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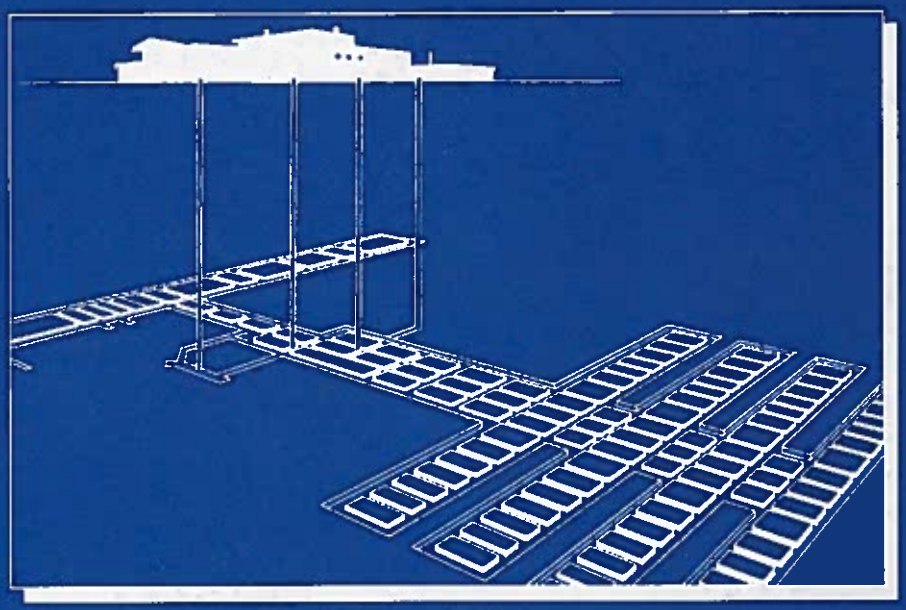
Compliance Application Guidance For The Waste Isolation Pilot Plant: A Companion Guide To 40 CFR Part 194



Schematic of the WIPP Disposal System

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Compliance Application Guidance for 40 CFR Part 194

Disclaimer

This Compliance Application Guidance (CAG) is a companion to the EPA final rule published on February 9, 1996, 61 Fed. Reg. 5224-5245 (to be codified at 40 CFR part 194). The February 9, 1996 final rule establishes the binding "compliance criteria" that will govern EPA's certification, pursuant to section 8(d) of the Waste Isolation Pilot Plant (WIPP) Land Withdrawal Act (Pub. L. No. 102-579), of the WIPP facility's compliance with EPA's final radioactive waste disposal regulations (40 CFR part 191). The CAG is intended solely as guidance. The CAG does not establish compliance criteria or any other binding rights and duties. The CAG summarizes and explains the final rule to assist the Department of Energy in the preparation and compilation of the WIPP Compliance Certification Application (CCA) and to assist in EPA's review of the CCA for completeness. Any inconsistencies between the CAG and the February 9, 1996 final rule are wholly inadvertent and, in all circumstances, the final rule is dispositive of any inconsistencies.

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Introduction

The Compliance Application Guidance (CAG) is a companion to the final rule published at 61 FR 5224, February 9,1996, "Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's (WIPP) Compliance With the 40 CFR Part 191 Disposal Regulations" (to be codified at 40 CFR Part 194).

The CAG summarizes and explains the February 9, 1996 final rule. The United States Environmental Protection Agency (EPA) developed this guidance to assist the United States Department of Energy (DOE) with the preparation of any Compliance Certification Application (CCA) for the WIPP and, in turn, to assist in EPA's review of the CCA for completeness and generally to enhance the readability and accessibility of the CCA for EPA and public scrutiny. It is EPA's intent that this guidance will facilitate the understanding that DOE and the public have of the specific information that is expected to be included in a *complete* application for certification of compliance. Examples used for clarification in this guidance should not be considered exhaustive or definitive, since they are provided merely to facilitate DOE's understanding of the types of information EPA is expecting.

EPA's final compliance criteria for the WIPP provide for EPA to determine that the CCA is "complete" as a preliminary step in its more extensive administrative review of the CCA. A completeness determination is a threshold determination that the application warrants further scrutiny, so that EPA, DOE, and the public do not invest major resources in a rulemaking proceeding for an incomplete document. The completeness determination does not represent final agency action. EPA will make a final decision about the CCA only when it ultimately certifies--pursuant to rulemaking procedures which will include public notice and ample opportunity for public comment--whether or not the WIPP facility will comply with the final disposal regulations.

Upon receipt of a full CCA from DOE, EPA will publish an Advance Notice of Proposed Rulemaking in the Federal Register that announces receipt of the application and initiates a public comment period. A copy of the application will be made available for public inspection in the Agency WIPP dockets, written public comments will be accepted, and, if sufficient interest is expressed, a hearing will be held in New Mexico. The public comment period will allow all interested parties to provide comments to EPA on the application. Subsequently, EPA will publish a Notice of Proposed Rulemaking in the Federal Register and provide a public comment period of at least 120 days, during which it will hold public hearings in New Mexico. EPA's Final Rulemaking Notice will be accompanied by a document summarizing significant comments and issues and providing EPA's responses.

EPA provided public notice and opportunity for public comment on a prior draft of this document. See 60 FR 53921, October 18, 1995. EPA was unable to provide additional opportunity for public comment on this guidance document after the issuance of the final compliance criteria (40 CFR Part 194), as some commenters had requested. EPA endeavored to

issue this guidance expeditiously after issuance of the final compliance criteria, because DOE is currently preparing the CCA.

The CAG summarizes and explains EPA's expectations of the format and content of the CCA, based on the February 9, 1996 final rule (hereafter referred to as "40 CFR Part 194). The technical and legal requirements pertaining to the CCA are addressed by 40 CFR Parts 191 and 194. The CAG's format follows that of 40 CFR Part 194, restating the rule language in *italics*, followed by the specific guidance for that section in standard type. Only those portions of 40 CFR Part 194 (and, by reference, applicable portions of 40 CFR Part 191) for which DOE is required to submit specific information to EPA, are addressed. Portions of 40 CFR Part 194 which are applicable only to EPA, such as Subpart D, were excluded from this guidance.

The information DOE presents in any compliance application must conform to the requirements of 40 CFR Part 194.

General Recommendations for Format

1. The application should include information (i.e., a matrix or cross-walk) that identifies where the specific requirements of 40 CFR Part 194 have been addressed (i.e., 40 CFR Section 194.42.....Chapter X, pages xxx). EPA does not intend that DOE should submit duplicative information if such information is needed to establish compliance with more than one requirement. In such instances, the Agency indicates in this document how it would like any compliance application to present the information and appropriate cross-references. DOE may decide how avoidance of duplication is best achieved.

2. Text should be augmented with graphical representations having sufficient scale and clarity to portray the intended subject matter accurately. The text should reference the source of the information (e.g., published or unpublished reports, field data, laboratory tests, expert judgment, modeling results).

3. DOE should prepare an executive summary to accompany the application that discusses major issues and presents the final compliance results.

4. Units should be listed in *Systeme Internationale* (SI) terminology where possible, with English units listed parenthetically.

5. The application should provide readily identified links between text, references, appendices, and other information used in the compliance demonstration.

6. The application should provide a subject index as part of the application. This index should contain key words and the sections and pages on which they are discussed in the application. If the information is in an appendix, it should be so noted along with the

section and page number. The following is an example of what should be in the subject index:

Topic	Section	Page(s)
Computer codes	5.7	pp. 5-70 to 5-80
	6.2-6.6	pp. 6-45 to 6-99
	Appendix CODES	pp. 1-250
Culebra Dolomite	2.4.3	pp. 2-56 to 2-58
	2.7.2	pp. 2-99
	6.4.1	pp. 6-105 to 6-111
	Appendix ABC	pp. 34-67
Gas generation	2.9.2	pp. 2-200
	6.6.3	pp. 6-145 to 6-159
	Appendix GG	pp. 99-112
Matrix of 191 and 194 requirements	1.1	pp. 1-10
Quality Assurance	5.1-5.15	pp. 5-1 to 5-144
QAPD	5.2	pp. 5-5 to 5-40
Input parameters	5.8	pp. 5-81 to 5-99
	Appendix PARAM	pp. 1-99
Computer codes	5.7	pp. 5-70 to 5-80

7. Information in the application related to analyses should be presented so that EPA may confirm the analyses. For example, the application should provide examples as appropriate to explain calculations. If the example calculations are complex, they may be placed in an appendix and appropriately cross-referenced in the main text.

8. The terms in the application must adhere to the definitions established by 40 CFR Parts 191 and 194. DOE should not redefine terms.

Subpart A--General Provisions

§194.1 Purpose, scope and applicability.

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

§194.2 Definitions.

See Appendix A: Definitions of 40 CFR Parts 191 and 194.

§194.3 Communications.

(a) Compliance application(s) shall be:
(1) Addressed to the Administrator; and
(2) Signed by the Secretary.
(b) Communications and reports concerning the criteria in this part shall be:
(1) Addressed to the Administrator or the Administrator's authorized representative; and
(2) Signed by the Secretary or the Secretary's authorized representative.

- Any compliance application should be signed by the Secretary and any subsequent communications regarding the application should be signed by either the Secretary or the Secretary's authorized representative.

- Any compliance application, and any other communications and/or reports concerning compliance with 40 CFR Part 194, unless otherwise specified, should be addressed to the Administrator, at the following address:

  United States Environmental Protection Agency
  Administrator
  Office of the Administrator (A-100)
  401 M Street, S.W.
  Washington, D.C. 20460

§194.4 Conditions of compliance certification.

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

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

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

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

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

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

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

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

(B) Releases from already-emplaced waste lead to committed effective doses that are or are expected to be in excess of those established pursuant to § 191.15 of this chapter. For purposes of this subparagraph (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.

- No information is required in a compliance application to fulfill this section of 40 CFR Part 194.

§194.5 Publications incorporated by reference.

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

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

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

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

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

(b) The publications listed in paragraph (a) of this section were approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected or obtained from the Air Docket, Docket No. A-92-56, room M1500 (LE131), U.S. Environmental Protection Agency, 401 M Street, SW,

Washington, DC 20460, or copies may be inspected at the Office of the Federal Register, 800 N. Capitol Street NW, 7th floor, Suite 700, Washington, DC, or copies may be obtained from the following addresses:

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

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

- No information is required in a compliance application to fulfill this section of 40 CFR Part 194.

§194.6 Alternative provisions.

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

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

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

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

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

- No information is required in a compliance application to fulfill this section of 40 CFR Part 194.

§194.7 Effective date.

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

- No information is required in a compliance application to fulfill this section of 40 CFR Part 194.

Subpart B—Compliance Certification and Re-certification Applications

§194.11 Completeness and accuracy of compliance applications.

Information provided to the Administrator in support of any compliance application shall be complete and accurate. The Administrator's evaluation for certification pursuant to section 8(d)(1)(B) of the WIPP LWA and evaluation for re-certification 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.

The concept of "completeness" is an administrative tool that EPA will use to screen any compliance certification application (CCA) received from DOE as a preliminary step in the more extensive technical review of the CAA. EPA intends to use the CAG to guide its determination whether DOE has submitted a "complete" CCA for the WIPP. However, the CAG is not legally binding for either EPA or DOE. The summarized information, clarifying information, interpretations, and examples contained in the CAG are based on the regulatory requirements established by 40 CFR Parts 191 and 194. Any inconsistencies between the CAG and these rules are inadvertent and, in all circumstances, 40 CFR Parts 191 and 194 are dispositive of any inconsistencies.

EPA's determination of completeness will focus on two questions: (1) Does the information provided address the specific requirements for compliance with 40 CFR Part 194? and (2) Is the information provided in what appears to be sufficient detail and format to enable the Agency to review the technical adequacy of the application? However, even if the application is determined to be complete, at any point during EPA's review of the application additional information may be requested to assist the Agency in determining compliance in accordance with §194.14(j).

The determination of completeness (or incompleteness) will be made by the Administrator, who will then inform DOE in writing of any such decision, pursuant to the provisions of this section of the compliance criteria. Any such written notification(s) to DOE will also be placed in the docket for public examination.

