Steve Z

OCT 18 1995

ENTERED

NOTE TO: WIPP Stakeholders

FROM: Tom Peake, Team Leader
Technical Review Team

Tom Peake

SUBJECT: Transmittal of the Draft Compliance Application Guidance (CAG) Document & Notice of Availability

Attached are courtesy copies of the draft CAG and a Federal Register Notice announcing the availability of the guidance document (to be published in the Federal Register shortly). The purpose of the CAG is to provide the Department of Energy (DOE) and the public with a clear explanation of what EPA expects in a complete compliance application. While the CAG is a guidance document and not a rule, EPA wants to ensure there is ample opportunity to obtain input from DOE and Stakeholders.

The attached CAG has been revised based on comments received on the March 1995 version. A draft checklist for the proposed 40 CFR part 194 has been added to facilitate the preparation of the certification application.

Again, EPA welcomes your comments on this draft by early December. If you have any questions, feel free to contact me at (202) 233-9310.

Attachments

OCT 31 1995

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ENVIRONMENTAL PROTECTION AGENCY

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Draft Compliance Application Guidance (CAG) Document

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Availability.

SUMMARY: Pursuant to the Waste Isolation Pilot Plant Land Withdrawal Act, Pub. L. No. 102-579, EPA has issued proposed criteria for certifying whether the Department of Energy's (DOE) Waste Isolation Pilot Plant (WIPP) is in compliance with EPA's radioactive waste disposal standards set forth at 40 CFR part 191 ("Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes"). See 60 FR 5766 (Jan. 30, 1995) (proposed compliance criteria). The EPA is developing a WIPP compliance application guidance document that is intended to be a companion to and based upon the WIPP compliance criteria. The EPA is hereby announcing that a draft WIPP compliance application guidance document is available for public comment. The draft guidance document summarizes and, in some instances, provides non-binding interpretations of the proposed WIPP compliance criteria published on January 30, 1995. The EPA will fully consider timely public comments in developing and revising the guidance document.

DATES: Comments in response to today's notice must be received by [Insert date 60 days from date

of publication].

ADDRESSES: Copies of the draft compliance application guidance document are available to the public at EPA Docket No. A-93-02 (Category II-B) maintained at the following addresses: (1) room 1500 (first floor in the Waterside Mall near the Washington Information Center), U.S. Environmental Protection Agency, Air Docket, 401 M Street, S.W., Washington, D.C. 20460 (open from 8:00 a.m. to 4:00 p.m. on weekdays); (2) EPA's docket in the Government Publications Department of the Zimmerman Library of the University of New Mexico located in Albuquerque, New Mexico (open from 8:00 a.m. to 9:00 p.m. on Monday through Thursday, 8:00 a.m. to 5:00 p.m. on Friday, 9:00 a.m. to 5:00 p.m. on Saturday, and 1:00 p.m. to 9:00 p.m. on Sunday); (3) EPA's docket in the Fogelson Library of the College of Santa Fe, located at 1600 St. Michaels Drive, Santa Fe, New Mexico (open from 8:00 a.m. to 12:00 midnight on Monday through Thursday, 8:00 a.m. to 5:00 p.m. on Friday, 9:00 a.m. to 5:00 p.m. on Saturday and 1:00 p.m. to 9:00 p.m. on Sunday); and (4) EPA's docket in the Municipal Library of Carlsbad, New Mexico, located at 101 South Halegueno (open from 10:00 a.m. to 9:00 p.m. on Monday through Thursday, 10:00 a.m. to 6:00 p.m. on Friday and Saturday, and 1:00 p.m. to 5:00 p.m. on Sunday). As provided in 40 CFR Part 2, a reasonable fee may be charged for photocopying docket materials.

Comments on the draft compliance application guidance document should be submitted, in duplicate, to: Docket No. A-93-02 (Category II-D), U.S. Environmental Protection Agency, Air Docket, Room M-1500 (LE-131), 401 M Street, S.W., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Tom Peake, U.S. Environmental Protection Agency, Office of Radiation and Indoor Air (6602J), 401 M Street, S.W., Washington, D.C. 20460; (202)233-9310.

SUPPLEMENTARY INFORMATION: The Department of Energy is proposing to use the Waste Isolation Pilot Plant (WIPP), located in Eddy County, New Mexico, as a deep geologic repository for the disposal of transuranic radioactive waste generated by nuclear defense activities. The 1992 Waste Isolation Pilot Plant Land Withdrawal Act, (Pub. L. No. 102-579), calls for the EPA to perform several regulatory activities for the WIPP including: (1) issuing radioactive waste disposal standards; (2) establishing criteria for the EPA to determine whether the WIPP complies with the radioactive waste disposal standards; and (3) certifying whether the DOE's WIPP facility complies with the disposal standards, based on a DOE submitted compliance certification application. See section 8 of the WIPP Land Withdrawal Act. The WIPP Land Withdrawal Act prohibits the DOE from commencing with the emplacement of transuranic waste for underground disposal at the WIPP until the EPA certifies that the facility will comply with EPA's radioactive waste disposal standards. See section 7(b) of the WIPP Land Withdrawal Act.

The EPA has issued final radioactive waste disposal standards, which are codified at 40 CFR part 191. See 58 FR 66398 (Dec. 20, 1993). The EPA has also proposed criteria, to be codified at 40 CFR part 194, for certifying whether the WIPP facility will comply with EPA's radioactive waste disposal standards. See 60 FR 5766 (Jan. 30, 1995) "Criteria for Certification and Determination of the Waste Isolation Pilot Plant's Compliance with Environmental Standards for the Management

and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes.". EPA recently announced that it was reopening the public comment period on the proposed compliance criteria. See 60 FR 39131 (August 1, 1995). The public is referred to the December 20, 1993 and January 30, 1995 Federal Register notices for more detailed information about the EPA's regulatory activities at the WIPP.

The compliance application guidance (CAG), the subject of this notice, is a guidance document for the proposed rule 40 CFR part 194. The proposed compliance criteria provide that EPA's evaluation for certifying, by rule, whether WIPP is in compliance with the radioactive waste disposal standards will be initiated after EPA determines that DOE has submitted a complete compliance certification application. See, e.g., 60 FR 5784-85. The draft CAG summarizes and interprets the proposed criteria related to the contents of the compliance certification application and, when revised, is intended to guide EPA's assessment of whether the DOE compliance application is complete.

By this notice, the EPA is inviting the public to participate in the development of the CAG, available in draft at the public dockets identified above, by submitting written comments for EPA's consideration. EPA requests public comments on all aspects of the draft CAG. In particular, EPA requests the public's views on the following questions: (1) Does the draft CAG clearly describe EPA's expectations of a complete application? (2) Are there areas where you believe the CAG may exceed the requirements of the proposed 40 CFR part 194? Please provide examples. (3) How can the guidance be improved? Please provide examples.

The draft CAG is based upon the proposed compliance criteria. The CAG, as revised, will not establish new compliance criteria or standards and will not establish binding rights or duties but will be a non-binding guide for EPA's completeness assessment. This notice is not inviting comments on the proposed compliance criteria. The request for public comments is limited to the contents of the draft CAG and its consistency with the proposed compliance criteria.

The draft CAG will be revised and made available to the public after the final compliance criteria are issued. Because it is a non-binding, interpretive document, the CAG is not subject to the notice-and-comment rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. 553. Thus, EPA does not plan to provide written responses to the public comments submitted. Nevertheless, EPA will fully consider public comments in developing the revised CAG and will make any revisions necessary to reflect modifications to the final compliance criteria.

As noted, the CAG will guide EPA's assessment of whether DOE's compliance certification application is complete. Subsequently, EPA will determine, by rule, whether the WIPP facility is in compliance with the EPA's radioactive waste disposal standards. See section 8 (d) of the WIPP Land Withdrawal Act. EPA's certification decision will be made only after EPA reviews DOE's compliance certification application based on the final compliance criteria, and conducts a WIPP certification proceeding in accordance with the Administrative Procedure Act rulemaking requirements at 5 U.S.C. 553. Thus, before the Administrator of EPA makes any final WIPP certification decision, EPA will issue a proposed decision in the Federal Register and provide an opportunity for public comment on the proposal. The subsequent final certification decision by the

Administrator will consider the comments received in response to the proposal and be accompanied with a reply to significant public comments.

Dated:

Mary D. Nichols, Assistant Administrator

Office of Air and Radiation

BILLING CODE 6560-50-P

Draft Guidance for Proposed 40 CFR 194

United States
Environmental Protection
Agency

Office of
Radiation
and Indoor Air

EPA 402-R-95-014

Compliance Application Guidance Document for 40 CFR Part 194

Federal Register Draft

September 1995

Compliance Application Guidance Document for 40 CFR Part 194
Federal Register Draft

Note

This draft of the Compliance Application Guidance is a companion to the proposed rule 40 CFR part 194. 40 CFR part 194 is still a proposal and may change, so the guidance may change. This draft document typically uses the term "should" in place of the terms "shall" and "must." Later guidance may change to reflect the requirements of the final 40 CFR part 194. The Compliance Application Guidance does not establish new compliance criteria or standards. With this document EPA is not establishing binding rights and duties; it will be a non-binding guide for EPA's completeness assessment.

Please send your comments on the Compliance Application Guidance to:

Docket Number A-93-02
US EPA Air Docket
Room M-1500 (LE-131)
401 M St., SW
Washington, DC 20460

If you have any questions contact:

Tom Peake
US EPA (6602J)
401 M St., SW
Washington, DC 20460
phone: (202)-233-9765

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Introduction

The Compliance Application Guidance (CAG) is a guidance document for the proposed rule 40 CFR part 194, "Criteria for the Certification and Determination of the Waste Isolation Pilot Plant's Compliance with Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes." *40 CFR part 194, for the Waste Isolation Pilot Plant only, supersedes the guidance found in Appendix C in 40 CFR part 191.* The CAG will be used by EPA as a checklist in determining if the Department of Energy (DOE) has submitted a complete compliance certification application for the Waste Isolation Pilot Plant in accordance with 40 CFR part 194. This document is not legally binding for the Department. The clarifying information provided in the CAG is within the framework established by 40 CFR parts 191 and 194. The CAG presents EPA's specific expectations of the format and content of the compliance certification application while the legal requirements are addressed by 40 CFR parts 191 and 194. Although the CAG's format follows that provided in 40 CFR part 194, the guidance addresses those portions of 40 CFR part 194 (and, by inference, applicable portions of 40 CFR part 191) for which the Department is required to submit information to EPA. Portions of 40 CFR part 194 that are applicable only to EPA are not discussed in this document, such as subpart D of 40 CFR part 194. The final version of this document may be published at the same time as the final 40 CFR part 194 or shortly thereafter.

This guidance has been developed in order to assist the Deparment of Energy in its preparation of the final application for certification of compliance for the Waste Isolation Pilot Plant. During EPA's exchanges with DOE and DOE's subcontractors, it has become apparent that some may be unclear as to what EPA expects in a complete application. The information in this guidance document is an attempt to provide DOE with a clear description of the information that EPA needs for a timely review. It is EPA's hope that through the preparation of this guidance, EPA, DOE and the public will have a common understanding of what is to be included in a complete application for certification of compliance.

This document also addresses *how* the information is expected to be presented. Although the Agency has stated that the proposed general layout of the application presented in DOE's Format and Content Guide is appropriate, the content of the application and its presentation of the information are extremely important. It is expected that the information that DOE presents in its application will conform to the requirements of 40 CFR parts 191 and 194, the WIPP Land Withdrawal Act, and this document. EPA further expects that the information in DOE's application will be complete, organized, clear and current.

The information in this guidance document reflects EPA's understanding of what is necessary for a complete application. This information may change as a result of comments on this document and changes to the proposed 40 CFR part 194. In addition, the performance assessment and/or other modeling may indicate that some items are not necessary to show compliance. In those instances, the application should include justification why the particular items are not important to a reasonable expectation of compliance. The application would not need to contain further

information on that item. Examples used for clarification purposes in this guidance should not be considered exhaustive since they are provided simply as aids in the understanding of the specific types of information EPA is expecting.

Section 194.03 Communications

This section specifies the Administrator as the addressee of the compliance application(s) and all subsequent communications regarding the application. The following address is provided as the Administrator's:

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

Questions that may arise regarding the application should be addressed to the Administrator's authorized representative at the following:

United States Environmental Protection Agency
Director
Office of Radiation and Indoor Air (6601J)
401 M Street, S.W.
Washington, D.C. 20460

The 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 other communications and/or reports concerning compliance with 40 CFR part 194 should be addressed to the Administrator or, where indicated, the Administrator's authorized representative.

Section 194.11 Completeness and accuracy of compliance applications

Information provided to the Administrator in support of any compliance application(s) should be complete and accurate. A compliance application is complete when the Agency is satisfied that the application contains the necessary information required by 40 CFR part 191 according to 40 CFR part 194. This document (the Compliance Application Guidance document) will provide guidance that the Agency will use in making a determination of completeness. A completed application should include all of the information requested in 40 CFR parts 191 and 194. In addition, all materials referenced in the application should be submitted as described in Section 194.13 of this document.

In the event that the Administrator deems the application incomplete, a list of deficiencies will be provided in writing to the Department. If the application is considered complete by the

Administrator, the Department will be informed in writing. The Administrator's evaluation for certification will not begin until the Secretary has been notified of the Administrator's decision of completeness.

Section 194.12 Submission of compliance application(s)

The Agency is requesting that thirty (30) paper copies (one original and twenty-nine (29) photocopies) of the compliance application and all supporting information be submitted to the Administrator. The phrase "[u]nless otherwise specified by the Administrator" is meant to allow for the possibility of alternative requirements for submission of compliance applications in the event that new submission methods are developed (e.g., electronic submission requirements). Details on the format of electronic submissions are to be determined.

Section 194.13 Submission of reference materials

The Agency is requesting ten (10) copies of any material referenced within the compliance application. It is the EPA's intent to allow for the possibility of alternative requirements for submission of reference materials in the event that new submission methods are developed (e.g., electronic submission requirements). As 40 CFR part 194 states, referenced materials which are widely available in standard textbooks need not be submitted. Details on electronic reference submission requirements are to be determined.

Section 194.14 Content of compliance certification application

40 CFR section 194.14 identifies information that should be included in any compliance certification application submitted to the EPA for review. This section provides general guidance on: disposal system description and design, assessment results, input parameters, assurance requirements, waste acceptance criteria, background radiation, topographic maps, climatological and meteorological conditions. Other sections of 40 CFR part 194 contain additional submittal requirements for some of these and other topics. Topics not specifically addressed here, but which are addressed in later sections are: quality assurance, models and codes, expert judgment, peer review, references and supporting materials, waste characterization, future states, monitoring, and underground sources of drinking water. In addition, where the Department believes that additional information is necessary to demonstrate compliance, the Department should submit such information.

The following discussion is provided to assist the Department in responding to the information requirements.

Description of "Vicinity"

The term "vicinity"is used frequently in the proposed rule, however, the term has not been

defined. "Vicinity" means the area at and around the WIPP that may have an affect on or is affected by the performance of the disposal system. The definition of "vicinity" may be different depending upon the situation and should be addressed accordingly. For example, an area of "vicinity" for geologic considerations could be different from the "vicinity" used in monitoring. It is up to the Department to propose and justify a definition for "vicinity" in each situation. In so doing, the Department is advised to take into consideration the context for which the term is being applied. The Department should identify in one location how the term vicinity is used and how its usage changes.

