragraph (b)(2)(iii) of this section. EPA's compliance decision will respond to significant and timely-received comments. A copy of our compliance decision will be placed in the public docket described in §194.67. DOE will comply with any requirements identified in the compliance decision and the accompanying inspection report.

(3) Subsequent to any positive determination of compliance as described in paragraph (b)(2)(iv) of this section, the Agency intends to conduct inspections, in

accordance with §194.24(h), to confirm the continued compliance of approved waste characterization programs and processes at transuranic waste sites. EPA will make the results of these inspections available to the public in the dockets described in §194.67.

(4) Subsequent to any positive determination of compliance as described in paragraph (b)(2)(iv) of this section, the Department must report changes or expansions to the approved waste characterization program at a site in accordance with the tier designations established in the Baseline Compliance Decision.

(i) For changes or expansions to the waste characterization program designated as “Tier 1,” the Department shall provide written notification to the Agency. The Department shall not ship for disposal at WIPP any waste that has been characterized using the new or revised processes, equipment, or waste streams until EPA has provided written approval of such new or revised systems.

(ii) For changes or expansions to the waste characterization program designated as “Tier 2,” the Department shall provide written notification to the Agency. Waste characterized using the new or revised processes, equipment, or waste streams may be disposed at WIPP without written EPA approval.

(iii) EPA may conduct inspections in accordance with §194.24(h) to evaluate the implementation of Tier 1 and Tier 2 changes or expansions to the waste characterization program at a site.

(iv) Waste characterization program changes or expansions that are not identified as either “Tier 1” or “Tier 2” will not require written notification by the Department to the Agency before implementation or before shipping waste for disposal at WIPP.

(5) Subsequent to any positive determination of compliance as described in

paragraph (b)(2)(iii) of this section, EPA may revise the tier designations for approving changes or expansions to the waste characterization program at a site using the following process:

(i) The Agency shall announce the proposed tier changes in a letter to the Department. The letter will describe the Agency's reasons for the proposed change in tier designation(s). The letter and any supporting inspection report(s) or other documentation will be placed in the dockets described in §194.67.

(ii) If the revised designation entails more stringent notification and approval requirements (*e.g.,* from Tier 2 to Tier 1, or from undesignated to Tier 2), the change shall become effective immediately and the site shall operate under the more stringent requirements without delay.

(iii) If the revised designated entails less stringent notification and approval requirements, (*e.g.,* from Tier 1 to Tier 2, or from Tier 2 to undesignated), EPA will solicit comments from the public for a minimum of 30 days. The site will continue to operate under the more stringent approval requirements until the public comment period is closed and EPA notifies DOE in writing of the Agency's final decision.

(6) A waste generator site that EPA approved for characterizing and disposing transuranic waste at the WIPP under this section prior to October 14, 2004, may continue characterizing and disposing such waste at the WIPP under paragraph (c) of this section until EPA has conducted a baseline compliance inspection and provided a Baseline Compliance Decision under paragraph (b)(2) of this section.

(i) Until EPA provides a Baseline Compliance Decision for such a site, EPA may approve additional transuranic waste streams for disposal at WIPP under the provisions of paragraph (c) of this section. Prior to the effective date of EPA's Baseline Compliance Decision for such a site, EPA will continue to conduct inspections of the site in accordance with §194.24(c).

(ii) EPA shall conduct a baseline compliance inspection and issue a Baseline Compliance Decision for such previously approved sites in accordance with the provisions of paragraph (b) of this section, except that the site shall not be required to provide written notification of readiness as described in paragraph (b)(2)(i) of this section.

(c) *Waste characterization programs at waste generator sites with prior approval.* For a waste generator site that EPA approved for characterizing and disposing transuranic waste at the WIPP under this section prior to October 14, 2004, the Agency will determine compliance with the requirements for use of process knowledge and a system of controls at waste generator sites as set in this paragraph (c). Approvals for a site to characterize and dispose of transuranic waste at WIPP will proceed according to this section only until EPA has conducted a baseline compliance inspection and provided a Baseline Compliance Decision for a site under paragraph (b)(2) of this section.