§194.12 Submission of compliance applications.

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

- DOE should provide 30 copies of the application.

EPA will provide DOE with information on an appropriate format for electronic submission of the application and the number of paper copies needed.

§194.13 Submission of reference materials.

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

EPA will provide DOE with information on an appropriate format for electronic submission of references and the number of paper copies needed.

§194.14 Content of compliance certification application.

Any compliance application shall include:

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

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

EPA expects that any compliance application will specify the:

- physical setting;
- size;
- county;
- township and range;
- roads;
- longitude and latitude;
- appropriate graphics (maps, at a minimum); and
- boundaries of the disposal system and 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.

Geologic and geophysical characteristics include regional and site:

- geologic history;
- stratigraphy;
- lithology;

- structural geology and geotectonics (e.g., geologic structure, tectonic history, lineaments, fault or fracture zones, earthquake occurrence, subsidence);
- seismic history (e.g., earthquake activity, relation of epicenters with geologic structures and/or geologic setting);
- geomorphology and topography (e.g., geomorphic units and processes, such as secondary topographic features caused by erosion);
- soil characteristics in the controlled area that affect infiltration and runoff (e.g., hydraulic conductivity, infiltration capacity); and
- natural resources (e.g., type, occurrence, location, extent of minerals, hydrocarbons and water, such as potash, oil, gas, irrigation water). See also §194.33 and §194.45.

Hydrologic, hydrogeologic, and geochemical descriptions are expected to include:

- For all geologic units in the disposal system, general hydraulic characteristics:
  - hydraulic conductivity;
  - storage coefficients;
  - transmissivity;
  - permeability;
  - thickness;
  - matrix and fracture characteristics; and
  - hydraulic gradients.

- For geological units that could be expected to transmit radionuclides to the accessible environment during the regulatory time frame:
  - regional and site-specific recharge and discharge areas;
  - groundwater flow patterns, including horizontal flow (e.g., potentiometric surface, flow direction, effect of density on flow direction) and the estimated vertical flow into transmissive units;
  - general physical characteristics (e.g., fracturing, porosity--total, effective, interstitial, and fracture--and saturated thickness);
  - general transport characteristics (e.g., logitudinal and transverse dispersivity, tortuosity, matrix and fracture characteristics, retardation (physical and chemical) and a discussion of the characterization method(s) used);
  - flow boundaries, magnitudes and flow rates;
  - depth to water table (where applicable); and
  - geochemistry and geochemical history (e.g., total dissolved solids, mineral content and distribution, fluid density, salinity).

EPA expects that any application will provide information on general hydrological, hydrogeological and geochemical characteristics of the geological units in the disposal system. In the description of the hydrogeology, hydrology and geochemistry, the application should discuss the geological units that could be expected to transmit radionuclides to the accessible environment during the regulatory time frame. For those geological units which are not expected to transmit

water, EPA recommends that the application discuss the basic hydrological properties that support this expectation.

(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 due to the presence of waste including, but not limited to, the effects of production of heat or gases from the waste.

EPA recommends that this information be presented in any compliance application as part of the waste information or the screening of events and processes. The information for this requirement should be appropriately cross-referenced in all of the sections in which it is discussed. See also §194.24, §194.32, and §194.54.

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

A complete description of the disposal system design should include the designs, with supporting documentation that demonstrates that the designs can be implemented and that they will function in the manner for which they were designed. See §194.15(b).

(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 the disposal regulations.

See §194.23, §194.24, §194.34, §194.42, §194.44, and §194.55 for relevant guidance.

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

EPA recommends that input parameter descriptions be linked to the appropriate discussions of models and data. See §194.23, §194.34, and §194.55.

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

See the guidance for assurance requirements at §194.41 through §194.46.

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

See the guidance for §194.24(c)(4).

(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.

EPA expects the description to include background radiation in:

- air;
- soil; and
- water.

EPA expects the procedures employed to determine such radiation to include:

- locations in which the measurements were made;
- dates on which the measurements were made;
- standard statistics, such as mean and standard deviation;
- discussion of problems (if any) encountered in the measurement process;
- identification of the instrument used and lower limit of detection for the instrumentation; and
- documentation that the measurements were quality assured.

(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.

EPA expects that:

- the contour interval will be sufficient to show clearly the pattern of surface water flow in the vicinity of the disposal system;
- the map(s) will include:
  - standard map notations and symbols;
  - 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.

EPA recommends that sufficient topographic and/or other maps be included, and that any information on the maps be discussed in the text of the application, so that any information on the maps will be clear to the reviewer.

(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.

EPA recommends that any compliance application list recent estimates, using existing written records, of climatologic and meteorologic conditions in the vicinity of the disposal system in tabular form, and briefly discuss the following:

- record of annual and monthly precipitation averages;
- record of monthly temperature averages and extremes;
- wind speed and direction information that forms the basis for the exposure pathway modeling; and
- an estimate of evapotranspiration.

EPA expects any compliance application to discuss the past climatologic and meteorologic conditions for the vicinity of the disposal system including:

- climate changes, including past glaciation events; and
- past precipitation and temperature averages and variability, estimated from the geologic record, or other means.

EPA expects that any compliance application will include a discussion of how climatologic and meteorologic conditions are expected to change during the 10,000-year regulatory time period.

EPA further expects any compliance application to state how climatologic and meteorologic changes were incorporated into the conceptual models used and how they were used in the performance and compliance assessments, including:

- potential changes and rates of change in precipitation, air temperatures, and resulting changes in potential evapotranspiration from the present;
- potential precipitation patterns that may evolve in the future as a result of climatic and geologic changes; and
- potential increased/decreased recharge to the disposal system.

For additional guidance, see §194.25, §194.32, §194.34, §194.54 and §194.55.

(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.

Even if the application is determined to be complete, at any point during EPA's review of the application additional information may be requested to assist the Agency in determining compliance in accordance with §194.14(j) .

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

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

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

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

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

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

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

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

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

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

Section 8(f) of the WIPP Land Withdrawal Act requires DOE to submit documentation of continued compliance with 40 CFR Part 191 every five years after the emplacement of waste begins, if the initial certification is granted, and until completion of the decommissioning phase. EPA expects the documentation to include any new information related to the disposal system that was obtained during the five-year period after the emplacement of waste began, or since the time of the most recent recertification.

EPA expects any compliance recertification application to include:

- information which updates the previous compliance certification or recertification;
- a short summary of information provided in previous compliance applications;
- updated computer codes; and
- a list of changes which may affect the predicted radionuclide releases from the disposal system. Possible changes include:
  - if the waste were emplaced so that high-curie waste is grouped together instead of equally distributed;
  - changes resulting from monitoring the disposal system, or data collected from continuing experiments, that alter the parameter values used in the models;
  - changes/improvements in the disposal system design, with documentation that the changes improve performance and that they will function in the manner for which they were designed; and
  - updated information from continuing studies.

If the computer codes are modified, DOE must submit updated codes and code listings. This should be accompanied by the appropriate performance and compliance assessments. See also §194.4, §194.23, §194.32, and §194.54.

EPA recommends that DOE continue geologic, geophysical, hydrogeologic, geochemical, hydrologic, and meteorological studies of the site and the surrounding area as appropriate. Any data, results, and interpretations yielded by such studies must be included in any compliance recertification application. EPA must be notified immediately of any significant information pursuant to §194.4.

EPA expects any compliance recertification application to include updated monitoring information as follows:

- pre-closure monitoring results collected during the five-year recertification period, and
- a discussion of the data quality acceptability;
  - the implications of the results;
  - whether the results change or challenge the conceptual or computer model of the disposal system, or a portion of the disposal system; and
  - whether, as a result of any changes, the projection of the system's performance should be revised. See also §194.23.

EPA expects any compliance recertification application to include updated waste emplacement information as follows:

- information regarding the wastes that were emplaced during the five-year period immediately following the time at which waste emplacement began, or the most recent compliance recertification.

If assumptions about the waste or other aspects of the disposal system change, it is expected that any compliance recertification application will contain the appropriate analyses describing such assumptions. EPA must be notified immediately of any significant information pursuant to §194.4.

EPA expects the waste emplacement information to include the following:

- the location and distribution of emplaced waste by waste components required for waste characterization. See also §194.24;
- confirmation that the location and distribution of waste conform to assumptions used in performance assessments. See also §194.23, §194.32, §194.33, §194.34, §194.54, and §194.55;
- waste characteristics of waste emplaced and a demonstration that they continue to fall within the requirements established under §194.24.

Subpart C -- Compliance Certification and Re-Certification General Requirements

§194.21 Inspections.

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

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

EPA expects any compliance application to include:

- a list of locations and facilities covered by this part. The list should include points of contact, phone numbers, etc.

(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.

EPA expects any compliance application to include:

- a complete list of the location of records, such as quality assurance records, data acquisition records, and other information used to support the compliance application. This list should be in the form of a table(s), cross-reference(s), or matrix, as appropriate. See §194.14.

(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.

- No information is required in a compliance application to fulfill this section of 40 CFR Part 194.

§194.22 Quality Assurance.

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

EPA expects any compliance application to include:

- DOE top tier QA documents for WIPP to demonstrate commitment to NQA-1 (1989), NQA-2, part 2.7 (1990), and NQA-3 (1989) standards;
- DOE principle contractor top tier QA documents, and a list of top tier QA documents of all non-principle and/or subcontractors performing listed quality affecting activities (see §194.22(a)(2)); and
- the effective date of top-tier document conformance with the NQA requirements for DOE and each listed contractor and subcontractor.

(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.

For each of the eight areas listed above, EPA expects any compliance application to:

- provide a list of quality affecting activities and items that are important to the demonstration of compliance;
- discuss the rationale used in preparation/development of the list;

- provide (and make available for field review) objective evidence to support proper implementation of the rationale;
- describe the process for selection of applicable NQA requirements and the means of implementation of these requirements;
- describe the means used to assess the flow down (or traceability) of applicable NQA requirements from top tier documents to implementing procedures for the listed activities;
- describe the nature and location of objective evidence which substantiates the traceability;
- provide the grading criteria and describe the nature and location of objective evidence which substantiates proper grading criteria application (if the graded QA approach has been applied to the requirements of any of the listed activities);
- provide the effective dates (month and year) of QA implementation conforming to NQA for each listed activity or item, and describe the nature and location of objective evidence which supports this determination (e.g., audit report, closeout of corrective action, etc.). A tabular format is suggested;
- describe the DOE and principal contractor QA assessments (audits) and corrective action programs by providing:
  - principal rules for auditors (i.e. management procedures) for these programs;
  - a list of principal activities that have been done (i.e. audits, surveillance, management reviews, tracking and closeout of corrective actions, and follow-up audits);
  - schedules of principal activities;
  - the nature and location of objective evidence which supports a determination that these program elements are effectively implemented; and
  - documentation of how the QA records (i.e. QA personnel training, QA audit reports, and tracking of deficiencies records) are maintained and providing the locations where the QA records are maintained.

The descriptions of listed activities and objective evidence of QA implementation should be sufficiently detailed to allow EPA to evaluate the DOE QA audit and corrective action programs through selection of a sample of activities, procedures, training records, etc., and verification of records in the field.

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.)

EPA expects any compliance application to:

- provide a list which identifies pre-existing data records packages which are used in the compliance demonstration and list the locations of these data records packages;
- provide the rationale and alternate methodologies used in qualifying each listed package;
- describe the QA requirements and the process for developing the qualification of existing data (QED) alternate methodologies, which may include the use of equivalent QA procedures, peer review procedures, corroborating data procedure, and confirmatory testing procedures;
- provide the QED governing documents that include procedures and management plans for independent review, peer review, use of corroborating data, etc;
- describe the nature and location of QA records generated during the conduct of QED (i.e., independent review team conclusions, qualification of independent personnel, review records, QED final decisions, auditing records, and deficiencies correction records);
- describe other records such as scientific notebooks, roadmaps, checklists, peer review process documentation and records, documentation of corroborating data, final decision and approval of qualified data records packages, data interpretations, parameter value determination process records; and
- describe the nature and location of objective evidence which demonstrates that QA requirements have been effectively implemented in the QED process.

(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.