Disposal system description

A description of the disposal system and those features that may affect disposal system performance is required pursuant to 40 CFR section 194.14(a). This includes the facility, the controlled area and the vicinity. As set forth in 40 CFR section 194.14(a), the following information should be included:

1. Location of the Disposal System and the Controlled Area

The Department should provide a general description of the location of the disposal system and the controlled area. Disposal system is defined in 40 CFR part 191 and encompasses all surface and subsurface areas that comprise the engineered and natural barriers used to isolate the radioactive waste. Controlled Area is defined in 40 CFR section 191.12(g) as: (1) a surface location, 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 the disposal system; and (2) the subsurface underlying such a surface location. The Agency expects that the Land Withdrawal Act boundary will be the controlled area for any application.

The general description of the controlled area should include information regarding the physical setting, size, the county, township and range, transportation routes, map coordinates (i.e., longitude and latitude) and adjacent property owners. Text should be augmented with graphical representations of the facility's location in relation to nearby towns and cities, the Land Withdrawal Act boundary, the prominent surface features and the disposal system geologic stratigraphy. All graphical representations should be of sufficient scale and clarity to accurately portray the intended subject matter.

2. Geology, Geophysics, Hydrogeology and Geochemistry of the Disposal System and Its Vicinity

The Department should provide a description of the geology and geophysics of the disposal system and its vicinity. Disposal system is defined in 40 CFR part 191 and encompasses all surface and subsurface area that comprise the engineered and natural barriers used to isolate the radioactive waste. The Department should propose and provide justification as to what area

"vicinity" should encompass for this particular situation.

The description should address both the current geological, geophysical, hydrogeological, and geochemical characteristics of the disposal system and its vicinity, as well as how such characteristics are anticipated to change during the 10,000-year regulatory time period (i.e., future variation in geologic processes) and how this information is used to support the disposal system conceptual model(s) and the performance assessment. The Department should include a discussion of the confidence in the data, limitations of the data, and any uncertainties present in the data supporting the description. At a minimum, the description should include the following items[1]:

Regional and Site Geology

a. geologic history (e.g., depositional history)

b. stratigraphy (e.g., form, arrangement, geographic distribution, chronological sequence, contact zones, age, thickness,)

c. lithology (e.g., rock composition, homogeneity in composition, color, mineralogical components, grain size, texture, laminations, degree of cementation, etc.)

d. structural geology, seismology, geotectonics (e.g., geologic structure, tectonic history, present and past stress regimes, lineaments, fault or fracture zones, earthquake occurrence, location of epicenters, relation of epicenters with geologic structures and/or geologic setting, seismic compressional and shear velocities, ground motion duration; processes, such as tectonism, metamorphism, plutonism, volcanism, hydrothermal, folding, faulting, tilting, jointing, deformation, density foundering, fracturing, uplift, sink, subsidence)

e. geomorphology and topography (e.g., geomorphic units, features and processes, such as secondary topographic features caused by erosion)

f. soil characteristics in the controlled area (e.g., bulk density, profile, porosity, permeability, hydraulic conductivity, particle size distribution, potential evapotranspiration, infiltration capacity)

g. natural resources (e.g., type, occurrence, location, extent of minerals, hydrocarbons and water, such as potash, oil, gas, irrigation water. See also

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[1]If any of these items are not applicable, the application should justify why they are not.

Sections 194.33 and 194.45.)

h. fracturing (geometry, orientation, filling, cementation, and roughness)

Hydrology and Hydrogeology

i. 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

j. regional and site-specific recharge and discharge areas (deep percolation, net infiltration, springs, seeps, stream baseflow)

k. ephemeral and permanent water bodies including active and inactive karst features (breccia pipes, sinkholes, etc.)

l. surficial drainage patterns, current and historical fluctuations (the historical drainage pattern should include information regarding the Ancestral Pecos River). This may include: location or waterway course, gradient, effect on geologic formations, and projection of effect of high water level on geologic formations (pluvial period effects)

m. general physical characteristics such as porosity (total, effective, interstitial, fracture) and saturated thickness

n. general hydraulic characteristics such as hydraulic conductivity, storage coefficients, transmissivity, permeability (intrinsic and relative), matrix and fracture characteristics, hydraulic gradients

o. general transport characteristics such as longitudinal and transverse dispersivity, tortuosity, matrix and fracture characteristics, retardation (physical and chemical) and a discussion of the characterization method(s) used

p. flow boundaries, magnitudes and flow rates

q. depth to water table and each water bearing unit

r. geochemistry and geochemical history of different geologic units (water quality, mineral content and distribution, fluid density, salinity, evidence of dissolutioning etc.)

s. identification of Underground Sources of Drinking Water (USDW) as defined in 40 CFR section 191.22 (this applies for undisturbed performance when there are

expected releases outside the Land Withdrawal Act boundary)

t. withdrawal rates (consumption) and other usage for aquifers currently producing water (e.g., Dewey Lake Redbeds)

u. brine pockets and their potential distribution in the controlled area

Information for the above listed items should be provided for all distinct geologic units and zones from and including the Bell Canyon Formation upward to the surficial deposits and Holocene soils. Additional geologic units which may have a bearing on the facility performance also should be discussed where appropriate. These may include, but not be limited to, underlying formations with known or potential resources, the Capitan Reef and those Salado Formation Marker Beds which would affect or be affected by the presence of the repository. Text should be augmented with graphical representations (e.g., stratigraphic columns, cross sections, isopachs), having sufficient scale and clarity to accurately portray the intended subject matter. The text should reference the source of the information (e.g., published or unpublished reports, field data, laboratory tests, expert judgement, modeling results) provided in the description.

3. Potential Pathways for Radionuclide Migration from the Disposal System to the Accessible Environment

The Department should provide a description of the potential pathways for radionuclide migration from the disposal system to the accessible environment. Determination of potential pathways will necessitate a review of the geology, hydrogeology, hydrology, topography, meteorology and manmade conduits. The description should address both the current pathways and pathways that may result over time, such as pathways resulting from changes in climatic conditions; fractures that form in the anhydrite due to gas generation in the waste; or further dissolutioning of the Culebra. If the Department believes that certain features (e.g., shafts, sealed and unsealed boreholes, solution features such as collapse zones) or geologic units or zones are not potential pathways, then information should be provided to support the claims. One acceptable method to support DOE's claims could be through the use of calculations. A hypothetical example is a one-dimensional analysis of impermeable units that shows transport would be only 50 meters over 10,000 years. Other methods are acceptable if they logically support the application's claims.

4. Projected Geophysical, Hydrologic and Geochemical Conditions of the Disposal System Due to the Presence of the Waste

This requirement addresses the need for the application to contain information on the response of the disposal system as a result of the presence of waste. The Department should provide a description of the geophysical, hydrological and geochemical conditions of the disposal system initially upon waste emplacement and as they are expected to change during the regulatory time period.

The description should include items such as:

a. gas generation

b. production of heat

c. closure of disposal rooms

d. expansion of disposal rooms

e. brine saturation

f. brine flow

g. creation and expansion of fractures

h. other processes and pathways identified by the Department

Disposal System Design

A description of the disposal system design is required pursuant to 40 CFR section 194.14(b). Disposal system is defined in 40 CFR part 191 and encompasses all surface and subsurface areas that comprise the engineered and natural barriers used to isolate the radioactive waste. The Department should submit information describing the design of such a system, including surface structures, subsurface structures remaining after closure, subsurface engineered barriers and natural barriers. This information should include proof that the engineered barriers will function as designed. The compliance application should included the complete design and support for credit claimed by DOE or the application will be considered incomplete. The description should address (see 40 CFR section 194.44 for further reference):

a. which geologic units comprise the natural barriers

b. engineered barrier design parameters, dimensions and materials of construction

c. engineered barrier/waste form modification design parameters (this includes listing the engineered barriers/waste form modifications and demonstrating how the barriers are expected to retard movement of radionuclides; an engineered barrier study is required in section 194.44, so the information for this section should be specific to those engineered barriers that are planned to be used.)

d. configuration of the disposal system including the waste emplacement areas, panels, emplacement drifts, boreholes and similar features. There should be descriptions of the portions of the underground facility that are considered part of

the engineered barrier system.

e. capacity of remote-handled and contact-handled transuranic waste

f. waste distribution (loading) within the repository

Text should be augmented with graphical representations having sufficient scale and clarity to accurately portray the intended subject matter. Where applicable, design drawings specifications submitted and the constructed facilities should be certified that they have been reviewed according to DOE's Orders and meet the appropriate codes and standards.

Assessment Results

40 CFR part 194.14 requires that performance or compliance assessment results conducted pursuant to the disposal regulations provided in Subparts B and C of 40 CFR part 191 be included in the compliance certification application. 40 CFR part 191.13 requires that performance assessments be conducted for transuranic radioactive waste disposal systems to determine if those systems will adversely affect human health or the environment. 40 CFR part 191.12 defines a performance assessment as 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 caused by all significant processes and events. Compliance assessments (194.55) used for individual and ground-water protection requirement comparisons only consider undisturbed disposal system performance, while performance assessments (194.34) consider both disturbed and undisturbed performance.

Input Parameters

40 CFR part 194.14(d) requires that the compliance certification application include an identification of all input parameters used in conducting the performance assessment and the compliance assessments required pursuant to 40 CFR sections 191.13, 191.15 and 191.24. Each input parameter should be described. Each sampled parameter should be accompanied with detailed information such as, but not limited to, a discussion of the parameter's sensitivity to performance, the type of probability distribution used, covariance, source of data, confirmation that the data has been quality assured and by what method, the model(s) in which the data are used. Similar information should be provided for non-sampled (i.e., considered constant) parameters, except for the probability related discussions. Parameter sheets in an appendix are acceptable, but tables of parameter values and ranges should be in the text where appropriate. For example a description of fluid flow in particular geologic units should be accompanied by tables listing applicable parameters and the location of the respective parameter sheets. In addition, see section 194.34 additional information. Parameters that are listed in tables and/or are considered important (e.g., transmissivity or borehole diameter) should be appropriately discussed in the text.

A complete application needs to list all of the input parameters used in the performance assessment and their corresponding name used in each of the computer codes. Values for constant input parameter values should also be tabulated. For input parameters whose values are constant throughout the analyses, there should be a brief explanation of why they are held constant. For input parameters that vary, there also needs to be a discussion that includes, at a minimum:

1) A description of the input parameter, including units;

2) The probability distribution type and the information used in its determination (e.g., data collected by the WIPP project, literature search, etc.) and the process used to review the data;

3) The lower and upper bounds of the sampled data range, the median, the geometric mean and geometric standard deviation, arithmetic mean and standard deviation of each input parameter;

4) Cumulative probability plots with the associated data tabulated;

5) Correlations between parameters;

6) Computational models in which they are used; and

7) The impact of each parameter on releases (sensitivity analyses).

For input parameters that are held constant, the Department will need to include the information in 1, and 6 above. This information for both the constant and variable input parameters should be tabulated in the application and also available in a documented computer format that EPA can used in its analyses. Also, as stated in 40 CFR section 194.27 on peer review, data used to support models and computer codes should be peer reviewed. See section 23 of this document for additional information on input parameters.

Assurance Requirements

40 CFR part 194.14(e) requires that the Department provide information demonstrating that the disposal system should meet the Assurance Requirements specified in 40 CFR part 191.14. These requirements include: (1) implementation of active institutional controls; (2) monitoring; (3) implementation of passive institutional controls; (4) use of engineered and natural barriers; (5) presence of resources; and (6) waste removal. In order to accomplish this, the Department should provide the methodology proposed to fulfill each of the assurance requirements. Documentation may be in the form of a plan detailing the methodology, procedures and equipment necessary to meet each requirement. For further details regarding each of the assurance requirements, the Department is directed to 40 CFR sections 194.41, 194.42, 194.43,

194.44, 194.45, 194.46 and to the corresponding sections of this guidance document. These topics should be in their own section of the application, except for the presence of resources which should be presented with the site characterization information.

Waste Acceptance Criteria

40 CFR part 194.14(f) requires that the Department identify the waste acceptance criteria which will be used to determine the types or forms of transuranic waste that can be disposed of in the disposal system. It is up to the Department to identify the unit (drum, storage box, TRUPACT container, etc.) to be used as the basis for the criteria. The Department will need to coordinate the development of the waste acceptance criteria with 40 CFR part 194.24. For example, the Department may determine that disposal of wastes containing greater than one percent liquids will negatively affect the performance of the disposal system. As a result of this determination, one element in the waste acceptance criteria may be that no drum (for example) having greater than one percent liquids will be accepted by the facility for disposal. The Department would then identify this criterion in the compliance application.

In addition to identifying the criteria, the Department also should provide the basis for selection of each criterion and state the self-imposed facility requirements which will be employed to ensure that the acceptance criteria will be adhered to. In providing the basis for the criteria, the Department should state for each criterion whether it is based on transportation and operational safety concerns or on the projected disposal system performance. When based on the projected disposal system performance, the Department should provide detailed information of how that particular inventory item and associated waste characteristic may affect performance.

The information on the waste acceptance criteria should be included in the discussion of waste characteristics required in Part 194.24.

Background Radiation

40 CFR part 194.14 requires that the Department describe background radioactivity existing in the vicinity. The environmental media to be included are: air, soil, surface water and groundwater. With respect to background radioactivity, the description should include an identification of the radionuclide and its activity measure within the sampled media. 40 CFR part 194.14(g) also requires that a description of the procedures used to determine background radioactivity and radiation be included in the application. The term "procedures" in this case refers to the sampling procedures and analytical procedures employed.

Topographic Maps

40 CFR part 194.14(h) requires that the Department provide one or more topographic maps of the vicinity.

Topographic maps should be used to provide information about the controlled area and the vicinity of the WIPP. They should show information such as the size, shape, and distribution of natural and manmade surficial features around WIPP, surface relief, physiography and structural features, such as fault, fold and joint systems; surface hydrology and flood plains; land use; controlled area boundary; location of planned passive and active institutional controls; location of active, inactive, and abandoned injection and withdrawal wells; and proposed monitoring stations and wells.

In addition to basic map features, 40 CFR part 194 also requires several other features to be included by the Department on the topographic maps. All required features are listed in 40 CFR part 194.14(h). All features should be clearly explained in a map legend. In order to clearly show all required features, the Department should include a series of topographic maps in different scales (regional and local) rather than include all the features on one map. Items 1-4 below should be identified on each topopgraphic map, but discussions of the other items may be addressed separately as appropriate. Each feature is discussed in detail below:

1. Contour Lines and Map Scale

Maps having a smaller scale (e.g., 1:5,280 or 1:24,000) should be used to show detailed features, while maps having a larger scale (e.g., 1:64,000 or 1:100,000) should be used for intermediate or regional features. 40 CFR part 194.14(h) requires that contours be included on the topographic maps and that the contour interval be sufficient to clearly show the pattern of surface water flow in the vicinity of the disposal system. Major contour lines should be clearly marked on the map with the appropriate land elevation. The scale also should be clearly indicated using bar scales marked in feet, miles, and kilometers. It is up to the Department to select the scale of the maps, but the Department should use the contour intervals appropriate for the scale.