(1) For each waste stream or group of waste streams at a site, the Department must:

(i) Provide information on how process knowledge will be used for waste characterization of the waste stream(s) proposed for disposal at the WIPP; and

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

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

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

(4) Subsequent to any positive determination of compliance as described in paragraph (b)(3) of this section, the Agency intends to conduct inspections, in accordance with §§194.21 and 194.24(h), to confirm the continued compliance of the programs approved under paragraphs (b)(2) and (b)(3) of this section. The results of such inspections will be made available to the public through the Agency's public dockets, as described in §194.67.

[63 FR 27404, May 18, 1998, as amended at 69 FR 42581, July 16, 2004]

Subpart B - Compliance Certification and Re-Certification Applications

§11. Completeness and accuracy of compliance applications

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

§12. Submission of compliance applications

Unless otherwise specified by the Administrator or the Administrator's authorized representative, 5 copies of any compliance application(s), any accompanying materials, and any amendments thereto shall be submitted in a printed form to the Administrator's authorized representative. These paper copies are intended for the official docket in Washington, DC, as well as the four informational dockets in Albuquerque and Santa Fe, New Mexico. In addition, DOE shall submit 10 copies of the complete application in alternative format (*e.g.,* compact disk) or other approved format, as specified by the Administrator's authorized representative.

[69 FR 42582, July 16, 2004]

§13. Submission of reference materials

Information may be included by reference into compliance applications(s), provided that the references are clear specific and that unless, otherwise specified by the Administrator or the Administrator's authorized representative, 5 copies of reference information are submitted to the Administrator's authorized representative. These paper copies are intended for the official docket in Washington, DC, as well as the four informational dockets in Albuquerque and Santa Fe, New Mexico. Reference materials that are widely available in standard text books or reference books need not to be submitted. Whenever possible, DOE shall submit 10 copies of reference materials in alternative format (*e.g.,* compact disk) or other approved format, as specified by the Administrator's authorized representative.

[69 FR 42582, July 16, 2004]

§14. Content of compliance certification application

Any compliance application shall include:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) A description of all waste emplaced in the disposal system since the most

recent compliance certification or re-certification application. Such description shall consist of a description of the waste characteristics and waste components identified in §§194.24(b)(1) and 194.24(b)(2);

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

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

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

Subpart C - Compliance Certification and Re-Certification

General Requirements

§21. Inspections

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

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

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

(b) Records (including data and other information in any form) kept by the Department pertaining to the WIPP shall be made available to the Administrator or the Administrator's authorized representative upon request. If requested records are not immediately available, they shall be delivered within 30 calendar days of the request.

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

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

§22. Quality assurance

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

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

(i) Waste characterization activities and assumptions;

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

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

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

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

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

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

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

(b) Any compliance application shall include information which demonstrates that data and information collected prior to the implementation of the quality assurance program required pursuant to paragraph (a)(1) of this section have been qualified in accordance with an alternate methodology, approved by the Administrator or the Administrator's authorized representative, that employs one or more of the following methods: Peer review, conducted in a manner that is compatible with NUREG-1297, “Peer Review for

High-Level Nuclear Waste Repositories," published February 1988 (incorporation by reference as specified in §194.5); corroborating data; confirmatory testing; or a quality assurance program that is equivalent in effect to ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c) and Section 17.1). (Incorporation by reference as specified in §194.5.)

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

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

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

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

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

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

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

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

§23. Models and computer codes

(a) Any compliance application shall include:

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

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

(3) Documentation that:

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

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

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

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

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

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

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

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

(2) General descriptions of the models; discussions of the limits of applicability of each model; detailed instructions for executing the computer codes, including hardware and software requirements, input and output formats with explanations of each input and output variable and parameter (e.g., parameter name and units); listings of input and output files from a sample computer run; and reports on code verification, benchmarking, validation, and quality assurance procedures;

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

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

(5) Any necessary licenses; and

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

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

§24. Waste characterization

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

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

(1) That all waste characteristics influencing containment of waste in the disposal system have been identified and assessed for their impact on disposal system performance. The characteristics to be analyzed shall include, but shall

not be limited to: Solubility; formation of colloidal suspensions containing radionuclides; production of gas from the waste; shear strength; compactability; and other waste-related inputs into the computer models that are used in the performance assessment.