EPA expects any compliance application to:

- specify, for each set of measured or published data, the level of quality indicators required to be for its intended use in the WIPP compliance demonstration (see guidance for §194.22(d)). When practicable, it must be expressed in terms of the data quality indicators on the list at §194.22(c). Alternatively, it is acceptable to specify the degree of uncertainty that is tolerable in the data to attain the required degree of confidence in the

results of the compliance demonstration. EPA will consider this information in evaluating the effectiveness of alternative methods for QED.

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

EPA expects any compliance application to:

- describe the use of each data set in the demonstration of compliance (e.g., construction of the distribution of an input parameter, selection of a particular conceptual model, basis of assumptions about the waste inventory which are used in the PA, etc.).
- describe how each data set was qualified. A tabular format is suggested; and
- provide objective evidence to demonstrate that the intended use of each data set was considered during the qualification process.

DOE should provide documentation to demonstrate the traceability of data, from collection through data interpretation, to determination of parameter values and PA input parameters which are based upon measured or published data. EPA will consider this information in its evaluation of the effectiveness of alternative methodologies for QED.

(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.

EPA may request additional documentation to verify QA implementation in selected program areas. Also, additional QA audits or other activities may be conducted in specific topic areas, if EPA identifies an area that is not clearly addressed in the compliance application documentation.

EPA may conduct a field inspection of selected records to verify DOE's QA implementation. Records which are cited by DOE as objective evidence must be made available for review. If classified material is involved, EPA will provide reviewers with clearances.

In the event that DOE cannot demonstrate the effectiveness of its QA assessment and corrective action programs, EPA will conduct independent QA audits of activities.

§194.23 Models and computer codes.

(a) Any compliance application shall include:

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

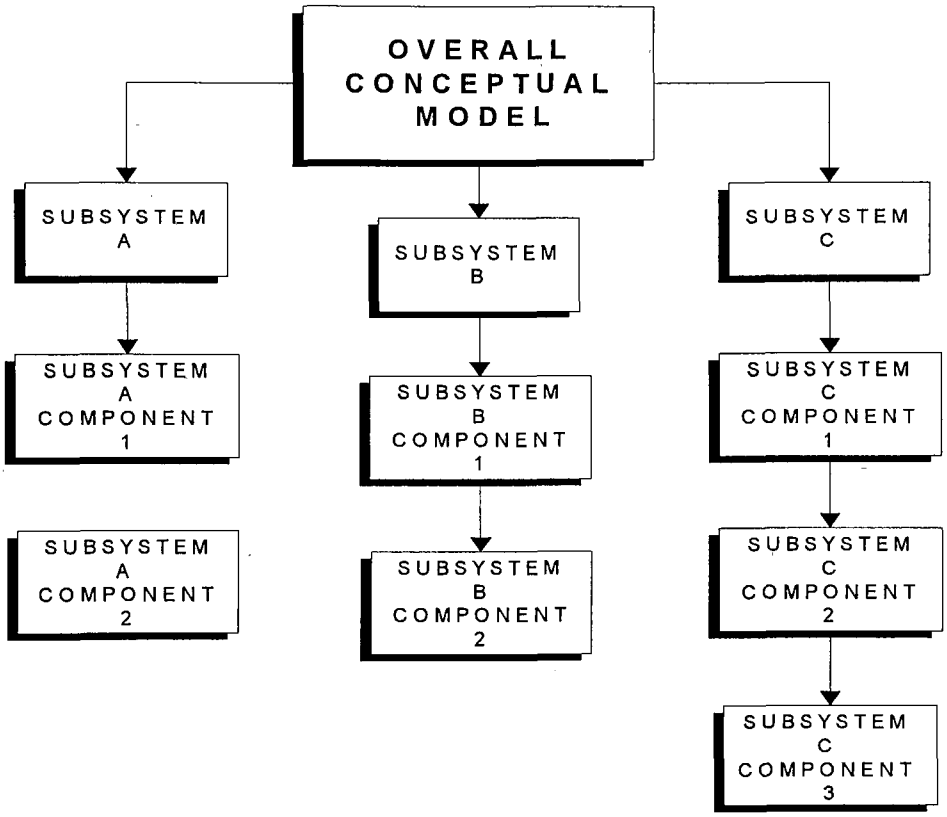
EPA expects any compliance application to include:

- a description of the conceptual models used; and
- a description of the scenario construction development.

Conceptual models provide a broad overview of the disposal system, including processes that may occur during the regulatory time frame at the WIPP, and they incorporate simplifying assumptions regarding the behavior of the disposal system. EPA expects that the documentation of conceptual models will discuss site and other characteristics, such as processes active on the site. The conceptual models used at WIPP should represent those characteristics and attributes of the WIPP disposal system that reasonably describe the disposal system's performance. EPA expects that conceptual models will be considered broadly, with conceptual models for the natural and engineered aspects of the WIPP and subsystem component models that describe in more detail each part of the total disposal system. See Figure 1. For example, the shaft seal subsystem consists of many individual components that make-up the total shaft seal system, and the process of gas generation consists of many individual components, such as the corrosion of metal drums and the interaction of cellulosic material and brine.

EPA expects any compliance application to use this broad conceptualization to identify the subsystem conceptual models. Both the overall site conceptual model and the subsystem conceptual models are expected to be peer reviewed. See §194.23(a)(3)(v) and §194.27.

FIGURE - 1 CONCEPTUAL MODEL



Each conceptual model selected should be discussed in sufficient detail to allow EPA to follow the logical development of each selected conceptual model, from characteristics learned following characterization and other activities that describe the disposal system and its subsystems, to the final conceptual models used.

As well as being a product, conceptual models also are an important part of the scenario construction (see §194.32). EPA expects scenario construction to be documented in sufficient detail to EPA to understand the relationship between the scenarios selected and why other scenarios were rejected.

(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.

EPA expects any compliance application to include:

- a description of plausible alternative conceptual models considered but not used; and
- an explanation of why these models were not used.

The description of rejected, plausible, alternative, conceptual models is not expected to be as comprehensive as that for the models actually used, but should adequately document why the models were not utilized.

Examples of plausible, alternative models are those used to describe ground water flow in the Culebra Dolomite (matrix, dual porosity, channeling) and flow in the Salado (clay, reconsolidation, Darcey flow).

(3) Documentation that:

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

EPA expects any compliance application to include a demonstration that:

- the conceptual models and scenarios reasonably represent the disposal system. See §194.32 and §194.54 for additional guidance.

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

EPA expects any compliance application to include:

- a discussion of the development of mathematical models based on the conceptual models.

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

EPA expects any compliance application to include:

- a discussion(s) of the numerical models developed from the mathematical models; and
- information which demonstrates the numerical models produce stable solutions.

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

EPA expects any compliance application to include a demonstration that:

- the computer models (codes) developed from numerical models are accurate;
- the computer codes are free of coding errors; and
- the computer codes produce stable solutions.

EPA recommends that the description of conceptual models show the connection between the system characteristics learned during site characterization and other activities, events, and processes that are represented in the conceptual models developed (see §194.32(e)). The information should also be reflected in the mathematical representation of conceptual models and numerical models, including initial and boundary conditions that are coded into the computer software that implements these models.

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

EPA expects any compliance application to include:

- a demonstration that the conceptual model(s) selected by DOE were peer reviewed and documented in accordance with §194.27.

EPA expects that peer review of conceptual models will evaluate the various subsystems of the site conceptual models. EPA expects each of these subsystems to be evaluated for its adequacy as a part of the conceptual model(s).

The fundamental question that peer review should answer is, "Do the final conceptual model(s) and the subsystem components used in the compliance application represent a reasonable approximation of the actual disposal system?" The results of the peer review process should be

documented according to the requirements of §194.27 to show clearly the subsystem components that were evaluated and the results of the peer review.

EPA expects any compliance application to include:

- documentation that demonstrates that the requirements of NUREG-1297, Section IV.5 have been fulfilled. Such documentation includes:
  - a listing of the reviewers;
  - acceptability requirements for each reviewer;
  - a discussion of the conceptual models peer reviewed;
  - individual statements by peer reviewers reflecting dissenting views;
  - an evaluation of data and information used to develop conceptual models, including attributes of the disposal system learned during site characterization activities, such as room creep closure or disturbed rock zone characteristics;
  - an evaluation of the validity of conceptual model assumptions;
  - an evaluation of alternate conceptual models;
  - an evaluation of the uncertainty in the conceptual models and a discussion of consequences if the conceptual model chosen is inappropriate for the site;
  - a statement indicating the adequacy of the conceptual models used for the disposal system;
  - a statement of the accuracy of the results based on the conceptual models employed; and
  - a discussion of the validity of the conclusions drawn based on the conceptual models.

(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.)

EPA expects any compliance application to include:

- a demonstration that the computer codes are documented in compliance with quality assurance requirements of ASME NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989 edition Section 6.

The development of computer codes should adhere to the quality assurance requirements specified in §194.22 and should be documented according to the requirements of ASME NQA-2a-1990 addenda, part 2.7, Section 6. EPA expects this documentation to include plan(s) for quality assurance software, software requirements documentation, software design and implementation documentation, software verification and validation documentation, and user documentation.

(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;

EPA expects any compliance application to include:

- a description of the theoretical background of each model; and
- a description of 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;

EPA expects any compliance application to include:

- a general description of each model;
- a description of limits of applicability of each model;
- detailed instructions for executing the computer codes;
- hardware and software requirements;
- input and output formats with explanations of each input and output variable and parameter;
- listings of input and output files from sample computer runs; and
- reports on code verification, benchmarking, validation, and quality assurance procedures.

EPA expects this documentation to present the general description of each model and describe any limiting assumptions or conditions placed on each model developed. These limitations, assumptions, or conditions should be presented with sufficient detail to allow the reviewer to understand their impact on the performance and accuracy of model results.

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

EPA expects any compliance application to include:

- detailed descriptions of the structure of computer codes; and
- a complete listing of the source codes.

EPA expects the documentation of computer codes to describe the structure of computer codes with sufficient detail to allow EPA to understand how software subroutines are linked and how the code structure operates to provide accurate solutions of the conceptual models. EPA recommends the usage of flowcharts to assist the reviewer's understanding of the linkage of code structure, code subroutines, and each computer code.

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

EPA expects any compliance application to include a:

- detailed listing of the code input parameters;
- listing of the input parameters that were sampled;
- description of the parameters, including units;
- listing of the model(s) and code(s) in which the parameter was used and the computer code (i.e., material and parameter) name(s) of the parameter that was sampled;
- discussion of any correlations between sampled parameters;
- discussion of the importance of the sampled parameter relative to final releases;
- discussion of how correlations between sampled parameters are addressed in performance assessments;
- description of data collection procedures;
- description of sources of data;
- description of data reduction and analysis;
- description of code input parameter development;
- discussion of the linkage between the input parameter information and the data used to develop the input information;
- listing of the sources of data used (e.g., experimentally derived, standard textbook values, and results of other computer codes); and
- data reduction/analysis used for performance assessment (PA) calculations, including an explanation of quality assurance activities. See §194.22 and §194.34(b) for additional guidance.

(5) Any necessary licenses; and

EPA expects any compliance application to include:

- any computer code licenses necessary to execute or use computer codes documented in any compliance application.

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

EPA expects any application to include:

- a discussion that explains how the effects of parameter correlation are incorporated;
- an explanation of the mathematical functions that describe these relationships; and
- a description of the potential impact on the sampling of uncertain parameters. See §194.34(b) for additional guidance.

EPA expects the effects of parameter correlation to be documented for both conceptual models and the formulation of computer codes. Sufficiently detailed instructions for the successful execution of the computer codes are expected to be provided with:

- a description of hardware and software requirements;
- complete input and output parameter formats, as part of the execution instructions;
- a complete listing and explanation of input and output files, that may be used for running sample computer runs;
- reports on code verification, benchmarking, and validation procedures; and
- evidence of adherence to the quality assurance procedures required in §194.22.

(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.

- EPA expects any compliance application to identify points of contact to facilitate this process.

§194.24 Waste Characterization.

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

EPA expects any compliance application to:

- provide a description (chemical, radiological, physical) of existing waste;
- list approximate quantities of waste components in each description; and

- provide similar descriptions for to-be-generated waste, to the extent practicable.