2. Date

The date on which the map was completed should be clearly indicated. In addition, the date of any field check and/or revisions also should be provided.

3. Map Orientation

The topographic map should include the map orientation. The orientation may be displayed using the north arrow.

4. Controlled Area Boundary

The topographic map should show the surface boundaries of the controlled area.

5. Floodplain Area

The topographic map should note the location of the 100-, 500- and 1,000-year floodplain of the Pecos River and discuss the path of other major rivers during and since the Pleistocene Epoch.

6. Surface Water Including Intermittent Streams

Temporary and permanent surface water bodies, and intermittent streams and dry channels should be included on the topographic maps and discussed in the hydrology section of the Facility Description section of the application.

7. Surrounding Land Uses

Current surrounding land uses such as residential, commercial, industrial, agricultural, and recreational should be indicated on the topographic map. These might include, but not be limited to, residential buildings, mining operation surface facilities, ore refining facilities, ranches, railroads, highways, reservations, parks, etc. Various line types should be used to delineate the boundaries of cities, towns, reservations, national and state parks, etc.

8. Location of Proposed Active and Passive Institutional Controls

The topographic map should show the location of proposed active and passive institutional controls. Active institutional controls that can be delineated on the map include fences, gates, guard buildings, etc. Passive institutional controls such as buildings, markers, statues also should be shown. Symbols representing the passive institutional controls should be clearly explained in a legend to the map.

9. Location of Any Active, Inactive, and Abandoned Injection and Withdrawal Wells

The location of any active, inactive, and abandoned injection and withdrawal wells should be noted on a topographic map. This includes wells located both within the controlled area and outside of the controlled area, but within the vicinity of the disposal system. Well depths and elevations should be reported elsewhere in the application (and cross-refereced) for comparison with the cross-sections and/or well logs.

10. Location of Proposed Monitoring Stations and Wells

The topographic map should designate the location of the proposed monitoring stations and wells. These monitoring stations and wells would not necessarily include those stations and wells that were employed during site characterization, but rather would include the stations and wells that will be employed pursuant to 40 CFR part 194.42. Well depths and elevations should be reported elsewhere in the application for comparisons with cross-sections and/or well logs.

Climatologic and Meteorologic Conditions

40 CFR part 194.14(i) requires that a description of past and current climatologic and meteorologic conditions in the vicinity. The past climatologic and meteorological conditions should be evaluated for the Pleistocene to the current historical record.

The description should include the following items and any other relevant items applicable to the present and past:

Current Climatologic and Meteorologic Conditions

a. recorded annual and monthly precipitation averages

b. recorded monthly temperature averages and extremes

c. wind speed and direction

d. evaporation data

e. atmospheric stability distributions

Past Climatologic and Meteorologic Conditions

a. climate changes, including past glaciation events

b. estimated historical precipitation averages and variability

c. estimated historical temperature averages and variability

In addition to the current and past climatologic and meteorological conditions, the description should also address how those conditions are projected to change during the 10,000-year regulatory time period. The application should state how these projections relate to the conceptual models used in the performance and compliance assessments. Long-term estimates should include, but not be limited to:

a. potential changes and rates of change in precipitation, air temperatures, and resulting changes in potential evapotranspiration from the present

b. potential regional wind flow and precipitation patterns that may evolve in the future as a result of climatic and geologic changes

c. potential for glaciation

General

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

2. The Department should prepare an executive summary of the application that generally discusses major issues and presents the final compliance results.

3. Units should be listed in SI terminology where possible, with English units listed parenthetically.

Section 194.15 Content of Compliance Determination Application(s)

Section 8(f) of the WIPP Land Withdrawal Act requires that the Department submit documentation of continued compliance with 40 CFR part 191 every five years, after the initial certification is granted, and until completion of the decommissioning phase. The documentation should include new information related to the disposal system that was obtained during the five-year period after certification of compliance or determination. As such, the submission need include only that information which updates the previous compliance certification or determination. Information which was provided in previous compliance applications or determinations need not be duplicated, but rather may be summarized and referenced. Changes that may affect the predictions of containment should be accompanied by the appropriate performance or compliance assessments. For example, if the waste were emplaced so that high-curie waste is grouped together instead of equally distributed in the repository as planned in the application, then there should be a new assessment. Other examples of changes could include those that result from monitoring the repository or data collected from continuing experiments that change parameter values used in the models. Changes in the computer code would be grounds for preparing another assessment.

40 CFR part 194.15 requires the following updated information:

Technical Information

It is anticipated that the Department will 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 should be included in the recertification documentation.

Monitoring Information

40 CFR part 194.42 requires that the Department monitor the disposal system to measure parameters which will provide input to the predicted performance of the disposal system and to detect the migration of waste toward the accessible environment. Any compliance determination application should include the monitoring results collected during that five-year period. The results should be accompanied by a discussion regarding the data quality acceptability and the implications of the results (i.e., do the results change or challenge the conceptual or computer model of the system or a portion of the disposal system such that the projection of the system's performance should be revised).

Waste Emplacement Information

The facility operating period for waste emplacement is projected to be approximately 25 years. As portions of the disposal system are filled and sealed, other portions will be mined and prepared for waste emplacement. The determination documentation should provide information regarding the wastes that were emplaced during the five-year period immediately following the most recent compliance certification or determination. If assumptions about the waste or other aspects of the disposal system change, it is expected that a recertification application will contain the appropriate analyses. The waste emplacement information should include the following:

a. location and distribution of emplaced waste by waste types as detailed in the information required for waste characterization (Section 194.24);

b. confirmation that the location and distribution of waste conform to assumptions used in performance assessment;

c. waste characteristics of waste emplaced and a demonstration that they continue to fall within the requirements established under the waste characterization section.

Updated Computer Code Documentation and Code Listings If Computer Code is Modified

Updated documentation provides a means for informing EPA of changes in the codes and what is known about them. It should include a provision for error reporting and a list of any revisions made to the first four categories of documentation. Updated documentation should also include computer-readable, paper source listings, and current and new versions as they are released. The updated documentation should provide the basis for the updated information for each recertification or if DOE deems that the changes have an impact on performance.

The following would need to be updated for any recertification if there are changes to the computer codes:

(1) Updated software summaries. Submit a new software summary when the information it contains changes, when new code versions are released, or when important changes in the code are made.

(2) Documentation revisions. Revise the documentation sent to EPA as needed whenever changes are made in the code, errors are found in the existing documentation, new limitations of the model are found, or new results of the assessment program described in part D appear. (CAG Section 194.4).

(3) Error reporting. (NQA-2a-1990, Part 2.7, Section 6.5(e)). Errors or omissions that could affect validity or appropriateness of the model itself or specific instances of its use (including input errors) should be reported to EPA promptly. Report action taken to correct the errors. State the significance of the errors in past, current, and future modeling activities.

(4) Computer files. Send EPA computer files containing the current code version, new versions as they are released, and necessary updates as they are determined. Include the input data for the example problems (see part C(6)). Include all necessary library routines. The means of transmittal may be any reasonable standard medium, such as high density nine-track magnetic tapes or CD-ROM or use of the File Transfer Protocol (FTP) over the Internet. The information should be in a standard format readable by a variety of computer systems and compatible with EPA computing systems. All files should be accompanied by printout from the runs which created them.

(5) Paper listing. Provide a printed listing of the current and new versions as they are released and updated. Code listings should include line numbers.

(6) Description of updates and new versions. All updates and new versions delivered to EPA should be accompanied by descriptions of the changes and appropriate documentation.

Section 194.22 Quality Assurance

The Department of Energy (DOE) is required to implement a Quality Assurance program that at a minimum meets the requirements of the American Society of Mechanical Engineers' (ASME) "Quality Assurance Program Requirements for Nuclear Facilities" (NQA-1-1989 edition), ASME's "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications" (NQA-2a-1990 addenda, part 2.7 to ASME NQA-2-1989 edition), and ASME's "Quality Assurance Program Requirements for the Collection of Scientific and Technical Information on Site Characterization of High-Level Nuclear Waste Repositories" (NQA-3-1989 edition, excluding Section 2.1(b) and (c)). The exclusion of Section 2.1(b) and (c) precludes the application of a graded approach to quality assurance.

The EPA criteria require submission of information that demonstrating the establishment and

execution of Quality Assurance programs for all aspects of the WIPP disposal system that affect the containment of waste. Aspects important to containment should be listed and the selection method and rationale identified along with the information demonstrating quality assurance. This information should include governing documents (e.g., Quality Assurance Requirements Documents (QARD), Quality Assurance Program Documents (QAPD), and Quality Assurance Program Plans (QAPP)) and implementation information (e.g., Quality Assurance Project Plans (QAPjP), Standard Operation Procedures (SOPs), Surveillance and Auditing records) covering the Quality Assurance program established for the WIPP.

The specific areas listed in 40 CFR part 194.22 (a)(2) requiring the implementation of quality assurance program are:

1. Waste characterization activities and assumptions;

2. Environmental monitoring, monitoring the performance of the disposal system, sampling, and analysis activities;

3. Field measurements of geological factors, ground water, meteorology, and topography;

4. Models and computer codes used for compliance;

5. Expert judgment elicitations;

6. Disposal system design and actions taken to ensure compliance with design specifications;

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

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

The Department is required to demonstrate that all data and information used in the compliance application which was collected prior to implementation of the Quality Assurance program required under 40 CFR part 194.22(a) be qualified by a Quality Assurance program equivalent in scope and implementation to ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda (part 2.7) to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c)). In order for a Quality Assurance program to be considered equivalent in scope to the ASME NQA-1989 and 1990 standards, the information provided should substantiate the requirements of these standards. An acceptable method of displaying this information is to cross reference the implemented Quality Assurance documents to the requirements of the ASME NQA-1989 and 1990 series. The certification of application should also contain reports from quality assurance activities used to qualify data, such as the individual review teams.

In the event that data and information collected prior to implementation of the Quality Assurance program required under 40 CFR part 194.22(a) cannot be qualified under a Quality Assurance program equivalent in scope to the ASME NQA-1989 requirements, an alternate method approved by the Administrator may be used. This method should demonstrate the process of qualification by including in the application the following information: a description of the method used to qualify the data; the complete records of the decision; the qualification of individuals making the decision (including background and evidence of independence to the project in question for peer review type of activities); the decision made for each data set; the list of all data sets not meeting qualification; and the records of any alternative method used. The use of alternative methods should include a description of the method and a justification for its use. Examples of alternative methods include: the use of peer review, corroboration of data sets, and/or confirmatory measurements.

In order to demonstrate and ensure the quality and applicability of data used to support a compliance application, the Department is required to address the following quality indicators:

1.) Accuracy;
2.) Precision;
3.) Representativeness;
4.) Completeness;
5.) Comparability;
6.) Reproducibility;
7.) Validation; and
8.) Verification.

Accuracy, precision, representativeness, completeness, and comparability are part of a process to ensure that acceptable data is used in analyses. In addition, it is an effective streamlining tool for the development of performance requirements that are appropriate for the intended use of the data. The EPA document entitled "Guidance for the Data Quality Objectives Process" (EPA QA/G-4) provides a comprehensive approach to the application of DQO's.

Data reproducibility, validation, and verification are quality indicators that serve as a systematic means of examining the implementation of a quality assurance program. As applicable, they may reflect the quality assurance/quality control activities of whole bodies of data.

The application of quality indicators may vary with importance or use of the data. Some more important parameters may need high accuracy and precision while other, less critical parameters can be used even with a large range of uncertainty without affecting confidence of the results. As part of the quality assurance documentation, the application should document the purpose for which the data were collected, the quality of the data, and what is considered as acceptable for the intended use. The documentation should also address the limits of the data.

Section 194.23 Models and computer codes

Performance Assessment (PA) is used to show a "reasonable expectation" that the cumulative releases of radionuclides to the accessible environment for 10,000 years after disposal meet certain requirements. Performance (and compliance) assessment modeling is accomplished by computer codes that attempt to represent the disposal system.

It is the EPA's expectation that code quality assurance, verification, validation (see definition later under section E of this discussion), peer review, and documentation will be completed before computer codes are used to model the Final Compliance Application Performance Assessment. EPA will evaluate models and computer codes as part of the review of the compliance application and future determinations. This section provides guidance for the documentation required on model development, software code development, verification and validation, quality assurance, peer review, and presentation of results.

Model and computer code documentation is comprised of:

A. Description of conceptual models, mathematical models, and numerical methods.
B. User's manual (including a software summary)
C. Programmer's manual
D. Code assessment

This guidance is designed for scientific, engineering, and mathematical codes. In developing the guidance, it was assumed that the codes are batch-oriented rather than interactive. If interactive codes are to be used, appropriate changes should be made in the documentation.

A. Conceptual Models, Mathematical Models, and Numerical Methods. (NQA-2a-1990, Part 2.7, Section 6.3; NQA-1-1989, Supp. 3S-1, Section 3.1).

The description of conceptual models, mathematical models and numerical methods will provide the basis for EPA's review of the theory and the assumptions underlying the PA computer codes. The documentation should contain justification for the use of the models, the conceptual model derivation, the mathematical derivations, and the solution methods used in the codes.

This section should provide a complete explanation of the methods used; in other words, "tell the complete story of model development and implementation." Documentation should include a derivation of, and justification for the use of the model(s) and should clearly explain model and code capabilities and limitations. This section should be sufficiently complete to stand alone as a basis for review of the methods used in developing the codes.

(1) Documentation of the Conceptual Models. (NQA-1-1989, Supp. 3S-1, Section 3.1(b)(4)). Completely show and explain the derivation of conceptual models. The explanation should be clear and easy for the reviewer to follow and evaluate with all steps

shown and clearly discussed. Explain why particular conceptual models were considered but not included.

(2) Documentation of the Mathematical Models. Completely and clearly show the derivation of mathematical models and how these models are realistic representations of the conceptual models. Show all limiting assumptions and boundary conditions introduced, such as flow and no flow boundary conditions around the hydrologic model.

(3) Statement and description of the problem. (NQA-1-1989, Supp. 3S-1, Section 3.1(b)(4)). Describe the overall nature and purpose of the general analysis in which the model will be used. State the specific aspects of the analysis for which the model will be used. Show the input and output parameters of the model. Input and output parameters should be discussed for each PA model (see 40 CFR 194.14 and this document under 194.14 Input Parameters).

(4) Structure of the system model. (NQA-1-1989, Supp. 3S-1, Section 3.1(b)(4)). The modeling information should describe the components (e.g., repository room model or the cuttings transport model) and their role in the overall performance assessment modeling effort. Show how each component model contributes to the complete solution of the problem and the linkages between the models. Use flowcharts and block diagrams to describe the mathematical solution strategy.

(5) General numerical procedures. (NQA-2a-1990, Part 2.7, Section 6.3(d)). Describe the numerical solution strategy and computational sequence. Use specific program flowcharts and block diagrams to clarify the description. Include references for the basic numerical procedures and identify the computer subroutines that address these numerical procedures. These references should be provided with the compliance application. For example, if the method solves a large set of linear equations, show the structure of the equations and how coefficients are determined. Show how the numerical strategy is related to the mathematical strategy (i.e., how boundary or initial conditions are introduced).

(6) Component models. For each component model noted in A(4) above, provide the following:

(a) Purpose. Describe the purpose of this component of the software codes (NQA-2a-1990, Part 2.7, Section 6.2(a)). If this code is used in only certain cases, state under what circumstances it is used.

