

REGULATORY CROSSWALK

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Regulatory Requirements		Responsive Chapters and Appendices
40 CFR § 191.13 Containment Requirements		
(a) Disposal systems for spent nuclear fuel or high-level or transuranic radioactive wastes shall be designed to provide a reasonable expectation, based upon performance assessments, that the cumulative releases of radionuclides to the accessible environment for 10,000 years after disposal from all significant processes and events that may affect the disposal system shall:	(1) Have a likelihood of less than one chance in 10 of exceeding the quantities calculated according to Table 1 (Appendix A)	Chapter 6.0
	(2) Have a likelihood of less than one chance in 1,000 of exceeding ten times the quantities calculated according to Table 1 (Appendix A).	Chapter 6.0
(b) Performance assessments need not provide complete assurance that the requirements of § 191.13(a) will be met. Because of the long time period involved and the nature of the events and processes of interest, there will inevitably be substantial uncertainties in projecting disposal system performance. Proof of the future performance of a disposal system is not to be had in the ordinary sense of the word in situations that deal with much shorter time frames. Instead, what is required is a reasonable expectation, on the basis of the record before the implementing agency, that compliance with § 191.13(a) will be achieved.		Chapter 6.0
40 CFR § 191.14 Assurance Requirements		
(a) Active institutional controls over disposal sites should be maintained for as long a period of time as is practicable after disposal; however, performance assessments that assess isolation of the wastes from the accessible environment shall not consider any contributions from active institutional controls for more than 100 years after disposal.		Chapter 7.0
(b) Disposal systems shall be monitored after disposal to detect substantial and detrimental deviations from expected performance. This monitoring shall be done with techniques that do not jeopardize the isolation of the wastes and shall be conducted until there are no significant concerns to be addressed by further monitoring.		Chapter 7.0 Appendix MON-2004
(c) Disposal sites shall be designated by the most permanent markers, records, and other passive institutional controls practicable to indicate the dangers of the wastes and their location.		Chapter 7.0
(d) Disposal systems shall use different types of barriers to isolate the wastes from the accessible environment. Both engineered and natural barriers shall be included.		Chapter 3.0 Chapter 7.0 Appendix BARRIERS

Regulatory Requirements	Responsive Chapters and Appendices
40 CFR § 191.14 Assurance Requirements	
<p>(e) Places where there has been mining for resources, or where there is a reasonable expectation of exploration for scarce or easily accessible resources, or where there is a significant concentration of any material that is not widely available from other sources, should be avoided in selecting disposal sites. Resources to be considered shall include minerals, petroleum or natural gas, valuable geologic formations, and ground waters that are either irreplaceable because there is no reasonable alternative source of drinking water available for substantial populations or that are vital to the preservation of unique and sensitive ecosystems. Such places shall not be used for disposal of the wastes covered by this part unless the favorable characteristics of such places compensate for their greater likelihood of being disturbed in the future.</p>	<p>Chapter 6.0 Chapter 7.0</p>
<p>(f) Disposal systems shall be selected so that removal of most of the wastes is not precluded for a reasonable period of time after disposal.</p>	<p>Chapter 7.0</p>
40 CFR § 191.15 Individual Protection Requirements	
<p>(a) Disposal systems for waste and any associated radioactive material shall be designed to provide a reasonable expectation that, for 10,000 years after disposal, undisturbed performance of the disposal system shall not cause the annual committed effective dose, received through all potential pathways from the disposal system, to any member of the public in the accessible environment, to exceed 15 millirems (150 microsieverts).</p>	<p>Chapter 8.0</p>
<p>(b) Annual committed effective doses shall be calculated in accordance with Appendix B of this part.</p>	<p>Chapter 8.0</p>
<p>(c) Compliance assessments need not provide complete assurance that the requirements of paragraph (a) of this section will be met. Because of the long time period involved and the nature of the processes and events of interest, there will inevitably be substantial uncertainties in projecting disposal system performance. Proof of the future performance of a disposal system is not to be had in the ordinary sense of the word in situations that deal with much shorter time frames. Instead, what is required is a reasonable expectation, on the basis of the record before the implementing agency, that compliance with paragraph (a) of this section will be achieved.</p>	<p>Chapter 6.0</p>
<p>(d) Compliance with the provisions in this section does not negate the necessity to comply with any other applicable federal regulations or requirements.</p>	<p>Chapter 1.0</p>
40 CFR § 191.23 General Provisions	
<p>(a) Determination of compliance with this subpart shall be based upon underground sources of drinking water which have been identified on the date the implementing agency determines compliance with Subpart C of this part.</p>	<p>Chapter 8.0</p>