The physical description of waste may include: the types of items, articles, and materials present in the waste (including void space); a description of physical forms and initial liquids present in the category (both free and bound); and the types and properties of the containers to be used for disposal.

The chemical description may include: process chemicals likely to be present in the waste; all added components (neutralizers, stabilizers, solidifiers, etc.) including approximate total quantities; and the chemical properties of other items present that could impact performance.

The radiological description may include: the species and quantities of the radioisotopes present in the waste; information on the expected distribution of curie loading by container; the surface radiation levels of containers, including types of radiation; and the classification of the waste material, such as contact-handled or remote-handled transuranic waste.

The waste description may be rather lengthy, due to the heterogeneous nature of transuranic waste and the presence of numerous components that are present in quantity and have the potential to affect solubility, gas generation, criticality, etc. EPA expects that the waste description will be detailed enough to enable EPA to have confidence that no component that is present in transuranic waste and has significant potential to influence releases of radionuclides has been overlooked. It is expected that the description will be semi-quantitative, based upon both waste measurement data and process knowledge that are readily available at the waste generator sites and well documented, best-judgement estimates of what will be generated in the future.

(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.

EPA expects any compliance application to provide a waste characterization analysis that includes:

- a detailed description of the analysis performed;
- a list of waste characteristics retained as a result of the analysis;
- a list of waste components influencing these characteristics that are retained as a result of the analysis;
- identification of all waste related inputs into computer models;
- a list of all waste characteristics and components (tabular format suggested) that were considered and excluded, including the rationale for exclusion.

EPA expects that DOE will present rationales, logical arguments, applications of screening procedures, results of bounding or sensitivity analyses, etc., beginning from the description required by §194.24(a) and leading to the selection of the important or significant waste components that will be limited and controlled to assure compliance with the disposal regulations. The identification of significant waste characteristics is an important step in this process, and EPA expects to see a list of all potential processes considered that involve waste and disposal system interactions. It should be obvious that any measured or assumed waste property that is used either directly or indirectly in performance assessments should be present on the list of waste characteristics and components, and that any significant waste characteristic or component is addressed in performance assessments.

In accordance with §194.27, a description of the scope of peer review of the waste characterization analysis is expected to be provided, along with a discussion of reviews of technical issues, evaluations and recommendations as to the adequacy of the analysis, and follow-up actions. Also, objective evidence supporting decisions (peer review process documentation, conclusions, etc.) and the location of the evidence should be cited.

(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.

EPA expects any compliance application to:

- specify the limiting value of the waste component;
- note whether the limiting value is an upper or lower limiting value; and
- provide the associated uncertainty with each waste component limiting value.

EPA expects the waste related inputs to computer models identified pursuant to §194.24(b)(1) to be clearly related to the waste components identified under §194.24(b)(2). Further, this relationship should result in the specification of delimiting values for each of the waste

components (maxima or minima, as appropriate), so that there is a clear connection between the waste related code inputs used to model performance and the components of the waste inventory.

For example, actinide solubility is modeled using assumptions about various components of the inventory (chelating agents, buffers, acids, bases, salts, etc.) that may influence solubility. Fulfillment of this requirement for the waste characteristic of actinide solubility would involve the specification of the limiting value for solubility, with the range of the components affecting solubility that are expected to be part of the total inventory.

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.

EPA expects any compliance application to provide:

- a description of the plausible combinations of upper and lower limits of waste and their associated uncertainties;
- a rationale for the selection of these combinations;
- the results of a modeling run of the code, using values to input parameters corresponding to values of waste components fixed at the limiting values;
- a demonstration that the results of the analysis show that the disposal system complies with the numeric requirements under these conditions; and
- documentation that the combination of the selected limits results 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.

EPA expects any compliance application to specify:

- the method which is/will be used to quantify each waste component (e.g., process knowledge, non-destructive assay, non-destructive examination, visual inspection, statistical sampling and analysis, etc.);
- how each method will be used to quantify the amounts of listed waste components prior to disposal;
- the procedure followed and the scale to which the method is applied (e.g., individual waste container, batch, statistical sample of drums, etc.);
- the instrumentation used and its sensitivity; and
- the parameter measured and how it is related to the waste component in question.

EPA also expects any compliance application to:

- describe how the data obtained by each method meet or exceed any quality assurance indicators or data quality indicators that have been assumed or derived relative to waste related inputs to the modeling of compliance.

Discussions of quantification methods may be referenced in documentation of existing quality assurance or methods documentation.

EPA expects any compliance application to:

- demonstrate the ability to quantify each of the listed waste components (for purposes of control, at the precision and accuracy adequate to assure that limiting values will not be exceeded in the inventory shipped to WIPP). See additional requirements at §194.24(c)(5).

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

EPA expects any compliance application to:

- provide information, including standardized guidance or directives, training documents, etc., used in connection with control of the use of process knowledge;
- cite (and make available for field review) objective evidence substantiating the degree of implementation of quality assurance (such as audit reports, status of corrective actions, etc.) for each generator site that is approved to use process knowledge for characterization; and
- provide an implementation plan for application of quality assurance requirements to process knowledge at remaining sites.

Refer to 194.22(a)(2)(i). "Waste characterization assumptions" means the use of process knowledge qualitatively or quantitatively to characterize transuranic waste for purposes of demonstrating compliance with 40 CFR Part 191, or for purposes of meeting waste acceptance criteria prior to shipment of waste to WIPP. EPA expects that this activity will be performed under a quality assurance program as required in 194.22(a)(1).

(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.

EPA expects any compliance application to:

- describe the system for maintaining centralized control over the waste characterization activities and the authorization of grants to generator sites to characterize and ship waste to WIPP;
- describe the mechanism for maintaining chain of custody over waste and waste records from the point of characterization to the point of disposal;
- describe controls currently in place for receipt of waste at the WIPP, including: provisions for records and shipment surveys, acceptance and emplacement of waste, and provisions for dealing with non-conforming waste/waste records; and cite applicable procedures;
- describe the record keeping/accounting system for controlling limited waste components for verification of emplacement of waste; and
- provide the current WIPP Waste Acceptance Criteria (WIPPWAC) document and identify all (WIPPWAC) requirements or controls that are relevant to compliance with 40 CFR Part 194 (i.e., those criteria specifically related to performance). See §194.14(f).

EPA expects any evidence that substantiates compliance to be provided as part of any compliance application, or when cited, to be available for inspection. This includes evidence that substantiates that waste components for which inventory limits were set in accordance with §194.24(c) are monitored, controlled, and accounted for in a systematic and traceable manner in the waste proposed for disposal at the WIPP, including waste that undergoes treatment or repackaging, remote-handled and contact-handled wastes, and to-be-generated waste.

(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.

EPA expects any compliance application to:

- describe all Performance Demonstration Programs (PDPs) used to certify the measurements capability and comparability of waste generation sites;
- provide all governing documents for PDPs;
- cite (and make available for field review) objective evidence of the status of current implementation of PDPs (schedule of past and planned tests, reports on test rounds conducted, etc.);
- provide or cite (and make available for field review) standardized Methods Manuals, Sampling and Analysis Procedures manuals, etc., which are used to standardize waste characterization methodologies, if not provided under §194.24(c)(2).
- cite (and make available for field review) objective evidence (e.g., audit reports, certification reports, etc.) of the status of current implementation methods/procedures.

See §194.22(a)(2) for guidance regarding quality assurance for waste characterization activities. EPA expects to see documentation of quality assurance for waste characterization activities from the point of generation (for to-be-generated waste) to the point of emplacement and disposal at the WIPP.

(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.

EPA expects any compliance application to:

- provide a final plan for waste loading that addresses the emplacement of waste and implements any assumptions about the distribution of such waste that were used in the descriptions of performance assessments, and provide a cross-reference to waste distribution assumptions made in performance assessments; and
- address the requirement of §194.24(f) in the emplacement plan by describing how the planned distribution will be achieved, with specification of acceptance criteria for implementation and the controls that will be in place to assure proper implementation of the plan.

(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.

This requirement is applicable to all waste proposed for emplacement in the WIPP. Any compliance application should demonstrate how this requirement will be addressed in its response to §194.24(c)(4). This requirement should also be addressed in recertification applications.

(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.

See discussion at §194.24(d). If random placement is assumed in performance assessments, documentation should be submitted that addresses how it will be achieved in actual emplacement.

(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.

EPA expects any compliance application to:

- describe the inventory of waste proposed for disposal at the WIPP in terms of the units specified in the limitations of the LWA, in addition to limits of important waste components; and
- describe how these limitations will be assured through implementation of the required system of controls.

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

See §194.21.

§194.25 Future State Assumptions.

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

EPA expects any compliance application to:

- identify and explain future state assumptions in reference to performance assessments and compliance assessments and clearly cross-reference where appropriate;
- provide a list showing where future state assumptions have been applied;
- document the scenarios in which the exempted characteristics (hydrogeologic, geologic or climatic) may interact and influence the assumptions; and
- indicate the potential variations, if any, in the assumed characteristics at the time of initiation.

(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.

EPA expects any compliance application to include:

- the potential impact of increased precipitation on recharge location and capacity, hydraulic gradient and characteristics in the Culebra member of the Rustler Formation and the Dewey Lake Formation;
- likely uncertainties associated with analyses conducted in accordance with §194.25(b)(1); and
- other potential changes to hydrogeologic conditions.

EPA expects the effects of hydrogeologic conditions to be considered as part of the analyses in compliance and performance assessments. See §194.32, §194.34, §194.54 and §194.55.

(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.

EPA expects any compliance application to:

- list the assumptions on which the geologic conditions in the disposal system are projected to change;
- list the changes in geologic conditions that are projected to change in both disturbed and undisturbed cases over the 10,000-year regulatory period;
- discuss how conditions are projected to change;
- document uncertainties in the analyses; and
- address other potential changes to geologic conditions.

EPA expects the effects of geologic conditions to be considered as part of the analyses in compliance and performance assessments. See §194.32, §194.34, §194.54 and §194.55.

(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).

EPA expects any compliance application to contain:

- a list of potential scenarios that are likely to be affected by climatic changes--in the form of increased precipitation and evaporation--over the 10,000-year regulatory period;
- a description of how these scenarios are likely to be affected;
- a discussion of the potential impact of climatic changes on the geologic conditions identified in §194.25 (b)(2); and
- other potential changes to climatic conditions.

EPA expects the effects of climatic conditions to be considered as part of the analyses in compliance and performance assessments. See §194.32, §194.34, §194.54 and §194.55.

§194.26 Expert Judgment.

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

(b) Any compliance application shall:

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

EPA expects any compliance application to:

- identify those places in the application where the results of any expert judgment elicitation were incorporated;
- explain why data were not obtained, either by experimentation or from the results of previous experiments; and
- include an estimate of the time and level of effort that would have been required to obtain data experimentally, if applicable.

(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.

EPA expects any compliance application to include:

- documentation of all interviews with expert panel members conducted during the formal elicitation process;

- any written material distributed to expert panel members by a facilitator;
- copies of written summaries of the responses that are given to the other experts (applies to the Delphi method) in cases where the responses of the experts were elicited individually by a facilitator;
- documentation of any interactive sessions among the experts themselves; and
- documentation of all presentations of technical evidence.

(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.

As part of the documentation requested by these rules, EPA recommends that any application include a curriculum vitae of each expert panel member that lists, at a minimum:

- past and present professional or contractual affiliations;
- publications and abstracts;
- work and educational experience;
- a history of research grants and monetary awards from DOE, including documentation of any honoraria received; and,
- a chart of the expert's employing organization that demonstrates the expert's affiliation with any individuals within the organization who perform work relevant to the WIPP.

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

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

EPA expects any compliance application to include:

- documentation of the question presented to the experts, including a copy of any statement of the issue and any similar statement sent to the nominating and selection committees; and,

- a discussion of the relationship of the final result of the expert judgment process to the statement of the issue presented to the experts, as incorporated into the compliance application.

(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.

EPA expects the documentation of efforts made to solicit experts not employed by DOE or its contractors to include:

- a list of all non-DOE employees and non-DOE contractors who were sent letters of nomination or were otherwise solicited for participation on the panel; and
- documentation of all responses to letters of solicitation by those potential participants.