(b) Assumptions and limitations. Describe the assumptions and limitations of each component model, including simplifying assumptions about the geometry and behavior of the system (NQA-2a-1990, Part 2.7, Section 6.2(c)). Include the known ranges of validity of the model for all variables. For empirical or semi-

empirical models, state the range and type of data on which the model is based (e.g., field or laboratory data). State any known uncertainty about validity of the model.

(c) Notation. Identify all algebraic variables used in the equations. Give the mathematical symbols used in both the fundamental mathematical equations and their equivalents in the numerical formulation. Also, give the computer variable name associated with each quantity and its unit of measurement.

(d) Derivation. A clear explanation of model derivation is critical to EPA's evaluation of the PA modeling system. Start the derivation from generally accepted principles and scientifically proven theories. Justify each step in the derivation and note how assumptions and limitations are introduced. For empirical and semi-empirical models, describe how experimental data are used to arrive at the final form (NQA-1-1989, Supp. 3S-1, Section 3.1(b)(2)). Clearly state the final mathematical form of the model and application in the computer code. Do not leave out any steps; make the documentation clear enough for reviewers to follow the derivation without having to derive intermittent steps.

(e) Application. Discuss the applicability of the component model to the physical system (NQA-2a-1990, Part 2.7, Section 6.2(a)). Point out any unsupported extrapolations of the model or uses beyond its intended range of applicability. Describe any restrictions on the use of the model (e.g., to a particular rock type). State whether the validity of the model will be affected by unusual or extreme conditions, such as high repository temperatures or pressures.

(f) Numerical method type. Identify any numerical method used in the model that goes beyond simple algebra (e.g., finite-difference, Simpson's rule, cubic splines, Newton-Raphson Methods, and Jacobian Methods). Explain and show in sufficient detail how these methods are implemented in the computer code so that an independent reviewer can understand.

(g) Derivation of numerical model. Derive the numerical procedure from the mathematical component model. Give references for all numerical methods. Give the final form of the numerical model and explain the algorithm. If the numerical model produces only an intermediate result, such as terms in a large set of linear equations that are later solved, explain how the intermediate results are used. State what variables are input to and output from the component model.

(h) Location. State where the component model (e.g., subroutine) is located within the code. Refer to the individual program module flowchart and code listing which will be part of the documentation.

(I) Numerical stability and accuracy. (NQA-2a-1990, Part 2.7, Section 6.2(b)). Discuss the stability and accuracy of the numerical model. Distinguish between those aspects of stability and accuracy which have been proven mathematically and those which have not been proven, but have been observed in practice.

(j) Alternatives. Discuss alternatives to the component model and state why this one was selected. All alternatives considered seriously, but not used should be included with an explanation as to why these alternatives were not used.

(7) Experience. (NQA-2a-1990, Part 2.7, Section 6.2(b)). Discuss the general performance of the entire model (e.g., typical execution run times, memory requirements, and typical accuracy of results). Note the conditions under which the model gives adequate, inadequate, or irrelevant results. Point out specific component models known to act poorly under certain circumstances. Give any general rules or recommendations to follow in use of the models.

B. User's Manual. (NQA-2a-1990, Part 2.7, Section 6.2(e), Section 6.3, Section 6.5).

The user's manual for the compliance application review plays two roles. First, it allows EPA staff to understand modeling results submitted by the Department. Second, it allows EPA to install and run the code on its own computer system. The User's Manual together with the Programmer's Manual (Section D), which contains the source code of each component program and the code listings required in section F should be sufficient to instruct the user how to set up and execute problems as well as resolve possible difficulties.

The user's manual should include a software summary. The software summary is a one or two page document that identifies the computer code, its purpose, version number, quality assurance status, hardware system information (e.g., platform and operating system) and gives other basic information about the code.

The items below should be documented fully and completely in order to enable a user unfamiliar with the code to run the code, understand the inputs, outputs and understand errors. The User's Manual should be clear and complete enough to allow execution of the codes without further assistance.

(1) Program considerations.

(a) Program options. Discuss the various program run time options, such as switches which are used to select different methods of numerical solution. Discuss the function of each program option; give special attention to effects of combinations of options. Relate options to the input values that control them.

(b) Program paths. Describe the purpose of each program module or program utility

(e.g., data listing and plotting program utilities). Use block diagrams and flowcharts to explain the paths the programs modules can take. Flowcharts should show how program modules are connected and what input/output files are used. If some modules are executed only under certain conditions, state those conditions. Show how the computational sequence and solution strategy described in part A(5) are related to the program module flow.

(c) Data Structures. Discuss how data are stored during computation.

(d) Initialization. List values automatically assigned to important variables. These should include values of physical significance and parameters which affect program execution. State where the values are initialized and whether they are default, fixed, or sampled values.

(e) Restart procedures. Describe any restart capabilities of the code and how they are used.

(f) Error processing. (NQA-2a-1990, Part 2.7, Section 6.5(e)). Describe the points of origin and likely causes of all major error messages, error switches, and abnormal stops.

(g) Input Data. (NQA-1-1989, Supp. 3S-1, Section 3.1(b)(2), Sections 194.14 and 194.34). All input files should be included and documented. Complete input data files used for the compliance application performance assessment execution should be included and documented. Complete example problems should be included and explained.

(h) Screen Output During Execution. Information output to the screen that is shown during program execution should be clear, meaningful, and useful. Details of program/model execution should be presented that show performance clearly.

(2) Data files. (NQA-2a-1990, Part 2.7, Section 6.3(b)).

(a) Content. Outline the general content, purpose, and organization of each data file.

(b) Use by program. Describe how and when the files are read and written by the program.

(c) Auxiliary processing. Describe any available auxiliary programs that create, modify, or use the files, such as listing and plotting programs.

(3) Input data. (NQA-2a-1990, Part 2.7, Section 6.3(b), Section 6.5(b), (c); NQA-1-1989, Supp. 3S-1, Section 3.1(b)(2), Section 194.14 and 194.34).

(a) General considerations.

(I) Techniques. Describe special input techniques and requirements (e.g., blank field treatment, order of items, field delineation).

(ii) Consecutive cases. If the code can retain input data from previous runs, give conditions for retention and reinitialization (i.e., restart procedures).

(iii) Defaults. Give the general conventions governing default values.

(b) Individual input records.

(I) Record identifier. Give the line identifier, if any, for this type of record.

(ii) Format. Specify the format of this record, if any.

(c) Input variables.

(I) Input variables. Identify the variables that will contain data given on this record.

(ii) Need. For each variable, specify whether input is necessary or optional for both start and restart runs.

(iii). Repetition. State how many of these input values are used in the program.

(iv) Units. For each input variable, state the dimensional units.

(vi) Default. State the default value, if any, for each field.

(vii) Description. Define the meaning of each variable and discuss its primary use within the code. State how the user should assign values in setting up a run.

(viii) Range. (NQA-2a-1990, Part 2.7, Section 6.3(c)). State the acceptable limits for each variable necessary for successful operation of the model in the programming sense .

(ix) Origin. The origin of each variable should be clearly shown in the documentation (i.e., experimental origin, expert panel solicitation, literature, etc.). A complete explanation of the source of origin should be included in the documentation with appropriate references. Also see section 34 of this guidance.

(4) System interface. (NQA-2a-1990, Part 2.7, Section 6.2(e), Section 6.5(d)).

(a) System dependent features. List the external functions supplied by the system and state the purpose of each. Include plot, mathematical, input/output and memory management libraries; standard FORTRAN intrinsic functions may be omitted.

(b) Compiler requirements. Specify what compilers have been used and any special options that are necessary. Include compiler options, such as indirect large core memory addressing.

(c) Hardware requirements. (NQA-2a-1990, Part 2.7, Section 6.2(d)). Describe the hardware needed to run the software and any special items needed. State the amount of central memory required for a typical case, or give an algorithm for finding the required amount of memory. PA codes should be portable to EPA computers or otherwise accessible to EPA staff.

(d) Control, input, or command files. (NQA-2a-1990, Part 2.7, Section 6.3(b)). All computer programs require some system commands to control program initiation, manipulation of files, and interaction with other programs. Describe the control inputs or command files necessary to run the code as part of a modeling analysis (NQA-2a-1990, Part 2.7, Section 6.3(b)). Use flowcharts to clarify program module connectivity. The appropriate level of detail will depend on the degree to which control inputs and command files contain logic affecting program flow, manipulation of files, and communication among programs. Give sample control input or command files. Discuss application dependence.

(5) Output. (NQA-2a-1990, Part 2.7, Section 6.5(c), CAG Section 194.34). Discuss the code output. Relate edited output to input options, and state the origin and meaning of the output variables. Describe any normalization of results and list associated dimensional units. Describe any graphical capabilities of the code or other software tools used to interpret results.

(6) Sample/Test problems. (NQA-1-1989, Supp. 11S-2, Section 2.2). The user's manual should include problems/tests that are prepared and documented so EPA staff can execute them. Choose problems or tests which demonstrate how the code is used. Input listings and sample output should be provided.

C. Programmer's Manual

Each computer program should have a Programmer's Manual. While the User's Manual is designed to provide instructions how to run the entire PA system of program modules, the Programmer's Manual is designed to fully document individual programs. The Programmer's Manual should contain a discussion of the theoretical background implemented by the program, a complete annotated listing of the program, a block diagram of critical elements and subprograms, and a complete flowchart of the program.

(1) Theoretical Background. Describe conceptual and mathematical models and numerical methods used, if any. This section should be sufficiently complete to stand alone as a basis for review of the methods used in developing this program.

(2) Program Listing. Fully document the program source code with clear comments throughout. Appendix B is a sample of the suggested program, subroutine, and function source code preamble documentation. Reference the guidance in Section C.

(3) Block Diagram. The block diagram should be the connectivity diagram of the subprograms and functions called by the main program.

(4) Program Flowchart. The program flowchart should be detailed enough for the reviewer to follow program operation. For example, the reviewer should be able to follow the flowchart through input of values, initialization of values, computation of results, and output of results.

(5) Data Structures. Describe the purpose and content of important common blocks and arrays. State the array dimensions. If dynamic dimensioning is used, describe the indexing algorithm and dynamic memory allocation procedures. This section, with a code listing, should be sufficient to allow the user to follow the flow of important data through the computational sequence. If variable names change from one module to the next completely document these name changes.

(6) Error Reporting. Error conditions and consequences of these errors should be completely documented. Suggestions about how to correct each error condition should be documented.

(7) Software Verification and Validation. Reference section D.(2).

(8) Peer Review. Reference section D.(1). (CAG section 194.27).

D. Code Assessment

The documentation on code assessment, peer review, quality assurance and support should describe to what extent and how the code has been verified and validated. It should also documents the various code versions in use and the steps being taken to control and maintain these versions. One purpose of this documentation is to keep all parties aware of the practical limitations of the code, to record application-oriented modifications, and to help ensure that the code is as error-free as possible. This section should document how Quality Assurance (CAG Section 194.22) and Peer Review (CAG Section 194.27) have been implemented.

The goal of this section for compliance application is to ensure that the PA computer codes have been adequately peer reviewed, validated, and quality assured. In addition, this document describes steps the Department is taking to ensure that code performance will not be degraded by future changes.

(1) Model peer review. (NQA-1-1989, Supp. 3S-1, Section 3.1(b)(6), CAG Section 194.27). Computer codes require peer review (CAG Section 194.27) to evaluate the adequacy of the conceptual model, the conceptual model implementation in computer code, and the implementation of important mathematical procedures. Peer review should be used for the major performance assessment models, such as the repository room model, the cuttings transport model, the flow and transport hydrological model, the source concentration model, and the calculation of CCDFs. This peer review process should be completely documented. (CAG Section 194.27, "Peer Review for High-Level Nuclear Waste Repositories," NUREG-1297).

(2) Software Verification and Validation. (NQA-2a-1990, Part 2.7, Section 4; NQA-1-1989, Supp. 3S-1, 4; NQA-1-1989, Supp 11S-2). All computer codes used in the PA system should be verified, validated, and documented as described below. Each individual element of a program or subprogram should be verified to produce designed results. Complete program modules should also be validated to perform as designed. Software verification is the process used during the development of software to ensure that each element of the program system performs as designed and that a computational model appropriately solves and implements the mathematical model. Software validation is the process used to ensure that a program or program system performs as designed and provides adequate results. In other words, it is the process of substantiating that the conceptual/mathematical/computational model is consistent with the intended application. Methods of validation include: (1) simulation of laboratory experiments; (2) field experiments; (3) analogy with a similar and previously validated model; and (4) peer review.

A software verification plan should be developed and documented to evaluate the performance of all the computer codes used for PA during software development. The program methods, procedures, and results should be documented and include evaluation and testing of individual components and subroutines, groups of interrelated component modules and subroutines, and the complete PA system of codes. The testing plan should examine error handling, boundary conditions, calculation errors, flow control, and hardware dependence, etc.

Verification of computer codes consists of static and dynamic verification and they should be applied at four levels: (1) interrelated program components; (2) interrelated groups of program subroutines and functions; (3) individual subprograms; and (4) line-by-line evaluation. These levels of evaluation characterize the execution of the total system of codes down through important individual code segments. Therefore, code verification ensures that all aspects of code behavior have been completely evaluated and documented.

Static examination consists of examination of the source code for logic errors and correct implementation of mathematical and computational equations and algorithms. Static evaluation examines source codes in sufficient detail to ensure the code is an adequate implementation of the model being considered. Static examination is accomplished by an independent reviewer auditing the source code for adherence to standards (i.e., the NQA standards), code quality (i.e., structural and functional characteristics), and code correctness.

The purpose of dynamic verification is to verify that the codes perform all of the design functions. Dynamic examination consists of executing the codes on test cases and verifying the adequacy of the results. Parametric sensitivity analysis, extreme value sampling, strong and weak mutation testing, and benchmarking are methods used for dynamic testing of computer codes. The final dynamic method is production testing that uses actual input data for the PA codes and an evaluation of the adequacy of the results.

Static and dynamic methods can be combined by examining the actual source codes' logic and implementation and by executing the code segment in question to ensure proper results are obtained. These methods can be used to test structural/functional code connections, such as statement testing, branch testing, condition testing, error handling, input-output performance, efficiency of algorithms; in other words, all aspects of the source code implementation. These evaluations should be completely documented.

Validation of PA software codes is performed during development and at the end of the software development phase to ensure that the PA system of codes produces results expected by the software design (i.e., appropriately implement conceptual models). Development of test plans and test cases are the primary method used to validate PA codes. Final validation tests all PA codes together to examine interaction of the complete system.

Verification and validation plans and results should be documented. The plan for verification and validation of the code should include past, ongoing, and planned future activities. Give descriptions of methods and procedures, input files, and results of specific test or benchmarking exercises with other computer codes. State what aspects of the code each test demonstrates and discuss how well the code performed. Describe any plans for modification of the model as a result of the test.

Additional guidance that may prove useful to the Department may be found in the code verification and validation sections of "Software Quality Assurance Program and Guidelines," (NUREG/BR-0167) and "Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry," (NUREG/CR-4640, PNL-5784).

In addition to documentation discussed above, Department will need to provide the following support for the computer codes used in any application:

Technical contact. (NQA-2a-1990, Part 2.7, Section 6.5(f)). Identify a person who can be contacted directly by the EPA staff with technical questions about installing and running the code. EPA should be informed whenever a new person is given this responsibility.