Regulatory Requirements		Responsive Chapters and Appendices
40 CFR § 191.24 Disposal Standards		
(a) Disposal systems.	(1) General. Disposal systems for waste and any associated radioactive material shall be designed to provide a reasonable expectation that 10,000 years of undisturbed performance after disposal shall not cause the levels of radioactivity in any underground source of drinking water, in the accessible environment, to exceed the limits specified in 40 CFR part 141 as they exist on January 19, 1994.	Chapter 8.0
(b) Compliance assessments need not provide complete assurance that the requirements of paragraph (a) of this section will be met. Because of the long time period involved and the nature of the processes and events of interest, there will inevitably be substantial uncertainties in projecting disposal system performance. Proof of the future performance of a disposal system is not to be had in the ordinary sense of the word in situations that deal with much shorter time frames. Instead, what is required is a reasonable expectation, on the basis of the record before the implementing agency, that compliance with paragraph (a) of this section will be achieved.		Chapter 6.0
40 CFR § 191.25 Compliance With Other Federal Regulations		
Compliance with the provisions in this subpart does not negate the necessity to comply with any other applicable federal regulations or requirements.		Chapter 1.0

Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.14 Content of Compliance Certification Application		
Any compliance application shall include:	(1) The location of the disposal system and the controlled area;	Chapter 1.0 Chapter 2.0 Chapter 3.0
(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:	(2) A description of the geology, geophysics, hydrogeology, hydrology, and geochemistry of the disposal system and its vicinity and how these conditions are expected to change and interact over the regulatory time frame. Such description shall include, at a minimum:	(i) Existing fluids and fluid hydraulic potential, including brine pockets, in and near the disposal system; and
		(ii) Existing higher permeability anhydrite interbeds located at or near the horizon of the waste.
	(3) The presence and characteristics of potential pathways for transport of waste from the disposal system to the accessible environment including, but not limited to: existing boreholes, solution features, breccia pipes, and other potentially permeable features, such as interbeds.	Chapter 2.0 Chapter 6.0 Chapter 8.0 Appendix DATA Appendix MON-2004 Appendix PA
	(4) The projected geophysical, hydrogeologic and geochemical conditions of the disposal system due to the presence of waste including, but not limited to, the effects of production of heat or gases from the waste.	Chapter 6.0 Appendix PA
(b) A description of the design of the disposal system including:	(1) Information on materials of construction including, but not limited to: geologic media, structural materials, engineered barriers, general arrangement, and approximate dimensions; and	Chapter 2.0 Chapter 3.0 Chapter 6.0 Appendix BARRIERS Appendix DATA Appendix MON-2004 Appendix PA

Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.14 Content of Compliance Certification Application		
	(2) Computer codes and standards that have been applied to the design and construction of the disposal system.	Chapter 3.0 Appendix BARRIERS Appendix PA
(c) Results of assessments conducted pursuant to this part.		Chapter 6.0 Chapter 8.0 Appendix BARRIERS Appendix MON-2004 Appendix TRU Waste
(d) A description of input parameters associated with assessments conducted pursuant to this part and the basis for selecting those input parameters.		Chapter 6.0 Chapter 8.0 Appendix PA
(e) Documentation of measures taken to meet the assurance requirements of this part.		Chapter 7.0 Appendix BARRIERS Appendix MON-2004
(f) A description of waste acceptance criteria and actions taken to assure adherence to such criteria.		Chapter 4.0 Appendix TRU Waste
(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.		Chapter 2.0 Appendix MON-2004
(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.		Chapter 2.0 Chapter 3.0 Appendix DATA Pocket Maps - Volume 1
(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.		Chapter 2.0 Chapter 6.0 Appendix PA

Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.14 Content of Compliance Certification Application		
(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.		No information required as part of this application. Any such actions would be required in the post-certification period.
40 CFR § 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.	Chapter 1.0
	(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.	No information required as part of this application.
(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.		Chapter 1.0
(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).		No information required as part of this application.
(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 required as part of this application.
40 CFR § 194.22 Quality Assurance		
194.22(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	Chapter 5.0 Appendix QAPD-2004

Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.22 Quality Assurance		
194.22(a) cont.	edition, and ASME NQA-3-1989 edition [excluding Chapter 2.1(b) and (c)]. (Incorporation by reference as specified in § 194.5.)	Chapter 5.0 Appendix QAPD-2004
	(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;	Chapter 5.0 Appendix AUD-2004 Appendix QAPD-2004
	(ii) Environmental monitoring, monitoring of the performance of the disposal system, and sampling and analysis activities;	Chapter 5.0 Chapter 7.0 Appendix AUD-2004 Appendix MON-2004 Appendix QAPD-2004
	(iii) Field measurements of geologic factors, ground water, meteorologic, and topographic characteristics;	Chapter 5.0 Appendix AUD-2004 Appendix DATA Appendix MON-2004 Appendix QAPD-2004
	(iv) Computations, computer codes, models and methods used to demonstrate compliance with the disposal regulations in accordance with the provisions of this part;	Chapter 5.0 Appendix AUD-2004 Appendix QAPD-2004
	(v) Procedures for implementation of expert judgment elicitation used to support applications for certification or recertification of compliance;	Chapter 5.0 Chapter 9.0 Appendix QAPD-2004

Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.22 Quality Assurance		
194.22(a) cont.	(vi) Design of the disposal system and actions taken to ensure compliance with design specifications;	Chapter 5.0 Appendix AUD-2004 Appendix QAPD-2004
	(vii) The collection of data and information used to support compliance application(s); and	Chapter 5.0 Appendix QAPD-2004
	(viii) Other systems, structures, components, and activities important to the containment of waste in the disposal system.	Chapter 5.0 Appendix QAPD-2004
(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" (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 17.1].		Chapter 5.0 Chapter 9.0 Appendix PEER-2004 Appendix QAPD-2004
(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;	Chapter 5.0 Chapter 9.0 Appendix PA Appendix PEER-2004 Appendix QAPD-2004
	(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;	Chapter 5.0 Chapter 9.0 Appendix PEER-2004 Appendix QAPD-2004

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Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.22 Quality Assurance		
194.22(a) cont.	(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;	Chapter 5.0 Chapter 9.0 Appendix PEER-2004 Appendix QAPD-2004
	(4) Data completeness, i.e., a measure of the amount of valid data obtained compared to the amount that was expected; and	Chapter 5.0 Chapter 9.0 Appendix PEER-2004 Appendix QAPD-2004
	(5) Data comparability, i.e., a measure of the confidence with which one data set can be compared to another.	Chapter 5.0 Chapter 9.0 Appendix QAPD-2004
(d) Any compliance application shall provide information which demonstrates how all data used to support the compliance application are qualified.		Chapter 5.0 Chapter 6.0 Appendix PA Appendix QAPD-2004 Appendix TRU Waste
(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.		No information required as part of this application.
40 CFR § 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.	Chapter 6.0 Chapter 9.0 Appendix BARRIERS Appendix PA
	(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.	Appendix BARRIERS Appendix PA

Regulatory Criteria		Responsive Chapters and Appendices	
40 CFR § 194.23 Models and Computer Codes			
	(3) Documentation that:	(i) Conceptual models and scenarios reasonably represent possible future states of the disposal system;	Chapter 6.0 Appendix PA
		(ii) Mathematical models incorporate equations and boundary conditions which reasonably represent the mathematical formulation of the conceptual models;	Chapter 6.0 Appendix PA
		(iii) Numerical models provide numerical schemes which enable the mathematical models to obtain stable solutions;	Chapter 5.0 Appendix PA
		(iv) Computer models accurately implement the numerical models; i.e., computer codes are free of coding errors and produce stable solutions;	Chapter 5.0 Appendix PA
		(v) Conceptual models have undergone peer review according to § 194.27.	Chapter 9.0 Appendix PEER-2004
(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.)		Appendix PA	

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Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.23 Models and Computer Codes		
<p>(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:</p>	(1) Descriptions of the theoretical backgrounds of each model and the method of analysis or assessment;	Appendix PA
	(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;	Appendix PA
	(3) Detailed descriptions of the structure of computer codes and complete listings of the source codes;	Appendix PA
	(4) Detailed descriptions of data collection procedures, sources of data, data reduction and analysis, and code input parameter development;	Appendix DATA Appendix PA
	(5) Any necessary licenses; and	No licenses required.
	(6) An explanation of the manner in which models and computer codes incorporate the effects of parameter correlation.	Appendix PA
<p>(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.</p>		Chapter 1.0
40 CFR § 194.24 Waste Characterization		
<p>(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 nondestructive examination/assay, or other information and methods.</p>		Chapter 4.0 Appendix DATA Appendix TRU Waste

Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.24 Waste Characterization		
<p>(b) The Department shall submit in the compliance certification application the results of an analysis which substantiates:</p>	<p>(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; compactibility; and other waste-related inputs into the computer models that are used in the performance assessment.</p>	<p>Chapter 4.0 Appendix PA Appendix TRU Waste</p>
	<p>(2) That all waste components influencing the waste characteristics identified in paragraph (b)(1) of this section have been identified and assessed for their impact on disposal system performance. The components to be analyzed shall include, but shall not be limited to: metals; cellulose; chelating agents; water and other liquids; and activity in curies of each isotope of the radionuclides present.</p>	<p>Chapter 4.0 Appendix PA Appendix TRU Waste</p>
	<p>(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.</p>	<p>Chapter 4.0 Appendix PA Appendix TRU Waste</p>
<p>(c) For each waste component identified and assessed pursuant to paragraph (b) of this section, the Department shall specify the limiting value (expressed as an upper or lower limit of mass, volume, curies, concentration, etc.), and the associated uncertainty (i.e., margin of error) for each limiting value, of the total inventory of such waste proposed for disposal in the disposal system. Any compliance application shall:</p>	<p>(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.</p>	<p>Chapter 4.0 Chapter 6.0 Chapter 8.0 Appendix PA Appendix TRU Waste</p>
	<p>(2) Identify and describe the method(s) used to quantify the limits of waste components identified in paragraph (b)(2) of this section.</p>	<p>Chapter 4.0 Appendix TRU Waste</p>
	<p>(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.</p>	<p>Chapter 4.0 Chapter 5.0 Appendix TRU Waste</p>

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Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.24 Waste Characterization		
	(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.	Chapter 4.0 Appendix TRU 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.	Chapter 4.0 Chapter 5.0 Appendix QAPD-2004
	(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.	Chapter 4.0
(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	Chapter 4.0
	(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.	Chapter 4.0
	(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.	Chapter 4.0
	(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.	Chapter 4.0
	(h) The Administrator will use inspections and records reviews, such as audits, to verify compliance with this section.	No information required as part of this application.

Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.25 Future State Assumptions		
<p>(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.</p>		<p>Chapter 6.0 Chapter 7.0 Appendix PA</p>
<p>(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.</p>	<p>(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.</p>	<p>Chapter 6.0 Appendix DATA Appendix PA</p>
	<p>(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.</p>	<p>Chapter 6.0 Appendix PA</p>
	<p>(3) In considering the effects of climatic conditions on the disposal system, the Department shall document in any compliance application, to extent practicable, the effects of potential changes to future climate cycles of increased precipitation (as compared to present conditions).</p>	<p>Chapter 6.0 Appendix PA</p>

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Regulatory Criteria		Responsive Chapters and Appendices	
40 CFR § 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.		No expert judgments were performed since the CCA.	
(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.	No expert judgments were performed since the CCA.	
	(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.	No expert judgments were performed since the CCA.	
	(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	No expert judgments were performed since the CCA.
		(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.	No expert judgments were performed since the CCA.
	(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	No expert judgments were performed since the CCA.

Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.26 Expert Judgment		
	(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.	No expert judgments were performed since the CCA.
	(5) Explain the relationship among the information and issues presented to experts prior to the elicitation process, the elicited judgment of any expert panel or individual, and the purpose for which the expert judgment is being used in compliance applications(s).	No expert judgments were performed since the CCA.
	(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).	No expert judgments were performed since the CCA.
	(7) Provide documentation that the following restrictions and guidelines have been applied in eliciting expert judgment:	(i) At least five individuals shall be used in any expert elicitation process, unless there is a lack or unavailability of experts and a documented rationale is provided that explains why fewer than five individuals were selected.
		(ii) At least two-thirds of the experts involved in an elicitation shall consist of individuals who are not employed directly by the Department or by the Department's contractors, unless the Department can demonstrate and document that there is a lack or unavailability of qualified independent experts. If so demonstrated, at least one-third of the experts involved in an elicitation shall consist of individuals who are not employed directly by the Department or by the Department's contractors.
	(c) The public shall be afforded a reasonable opportunity to present its scientific and technical views to expert panels as input to any expert elicitation process.	
		No expert judgments were performed since the CCA.

Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.26 Expert Judgment		
40 CFR § 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;	Chapter 9.0 Appendix PEER-2004
	(2) Waste characterization analyses as required in § 194.24(b); and	Chapter 9.0 Appendix PEER-2004
	(3) Engineered barrier evaluation as required in § 194.44.	Chapter 9.0 Appendix PEER-2004
(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." (Incorporation by reference as specified in § 194.5.)		Chapter 9.0 Appendix PEER-2004
(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	Chapter 9.0 Appendix PEER-2004
	(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.	Chapter 9.0 Appendix PEER-2004
40 CFR § 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.		Appendix TRU Waste

Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 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 period.		Chapter 6.0 Appendix PA
(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 period. 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 period.		Chapter 6.0 Appendix PA
(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.		Chapter 6.0 Chapter 7.0 Appendix PA
(d) Performance assessments need not consider processes and events that have less than one chance in 10,000 of occurring over 10,000 years.		Chapter 6.0 Appendix PA
(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 period and may affect the disposal system;	Chapter 6.0 Appendix DATA Appendix PA
	(2) Identifies the processes, events or sequences and combinations of processes and events included in performance assessments; and	Chapter 6.0 Appendix PA
	(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.	Chapter 6.0 Appendix PA

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Regulatory Criteria		Responsive Chapters and Appendices	
40 CFR § 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 period.		Chapter 6.0 Appendix DATA	
(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 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.	Chapter 6.0 Appendix DATA Appendix PA	
	(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.	Chapter 6.0	
	(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.	Appendix DATA
		(ii) The total rate of deep drilling shall be the sum of the rates of deep drilling for each resource.	Appendix DATA
(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.	Appendix DATA	
	(ii) The total rate of shallow drilling shall be the sum of the rates of shallow drilling for each resource.	Appendix DATA	
	(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.	Chapter 6.0 Appendix DATA	

Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.33 Consideration of Drilling Events in Performance Assessments		
(c) Performance assessments shall document that in analyzing the consequences of drilling events, the Department assumed that:	(1) Future drilling practices and technology will remain consistent with practices in the Delaware Basin at the time a compliance application is prepared. Such future drilling practices shall include, but shall not be limited to: the types and amounts of drilling fluids; borehole depths, diameters, and seals; and the fraction of such boreholes that are sealed by humans; and	Chapter 6.0 Appendix DATA Appendix PA
	(2) Natural processes will degrade or otherwise affect the capability of boreholes to transmit fluids over the regulatory time frame.	Chapter 6.0 Appendix DATA Appendix PA
(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.		Appendix DATA Appendix PA
40 CFR § 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.		Chapter 6.0
(b) Probability distributions for uncertain disposal system parameter values used in performance assessments shall be developed and documented in any compliance application.		Appendix PA
(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.		Chapter 6.0 Appendix PA
(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.		Chapter 6.0

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Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.34 Results of Performance Assessments		
(e) Any compliance application shall display the full range of CCDFs generated.		Chapter 6.0
(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.		Chapter 6.0
40 CFR § 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.		Chapter 7.0
(b) Performance assessments shall not consider any contributions from active institutional controls for more than 100 years after disposal.		Chapter 6.0 Chapter 7.0
40 CFR § 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;	Chapter 7.0 Appendix MON-2004
	(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.	

Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.42 Monitoring		
<p>(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.</p>		<p>Chapter 7.0 Appendix MON-2004</p>
<p>(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.</p>		<p>Chapter 1.0 Chapter 4.0 Chapter 7.0 Appendix MON-2004</p>
<p>(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.</p>		<p>Chapter 7.0 Appendix MON-2004</p>
<p>(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:</p>	<p>(1) Identify the parameters that will be monitored and how baseline values will be determined;</p>	<p>Chapter 1.0 Chapter 4.0 Chapter 7.0 Appendix MON-2004 Appendix DATA</p>
	<p>(2) Indicate how each parameter will be used to evaluate any deviations from the expected performance of the disposal system; and</p>	
	<p>(3) Discuss the length of time over which each parameter will be monitored to detect deviations from expected performance.</p>	