(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.

EPA expects any compliance application to include:

- documentation and descriptions of the methods used to solicit participation of the public, including outside groups and individuals; and
- copies of any publicly available notices that solicited presentations from the public.

§194.27 Peer review.

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

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

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

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

For guidance on the technical scope of peer reviews for §194.27(a)(1-3), see §194.23, §194.24, and §194.44.

Documentation of peer reviews should be presented in a consistent manner. EPA recommends that the documentation of peer reviews be compiled in a chapter separate from the chapters addressing conceptual models, waste characterization, and engineered barriers, in accordance with §194.27(a). Decisions involving peer review should be clearly indicated in the topical chapters and cross-referenced with the peer review reports as appropriate.

Peer review of the evaluation of engineered barriers should incorporate all alternatives considered, whether DOE has selected or rejected them for use at the WIPP Peer review should consider alternate engineered barriers rejected in the manner described in §194.44(c)(2).

(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.)

As defined by NUREG-1297, a "peer review" is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work, performed by peers who are independent of the work being reviewed. Peer review reports should clearly demonstrate:

- the structure of the peer review group for any given issue, including how relevant technical disciplines were represented;
- the technical qualifications of peer reviewers to review a given issue;
- the independence of the peer reviewers from the original work, including the rationale why someone with greater independence was not selected, if necessary;
- the process of the peer review, including how a given issue was presented to peer reviewers;
- the conclusions the peer reviewers reached, including dissenting views if they exist; and
- how DOE incorporated those conclusions.

(c) Any compliance application shall:

(1) Include information that demonstrates that peer review processes required in paragraph (a), 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

In order to determine substantial equivalence to NUREG-1297, it is particularly important that EPA receive documentation of the technical qualifications and independence of the peer reviewers.

(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.

EPA recommends that peer reviews conducted prior to the implementation 40 CFR Part 194, as well as any peer reviews in addition to those required in §194.27(a), be documented in a manner similar to that described in the guidance for §194.27(b). EPA does not consider an internal technical review to be equivalent to a peer review.

§194. 31 Application of release limits.

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

EPA expects any compliance application to provide:

- estimated curies of each radionuclide in the disposal system at the time of disposal;
- a description of the process used to determine the activity of each radionuclide (see §194.24);
- the current estimate of the activity (in curies) of each radionuclide;
- the estimated upper limit of the activity (in curies) of each radionuclide (see § 194.24);
- a description of the procedure used to estimate the units of waste proposed for disposal (according to the transuranic waste described in Note 1(e) of Appendix A to 40 CFR Part 191);
- example calculations of release limits; and
- identification of the relative contribution of each radionuclide to the normalized release.

§194.32 Scope of performance assessments.

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

EPA recognizes that performance assessments and/or other modeling may indicate that some items are not necessary to demonstrate compliance. In those instances, any compliance application should include justification why the particular items are not important to a reasonable expectation of compliance. See §194.32(e)(1) for additional guidance.

(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.

EPA expects any compliance application to include a discussion of:

- the method used to implement or incorporate the probability of mining in each century;
- how the mining rate effects are incorporated in performance assessments, including example calculations;
- how institutional control credit(s) were applied in the performance assessments (see §194.41 and §194.43), including the time period that credit for institutional controls is assumed in the performance assessments;
- the change in random sampling of hydraulic conductivity (using a probability distribution with a range of 1 to 1000);
- how mining is incorporated into performance assessments;
- evidence that the randomly sampled change in hydraulic conductivity was multiplied equally in all projected mined-out areas;
- the identity and extent of minable mineral resources currently extracted in the Delaware Basin; and
- the identity of minable, mineral resources in the controlled area, and the extent to which the resources are similar in quality and type to those resources currently extracted from the Delaware Basin.

EPA also expects any compliance application to include:

- graphics to illustrate the expected extent of the resources used in the performance assessment.

No distribution need be developed to determine the century in which mining occurs. Instead, the Department should employ a scheme that examines each century separately and determines probabilistically whether mining occurs within that century based on a likelihood of 1 in 100. One determination or "iteration" would be conducted for each century, starting with the first century after the time of disposal and proceeding chronologically until making a positive determination that mining has occurred. For example, within each iteration, an integer from 1 to 100 would be selected, *at random*, with each integer equally likely to be chosen. If the integer "1" (one) is randomly selected, then mining is assumed to occur in the century corresponding to that iteration, with the first iteration corresponding to the first century, the second iteration corresponding to the second century and so forth. If after the end of 100 iterations, the integer "1" has not been selected, then mining should be assumed not to occur within the particular sequence or combination of processes and events under consideration.

As an example, the first iteration might result in the integer "33" being selected, signifying that mining does *not* occur in the first century. Proceeding to the second iteration, the integer "15" is selected, signifying that mining does not occur in the second century. In the third iteration, the integer "1" is selected, signifying that mining occurs at the start of the third century after disposal. This set of iterations would therefore be complete. A new set of iterations would be conducted when calculating the consequences of a different sequence or combination of processes and events.

The probability of 1 in 100 is subject to modification by passive institutional controls and active institutional controls in the first few hundred years after the time of disposal. If active institutional controls and passive institutional controls were predicted collectively to reduce the likelihood of mining by a factor of 3 in the first century, then this condition should be incorporated into the appropriate iteration. For example, the probability of mining in the first century would be adjusted to be 1 in 300 to reflect this factor of 3. Therefore, when conducting the iteration corresponding to the first century, a random integer would be selected from 1 to 300, with each integer being equally likely. If the outcome is the integer "1" (one), then mining should be assumed to occur at the start of the first century after disposal. Otherwise, the second iteration should be performed using the appropriate probability, continuing further iterations as necessary until either a "1" is generated or 100 iterations have been performed.

EPA recommends the discussion of mining assessments be limited to changes of 1 to 1000 times the hydraulic conductivity in the Culebra Dolomite. EPA recognizes that other numerical changes to the hydraulic conductivity values may be more appropriate for use in representing the effects of mining, and that some parameter other than hydraulic conductivity might be demonstrated to incorporate, equally or better, the potential effects of mining in performance assessments. DOE may elect to use an additional parameter, but any compliance application should demonstrate that the use of this other parameter is as or more appropriate than hydraulic conductivity in reflecting the potential effects of mining on the disposal system.

If an approach different than the hydraulic conductivity is developed and selected by DOE, then EPA expects that the different approach (i.e., conceptual model) will be peer reviewed and documented according to §194.27.

(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.

EPA expects any compliance application to:

- provide an analysis of the effects of any activities on the disposal system;
- identify the activities that occur, or are expected to occur, in the vicinity of WIPP soon after disposal, including the extraction of mineral resources similar in quality and type to those currently extracted;
- discuss the potential effects of such activities identified to occur, or expected to occur, in the vicinity of WIPP soon after disposal;
- discuss potential effects of existing boreholes;
- discuss the process by which the expected lives of the oil and gas fields in existing leases were estimated; and
- identify existing leases that are being developed, or that can be reasonably expected to be developed in the near future, in the vicinity of the controlled area.

EPA recommends that the terms "near future" and "soon after disposal" for oil and gas drilling be considered to consist of the expected lives of the oil and gas fields in existing leases that can be reasonably expected to be developed in the vicinity of the WIPP.

For mining, the terms "near future" and "soon after disposal" should be applied to the estimated lives of existing mines and plans for new mines in the vicinity of WIPP. EPA recommends that DOE use minable reserves in estimating mine lives and the extent of potential mining. When establishing the rate of growth for mines, DOE should consider both the historical growth of mines and the potential for new mines that may be developed in the vicinity of WIPP.

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

EPA expects any compliance application to:

- list the processes, events or sequences of processes and events that were not included in performance assessment results; and
- discuss the reasons why processes, events or sequences of processes and events were not included in performance assessment results.

(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;

See §194.25 and §194.14.

EPA expects any compliance application to:

- identify any human-initiated processes and events that may occur during the regulatory time frame;
- identify potential natural processes and events that may occur during the regulatory time frame and how they may affect the disposal system;
- identify the sequences and combinations of potential processes and events that may occur during the regulatory time frame and may affect the disposal system;
- discuss how the events and processes were identified (e.g., through the use of a comprehensive list with a derivation of the list);
- discuss the screening criteria and the procedure(s) used to include and eliminate processes and events;
- discuss the application of the screening criteria to the processes and events that may occur during the regulatory time frame and may affect the disposal system;
- discuss the effects of potential changes to geologic conditions, including, but not limited to:
    - dissolution;
    - near surface geomorphic processes; and
    - related subsidence in the geologic units of the disposal system;
- evaluate and discuss near future fluid injection activities and other existing boreholes as part of the performance assessment;
- identify existing leases in the vicinity of the disposal system with boreholes that are being used for fluid injection activities;
- identify existing leases in the vicinity of the disposal system that can be reasonably expected to be developed (e.g., for fluid injection activities) in the near future; and
- link site, waste, laboratory and other characterization information to the potential processes, events or sequences and combinations of processes and events, and the conceptual models. It is expected such linkage will be accomplished through appropriate discussions in the text and the use of cross-references.

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

EPA expects any compliance application to include the performance assessment evaluations of:

- mining;
- deep drilling; and
- shallow drilling.

EPA expects any compliance application to:

- list and discuss the events and processes and the combinations of potential processes, events or sequences and combinations of processes and events, that could have an effect

on radionuclide transport to the accessible environment and that are included in the performance assessment;

- discuss the effect of the sequence of processes and events on the disposal system on the performance assessment calculations; for example, the relative timing of mining and a deep drilling event that intersects the waste may affect the amount of radionuclides that may reach the accessible environment during the regulatory time frame;
- specify the models and codes in which the individual potential processes, events or sequences and combinations of processes and events are included. As a hypothetical example: Gas generation is a process associated with the waste that could affect room closure and releases from a drilling event: Gas generation is discussed in the conceptual models found in chapter x.x.x and the computer models discussed in chapter x.x.x;
- indicate that events and processes incorporated into the performance assessment are reflected in the appropriate portions of the application; for example, incorporation of the process of gas generation in the waste (if it occurs) into performance assessment modeling should be identified and discussed in any compliance assessment and cross-referenced appropriately;
- provide documentation that the conceptual models used in performance assessments were peer reviewed (see §194.23 and §194.27);
- discuss the final combinations of events and processes in the context of the final conceptual scenarios used in performance assessments (see §194.23); and
- discuss how the retained potential processes, events or sequences and combinations of processes and events were constructed into the scenarios used in performance assessments.

It is expected that the general classes of scenarios (e.g., undisturbed processes, events, or sequences and combinations of processes and events; drilling events; mining events; and the combination of drilling and mining events) used in performance assessments will be discussed separately. For disturbed scenarios constructed for use in performance assessments, it is expected that the discussion will refer to the undisturbed scenarios, and focus on those elements (e.g., processes and events) that differ from the undisturbed scenarios.

(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.

EPA expects any compliance application to provide:

- a list of events and processes or sequences and combinations of processes and events that may occur during the regulatory time frame;
- the rationale for each process and event or sequences and combinations of processes and events screened out; and
- evidence that the screening process was quality assured for the individual potential processes, events, or sequences and combinations of processes and events.

§194.33 Consideration of drilling events in performance assessments.

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

EPA expects any compliance application to:

- discuss how deep drilling is conducted for each resource;
- discuss how shallow drilling is conducted for each resource; and
- demonstrate that boreholes drilled after closure of the disposal system have been evaluated for their effect on the properties of the disposal system, and show the manner in which they were evaluated.

(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.*

EPA expects any compliance application to:

- demonstrate that exploratory and development wells were included in the analysis of inadvertent and intermittent intrusion by drilling for resources and the manner in which they were evaluated.

(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.*

EPA expects any compliance application to:

- provide documentation that drilling events were assumed to occur in the Delaware Basin at random intervals in time and space during the regulatory time frame; and
- discuss the method and assumptions (e.g., Poisson process) and their application to the drilling issue.

(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.*

EPA expects any compliance application to:

- identify the resources for which deep drilling is used;
- estimate the number of deep drilling events for each resource that has occurred over the past 100 years;
- discuss the methodology used to calculate the frequency of the deep drilling rate; and
- identify the sources of information used to estimate the number of deep drilling events.