Response to EPA questions. (NQA-2a-1990, Part 2.7, Section 6.5(f)). Provide responses to questions by EPA concerning the model, its use, or installation. Questions will state whether written response, response by telephone, or a meeting is required.

Section 194.24 Waste characterization

Existing and future contact-handled and remote-handled transuranic waste (CH-TRU and RH-TRU respectively) destined for disposal at the WIPP must be characterized for three main purposes related to EPA's jurisdiction: 1) to identify what waste is planned for disposal at the WIPP; 2) to determine release limits for the WIPP based on the total inventory of curies; and 3) to demonstrate compliance with the disposal regulations in subparts B and C of 40 CFR part 191. While EPA expects the Department to describe the waste destined for the WIPP, the Agency does not expect DOE to measure or quantify all possible characteristics or properties of TRU waste. The Department should identify all waste characteristics which are important to system performance and use this information as the basis for waste characterization activities. As stated in the proposed rule, any application for certification shall identify, in detail, the chemical, radiological and physical characteristics of all waste proposed for disposal in the disposal system. It is expected that the application will list all of the waste intended for disposal at WIPP and their associated waste characteristics and use this as a basis for the identification of the important waste characteristics. The term "important" as used in this section is considered to include waste characteristics that may singly or in combination affect the WIPP's ability to contain radionuclides. The application should list and discuss those characteristics considered "important" as identified in the waste characterization study. The application should also list and discuss why other characteristics were deemed "unimportant" to system performance. Any characteristic (e.g., solubility, curie inventory, liquid saturation, metal content, waste compressibility) deemed important in the past by DOE, such as in past performance assessments, should be considered important in the application unless the Department demonstrates otherwise. These important characteristics should be linked to the waste which exhibits the characteristics.

The application should address the following information:

1) A study of waste characteristics to determine those which are important to the containment of the waste;

2) A description of the waste envelope established for WIPP wastes;

3) A description of the established categories of waste which are expected to behave similarly in the disposal system;

4) An overall description of the waste detailing the physical, chemical and radiological properties of each category of waste;

5) The identification of all the waste analysis methods to be used; and

6) A description of the established system of controls.

1. Waste Characterization Study

A study of the characteristics of the waste must be performed in order to determine their effect on the performance of the disposal system and the system's ability to contain radionuclides; this includes, but is not limited to, determining the effect of the waste on processes which are generally expected to influence containment, such as gas generation. The results of this study will dictate the breadth of the characterization to be performed. The study should be based on a list of all known and to-be-generated inventory items and their associated waste characteristics. Inventory items would include anything that DOE expects will be placed in the WIPP, such as glass beakers, paper, glove box constituents, chelators, iron, and the specific radionuclides.

The application will need to demonstrate that in identifying the important waste characteristics a defensible screening process has been applied to the initial list of waste. The Department may choose how to screen the waste, but its expected that relevant literature will have been examined, existing and ongoing DOE and contractor studies will have been reviewed, and that appropriate experiments and analyses will have been conducted where necessary. In cases where the initial screening may not be sufficient to discount certain characteristics (including those characteristics explicitly included in 194.24), the Department should conduct calculations to demonstrate that a particular characteristic of the waste is or is not important.

The application must demonstrate that the study includes:

a) Consideration of all reasonable characteristics of transuranic waste proposed for disposal at the WIPP (listed completely). At a minimum, the applicant must include the following in the study: waste form; free liquid content and liquid saturation; pyrophoric and explosive content; factors affecting the solubilization and mobilization of radionuclides (including formation of colloidal suspensions containing radionuclides); production of gas from the wastes; nuclear criticality; generation of heat in the disposal system; and the impact of non-radioactive hazardous components of the waste.

b) Consideration of the processes related to the performance of the disposal system which may be influenced by the individual and combined characteristics of the waste (listed completely). Some examples include identifying the:

-Waste related physical and chemical processes likely to occur at WIPP and the potential set of conditions likely to exist in the repository as a result of these processes, such as the Ph of the liquid (from the waste and the brine) in the repository.

- Characteristics of the waste which influence the mobilization of radionuclides (e.g., solubilization and colloid formation) and the relative significance of each. For example, the presence of chelators, ligands, buffers, or compounds could affect pH, as well as interactive processes (such as carbon dioxide generation) that

could create conditions favorable for the mobilization of radionuclides.

- Characteristics of the waste which influence gas generation and the relative contribution of each to the gas generation process over time.

- Characteristics of the waste which influence criticality under disposal conditions (e.g., the presence of moderators, neutron poisons, getters, precipitation and adsorption characteristics that could concentrate fissile material). An estimate of the probability of a criticality event should be provided.

- Effects of increased temperatures from criticality or exothermic reactions on processes such as gas generation and deformation of the disposal system.

- Impact of the presence of free or bound water (or other liquid in the waste) on gas generation and radionuclide solubility.

- Effects of various waste emplacement (i.e., loading) schemes and the curie content of transuranic isotopes in individual drums (or other containers) on potential releases to the environment through cuttings from intrusion drilling.

c) Documentation which justifies the decision to include or exclude a waste characteristic for use in the performance assessment. Should the applicant believe that additional characteristics of the waste need to be considered, the Department is encouraged to add them. In addition, DOE may exclude the analysis of one or more waste characteristics if the Department can demonstrate that the property(s) is/are not important to containment of the waste.

The discussion of this study should address the following: the documentation of the methodology used to assess each characteristic of the waste; the results for each characteristic (a table may be used for this purpose); and information describing the importance of a particular characteristic. Uncertainties in the waste characteristics should also be addressed.

2. Waste Envelope

The Department must provide a defensible estimate of the important waste characteristics used in the performance assessment modeling. This estimate should incorporate information from the waste characterization study. The results for each characteristic may be expressed as a value or range of values expected to be present in the total inventory destined for disposal. Such quantification is to be expressed as a limiting value (maximum or minimum, depending on whether containment is degraded or improved) or range of values (maximum and minimum) over which performance assessment sampling may have been conducted for each waste characteristic selected for retention. The Department must demonstrate that the WIPP complies with the containment, individual and groundwater protection requirements of 40 CFR part 191 over the

entire range of values for each waste characteristic. This demonstration should include an analysis for which all of the important waste characteristics simultaneously have values that would produce the greatest releases, all other things equal. If, for example, iron content is determined to be important, the application should provide an estimate of the amount of iron (such as a range of iron mass between 10 and 100 tons) that DOE intends to place in the WIPP. There should be an analysis that includes the maximum amount of iron (100 tons) that may be shipped to WIPP, and this analysis should also include the highest radionuclide solubilities expected (assuming solubility is considered important) and any other important characteristics at their respective limits.

3. Waste Categories

The Department must develop categories of waste which are expected to behave similarly in the disposal system, including under conditions of intrusion into the repository. Waste categories should be composed of the inventory items that would behave similarly in the WIPP. There should be a discussion of the waste category and its relationship to the performance assessment. Once established, the Department should use the waste categories to describe, track and analyze the performance of the waste (and its containment) in the WIPP.

The Department should avoid the use of categories of "miscellaneous" waste that are commonly used at generator sites. Unless the Department can demonstrate through use of representative data that such undifferentiated waste can be expected to be inert with respect to compliance or behave relatively uniformly as a category in the disposal system, the Department should not use of a "miscellaneous" waste category.

4. Waste Description

The Department must provide a detailed narrative that identifies and describes the physical, chemical, and radiological characteristics of each category of waste established. The Department may supplement the narrative with the use tables to present the various categories. In developing the detailed narrative of the waste in each category, consider the following:

> Physical Characteristics - Provide a comprehensive description of the types of items, articles, and materials present in the waste and how they are grouped together (segregated or not); a description of the waste matrices, 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.
>
> Chemical Characteristics - Provide a detailed description of all process chemicals likely to be present in the waste and all added components (neutralizers, stabilizers, solidifiers, etc.) including approximate total quantities. In addition, provide information about the chemical properties of other items present that could impact performance.

Radiological Characteristics - List the species and quantities of the radioisotopes present in the waste, including significant daughter radioisotopes. Also, provide information on the expected distribution of curie loading by container, TRUPACT shipment, room or other unit as established for the tracking system; the surface radiation levels of containers, including types of radiation; the surface-removable contamination levels; and the classification of the waste material as CH-TRU or RH-TRU.

5. Waste Analysis Methods

The Department must include a detailed description of the methods or combination of methods selected for analyzing the inventory important waste characteristics and their associated components. The description should include the uncertainty associated with each method. Numerous waste characterization methods exist, including sampling and analysis, radioassay, real-time radiography, and process knowledge. The Agency is not specifying that any particular method be used; however, each method that is used must be fully identified and described. This description must identify the waste form that is characterized; the facility where the method is used; and the comparability of each method among the waste generating/characterizing facilities. Where numerical values are obtained, the limits of the analytical method used must be discussed, including error bands. The link to PA should also be discussed. Where qualitative methods are used, a discussion of the uncertainty must be included. The Agency does not expect the Department to conduct sampling and analysis of every drum, but it is expected that sampling and analysis will be conducted periodically in order to assess the quality of the other waste analysis methods.

Waste characterization methodologies should be directly related to system performance with the establishment of data quality objectives for each specific waste parameter. Requirements for data quality objectives are addressed in section 194.22 of this document.

The use of process knowledge to characterize wastes is allowed; however, in so doing, the Department must demonstrate the following:

a) process knowledge is clearly defined and implemented consistently among the different waste generating/characterizing facilities (including a discussion of its application at each facility);

b) how the process knowledge will be verified through a combination of documentation, process controls, audits and statistically valid sampling and analysis;

c) characterization is substantiated through the submission of process description documentation; and

d) the confidence level in the parameters quantified meets or exceeds the data quality needs for their intended use in the performance assessment.

6. System of Controls

The Department must develop and institute an accountability system which includes measurement, monitoring, sampling, and record keeping in order to ensure that waste and each associated important characteristic of waste actually falls within the specified values or ranges (i.e., waste envelope) used in the application prior to emplacing the waste in the disposal system. It is expected that when the Agency conducts an inspection at a generator site or the disposal facility, DOE will have available for immediate access the information detailing the amount and characteristics of each category delivered to WIPP and the location of the waste categories in the disposal facility.

The application must provide the following:

a) the identification and description of the accountability system developed to track waste to be emplaced in the disposal system (the system should be able to identify non-compliance waste before the waste is emplaced);

b) the unit of waste to be tracked;

c) an implementation plan which includes a discussion of safeguards in the system;

d) an analysis of the uncertainty associated with the administrative controls used in the accountability system;

e) assurance that the tracking system is of sufficient accuracy to ensure that waste placed in the WIPP falls within the approved waste envelope; and

f) assurance that the tracking system has the ability to separately track contact-handled and remote-handled waste.

Waste characterization activities must meet the requirements specified in 40 CFR section 194.22 Quality Assurance and 40 CFR section 194.27 Peer Review. The Agency will verify the waste characterization requirements of this section through audits and inspections.

Section 194.25 Future States Assumptions

Changes in geologic, hydrologic and climatic conditions are expected to be incorporated into assessments of the WIPP's performance (see CAG section 194.14 for more information). However, 40 CFR Section 194.25(a) requires that "characteristics of the future" or "future states" be assumed by the applicant to remain what they are today. In evaluating the performance of the disposal system over the 10,000 year regulatory period, it is necessary to make assumptions concerning certain aspects of human existence and societal conditions. Recognizing the highly

speculative nature of such assumptions, EPA is requiring that the applicant presume that human existence and societal conditions which exist today will continue to exist over the 10,000 year regulatory period. For purposes of this section, the term "today" means "the date of the application." The current practice for those applicable items should be substantiated in the application. The following are examples for which the future states presumption may be made. These examples relate to compliance with 40 CFR Sections 194.33, 194.51, 194.52 and 194.55. Section 194.33 establishes future states assumptions related to human-initiated processes and events.

Average Man

1. Physical Characteristics

   The applicant should assume that the current physical characteristics exhibited by an average human being today also will be exhibited by individuals living during the 10,000 year regulatory time period. For example, if an average adult, representative of the current population of the United States, weighs 70 kilograms, is 170 cm in height, is 30 to 40 years of age, and has an average life expectancy of 70 years, then persons living in the future also shall be assumed to exhibit the same characteristics. Assumptions regarding the future state of human physiology are an important consideration in exposure risk calculations.

2. Living Habits

   The applicant should assume that the current living habits of an average adult, representative of the current population of the United States, will continue to be exhibited over the 10,000 year regulatory time period. Living habits include, but are not limited to dietary habits, work habits, and recreational habits. If, for example, the average individual's diet currently consists of: 200 g/d vegetables, 140 g/d fruits, 0.4 l/d milk, 170 g/d beef, and 54 g/d fish, then it shall be assumed that the same will be true for the average individual living in the future. Assumptions regarding the future state of human living habits are an important consideration in risk calculations.

3. Technology

   The state of technology used today should be assumed to continue throughout the regulatory time frame.

Section 194.26 Expert Judgment

EPA recognizes that expert judgment may be necessary to support disposal system compliance analyses. However, the use of expert judgment is limited to situations where data are not

reasonably obtained through data collection or experimentation. Although no particular method for expert judgment elicitation has been prescribed by the Agency, several guidelines and restrictions apply. For example, all data resulting from expert judgment elicitation should be identified, and the process of eliciting expert judgment should be described and document, including the basis behind the results. In addition, the Department should provide information which demonstrate that the restrictions applicable to panelist selection and expert judgment elicitation have been applied. Further, the application should provide information demonstrating that selected individual(s) qualifications meet or exceed that required for the material under review. Also, the elicitation process must afford opportunity for outside groups and individuals to present their scientific and technical views. Finally, the expert judgment elicitation must meet the requirements in section 194.22 Quality Assurance.

In addition, it is recommended, but not required that the Department consider the following general areas while developing the expert elicitation process, and providing documentation on these areas:

1. Bias of the individuals
2. Parameter definition
3. Methods of topic assessment
4. Factors and assumptions
5. Sources of uncertainty

1. Bias of the individuals

Individuals' special interests on the outcomes of the activity should be explored. While EPA recognizes that bias cannot be eliminated, DOE should aim for a balanced panel.

2. Parameter or topic definition

The expert should agree upon the definition of the parameter or topic needed to be quantified. In addition to being presented appropriate background information, this exercise may involve acquiring information about other parameters or other information in the performance assessment. In addition, the application should discuss the types of information considered acceptable (for example, anecdotal information could be considered unacceptable) by the expert judgment participants for the individual parameter or topic.

3. Methods of topic assessment

Methods for measurement and assessment of the parameter under investigation are reviewed by experts. This serves several purposes. First, it may provide the participants of the expert elicitation group better insight into the participants particular strengths and weaknesses (e.g., theory, laboratory experiments, field measurements, etc.).

4. Factors and Assumptions

A list of factors and assumptions that the parameter under investigation depends on is created by the experts. Participants should be asked to list those assumptions that they would be making when assessing the uncertainty about the parameter or topic. The discussion arising about the couplings and the assumptions can lead the participants to provide a better definition of the parameter or topic for assessment.

5. Sources of Uncertainty

The participants are asked to list the uncertainties and assess their contributions to the parameter uncertainty.