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Regulatory Criteria		Responsive Chapters and Appendices	
40 CFR § 194.43 Passive Institutional Controls			
(a) Any compliance application shall include detailed descriptions of the measures that will be employed to preserve knowledge about the location, design, and contents of the disposal system. Such measures shall include:	(1) Identification of the controlled area by markers that have been designed, and will be fabricated and emplaced to be as permanent as practicable;	Chapter 7.0	
	(2) Placement of records in the archives and land record systems of local, State, and Federal governments, and international archives, that would likely be consulted by individuals in search of unexploited resources. Such records shall identify:	(i) The location of the controlled area and the disposal system;	Chapter 7.0
		(ii) The design of the disposal system;	Chapter 7.0
		(iii) The nature and hazard of the waste;	Chapter 7.0
		(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	Chapter 7.0
		(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.	Chapter 7.0
	(3) Other passive institutional controls practicable to indicate the dangers of the waste and its location.	Chapter 7.0	
(b) Any compliance application shall include the period of time passive institutional controls are expected to endure and be understood.		Chapter 7.0	
(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		Chapter 7.0	

Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.43 Passive Institutional Controls		
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.		
40 CFR § 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.		Chapter 3.0 Chapter 7.0 Appendix BARRIERS Appendix PA
(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.		Chapter 7.0 Appendix BARRIERS
(c)	(1) In conducting the evaluation of engineered barrier alternatives, the following shall be considered, to the extent practicable:	Chapter 7.0 Appendix BARRIERS
	(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;	

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Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.44 Engineered Barriers		
	<ul style="list-style-type: none"> (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. 	
	<p>(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.</p>	Chapter 7.0 Appendix BARRIERS
	<p>(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.</p>	Chapter 7.0 Appendix BARRIERS
	<p>(e) The evaluation described in paragraphs (b), (c) and (d) of this section shall consider engineered barriers alone and in combination.</p>	Chapter 7.0 Appendix BARRIERS

Regulatory Criteria	Responsive Chapters and Appendices
40 CFR § 194.45 Consideration of the Presence of Resources	
Any compliance application shall include information that demonstrates that the favorable characteristics of the disposal system compensate for the presence of resources in the vicinity of the disposal system and the likelihood of the disposal system being disturbed as a result of the presence of those resources. If performance assessments predict that the disposal system meets the containment requirements of § 191.13 of this chapter, then the Agency will assume that the requirements of this section and § 191.14(e) of this chapter have been fulfilled.	Chapter 2.0 Chapter 6.0 Chapter 7.0
40 CFR § 194.46 Removal of Waste	
Any compliance application shall include documentation which demonstrates that removal of waste from the disposal system is feasible for a reasonable period of time after disposal. Such documentation shall include an analysis of the technological feasibility of mining the sealed disposal system, given technology levels at the time a compliance application is prepared.	Chapter 7.0
40 CFR § 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.	Chapter 8.0
40 CFR § 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.	Chapter 8.0
40 CFR § 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 period 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.	Chapter 8.0 Appendix PA

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Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.54 Scope of Compliance Assessments		
(a) Any compliance application shall contain compliance assessments required pursuant to this part. Compliance assessments shall include information which:	(1) Identifies potential processes, events, or sequences of processes and events that may occur over the regulatory time frame;	Chapter 8.0 Appendix PA
	(2) Identifies the processes, events, or sequences of processes and events included in compliance assessment results provided in any compliance application; and	Chapter 8.0 Appendix PA
	(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.	Chapter 8.0 Appendix PA
(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	Chapter 8.0 Appendix PA
	(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.	Chapter 8.0 Appendix PA
40 CFR § 194.55 Results of Compliance Assessments		
(a) Compliance assessments shall consider and document uncertainty in the performance of the disposal system.		Chapter 6.0 Chapter 8.0
(b) Probability distributions for uncertain disposal system parameter values used in compliance assessments shall be developed and documented in any compliance application.		Chapter 8.0 Appendix PA

Regulatory Criteria		Responsive Chapters and Appendices
40 CFR § 194.55 Results of Compliance Assessments		
(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;	Chapter 8.0 Appendix PA
	(2) Estimated radionuclide concentrations in USDWs pursuant to § 194.53; and	Chapter 8.0
	(3) Estimated dose equivalent received from USDWs pursuant to § 194.52 and § 194.53.	Chapter 8.0
(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.		Chapter 8.0
(e) Any compliance application shall display:	(1) The full range of estimated radiation doses; and	Chapter 8.0
	(2) The full range of estimated radionuclide concentrations.	Chapter 8.0
(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.		Chapter 8.0

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