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

EPA expects any compliance application to:

- identify the total rate of deep drilling.

(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.*

EPA expects any compliance application to:

- identify the resources for which shallow drilling is used;
- estimate the number of shallow drilling events for each resource that has occurred over the past 100 years;
- discuss the methodology used to calculate the frequency of the shallow drilling rate; and
- identify the sources of information used to estimate the number of shallow drilling events.

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

EPA expects any compliance application to:

- identify the total rate of shallow drilling.

(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.*

If DOE, in its consideration of the historical rate of shallow drilling, considers only resources of similar type and quality to those in the controlled area, any compliance application should:

- include a discussion of resources in the controlled area and their type and quality;
- discuss the use of resources of similar type and quality in the Delaware Basin; and

- list the sources used to estimate the type and quality of resources and the nature of the use of similar resources in the Delaware Basin.

If DOE does not limit consideration of shallow drilling to only resources of similar type and quality to those in the controlled area, compliance applications need not address the quality of the resources 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;*

EPA expects any compliance application to identify:

- current drilling practices in the Delaware Basin;
- the current drilling practices that affect performance assessments;
- types and amounts of drilling fluids;
- borehole depths typically used;
- borehole diameters typically used;
- seals typically used;
- the fraction of boreholes sealed by humans today; and
- the source(s) of the above information.

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

EPA expects any compliance application to:

- identify the processes that are expected to affect boreholes over time;
- discuss the portions of the borehole over which particular processes are expected to act. For example, creeping of the salt is one process that could affect a borehole in the salt section, while other processes may affect other portions of a borehole;
- discuss the effects that natural degradation are expected to have on the capability of boreholes to transmit fluids; and
- identify the models in which borehole degradation is addressed.

(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.*

EPA expects that the discussion of drilling will be in its own section in any compliance application. This section in the application should cross-reference the specific parts of the

application that use this information or have closely related information, such as the discussion that addresses the requirements for models and codes in §194.23.

§194.34 Results of performance assessments.

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

EPA expects any compliance application to:

- demonstrate that the results of performance assessments were assembled into CCDFs; and
- demonstrate that the CCDFs represent the probability of exceeding various levels of cumulative release caused by all significant processes and events; and
- demonstrate that all significant processes and events were incorporated into the CCDFs that are presented.

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

For additional guidance, see §194.23 and §194.55.

EPA expects any compliance application to:

- discuss the sources used and the methods by which each of the probability distributions were developed (e.g., experimental data, field data, etc.);
- identify the functional form of the probability distribution (e.g., lognormal, uniform) used for the sampled parameters;
- describe the statistics of each probability distribution, including the values for the lower and upper ranges, mean (geometric mean when appropriate), and median;
- identify the importance of the sampled parameter relative to final releases; and
- demonstrate that the data used to develop the input parameter probability distribution were qualified and controlled in accordance with §194.22.

(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.*

EPA expects any compliance application to:

- discuss the computational techniques used for random sampling; and
- demonstrate that sampling occurred across the entire range of each parameter.

(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.*

EPA expects any compliance application to:

- identify the number of CCDFs generated;
- discuss how DOE determined the number of CCDFs to be generated;
- list the probabilities of exceeding cumulative releases of 1 and 10 for each CCDF generated; and
- demonstrate that the maximum CCDFs generated, at cumulative releases of 1 and 10, exceeds the 99th percentile with at least a 0.95 probability, with a discussion that includes examples of calculations.

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

EPA expects any compliance application to:

- display the full range of CCDFs generated;
- present the appropriate information so that EPA may confirm the DOE's performance assessment analyses, including steps used to arrive at the result and the data values that are represented by the CCDFs; and
- include descriptive statistics such as the range, mean, median, etc., for the range of CCDFs at cumulative releases of 1 and 10.

(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.

EPA expects any compliance application to:

- present the appropriate information, including steps used to arrive at the result and the data used in the analysis, so that EPA can confirm that the mean of the population of CCDFs meets the containment requirements of 40 CFR 191.13 with a 95 percent level of statistical confidence;
- identify the mean of the sample of CCDFs generated for the cumulative releases at 1 and 10 as specified in 40 CFR 191.13; and
- identify the values of the CCDFs associated with a 95 percent level of statistical confidence of the mean of the population for the cumulative releases at 1 and 10 as specified in 40 CFR 191.13.

§194.41 Active Institutional Controls.

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

EPA expects any compliance application to include:

- descriptions of active controls;
- the location of active controls;
- the period of time active controls are proposed to remain active;
- assumptions pertaining to the effectiveness of active controls (in terms of preventing or reducing radionuclide releases);
- the justification for assumed credit; and
- the methodology for determining assumed credit.

A graphic representation may be used to illustrate the assumed effectiveness of active controls over time.

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

Since EPA may allow up to 100 years credit for active institutional controls, EPA expects that DOE's implementation plan for such controls will clearly articulate why credit is warranted for the proposed time frame. For example, if DOE assumes the full 100 years of credit, the information provided in any compliance application relative to active institutional controls is expected to support that assumption.

§194.42 Monitoring.

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

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

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

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

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

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

(6) Gas quantity and composition; and

(7) Temperature distribution.

EPA expects any compliance application to:

- describe the methodology of the analysis of the effects of disposal system parameters on the containment of waste;
- describe the results of the above analysis of disposal system parameters on containment of waste;
- explain why DOE has selected or rejected characteristics for pre- and post-closure monitoring;
- provide a complete list of parameters evaluated in the analysis, including at a minimum:
  - properties of backfilled material;
  - stress and extent of deformation;
  - initiation or displacement of major brittle deformation features;
  - ground water flow and other effects of human intrusion;
  - brine quality, flux, composition, and spacial distribution;
  - gas quantity and composition; and
  - 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.

EPA expects any compliance application to include:

- documentation that substantiates decisions not to monitor a particular disposal system parameter analyzed pursuant to §194.42(a).

(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.

EPA expects any compliance application to include:

- a description of disposal system parameters identified to be monitored during pre-closure;
- an explanation of parameters considered significant and documentation that substantiates any decision not to monitor a disposal system parameter analyzed pursuant to §194.2(a) because it is not deemed to be significant;
- an explanation of why monitoring is not practicable for parameters found to be significant, but not chosen for monitoring;
- a discussion and explanation of when pre-closure monitoring is to begin; and
- a discussion and explanation of when pre-closure monitoring will end.

Results of pre-closure monitoring could be used to verify inputs to the performance assessment models that predict disposal system behavior over time. Any monitoring to be conducted should be detailed in a monitoring plan in accordance with §194.42(e). For example, panel rooms may be instrumented during the pre-closure phase to measure parameters that affect both the long-term performance of the disposal system and the predictions made by performance assessments.

(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.

EPA expects any compliance application to:

- include an explanation when post-closure monitoring will commence;
- include a description of the post-closure monitoring to be conducted;
- document how the monitoring will be effective to detect substantial and detrimental deviations from expected performance;
- identify the monitoring to be conducted pursuant to applicable hazardous waste regulations for 40 CFR Parts 264, 265, 268 and 270;
- describe how post-closure monitoring is complementary to applicable federal hazardous waste regulations at parts 264, 265, 268, and 270 of this chapter; and
- explain how the monitoring techniques 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.

EPA expects any compliance application to include:

- a pre-closure plan that identifies:
  - a description of the monitoring plan required before waste is emplaced and any monitoring to be performed after panel rooms are filled during pre-closure operations;
  - the parameters to be monitored;
  - how the baseline for each parameter will be determined;
  - how monitoring results of each parameter will be used to evaluate the performance of the disposal system;
  - approximately when monitoring for each parameter is planned to begin; and
  - how long each parameter will be monitored.

- a post-closure plan that identifies:
  - the parameters to be monitored;
  - how the baseline for each parameter will be determined;
  - how monitoring results of each parameter will be used to evaluate the performance of the disposal system;
  - approximately when monitoring for each parameter is planned to begin; and
  - how long each parameter will be monitored.

EPA expects the discussion of the monitoring plan to include descriptions of:

- the environmental media (i.e., air, soil, groundwater, surface water, sediment, subsurface gas), biota (i.e., vegetation and/or small mammals), or microbiota to be monitored; and
- the proposed monitoring network (sampling locations) and a justification of its design.

The design of the monitoring network should take into account potential spatial and temporal changes in the disposal system and any releases that may affect long-term performance of the disposal system. Spatially, the plan should allow for sufficient samples to be collected to define adequately the extent of any relevant release and account for changes in the dimensions of the disposal system over time. The plan should consider the potential for spreading of a relevant release plume with time and for concentration variations due to physical and chemical processes, such as retardation and degradation.

EPA expects any compliance application to identify:

- background sampling stations and their locations;
- sampling method and equipment; and
- the type and number of samples to be collected.

The plan should specify whether the samples collected will be grab, composite, or integrated. A grab sample is an individual sample taken at a specific location at a specific time. A composite sample is a combination of more than one sample collected at various sampling locations and/or different times. An integrated sample is a continuously collected single sample taken to describe a population in which one or more parameters vary with time or space.

EPA expects any compliance application to identify:

- sample preservation and handling;
- chain of custody;
- analytical methods;
- detection limits;
- the monitoring schedule, including the proposed initiation date and the frequency with which monitoring will be conducted (schedule of the occurrence of monitoring events); and
- data evaluation and presentation methods (statistics).

All monitoring should follow properly documented and implemented Quality Assurance and Quality Control procedures, as described in §194.22. Monitoring is subject to inspection by EPA, in accordance with §194.21.

§194.43 Passive Institutional Controls.

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

EPA expects any compliance application to include:

- detailed descriptions of passive controls; and
- locations of passive controls.

EPA expects any compliance application will describe how the Passive Institutional Controls (PICs) planned for implementation will describe the disposal system's:

- location;
- design; and
- contents.

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;

EPA expects any compliance application to include:

- a time line for implementation/construction and emplacement of markers; and
- a description of the markers (e.g., size, materials, etc.).

(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.

EPA expects any compliance application to identify the:

- location of archives -- of local, State, and Federal governments (to include Native American governments as well) -- in which records will be placed;
- location of land record systems of local, State and Federal governments in which records will be placed;
- location of international archives in which records will be placed;
- time line for implementation and emplacement of records; and
- the practices employed by each archive and repository for maintaining records and making them accessible to the public.

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.

EPA expects any compliance application to describe how records will identify:

- the location of the controlled area and the disposal system;
- the design of the disposal system, as identified in accordance with § 194.14(b);
- nature and hazard of the waste, as identified in accordance with § 194.24(a);
- geologic data;
- geochemical data;
- hydrologic data;
- other site data;
- analyses relating to backfill of excavated areas;
- analyses relating to shaft sealing;
- analyses relating to waste interaction with the disposal system; and
- other tests, experiments, or analyses pertinent to the containment of waste in the disposal system.

EPA believes that such information could reasonably be identified in archives by incorporating relevant parts of compliance applications into records planned for archiving. DOE may choose simply to state the location of the information contained in §194.43(a)(2)(iv) and (v) above; however, EPA recommends that actual location(s) be easily accessible to future "individuals."

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

EPA expects any compliance application to identify and describe:

- other practicable passive controls proposed for use at the WIPP.

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

EPA expects any compliance application to include:

- the period of time passive controls are expected to endure and be understood;
- the basis for estimating the time period; and
- any assumptions pertaining to the effectiveness of passive controls.

(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.

EPA may allow up to approximately 700 years of credit for passive institutional controls in performance assessments. If DOE proposes a credit, EPA expects that DOE's implementation plan for such controls will clearly articulate why credit is warranted for the proposed time frame. For example, if DOE assumes credit for as long as 700 years after disposal, the information provided in the compliance application relative to PICs is expected to support that assumption. Under no circumstance may passive controls be assumed to eliminate human intrusion entirely.

If DOE assumes credit for passive controls, EPA expects any compliance application to identify:

- the estimated effectiveness of passive controls over time, in terms of reducing the likelihood of potential human intrusion; for example, a graphic representation illustrating how credit will diminish over time;
- the methodology employed to estimate the effectiveness of passive controls; and
- justification for the proposed credit, based on how well the controls are expected to endure and be understood.