The application should provide the following documentation for expert judgment:

1. All instances in which expert judgment is used, and providing a table that cross-references other sections of the application where the expert judgment data are used

2. An explanation of the reasons that support the Department 's selection of the use of expert judgment elicitation instead of experimentation

   - As stated in 40 CFR part 194, expert judgment should not substitute for information that could be reasonably obtained through data collection or experimentation. In justifying the use of expert judgment, DOE should explain why data collection or experimentation is not reasonable. The Department should also provide information regarding the availability of experimental data that are in the process of being collected. The Agency will consider such information when evaluating the completeness of the application, data quality, and potential conditions of compliance.

3. Identification of experts (by name and affiliation), including information which demonstrate that the expertise of the group as a whole has the relevant knowledge required

   - This could be done with a curriculum vitae should be presented on each expert panel member which lists, at a minimum: past and present professional or contractual affiliations, memberships in any honorary societies, list of publication and abstracts, work and educational experience, lectureship positions, professional awards and a history of grants and monetary awards for research received.

4. Description of the process for expert judgment elicitation

5. Information that demonstrates restrictions on the selection of individual(s) and eliciting

expert judgment have been applied

- If the expert panel member's employing organization performs work relevant to the WIPP, an organization chart should be presented which demonstrate that there is an absence of influence from anyone working on the WIPP project.

-If the panel member is employed by the same organization that requests the elicitation or by an organization performing the work for DOE on WIPP, an organizational chart should be presented which demonstrate the absence of influence of the requesting party over the panel member.

-Supporting documentation should be provided, in instances where an expert panel consists of fewer than two-thirds non-DOE employees (including contractors and sub-contractors), which documents any efforts made to solicit the participation of non-DOE members. Sufficient documentation should consist, at a minimum, of a list of all non-DOE employees who were sent letters of nomination or were otherwise solicited for participation on the panel. A documentation of all responses to letters of solicitation by those potential individuals should be submitted. (Note that, as stated in the proposed criteria, in no case should fewer than one-half of the experts be non-DOE employees.)

6. A discussion explaining the relationship between the information presented, the questioned asked, the judgment of any expert or individual, and the purpose for which the expert judgment is being used

7. Presentation of the results of the expert judgment elicitation and the reasoning behind the results

8. Background information provided to the experts

9. Questions or issues presented for elicitation

10. Information presented by outside groups and individuals, including names, affiliation, and information provided to the experts

11. Interviews used to elicit judgment from experts

12. Deliberations and formal interaction among experts

13. Information that demonstrate that expert judgment elicitation and results meet requirements in section 22.

Section 194.27 Peer Review

Peer review represents an important part of the process of assessing the methods, assumptions, data, and results of performance and compliance assessments. EPA believes that peer review can be helpful as a means of validating such information. Peer review is required in 40 CFR 194.27. Peer review involves a group of experts who are convened to review work conducted by their peers to determine whether the work was performed appropriately and in keeping with the purpose intended. In contrast, a technical review is a review by which the particular code, experiment, or study is determined to have meet the requirements of the code, experiment, or study. The peer review process is used in certifying or determining compliance. DOE should present information demonstrating that its peer review program conforms to the guidelines put forth in NUREG 1297 "Peer Review for High-Level Nuclear Waste Repositories." The Department should include information which demonstrates that peer review has been used to evaluate the following:

1. Engineered barrier study

2. The adequacy of the selection criteria used to screen features, processes, and events

3. Process of qualifying "existing data"

4. Models and computer codes

   - The adequacy and suitability of conceptual, mathematical and numerical models

   - Major PA program modules (e.g., the repository room model, the cuttings transport model, the flow and transport hydrological model, the source concentration model, the CCDF derivation and presentation programs)

5. Data used in models and computer codes

   - Input parameter probability distributions

   - The adequacy of data to confirm models

6. Waste characterization

   - Waste characterization study

   - Adequacy of categories of wastes

   - Adequacy of values, or ranges of values, for waste characteristics (i.e., waste envelope) and DOE's process to obtain the values (e.g., waste characterization

methods)

- Adequacy of waste control system to track WIPP waste from transport to emplacement in the WIPP, and which can ensure emplaced waste meets the waste envelope of the application of certification

Section 194.31 Application of release limits

For purposes of calculating radionuclide releases at the WIPP, the application for certification of compliance should use an estimate of the curie activity expected to comprise the total inventory 100 years after disposal of the waste. The waste disposal period (from 40 CFR section 191.02) begins when all of the shafts to the repository are backfilled and sealed. As long as the release limit calculations are clearly delineated, the information from this section can be discussed with the information on waste characterization from section 24.

Notes on the Application of Table 1, 40 CFR part 191

The release limits in Table 1 apply to the amount of wastes destined for WIPP containing one million curies of alpha-emitting transuranic radionuclides with half lives greater than 20 years. In using the release limits for the WIPP, the quantities in Table 1 should be applied to the inventory of waste expected to be included in the disposal system 100 years after disposal compared to the various units of TRU waste (see example below).

The application should list the radionuclides according to Table 1 of 40 CFR part 191, including the concentrations expected at the time of disposal and at 100 years after disposal (i.e., the inventory range and appropriate statistics of the estimated waste envelope). The application should also include the same information for significant decay products. The application should include at least a summary of the calculations used to develop the TRU unit for the radionuclides and their relative contribution to the normalized releases.

While the release limits are calculated for the entire inventory, the application should also list radionuclide concentrations according to the assumptions used in the performance assessment. The application should reflect the expected radionuclide distribution in the repository (see section 24 of this guidance for more information on this topic). If the performance assessment assumes that radionuclides will be evenly distributed throughout the repository, the application should reflect this distribution. If the performance assessment assumes some other waste emplacement plan (such as a concentration of high curie drums in one panel), the application should reflect the plan used. Whatever distribution is used, its affect on the performance assessment should be discussed.

Once release limits for WIPP have been determined, they should be used to demonstrate compliance with the requirements of 40 CFR section 191.13. In cases where a mixture of

radionuclides is projected to be released to the accessible environment, the limiting values should be determined as follows: For each radionuclide in the mixture, determine the ratio between the cumulative release quantity projected over 10,000 years and the limit for that radionuclide as determined from Table 1 and the notes on applying Table 1. The sum of such ratios for all the radionuclides in the mixture may not exceed one (1) with regard to 40 CFR section 191.13(a)(1) and may not exceed ten (10) with regard to 40 CFR section 191.13(a)(2).

For example, if radionuclides A, B and C are projected to be released in amounts Q_a, Q_b, and Q_c, and if the applicable release limits are RL_a, RL_b. and RL_c, then the cumulative releases over 10,000 years should be limited so that the following relationship exists (for a normalized release of 1 in accordance with 40 CFR section 191.13 (a)(1)):

$$\frac{Q_a}{RL_a} + \frac{Q_b}{RL_b} + \frac{Q_c}{RL_c} \leq 1.$$

Example calculations for a hypothetical inventory of three radionuclides:

TRU Unit $$\frac{3{,}500{,}000 \text{ curies TRU}}{1{,}000{,}000 \text{ curies TRU}} = 3.5$$

	Activity (hypothetical)	Projected Release (p=0.1)	Factor from Table 1	Release Limit
Pu-X	2.0×10^6 Ci	200 Ci	100	100 x 3.5=350
Am-Y	1.0×10^6 Ci	75	100	100 x 3.5=350
Pu-Z	0.5×10^6 Ci	25	100	100 x 3.5=350
Total	3.5×10^6 Ci			

Cumulative Normalized Release $$\frac{200 \text{ curies Pu-X1}}{350} + \frac{75 \text{ curies Am-X1}}{350} + \frac{25 \text{ curies Pu-X2}}{350} = 0.85$$

0.856 is less than one, so it satisfies this part of the calculation.

Section 194.32 Scope of performance assessments

As stated in 40 CFR part 191, performance assessment means an analysis that: 1) Identifies the processes and events that might affect the disposal system; 2) examines the effects of the 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." Performance assessments should consider both natural and human-initiated events that may affect releases for a period of 10,000 years after closure of the repository. Performance assessments do not have to consider process, events, or sequences of processes and events that have less than one chance in 10,000 of occurring over 10,000 years.

The identification of processes and events in number 1 above is typically interpreted to mean the identification of scenarios, or alternative "realities" that could exist at the site in the future. The main concern for 40 CFR parts 191 and 194 are those scenarios that could impact on the transport of radioactive materials to the accessible environment. While the separation of an event and process may sometimes be unclear or part of a continuum, for purposes of discussion, an "event" is defined as a short-term discrete occurrence, such as an earthquake; a "process" is more or less long-term and ongoing, such as ground-water flow or creep closure of a repository room.

Natural features, events, processes (feps) and human-initiated events that could potentially affect the repository under undisturbed and disturbed conditions are the components of what are commonly referred to as scenarios. The combination of natural features, events, processes and human-initiated events that survive the screening process form the scenarios to be evaluated for their potential contribution to releases. If expert judgment (as defined in 194.26) is used in this process, it should be clearly identified and documented.

Items investigated and the method used to arrive at the final scenarios retained for analysis should be fully documented. In order to be complete, the WIPP application should clearly:

1) Identify an initial comprehensive list of potential features, events and processes that could potentially affect repositories;

2) Identify the source of the comprehensive list and discuss the method by which it was developed;

3) Discuss the screening criteria and procedure for initially eliminating processes and events in the comprehensive list;

4) List the features, events and process and the combinations of feps that, at the WIPP site, could have an effect on radionuclide transport to the accessible environment and discuss the rationale for excluding those events and processes that have been screened out. Calculations should be presented as part of this process; and

5) Specify the combination of features, events and processes retained for consequence analysis.

Where possible, there should be a discussion and a quantitative analysis presented (as opposed to

referenced) in the application for each "feature, event, or process." If there is not a quantitative analysis, there should be a logical argument to support the lack of a quantitative analysis.

The features, events, and processes selection/exclusion process should address at least the following criteria:

1. Physical reasonableness
   The Department should address whether a process or event could conceivably occur or has already occurred in the Delaware Basin or under similar geologic conditions. If the event or process happened in the past, it also could happen in the future and should be considered. There should be some ranking system that would demonstrate the following information: whether or not the event or process is physically possible at WIPP; whether or not there is evidence on which to base a quantitative analysis; or whether or not an event has previously happened at or near the WIPP site. For example, near-surface dissolutioning may have a high ranking, but igneous intrusions may have a low ranking.

2. The probability of the event or process
   The Department should list and discuss the probability of the events and processes that could occur at WIPP. Those events and processes with probabilities less than 10^{-8} yr (1 in 10,000 over 10,000 years) do not need additional analyses. Indirect events or processes, such as drilling into the Culebra but not into the waste, should be considered if they could potentially affect transport of the radionuclides within the disposal system. The method(s) used to determine the probability of an event should be discussed, including general calculations. The discussion should address the uncertainty associated with trying to estimate the probability of each event or process (e.g., lack of data).

3. Regulatory guidelines or requirements
   As stated previously, the Department need not consider any event or process with a probability of less than 10^{-8} yr (1 in 10,000 over 10,000 years). In addition, two scenarios that do not have to be considered are intentional intrusion[2] into the waste and potash mining effects within the disposal system. The specific regulatory requirements on this screening criterion can be found in the sections on future states assumptions (194.25) and consideration of human-initiated processes and events (194.33).

4. The potential consequences or outcome of the event or process
   The use of consequences as a screening criterion should be applied to the events and processes only after other criteria have been examined. For example, the probability of the event or process should be examined before the consequence. In order for an event or process to be screened out on the basis of its consequence, the Department should demonstrate, through the use of calculations if possible, that the potential consequence of

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[2]Intentional intrusion means an intrusion with the intent to drill for the radioactive waste in the disposal system.

the event or process does not contribute to movement of radionuclides toward the accessible environment.

The methodology should be applied consistently to all features, events, and processes. The groups of features, events, and processes remaining after screening will need to be combined into conceptual scenarios and this process will need to be documented in the application. Issues such as timing of combination of events should be addressed. As these conceptual scenarios are turned into computational scenarios, the steps used and assumptions made in the process should be clearly discussed (see Part 194.23 on Models and Codes).

In addition to the analysis of the random drilling that is occurring in the Delaware Basin (see Part 194.33), the application should include, in the performance assessment analysis, the potential effects of wells drilled under Federal Oil and Gas Leases No. NMNM 02953 and No. NMNM 02953C[3]. The application should include a discussion of the analysis and the process used to estimate the impact of wells drilled on these leases.

Section 194.33 Consideration of Human-Initiated Processes and Events

40 CFR section 191.13 requires that all significant processes and events which may affect the disposal system be evaluated to determine the cumulative releases of radionuclides to the accessible environment. Processes and events may result from natural or human-initiated events. 40 CFR section 194.33 requires that the Department assess the affects of human-initiated events on the performance of the disposal system. Among the potential human-initiated events, drilling is considered to have the greatest potential impact on disposal system performance. By limiting human-initiated events to drilling for resources, the Department is evaluating the most conservative human-initiated scenario. EPA does not interpret drilling events to include actual mining activities. However, the term drilling events would include any drilling associated with mining activities, such as drilling conducted to determine the presence or extent of minerals or ore.

Inadvertent and intermittent drilling events are separated into two categories per 40 CFR section 194.33(b)(3). The first category, human intrusion, is defined to include those drilling events that will reach or intersect the level of waste (at approximately 650 meters below the surface). In other words, human intrusion consists of the deep wells in the Delaware Basin. Such an event may directly affect the integrity of the disposal system. Examples of a human intrusion drilling event are the exploration for oil and natural gas resources and the use of injection wells around the repository. The second category, human activity, is defined to include those shallow (less than about 650 meters below the surface) drilling events that may affect the disposal system, but

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[3]As stated in section 4(b)(4) of the Land Withdrawal Act, Congress provisionally excepted these leases from the general exclusion of surface or subsurface mining or oil or gas production.

do not reach or intersect the level of waste within the disposal system. An event falling under this category may not directly affect the disposal system's integrity, but may impact the system indirectly by creating new groundwater flow pathways or otherwise altering the area hydrogeology. Two examples of a human activity event are drilling to explore for potash and drilling of water wells.

The Department should determine the frequency with which drilling events are likely to take place over the 10,000 year regulatory time period and the consequences which are likely to occur as a result. 40 CFR section 194.33(b)(4) and (5) specify the method to be used for calculating event frequency for human intrusion events and human activity events, respectively. Prior to conducting these calculations, the Department should note four factors which apply to both categories. First[4], in accordance with 40 CFR section 194.33(a), if it can be demonstrated to EPA that a specific type of human intrusion or human activity will not affect the disposal system, then the Department is not required to conduct further analyses of that specific type of human intrusion or human activity event. Second, in accordance with 40 CFR section 194.33(b)(2), all human intrusion and human activity events should be assumed to occur at randomly throughout the regulatory time frame. Third, in accordance with 40 CFR section 194.33(b)(4) and (5), the Department should use the Delaware Basin as the area in which to consider human intrusion and human activity events. Once the rate of events is determined for the Delaware Basin it will need to be appropriately scaled for the area of concern (i.e., controlled area or vicinity). Fourth, the Department should use the past 50 years as the time period for which human intrusion and human activity events are evaluated in the frequency determination.