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

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

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

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

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

(3) Provide information that demonstrates that the use of acceptable knowledge to quantify components in waste for disposal conforms with the

quality assurance requirements of §194.22.

(4) Provide information which demonstrates that a system of controls has been and will continue to be implemented to confirm that the total amount of each waste component that will be emplaced in the disposal system will not exceed the upper limiting value or fall below the lower limiting value described in the introductory text of paragraph (c) of this section. The system of controls shall include, but shall not be limited to: Measurement; sampling; chain of custody records; record keeping systems; waste loading schemes used; and other documentation.

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

(d) The Department shall include a waste loading scheme in any compliance application, or else performance assessments conducted pursuant to §194.32 and compliance assessments conducted pursuant to §194.54 shall assume random placement of waste in the disposal system.

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

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

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

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

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

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

[61 FR 5235, Feb. 9, 1996, as amended at 69 FR 42583, July 16, 2004]

§25. Future state assumptions

(a) Unless otherwise specified in this part or in the disposal regulations, performance assessments and compliance assessments conducted pursuant the provisions of this part to demonstrate compliance with §191.13, §191.15 and part 191, subpart C shall assume that characteristics of the future remain what they are at the time the compliance application is prepared, provided that such characteristics are not related to hydrogeologic, geologic or climatic conditions.

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

(1) In considering the effects of hydrogeologic conditions on the disposal system, the Department shall document in any compliance application, to the extent practicable, the effects of potential changes to hydrogeologic conditions.

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

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

§26. Expert judgment

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

(b) Any compliance application shall:

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

(2) Describe the process of eliciting expert judgment, and document the results of expert judgment elicitation processes and the reasoning behind those results. Documentation of interviews used to elicit judgments from experts, the questions or issues presented for elicitation of expert judgment, background information provided to experts, and deliberations and formal interactions among experts shall be provided. The opinions of all experts involved in each elicitation process shall be provided whether the opinions are used to support compliance

applications or not.

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

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

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

(4) Provide information which demonstrates that:

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

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

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

(6) Provide documentation that the initial purpose for which expert judgment was intended, as presented to the expert panel, is consistent with the purpose for

which this judgment was used in compliance application(s).

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

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

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

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

§27. Peer review

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

(1) Conceptual models selected and developed by the Department;

(2) Waste characterization analyses as required in §194.24(b); and

(3) Engineered barrier evaluation as required in §194.44.

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

(c) Any compliance application shall:

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

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

Containment Requirements

§31. Application of release limits

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

§32. Scope of performance assessments

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

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

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

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

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

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

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

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

§33. Consideration of drilling events in performance assessments

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§34. Results of performance assessments

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

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

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

(d) The number of CCDFs generated shall be large enough such that, at cumulative releases of 1 and 10, the maximum CCDF generated exceeds the 99th percentile of the population of CCDFs with at least a 0.95 probability. Values of cumulative release shall be calculated according to Note 6 of Table 1, appendix A of part 191 of this chapter.

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

(f) Any compliance application shall provide information which demonstrates that there

is at least a 95 percent level of statistical confidence that the mean of the population of CCDFs meets the containment requirements of §191.13 of this chapter.

Assurance Requirements

§41. Active institutional controls

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

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

§42. Monitoring

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

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

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

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

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

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

(6) Gas quantity and composition; and

(7) Temperature distribution.

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

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

(d) Post-closure monitoring. The disposal system shall, to the extent practicable, be monitored as soon as practicable after the shafts of the disposal system are backfilled

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

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

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

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

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

§43. Passive institutional controls

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

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

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

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

(ii) The design of the disposal system;

(iii) The nature and hazard of the waste;

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

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

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

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

(c) The Administrator may allow the Department to assume passive institutional control credit, in the form of reduced likelihood of human intrusion, if the Department demonstrates in the compliance application that such credit is justified because the

passive institutional controls are expected to endure and be understood by potential intruders for the time period approved by the Administrator. Such credit, or a smaller credit as determined by the Administrator, cannot be used for more than several hundred years and may decrease over time. In no case, however, shall passive institutional controls be assumed to eliminate the likelihood of human intrusion entirely.