If any credit is assumed for passive controls, credit should begin at the time of disposal (i.e., when the shafts of the disposal system are backfilled and sealed), although some of the credit may not be needed in light of credit for active institutional controls.

EPA will make its determination regarding credit for passive controls based on the two aspects of PICs identified in §194.43(c): that they are expected to endure for the proposed period, and that they are expected to be understood by potential intruders for the proposed period. EPA expects that DOE's justification of the proposed credit will clearly address these two aspects. The first aspect, the period of time for which the markers "are expected to endure," is likely to require a deterministic analysis, based on scientific data, that takes into account assumptions like those outlined in the CAG for §194.43(a)(1).

The second aspect, the period of time for which the markers will "be understood by potential intruders," is likely to require qualitative analysis and discussion. EPA expects that DOE will establish a framework of assumptions for PICs that is a prudent extrapolation of the future state assumptions established in §194.25. For example, §194.25 may allow DOE to assume, *for the purpose of developing the performance assessment models*, that particular governmental regulations will remain in force. Such an assumption would be inappropriate, however, in the justification of credit for PICs. Instead, DOE may choose to assume that while some form of governmental regulation exists, the exact form and content of any regulation cannot be identified with certainty. In other words, DOE may not a priori rely on the future states assumption in this context. Rather, DOE must demonstrate--based on the particular measures at issue and documented, reasoned justification--why any assumptions made in these circumstances are sound.

EPA believes that there are certain societal "common denominators," such as the existence of some form of government and some level of regulatory control over the exploration for and development of resources, that could be considered in the discussion of PICs. These common denominators are patterns of human behavior that may be detected throughout history and around the world. The degree to which the PICs implemented at the WIPP rely on common denominators will determine the degree to which the PICs are effective at being understood by potential intruders in the future. Other examples of common denominators (but by no means a comprehensive list) are: the ability of pictures to convey meaning, the curiosity of humans, the expectation that some people will avoid, ignore or be ignorant of governmental controls, the use of the written word to transmit information and concepts, and story-telling or the generational "passing down" of history.

Explicit application of future state assumptions to passive controls -- i.e., the assumption that all present-day societal and demographic factors will remain constant -- will not be considered by EPA to justify adequately the design of PICs or the estimation of credit.

§194.44 Engineered Barriers.

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

EPA expects (a) barrier(s) to be selected that will address uncertainties identified in the evaluation of disposal system performance and will reduce those uncertainties. Examples of key disposal system parameters that could be addressed by the incorporation of an engineered barrier are the shear strength and mobility of the waste. The desired reduction in uncertainty could be accomplished by including a barrier -- with predictable, tested, and demonstrated performance characteristics -- that may be emplaced in a manner consistent with the desired performance. The development of engineered barriers related to input parameters for use in the performance assessment modeling codes must be documented in accordance with the requirements established in §194.23(c)(4).

EPA expects any compliance application to:

- specify the method for incorporating the engineered barriers;
- provide a qualitative evaluation and justification of the barrier's ability to prevent or substantially delay the movement of water or radionuclides toward the accessible environment;
- clearly explain how inclusion of the selected engineered barrier(s) contributes to system performance; and
- qualitatively discuss the reduction in uncertainty associated with engineered barrier performance in relation to total system performance.

(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.

EPA expects any compliance application to include documentation of an evaluation of benefits and detriments of the following barriers:

- cementation;
- shredding;
- supercompaction;
- incineration;
- vitrification;
- improved waste canisters;
- grout and bentonite backfill;
- melting of metals;
- alternative configurations of waste placements in the disposal system;
- alternative disposal system dimensions; and
- other barriers or combinations of barriers.

EPA expects the evaluation of engineered barriers to contain the following elements:

- a list of all barriers to be considered;
- clearly defined screening criteria;
- a justification for "screening out" any barriers;
- a list of all barriers to be evaluated;
- an evaluation against the factors listed in §194.44(c)(1);
- a justification for not completing the full evaluation of any barrier; and
- a final, comparable benefit/detriment evaluation in matrix or tabular form.

EPA expects the evaluation of engineered barriers to have a broad scope that encompasses all current waste isolation technologies suitable for use at the WIPP, as well as any that are under development, and: (1) could reasonably be expected to reach fruition during the operating life of the WIPP facility; (2) have enough data available to allow comparison with current methods; and (3) are developed to the point that the other system factors listed in §194.44(c) can be evaluated. EPA expects barriers to be evaluated consistently so that they may be compared.

In performing the peer review of the evaluation of engineered barriers described in §194.44(b), as required in §194.27(a), the following issues should be included in the technical scope of the review: (1) the adequacy of the scope of alternatives considered; (2) the adequacy and

appropriate application of the screening criteria; (3) the factors against which the barriers were evaluated meet the regulatory requirements and are sufficient to allow evaluation of the barriers; (4) the barriers were adequately evaluated; and (5) in the selection of a barrier and subsequent parameter development, that the parameters were appropriately developed to support PA (this portion may be covered under the peer review of models and codes (see §194.23(a)(3)(v)), as required by §194.27(a).

(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.

EPA expects any compliance application to:

- demonstrate that all engineered barriers identified in accordance with §194.44(b) were considered based on the following factors:
  - the ability of the engineered barrier to prevent or substantially delay the movement of water or waste toward the accessible environment;
  - the impact on worker exposure to radiation both during and after incorporation of engineered barriers;
  - the increased ease or difficulty of 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;
  - public comments requesting specific engineered barriers;
  - the increased or reduced total system costs;

- 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); and
- the effects on mitigating the consequences of human intrusion;

or:

- justify for each barrier why consideration of such factors was not "practicable;"

or:

- justify why a barrier was rejected prior to completion of the consideration of all nine factors identified in §194.44(c)(2);

or

- use a combination.

(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.

EPA expects a clear distinction between these four types of waste:

- existing waste already packaged;
- existing waste not yet packaged;
- existing waste in need of re-packaging; and
- to-be-generated waste.

EPA expects any compliance application to:

- clearly delineate the effects of the four waste groupings ("existing waste already packaged, existing waste not yet packaged, existing waste in need of re-packaging, and to-be-generated waste") on the evaluation of benefits and detriments and reflect the effects in the barrier(s) selected.

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

EPA recognizes that some engineered barriers (i.e., shredding) may have little benefit alone, but may be greatly enhanced when performed in combination with other options (e.g., cementation).

EPA expects DOE to carry out evaluations of combinations of engineered barriers that are the most beneficial regarding the factors listed in §194.44(c)(1) above.

§194.45 Consideration of the presence of resources.

Any compliance applications 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.

EPA expects any compliance application to:

- document that the effects of mining and drilling over the regulatory time frame have been incorporated into performance assessments according to the requirements of §194.32, §194.33, and §194.43;
- document that performance assessments incorporate the effects on the disposal system of any activities that occur in the vicinity of the disposal system or are expected to occur in the vicinity of the disposal system soon after disposal, according to the requirements of §194.32; and
- document whether the results of performance assessments demonstrate compliance with the containment requirements of §191.13.

EPA expects that detailed information on these and other related topics -- such as descriptions of the conceptual or computer models used for human intrusion in performance assessments, maps showing the locations of various resources, and data bases of drilling information -- will be presented and discussed in other sections of any compliance application. It is acceptable not to reiterate such information contained in other sections of the compliance application *provided that* clear cross-references are provided so that EPA may confirm that the analysis has been accomplished as described in the bullets above. At a minimum, any compliance application should address this assurance requirement by clearly stating whether the above conditions have been met, and by providing specific references to where detailed information on incorporation of human intrusion into performance assessments can be found elsewhere in the application.

§194.46 Removal of Waste.

Any compliance application shall include documentation which demonstrates that removal of waste 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.

EPA expects the required analysis to include:

- a sequence of procedures or steps which would need to be accomplished in order for waste to be removed from the disposal system after closure;
- a discussion of how the sequence described above could be implemented, including descriptions of how currently available equipment and technologies could be utilized; and
- an estimate of how long after disposal it would be technologically feasible to remove the waste, based on the disposal system design and closure, and using the system and equipment described in the application.

EPA expects that further information related to removal of waste -- such as descriptions of the design of the disposal system, use of engineered barriers, and conceptual or computer models used to predict performance of closure seals -- will be discussed in greater detail in other sections of any compliance application (e.g., §194.14, §194.23, §194.44). EPA expects such information to be clearly cited (where used as the basis for stating a conclusion) and cross-referenced.

§194.51 Consideration of protected individual.

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

For guidance regarding documentation of compliance assessments, see §194.54 and §194.55.

EPA expects that, in determining the location of the maximally exposed individual, compliance assessments will:

- present information on doses from individual pathways; and
- show the sum of the doses from all pathways.

The location of the maximally exposed individual would be the location with the largest dose from all pathways. EPA expects any compliance application to:

- identify this location and the position of the individual relative to the controlled area and the disposal system, using map coordinates.

For the air pathway, the location of the maximally exposed individual may be within the controlled area. However, the location of the protected individual is restricted to outside the controlled area for the ground water pathway. For additional guidance on consideration of exposure pathway, see §194.52.

EPA expects any compliance application to:

- discuss the methods used to identify the location of the maximally exposed individual; and
- document the results of the modeling used to determine the location.

Intermediate and final calculations should be provided so that EPA may confirm the analyses.

§194.52 Consideration of exposure pathways.

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

For guidance regarding documentation of compliance assessments, see §194.54 and §194.55.

EPA expects compliance assessments to:

- identify and consider all potential exposure pathways associated with undisturbed performance.

Several different radionuclide release pathways should be postulated, each potentially resulting in different exposures.

DOE should construct exposure pathways and use exposure parameter values that are consistent with pathways and values already in use by EPA for conducting risk assessments. If default exposure parameters are used, they should be referenced clearly. However, 40 CFR 191.15 does not require that DOE perform risk assessments or dose-to-risk conversions.

EPA expects that compliance assessments will:

- discuss the assumptions, methodologies, and results of analyses of exposure pathways.

Items such as dose coefficients that may be found in readily obtainable documents need not be reproduced, but appropriate references for such items should be indicated in the application in the event that they are used. Enough information should be provided in the application so that EPA may confirm pathways analyses.

Detailed information on exposure parameters and dose conversions must be provided to the extent necessary to support the assumptions and models used in compliance assessments. Simplified models may be used to estimate radiation doses to individuals. Such models would be

adequate to demonstrate compliance if it can be shown that the simplified models are more conservative than more detailed and complex models are expected to be.

§194.53 Consideration of underground sources of drinking water.

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

For guidance regarding documentation of compliance assessments, see §194.54 and §194.55.

EPA expects that compliance assessments will:

- discuss the assumptions and approaches (e.g., modeling of ground-water flow, total dissolved solids per liter) used to consider USDWs, as well as the uncertainty associated with the analyses. Enough information should be provided so that EPA may recreate the analyses.
- indicate the estimated concentrations of radionuclides in affected USDWs in the accessible environment, and show that MCLs for radionuclides in USDWs in the accessible environment will not be exceeded during the regulatory time period.

Detailed information on the location and nature of USDWs must be provided to the extent necessary to support the assumptions used in compliance assessments. Simplified models may be used to estimate radionuclide concentrations in groundwater. Such models would be adequate to demonstrate compliance if it can be shown that the simplified models are more conservative than more detailed and complex models would be expected to be.

EPA expects that compliance applications--to the extent necessary to support models and assumptions used in compliance assessments--will:

- identify and characterize any USDWs in the accessible environment expected to be affected by the disposal system. Their location should be shown on maps with information such as cross-sections and plan views with township, range, and estimated latitude and longitude of the center of the USDW.

- describe why any USDWs in the vicinity of the disposal system that are not included in the analyses are not expected to be affected by the disposal system over the regulatory time frame.

- document current and potential groundwater flow rates and direction, to determine if interconnections specified in §194.53 could result in the migration of radionuclides from the disposal system to the accessible environment within the 10,000 year regulatory time period. Information assembled to satisfy §194.14(a)(3) may be used to support the fulfillment of this requirement, if clearly and appropriately cross-referenced.

§194.54 Scope of compliance assessments.