As stated above, the method to be used in calculating the frequency of human intrusion events is provided in 40 CFR section 194.33(b)(4). This method is as follows:

1. The Department should first identify each type of human intrusion which has occurred within the Delaware Basin during the last 50 years. Oil and natural gas drilling and injection well operations are examples of possible types of human intrusion.

2. The Department then should determine the number of occurrences of each type of human intrusion over the 50 year time period. For example, the Department may determine that over the past 50 years 1,500 oil wells and 1,000 gas wells and some injection wells have been drilled within the Delaware Basin.

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[4]For purposes related to the scope of performance assessment screening process, it is taken as an established fact that drilling is physically reasonable and is not excluded by regulation. The probability of drilling into the disposal system is significant, and it is the specific probability (based on the drilling rate) that needs to be determined. Once the probability of drilling is determined, the consequences then need to be analyzed.

3. To determine the number of occurrences per area, the Department then is directed to divide the occurrences of each type of human intrusion by the area encompassed by the Delaware Basin. This should be accomplished in square kilometers. For example, the Department would divide the number of oil wells (1,500) and the number of gas wells (1,000) by 25,850 km^2. (Please note that the Department should determine the area of the Delaware Basin in accordance with the regulatory definition of the basin. The Department should not, in any way, construe the number presented here as the accepted number. This number has been provided only as an example.) The resulting number of occurrences per area in this example would equal 0.0580 oil wells/km^2 and 0.0387 gas wells/km^2.

4. The total number of occurrences for each type of human intrusion then is divided by 50 to yield the annual rate of occurrence. For example, number of occurrences of oil wells per area (0.0580 wells/km^2) and gas wells per area (0.0387 wells/km^2) would be divided by 50. This would result in an oil drilling rate of 0.0012 and a gas drilling rate of 0.0008.

5. The Department should assume that the rate of occurrence for each type of human intrusion remains constant throughout the 10,000 year regulatory time period. Therefore, the rate of occurrences for each type of human intrusion should be multiplied by 10,000 years. For example, the rate of oil drilling would equal 12 wells/km^2/10,000 years. Likewise, the rate of gas drilling also would equal 8 wells/km^2/10,000 years.

6. Once the rate of occurrence per 10,000 years has been determined for each type of human intrusion, the Department is directed to sum these rates. The resulting rate is the total rate of all types of human intrusion under consideration. For example, if the drilling rate of oil is 12 wells/km^2/10,000 years and gas is 8 wells/km^2/10,000 years then the total rate of occurrence of human intrusion would equal 20 wells/km^2/10,000 years.

7. If the total rate of occurrence of human intrusion is less than the regulatory lower limit of 25/km^2/10,000 years or greater than the regulatory upper limit of 62.5/km^2/10,000 years, then the Department should adjust the total rate of each type of human intrusion proportionally to result in a total rate which falls within the permissible regulatory range. For example, if the total rate of occurrence of human intrusion equaled 20 wells/km^2/10,000 years, then the rate of each type of human intrusion (oil and gas drilling) would be increased proportionally to yield a total result of 25/km^2/10,000 years. This increase would be apportioned as follows:
(12 oil wells/km^2/10^3 yrs * 25/20) + (8 gas wells/km^2/10^3 yrs * 25/20) =
(12 * 1.25) + (8 * 1.25)=15 oil wells/km^2/10^3 yrs + 10 gas wells/km^2/10^3 yrs =
25 wells/km^2/10,000 years.

8. The Department may reduce the total rate of occurrence of human intrusion in accordance with the passive institutional controls provisions. For further direction regarding this possible reduction, the Department is directed to 40 CFR sections 194.41 and 194.43(c) and the applicable sections of this guidance.

The Department should note that, per 40 CFR section 194.33(b)(4)(iii), in lieu of applying the above method, the Department may choose to assume that the total rate of occurrence of human intrusion is equal to the regulatory upper limit of 62.5/km^2/10,000 years.

40 CFR part 194.33(b)(5) specifies the method to be used to calculate the frequency of human activity. This method is similar to that employed for calculating the frequency of human intrusion, with the exception that no regulatory lower and upper limits are imposed on the rate and that resource quality may be taken into account. The method is as follows:

1. The Department should first identify each type of human activity which has occurred within the Delaware Basin during the last 50 years. Water and potash drilling operations are examples of possible types of human activities.

2. The Department then should determine the number of occurrences of each type of human activity over the 50 year time period. For example, the Department may determine that over the past 50 years 900 water wells and 1,800 potash wells have been drilled within the Delaware Basin.

3. To determine the number of occurrences per area, the Department is directed to divide the occurrences of each type of human activity by the area encompassed by the Delaware Basin. This should be accomplished in square kilometers. For example, the Department would divide the number of water wells (900) and the number of potash wells (1,800) by 25,850 km^2. (Please note that the Department should determine the area of the Delaware Basin in accordance with the regulatory definition of the basin. The Department should not, in any way, construe the number presented here as the accepted number. This number has been provided only as an example.) In this example, the resulting number of occurrences per area would equal 0.0348 water wells/km^2 and 0.0696 potash wells/km^2.

4. The total number of occurrences for each type of human activity then is divided by 50 to yield the rate of occurrence. For example, number of occurrences of water wells per area (0.0348 wells/km^2) and potash wells per area (0.0696 wells/km^2) would be divided by 50. This would result in a water drilling rate of 0.0007 and a potash drilling rate of 0.0014.

5. The Department should assume that the rate of occurrence for each type of human activity remains constant throughout the 10,000 year regulatory time period. Therefore, the rate of occurrences for each type of human intrusion should be multiplied by 10,000 years. For example, the rate of water drilling would equal 7 wells/km^2/10,000 years. Likewise, the rate of potash drilling also would equal 14 wells/km^2/10,000 years.

6. Should the Department determine that a particular resource is exploited at significantly different rates based on the resource's quality, then the Department may make a demonstration to EPA that the rate applicable to areas with resource quality similar to the controlled area should be used rather than a rate applicable to the entire Delaware Basin. For example, the Department may determine that the quality of groundwater within the

Delaware Basin differs significantly from one area to another. As a result, the use (e.g., domestic vs. stock vs. irrigation vs. dust suppression) to which that water is applied, as well as the corresponding drilling rate, also varies significantly. Within the controlled area, the Department may determine that the groundwater is generally poor, and therefore, is used only for the purpose of dust suppression. DOE could then take the historical rate of drilling into waters of similar quality as the water in the controlled area instead of the whole Delaware Basin. The corresponding drilling rate for this use was 5 wells/km^2/10,000 years. In this example, if EPA accepted a demonstration that the quality of water in the controlled area was substantively different from the Basin as a whole, and therefore, a subset of the Basin, then the water quality in the controlled area should be used to set the drilling rate. In this case, the Department could use 5 wells/km^2/10,000 years as the drilling rate for water.

7. The Department may reduce the total rate of occurrence of human intrusion in accordance with the passive institutional controls provisions. For further direction regarding this possible reduction, the Department is directed to 40 CFR sections 194.41 and 194.43(c) and the applicable sections of this guidance.

As indicated earlier, upon determining the frequency with which inadvertent and intermittent drilling events are likely to take place over the 10,000 year regulatory time period, the Department should next determine and evaluate the potential consequences of those events. The Department should accomplish this for both human intrusion and human activity events.

In evaluating consequences, the Department should examine the consequence of human-initiated events which occur within the controlled area and its surrounding vicinity. Human intrusion events include those that reach the level of the waste. Human activity events include those that do not reach the level of the waste in the disposal system, but, nonetheless, may affect the disposal system. No definitive boundary is provided in the regulations or this guidance regarding the delineation of the "vicinity" of the controlled area. As a result, the Department should propose and justify in the compliance application the relevant boundaries of the controlled area's surrounding vicinity. The Department is reminded, however, that events which do not have the potential to affect the disposal system are not to be considered in the analysis. As stated in section 14 of this document, vicinity may be described as that area in which an event could affect the disposal system. For example, although shallow water wells located five miles north of the controlled area's northern boundary will not directly intersect nor directly impact the integrity of the disposal system, their presence could result in a change in the recharge and groundwater flow patterns or rate which may cause a decrease in the migration time of radionuclides to the accessible environment. These water wells then would be considered to be located in the vicinity of the controlled area.

As stated earlier, the Department should assume that the events take place randomly in time and space. The Department also should assume that if more than one event is projected to occur, the consequence of each occurrence is to be added to the consequences of previous occurrences. In this way, the cumulative consequences of all occurrences will be determined. For example, the

Department would determine the consequence of the initial occurrence using a performance assessment analysis. This consequence may increase the gas generation rate within the repository. The consequence of the next occurrence then is calculated, taking into account the new gas generation rate caused by the first occurrence.

In assessing consequences, 40 CFR section 194.33(b)(6) directs the Department to apply the concept of future states to the engineering mechanics of the human-initiated events. This would include, but not be limited to, the types and amounts of drilling fluids, borehole depths, borehole diameters and borehole seals. For example, current drilling practices for oil and gas exploration in the Delaware Basin may use fresh water-based drilling mud to initiate a borehole, followed by brine water-based drilling mud to drill through the salt formations, followed by cut brine or a brine/fresh water mix with salt gel and caustic. In accordance with 40 CFR section 194.33(6), the Department would assume that the same drilling fluids would be employed throughout the regulatory time period.

The Department is also directed per 40 CFR section 194.33(b)(6)(b) that in evaluating consequences of human-initiated events: 1) boreholes will be assumed to be sealed at the same rate for which boreholes in the Delaware Basin have been sealed over the past 50 years; and 2) natural processes will be assumed to degrade or otherwise affect the permeability of boreholes over the 10,000 year regulatory time period.

The time period for which the Department should assume the borehole sealing rate begins with 50 years prior to the approximate date of submittal of the compliance application. To determine the borehole sealing rate, the Department should evaluate any regulatory requirements for well plugging and abandonment which have been in place and enforced over the 50 year time period, industry records, driller surveys, field records, etc.

Section 194.34 Results of performance assessments

40 CFR part 191 assumes that, wherever practicable, the probabilistic results of performance assessments will be presented in complementary cumulative distribution function (CCDF) to determine compliance with 40 CFR section 191.13. 40 CFR section 194.34 further states for the Department to submit CCDFs that represent the probability of exceeding various levels of cumulative releases caused by all significant process and events. The development of complementary cumulative distribution functions will need to be fully and clearly documented.

The Department will need to present complementary cumulative distribution functions that indicate the probability of exceeding the various levels of cumulative release. At a minimum, the data sets used to generate the CCDFs at summed normalized releases of 1 and 10 respectively, (see Table 1, note 6 of Appendix A of 40 CFR 191) should be presented in a tabulated form as well as available in a computerized format that EPA can analyze. The summed normalized values should also be presented in tabular form for at least the containment requirement probabilities of 0.1 and 0.001.

Once the probability distributions with their associated properties are developed, individual parameter values will need to be randomly sampled from the distributions. Any method used to sample parameter values should be fully discussed. The sampled values will need to be presented in a documented computer format. It is adequate to use the parameter sheet format presentation like that provided in Volume 4 of the 1992 WIPP PA as long as the appropriate formation (as presented above and in section 14 of this document) is included.

40 CFR section 194.34(b) requires that DOE should generate enough CCDFs so that there is a 0.95 probability that the 99th percentile CCDF will be exceeded. The Agency believes that the effect of this approach will be that the number of CCDFs generated will be large enough to ensure that a full range of realizations has been generated. In other words, there should be a high degree of confidence that very few CCDFs in the population of CCDFs are greater than those generated in the sample. EPA estimates that this will require at least several hundred realizations for successively generated CCDFs that are independently chosen and are uncorrelated. Assumptions that induce correlations between successively generated CCDFs would dictate a larger sample size than for the independent and uncorrelated CCDFs. The application should include a discussion that supports the sample size used by DOE in the performance assessment.

The full range of CCDFs generated is to be presented in plots that show the behavior of the individual CCDFs. The number of plots necessary will depend on the number of CCDFs that are generated for subsection (b) above. The CCDF curves should be numbered as practicable and the individual data points used to develop each individual CCDF should be available for computer analysis. At a minimum, the value of each CCDF at normalized release limits of 1 and 10 should be provided in tabular form. In addition, the mean, median, the 10th, 90th, and 99th quantile results should be presented, similar to what has been done in past performance assessments. In addition, the CCDFs should be presented in such a manner that they can be reproduced by EPA.

40 CFR section 194.34(d) requires evaluation of the 95 percent upper confidence limit (UCL) of the mean probability of exceeding the specified release levels to determine if the requirements of 40 CFR section 191.13(a) are satisfied. The UCL of the mean probabilities at normalized releases of 1 and 10 will be compared with the numerical requirements of 191.13 so the discussion should focus on the calculation of the mean and UCL at those two normalized releases.

Section 194.41 Active Institutional Controls

40 CFR section 194.41 requires that the Department provide a detailed description on plans for complying with the active institutional control assurance requirement stated in 40 CFR section 191.14. Active institutional control as defined in 40 CFR section 191.12(f) 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. 40 CFR section 194.41(a) directs the Department to provide detailed descriptions of the proposed active institutional controls, the control's location, and the period of time the controls are proposed to remain active. The Department also should discuss the methodology and procedures necessary to implement the proposed controls. For example, the Department could provide a plan describing the proposed security procedures and equipment necessary to control access to the site. These might include a 24-hour surveillance system, fence, locked entrance, warning signs, guard posts and controlled roadway access system. The location of each primary component, such as the fencing, guard posts, warning signs, etc., should be specified. As another example, the Department could provide a contingency plan to be enacted should a release occur which requires remedial actions.

40 CFR section 194.41(a) requires that the time period in which the facility intends to keep the control active be specified, although 40 CFR section 194.41(b) limits, to 100 years, the amount of time that the Department can take credit within the performance assessment for any active institutional controls. The Department should note that if the control is planned to be maintained for a period of time less than 100 years, performance assessment credit for that control may be taken only for the actual time that the control are expected to remain active and may not be taken for the full 100 year time period. It should be noted that 40 CFR section 191.14(a) requires that active institutional controls be maintained for as long a period of time as is practicable after disposal. Any assumptions taken in the performance assessment regarding the effectiveness of active institutional controls should be clearly supported in the information provided under this section.

Section 194.42 Monitoring

The 40 CFR section 191.14(b) monitoring assurance requirement states that disposal systems should be monitored to detect substantial and detrimental deviations from expected performance until it is determined that there are no significant concerns to be addressed by further monitoring. In considering potential parameters whose monitoring may provide the necessary information to detect such deviations, monitoring solely for radionuclides is not likely to yield sufficient information. Additional parameters can be identified which might provide information regarding disposal system performance. For example, benign tracers could be introduced into the repository with the intent of monitoring for those tracers in the groundwater at a variety of distances from the facility. Such monitoring might assist in evaluating the length of time it might take for radionuclides to reach the accessible environment. Regardless of the parameters selected, any monitoring techniques employed should not jeopardize the long-term isolation capabilities of the disposal system.

To further clarify implementation of the 40 CFR part 191 monitoring assurance requirement, EPA has provided additional directions to the Department in 40 CFR section 194.42. This section of the regulations separates monitoring into two categories: post-closure monitoring and pre-closure monitoring.