§44. Engineered barriers

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

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

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

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

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

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

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

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

(vi) Public comments requesting specific engineered barriers;

(vii) The increased or reduced total system costs;

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

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

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

(d) In considering the ability of engineered barriers to prevent or substantially delay the movement of water or radionuclides toward the accessible environment, the benefit and detriment of engineered barriers for existing waste already packaged, existing waste not yet packaged, existing waste in need of re-packaging, and to-be-generated waste shall be considered separately and described.

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

§45. Consideration of the presence of resources

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

§46. Removal of waste

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

Individual and Ground-water Protection Requirements

§51. Consideration of protected individual

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

§52. Consideration of exposure pathways

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

§53. Consideration of underground sources of drinking water

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

§54. Scope of compliance assessments

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

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

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

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

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

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

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

§55. Results of compliance assessments

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

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

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

(1) Estimated committed effective doses received from all pathways pursuant

to §194.51 and §194.52;

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

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

(d) The number of estimates generated pursuant to paragraph (c) of this section shall be large enough such that the maximum estimates of doses and concentrations generated exceed the 99th percentile of the population of estimates with at least a 0.95 probability.

(e) Any compliance application shall display:

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

(2) The full range of estimated radionuclide concentrations.

(f) Any compliance application shall document that there is at least a 95 percent level of statistical confidence that the mean and the median of the range of estimated radiation doses and the range of estimated radionuclide concentrations meet the requirements of §191.15 and part 191, subpart C of this chapter, respectively.

Subpart D - Public Participation

§61. Advance notice of proposed rulemaking for certification

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

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

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

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

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

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

§62. Notice of proposed rulemaking for certification

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

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

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

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

§63. Final rule for certification

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

(b) A document summarizing significant comments and issues arising from comments received on the Notice of Proposed Rulemaking, as well as the Administrator's response to such significant comments and issues, will be prepared and will be made available for inspection in the dockets established pursuant to §194.67.

§64. Documentation of continued compliance

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

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

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

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

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

§65. Notice of proposed rulemaking for modification or revocation

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

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

§66. Final rule for modification or revocation

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

(b) A document summarizing significant comments and issues arising from comments received on the Notice of Proposed Rulemaking as well as the Administrator's response

to such significant comments and issues will be prepared and will be made available for inspection in the dockets established pursuant to §194.67.

§67. Dockets

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

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

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

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

Condition 2: §194.22: Quality Assurance. The Secretary shall not allow any waste generator site other than the Los Alamos National Laboratory to ship waste for disposal at the WIPP until the Agency determines that the site has established and executed a quality assurance program, in accordance with §§194.22(a)(2)(i), 194.24(c)(3) and 194.24(c)(5) for waste characterization activities and assumptions. The Agency will determine compliance of site-specific quality assurance programs at waste generator sites using the process set forth in §194.8.

Condition 3: §194.24: Waste Characterization. The Secretary may allow shipment for disposal at the WIPP of legacy debris waste at the Los Alamos National Laboratory ("LANL") that can be characterized using the systems and processes inspected by the Agency and documented in Docket A-93-02, Item II-I-70. The Secretary shall not allow shipment of any waste from any additional LANL waste stream(s) or from any waste generator site other than LANL for disposal at the WIPP until the Agency has approved the processes for characterizing those waste streams for shipment using the process set forth in §194.8.

Condition 4: §194.43, Passive institutional controls.

(a) Not later than the final recertification application submitted prior to closure of the disposal system, the Department shall provide, to the Administrator or the Administrator's authorized representative:

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

(2) documentation showing that the granite pieces for the proposed monuments and information rooms described in Docket A-93-02, Item II-G-1, and

supplementary information may be: quarried (cut and removed from the ground) without cracking due to tensile stresses from handling or isostatic rebound; engraved on the scale required by the design; transported to the site, given the weight and dimensions of the granite pieces and the capacity of existing rail cars and rail lines; loaded, unloaded, and erected without cracking based on the capacity of available equipment; and successfully joined.

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

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

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

[63 FR 27405, May 18, 1998]