Since much of the information for compliance assessments may be the same as that used for performance assessments, an application may discuss common information in one location. The application should identify the common information and cross-reference the specific topics, so that the flow of the information is not disrupted or confused.

(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;

EPA expects any compliance application to:

- identify potential processes, events, or sequences of processes and events that may occur over the regulatory time frame (see §194.14 and §194.25).

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

EPA expects any compliance application to:

- list, in the compliance assessment discussion, the potential process, events or sequences of processes and events that may occur over the regulatory time frame and which are included in the compliance assessment;
- identify and explain how the screening criteria of "unlikely natural events" is addressed; and
- identify and reference the appropriate discussions in the performance assessment section, if the performance assessment's discussion of processes, events or sequences of processes and events is used for compliance assessment purposes (see §194.32).

The processes, events, or sequences of processes and events for this section are limited to undisturbed performance, where undisturbed performance (from 40 CFR Part 191) means 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.

(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.

EPA expects any compliance application to:

- list the processes, events, or sequences of processes and events that were considered but not included in compliance assessment analyses; and
- discuss the reasons why processes, events, or sequences of processes and events were not included in compliance assessment results.

(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

EPA expects any compliance application to include:

- evidence that the compliance assessment calculations include the effects of existing boreholes in the vicinity of the disposal system, and explain how existing boreholes were considered.

(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.

EPA expects any compliance application to:

- identify any activities that occur in the vicinity of the disposal system prior to or soon after disposal; and
- demonstrate which processes, events or sequences of processes and events were included in the compliance assessment calculations, including, but not 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 that may be used for fluid injection activities (see §194.32).

§194.55 Results of compliance assessments.

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

EPA expects any compliance application to:

- identify where compliance assessment uncertainty is documented;
- document the uncertainty in the performance of the disposal system for compliance assessment purposes; and
- discuss how the uncertainty is considered in the compliance assessment.

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

EPA expects any compliance application to:

- identify the probability distributions used for compliance assessments. Cross-reference to performance assessment probability distributions is acceptable, but performance assessment probability distributions that are not used in the compliance assessment should be noted. See §194.34;
- describe the parameters, including units;
- identify the model(s) and code(s) in which each parameter was used and the computer code (i.e., material and parameter) name(s) of the parameter that was sampled;
- identify any correlations between sampled parameters;
- discuss how correlations between sampled parameters are addressed in performance assessments;
- identify the functional form of the probability distribution (e.g., lognormal, uniform) used for the sampled parameters;
- fully describe the statistics of each probability distribution, including the values for the lower and upper ranges, mean (geometeric mean when appropriate), and median;
- identify the importance of the sampled parameter relative to final releases, and to the intermediate results calculated by the codes that use the parameter. For example, a parameter may have an important role in a particular process, but may not have as significant an effect on the results of compliance assessments. EPA recommends that this information be presented in a table, as well as briefly discussed in the text;
- demonstrate that the data used to develop the input parameter probability distribution have been qualified and controlled in accordance with §194.22; and
- discuss the linkage between the input parameter information and the data used to develop the input information.

(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;

EPA expects any compliance application to:

- indicate the methodology used to estimate committed effective doses received from all pathways in accordance with §194.51 and §194.52;
- provide information so that EPA may confirm the analyses; and
- list and discuss estimated committed effective doses.

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

EPA expects any compliance application to:

- identify underground sources of drinking water in the vicinity of WIPP;
- discuss potential pathways by which radionuclides could travel to an underground source of drinking water;
- discuss why any underground sources of drinking water in the vicinity of WIPP would not be expected to be affected; and
- identify the radionuclide concentrations in the USDWs in the accessible environment that are expected to be affected by the disposal system over the regulatory time frame.

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

EPA expects any compliance application to:

- discuss the method for estimating the dose from any USDW that is expected to be affected by the disposal system;
- identify the estimated dose; and
- provide information so that EPA may confirm the analyses.

(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.

EPA expects any compliance application to:

- discuss the method used to calculate that the maximum estimates of doses and concentrations exceed the 99th percentile of the population of estimates with at least a 0.95 probability;
- list and discuss the sample size used for the analyses;
- identify the estimate of doses and concentrations at the 99th percentile in the calculated sample; and
- provide information so that EPA may confirm the analyses.

(e) Any compliance application shall display:
(1) The full range of estimated radiation doses; and

EPA expects any compliance application to:

- list the lower and upper values of the estimated doses, along with other descriptive statistics, such as the mean, median, and standard deviation;
- list and discuss the sample size used to develop the full range of estimated doses;
- identify the time period for which the doses apply;
- provide information so that EPA may confirm the analyses.

(2) The full range of estimated radionuclide concentrations.

EPA expects any compliance application to:

- list the lower and upper values of the estimated radionuclide concentrations, along with other descriptive statistics, such as the mean, median, and standard deviation;
- list and discuss the sample size used to develop the full range of estimated radionuclide concentrations;
- identify the time period for which the doses were calculated;
- identify the location (estimated spatial coordinates) for which the estimates apply; and
- provide information so that EPA may confirm the analyses.

(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.

EPA expects any compliance application to:

- provide information so that EPA may confirm the analyses, including steps used to arrive at the result and the data used in the analyses; and
- provide descriptive statistics, including the lower and upper limits of the range, the mean, and the median of estimated doses and radionuclide concentrations.

Appendix A Definitions from Parts 191 and 194

The following definitions have been excerpted from the respective portions of 40 CFR Parts 191 and 194 and they are reproduced here for convenience. Unless otherwise indicated in Part 194.02, all terms have the same meaning as in part 191.02, 191.12 of this chapter.

40 CFR Part 191.02 Definitions

(a) *Agency* means the Environmental Protection Agency.

(b) *Administrator* means the Administrator of the Environmental Protection Agency.

(c) *Commission* means the Nuclear Regulatory Commission.

(d) *Department* means the Department of Energy.

(e) *NWPA* means the Nuclear Waste Policy Act of 1982 (Pub. L 97-425).

(f) *Agreement State* means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended (68 Stat. 919).

(g) *Spent nuclear fuel* means fuel that has been withdrawn from a nuclear reactor following irradiation, the constituent elements of which have not been separated by reprocessing.

(h) *High-level radioactive waste*, as used in this part, means high-level radioactive waste as defined in the Nuclear Waste Policy Act of 1982 (Pub. Law 97-425).

(i) *Transuranic radioactive waste*, as used in this part, means waste containing more than 100 nanocuries of alpha-emitting transuranic isotopes, with half-lives greater than twenty years, per gram of waste, except for: (1) High-level radioactive wastes; (2) wastes that the Department has determined, with the concurrence of the Administrator, do not need the degree of isolation required by this part; or (3) wastes that the Commission has approved for disposal on a case-by-case basis in accordance with 10 CFR part 61.

(j) *Radioactive waste*, as used in this part, means the high-level and transuranic radioactive waste covered by this part.

(k) *Storage* means retention of spent nuclear fuel or radioactive wastes with the intent and capability to readily retrieve such fuel or waste for subsequent use, processing, or disposal.

(l) *Disposal* means permanent isolation of spent nuclear fuel or radioactive waste from the accessible environment with no intent of recovery, whether or not such isolation permits the recovery of such fuel or waste. For example, disposal of waste in a mined geologic repository occurs when all of the shafts to the repository are backfilled and sealed.

(m) *Management* means any activity, operation, or process (except for transportation) conducted to prepare spent nuclear fuel or radioactive waste for storage or disposal, or the activities associated with placing such fuel or waste in a disposal system.

(n) *Site* means an area contained within the boundary of a location under the effective control of persons possessing or using spent nuclear fuel or radioactive waste that are involved in any activity, operation, or process covered by this part.

(o) *General environment* means the total terrestrial, atmospheric, and aquatic environments outside sites within which any activity, operation, or process associated with the management and storage of spent nuclear fuel or radioactive waste is conducted.

(p) *Member of the public* means any individual except during the time when that individual is a worker engaged in any activity, operation, or process that is covered by the Atomic Energy Act of 1954, as amended.

(q) *Critical organ* means the most exposed human organ or tissue exclusive of the integumentary system (skin) and the cornea.

40 CFR Part 191.12 Definitions

Accessible environment means: (1) The atmosphere: (2) land surfaces; (3) surface waters; (4) oceans; and (5) all of the lithosphere that is beyond the controlled area.

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.

Annual committed effective dose means the committed effective dose resulting from a one-year intake of radionuclides released plus the annual effective dose caused by direct radiation from facilities or activities subject to subparts B and C of this part.

Aquifer means an underground geological formation, group of formations, or part of a formation that is capable of yielding a significant amount of water to a well or spring.

Barrier means 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.

Controlled area means: (1) A surface location, to be identified by passive institutional controls, that encompasses no more than 100 square kilometers and extends horizontally no more than five kilometers in any direction from the outer boundary of the original location of the radioactive wastes in a disposal system: and (2) the subsurface underlying such a surface location.

Disposal system means any combination of engineered and natural barriers that isolate spent nuclear fuel or radioactive waste after disposal.

Dose equivalent means the product of absorbed dose and appropriate factors to account for differences in biological effectiveness due to the quality of radiation and its spatial distribution in the body; the unit of dose equivalent is the "rem" ("sievert" in SI units).

Effective dose means the sum over specified tissues of the products of the dose equivalent received following an exposure of, or an intake of radionuclides into, specified tissues of the body, multiplied by appropriate weighting factors. This allows the various tissue-specific health risks to be summed into an overall health risk. The method used to calculate effective dose is described in Appendix B of this part.

Ground water means water below the land surface in a zone of saturation.

Heavy metal means all uranium, plutonium, or thorium placed into a nuclear reactor.

Implementing agency means:

(1) The Commission for facilities licensed by the Commission;

(2) The Agency for those implementation responsibilities for the Waste Isolation Pilot Plant, under this part, given to the Agency by the Waste Isolation Pilot Plant Land Withdrawal Act (Pub. L. 102-579, 106 Stat. 4777) which, for the purposes of this part, are:

(i) Determinations by the Agency that the Waste Isolation Pilot Plant is in compliance with subpart A of this part;

(ii) Issuance of criteria for the certifications of compliance with subparts B and C of this part of the Waste Isolation Pilot Plant's compliance with subparts B and C of this part;

(iii) Certifications of compliance with subparts B and C of this part of the Waste Isolation Pilot Plant's compliance with subparts B and C of this part;

(iv) If the initial certification is made, periodic recertification of the Waste Isolation Pilot Plant's continued compliance with subparts B and C of this part;

(v) Review and comment on performance assessment reports of the Waste Isolation Pilot Plant; and,

(vi) Concurrence by the Agency with the Department's determination under § 191.02(I) that certain wastes do not need the degree of isolation required by subparts B and C of this part; and,

(3) The Department of Energy for any other disposal facility and all other implementation responsibilities for the Waste Isolation Pilot Plant, under this part, not given to the Agency.

International System of Units is the version of the metric system which has been established by the International Bureau of Weights and Measures and is administered in the United States by the National Institute of Standards and Technology. The abbreviation for this system is "SI."

Lithosphere means the solid part of the Earth below the surface, including any ground water contained within it.

Passive institutional control means: (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.

Performance assessment means an analysis that: (1) Identifies the processes and events that might affect the disposal system; (2) examines the effects of these processes and events on the performance of the disposal system; and (3) estimates the cumulative releases of radionuclides, considering the associated uncertainties, caused by all significant processes and events. These estimates should be incorporated into an overall probability distribution of cumulative release to the extent practicable.

Radioactive material means matter composed of or containing radionuclides, with radiological half-lives greater than 20 years, subject to the Atomic Energy Act of 1954, as amended.

SI unit means a unit of measure in the International System of Units.

Sievert is the SI unit of effective dose and is equal to 100 rem or one joule per kilogram. The abbreviation is "Sv."

Undisturbed performance means 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

Waste, as used in this part, means any spent nuclear fuel or radioactive waste isolated in a disposal system.

Waste form means the materials comprising the radioactive components of waste and any encapsulating or stabilizing matrix.

40 CFR Part 194.02 Definitions

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

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

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

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

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

Department means the United States Department of Energy.

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

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

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

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

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

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

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

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

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

Secretary means the Secretary of Energy.

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

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

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

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

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

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

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