Post-Closure Monitoring

40 CFR section 194.42(a)(i) requires that the Department conduct post-closure monitoring for the purpose of detecting movement of radionuclides toward the accessible environment at the earliest practicable time. Post-closure monitoring begins when all disposal system shafts have been backfilled and sealed. The post-closure monitoring period ends when the Department can demonstrate to EPA that there are no significant concerns to be addressed by further monitoring. Any monitoring to be conducted should be detailed in a monitoring plan included in the compliance application as required by 40 CFR section 194.42(a)(ii). The plan should be consistent with the hazardous waste regulations specified in 40 CFR parts 264, 265, 268, and 270. In addition, the plan should not include techniques which would jeopardize the containment of the waste in the disposal system.

40 CFR section 194.42(a)(ii)(1-3) requires that, at a minimum, the plan should: (1) identify the parameters to be monitored (both radiological and non-radiological); (2) identify how the baseline for each parameters will be determined; (3) indicate how the monitoring results of each parameter will be used to evaluate the performance of the disposal system; and (4) discuss the length of time over which each parameter will be monitored.

The discussion of the monitoring plan should include the following:

- Description 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.

- Description of the proposed monitoring network (sampling locations) and defense of its design. The design of the monitoring network should take into account potential spatial and temporal changes in the disposal system and any contaminate plume which may occur over time. Spatially, the plan should allow for sufficient samples to be collected to adequately define the extent of any release and account for changes in the dimensions of the disposal system over time. Temporally, the plan should account for potential spreading of a release plume with time and for concentration variations due to physical and chemical processes such as retardation and degradation.

- Description and location of background sampling stations.

- Description of sampling method and equipment.

- 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. When a release is known to vary with time, grab samples collected at suitable intervals and analyzed separately can indicate the magnitude and duration of variations. A composite sample is a combination of more than one sample collected at various sampling locations and/or different times.

The use of composite samples generally yields average values which may not accurately describe the distribution of release concentrations. 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. Time is the most common parameter over which sampling periods are integrated.

- Sample preservation and handling.
- Chain of custody.
- Analytical methods.
- Detection limits.
- Monitoring schedule including the proposed initiation date to begin actual monitoring and the frequency with which monitoring will be conducted (schedule of the occurrence of monitoring events).
- Data evaluation and presentation methods (statistics).
- Evidence of the feasibility and effectiveness of the proposed monitoring approaches

Monitoring should be designed to detect the migration of radionuclides toward the accessible environment and also determine the physical extent of the release. This information should be used to determine if there is are substantial and detrimental deviations from expected performance. All monitoring should follow properly documented and implemented quality assurance and quality control procedures required pursuant to 40 CFR section 194.22. In addition, in accordance with 40 CFR section 194.21, monitoring is subject to inspection by EPA.

Pre-Closure Monitoring

40 CFR section 194.42(b)(i) requires that, to the extent practicable, the Department conduct pre-closure monitoring of parameters whose measurement, prior to closure of the repository, may provide valuable information concerning how the disposal system ultimately will behave over the 10,000 year regulatory time period. The purpose of pre-closure monitoring is to produce data that can be used in recertification applications. Results from pre-closure monitoring could be used, for example, as background values against which a comparison can be made once waste has been emplaced into the repository. In addition, such monitoring results could be used as input to the performance assessment models which predict repository behavior over time. Pre-closure monitoring should begin as soon as practicable after approval of the compliance application and should be initiated prior to any emplacement of waste in the facility. The pre-closure monitoring period is deemed to end when the last container of waste is emplaced, but before the disposal system shafts have been backfilled and sealed. Any monitoring to be conducted should be documented in the compliance application. The plan should be consistent,

where applicable, to the hazardous waste regulations specified in 40 CFR parts 264, 265, 268, and 270. In addition, the plan should not include techniques which would jeopardize the containment of the waste in the disposal system. The pre-closure monitoring documentation should include the same elements as those discussed above for post-closure monitoring. Processes or parameters that are monitored during operation and after closure should be addressed in both the pre-closure and post-closure monitoring plans, or at least cross-referenced if the information is applicable to both types of monitoring.

EPA has identified several parameters in 40 CFR section 194.42(b)(i) for which pre-closure monitoring should be conducted: (1) brine quantity; (2) flux; (3) composition; (4) spatial distribution; (5) gas quantity and composition; and, (6) temperature distribution. Recognizing that there may be additional parameters that may provide useful information of disposal system performance, EPA has required, pursuant to 40 CFR section 194.42(b)(ii), that the Department conduct a pre-closure study to determine the effect of other parameters on the disposal system's ability to contain waste and to predict future performance. An example of a process related to long-term performance that could be monitored during pre-closure is room closure. The results of this monitoring could be compared to the modeling to determine if room closure is occurring as predicted. At a minimum, the facility should include in its study the following parameters: backfilled mechanical state including porosity, permeability, and degree of compaction and reconsolidation; extent of deformation of the surrounding roof, walls and floor of the disposal room; and initiation or displacement of major brittle deformation features in the roof or surrounding rock. The complete list of study parameters, the methodology and results of the study should be provided to EPA in the compliance application. The application should include an explanation, based on study results, of why DOE has selected and rejected characteristics for monitoring.

Section 194.44 Engineered barriers

Disposal systems should incorporate both natural and engineered barriers for the purpose of meeting assurance requirements specified in 40 CFR section 191.14. The geologic units within the controlled area are considered to act as the natural barriers. The Department is responsible for incorporating engineered barriers. The application for certification of compliance will need to include a list and discussion of the planned natural and engineered barriers and the potential for those barriers to reduce uncertainty with long-term compliance (such as the potential to keep radionuclides in the repository and to keep brine from entering the repository).

A barrier may be a geologic structure, a canister, a waste form with physical and chemical characteristics that decreases radionuclide movement from the repository, or a material placed over and around waste, provided that the material or structure substantially delays movement of water or radionuclides. Engineered barriers are man-made barriers used to prevent or substantially delay movement of water or radionuclides toward the accessible environment. Engineered barriers used to meet the assurance requirements are in addition to those (e.g., low permeability shaft seals) used in the baseline for comparison. Man-made barriers include

modifications to the waste form as well as design enhancements of the underground facility. Some examples of engineered barriers include: waste drums, modifications to the waste form with physical and chemical characteristics provided that the engineered barriers employed substantially delay movement of water or radionuclides.

1) Content of Engineered Barriers Study

While the disposal standards and the WIPP Land Withdrawal Act require the use of engineered barriers, including waste form modifications and design barriers, they do not specify how many or what kinds of engineered barriers should be used. In 40 CFR section 194.44, EPA is proposing that DOE complete a study of engineered barriers and that the results of such a study be submitted with the compliance application for the WIPP. The requirements for the engineered barriers study are outlined in 40 CFR section 194.44 and listed below.

In conducting the evaluation of engineered barriers (waste form modifications and design barriers), the following should be considered:

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

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

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

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

v) the increased or reduced uncertainty in compliance assessment;

vi) the increased or reduced public confidence in the performance of the disposal system (a barrier requested in public comments should be considered in order to increase public confidence);

vii) the increased or reduced total system costs;

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

ix) the effects on mitigating the consequences of human-initiated processes and events.

Any weighting scheme identified for the aforementioned parameters should be clearly indicated in the study, including DOE's interpretation of the relative importance of each parameter

indicated.

The results of this evaluation should be included in any application for certification of compliance and should be used to justify the selection or rejection of each engineered barrier evaluated. The following provides guidance in what the Agency expects to be addressed to fulfill the requirements of the engineered barriers study.

2) Guidance for Engineered Barriers Study

The engineered barriers study should address the matters listed in 40 CFR section 194.44(c). Unless otherwise stated below or elsewhere, the Agency recommends--but does not require--the format of the Final Report of the Engineering Alternatives Task Force (July 1991) be used when displaying results of its evaluation for the engineered barriers considered. Additionally, the following guidance is provided:

(a) Evaluations of each engineered barrier will also include discussions of how the uncertainty in assuring compliance with 40 CFR part 191 either increases or decreases as a result of each alternative.

(b) The engineered barriers study should have the following analyses:

A qualitative analysis of all alternatives identified, including the current status of the technology (conceptual, research and development, pilot scale, or full-scale demonstration stages). The qualitative analysis should discuss whether sufficient data exists to evaluate the technology. The study should clearly reference the data/studies which form the basis for evaluating each alternative.

The quantitative analysis of the engineered barriers study may be completed in two phases: Phase 1 may be a preliminary quantitative screening of these alternatives to focus the study on the most feasible alternatives with phase 2 consisting of the analyses of the remaining engineered alternatives.

(c) The Department should evaluate the benefit and detriment of waste form modifications, including, but not limited to: cementation, shredding, supercompaction, incineration, vitrification, improved waste canisters, and the melting of metals.

(d) Potential design enhancements (such as different room layout, waste emplacement strategies, etc) of the underground WIPP facility should be evaluated as engineered alternatives in the engineered barrier study. In evaluating these engineered barriers, the Department should evaluate the benefit and detriment of engineered barrier alternatives including, but not limited to, such engineered barriers as grout and bentonite backfill, alternative configurations of waste placement in the disposal system, and alternative disposal system dimensions.

(e) The study should be peer reviewed in accordance with the requirements of 40 CFR part 194.27.

(f) The engineered barriers study should qualitatively consider public input in decisions related to engineered barriers.

(g) The study should consider engineered barriers alone and in combination, where appropriate, for the full scale (phase 2) analysis.

3) Engineered Barriers Incorporated into the Repository

Using the results of the engineered barriers study in the application, the Department should describe the engineered barriers that are to be applied in the repository. The application should address the following:

(a) Waste Form Modifications

The Department should list the modifications applied to the waste, by characteristics or other types of groups that exhibit similarities (such as metals, rubbers, etc.) identified by the Department. In addition, the Department should list and discuss how the modifications will affect the material-property and other relevant parameters (such as waste porosity, gas generation potential) used in the performance and compliance assessment analyses.

(b) Design barriers

The Department should list and describe the engineered barriers planned for use in the disposal system, the general method by which they will be emplaced, how they are expected to reduce uncertainty of long-term compliance and the resulting material-property and other relevant parameters (such as seal permeability) to be used in the performance and compliance analyses.

If backfill materials are used in the emplacement drifts and boreholes and other drifts (mains, submains, etc.) should be described, including discussions on parameters such as:

- backfill particle size distribution, permeability, and porosity;
- physical and chemical characteristics, including long term compatibility between different components of the system;
- density after emplacement;
- mechanical properties; and
- changes in density and physical characteristics with time (especially in the presence of liquid).

The application should include for any engineered barrier, including seals, the complete

design, plans for implementation and support for the credit claimed by DOE or the application will be considered incomplete. Preliminary conceptual models are not adequate.

Section 194.45 Consideration of the presence of resources

Any application for certification of compliance shall include information which demonstrates that the favorable characteristics of the WIPP compensate for the presence of resources and the likelihood of human-initiated activities as a result of the presence of those resources. The applicant should characterize the currently exploited and potential resources present and describe the profit oriented extractibility of the resources so identified. This demonstration should include the nature, location, extent, and numerical confidence of the resource estimates. Effects of current and potential future exploration and exploitation (e.g., subsidence, effect on aquifer water levels) should also be addressed.

This information should be presented as part of the site characterization information discussed in 194.14; the numerical consideration should presented in the performance and compliance assessments. Also see section 194.33.

Section 194.51 Consideration of protected individual

The annual committed effective dose (CED), received through all potential pathways from the disposal system, to any member of the public in the accessible environment, is not to exceed 15 millirems. For estimates of the CED, it is assumed that the protected individual is the maximally exposed individual, or that individual who resides at the location in the accessible environment where that individual would be expected to receive the highest exposure from radionuclide releases from the disposal system. Annual committed effective doses shall be calculated in accordance with Appendix B of 40 CFR part 191.

In determining the location of the maximally exposed individual, the Department should 1) present information on doses from individual pathways and 2) sum the dose from all pathways. The location with the largest dose from all pathways would be the location of maximally exposed individual. The application should identify this location using map coordinates, and the position of the individual relative to the controlled area and the repository.

By definition of the accessible environment, the location of the dose via the air pathway could be within the controlled area. However, if ground water is the route of concern, the location of the protected individual is restricted to outside the controlled area. The Department should include a discussion explaining the methods used to identify the location of the maximally exposed individual, and provide the results of the modeling use to determine the location. Intermediate and final calculations should be provided so that EPA can recreate the analysis.

If the application demonstrates that, for the regulatory time frame, there are no predicted releases under undisturbed conditions to the accessible environment via any pathway, then the application should state that doses from releases would be zero, and no further consideration of the protected individual is necessary.

Section 194.52 Consideration of exposure pathways

The Department should identify and consider all potential exposure pathways (i.e., releases to air, water, and land in the vicinity of the WIPP) associated with undisturbed performance by which radionuclides may reach the accessible environment. Several different release and exposure scenarios may be postulated for the WIPP, each potentially resulting in different exposures. For the water pathway, analyses used for certifications or determinations of compliance should assume that individuals consume two liters of water per day from any underground source of drinking water in the accessible environment.

To the extent possible, DOE should construct exposure scenarios and use default exposure parameter values consistent with scenarios and values already in use by EPA for conducting risk assessments. The application will need to discuss the assumptions and methodology used and results for the analysis. Items such as dose coefficients found in readily obtainable documents do not have to be reproduced, but the page numbers of the references should be provided in the application. Enough information should be provided in the application so that EPA can recreate the analysis.

Scenarios specific to radionuclide exposures are provided in *Risk Assessment Guidance for Superfund: Volume I, Human Health Evaluation Manual, Part B, Development of Preliminary Remediation Goals* (EPA 1991; PB92-963333). Other useful Agency guidance documents include:

- *Risk Assessment Guidance for Superfund: Volume I, Human Health Evaluation Manual, Part A, Baseline Risk Assessment*, EPA 540/1-89-002.
- *Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors*, OSWER Directive 9285.6-03;
- *Exposure Factors Handbook*, EPA 600/8-89/043; and

In addition, Agency-approved dose-to-risk conversion factors can be found in:

- *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion*, Federal Guidance Report No. 11, EPA 520/1-89-002; and in
- *External Exposure to Radionuclides in Air, Water, and Soil*, Federal Guidance Report No. 12, EPA 402-R-93-081.

New documents and updates to the above documents may be available so EPA should be

contacted before calculations begin.

Section 194.53 Consideration of underground sources of drinking water

40 CFR section 191.24(a)(1) requires that disposal systems be designed to provide a reasonable expectation that the undisturbed performance will not result in radioactive contamination of an Underground Source of Drinking Water (USDW) above allowable levels during the 10,000 year regulatory time period. An Underground Source of Drinking Water is[5] an aquifer or its portion which:

(1) Supplies any public water system; or
(2) Contains a sufficient quantity of ground water to supply a public water system; and
    (i) currently supplies drinking water for human consumption; or
    (ii) contains fewer than 10,000 milligrams of total dissolved solids per liter;
(3) Is not an exempted aquifer.

Potable water typically contains less than 500 mg/l TDS, while irrigation and livestock water can contain up to about 3,000 mg/l TDS. Although potable water exhibits a much lower TDS than 10,000 mg/l, EPA selected to protect groundwater containing the higher concentrations because such water conceivably could be treated to the lower concentrations. In addition, USDWs in the controlled area should not be considered; the regulations apply to those USDWs outside the controlled area.

In accordance with 40 CFR section 191.23, all USDWs outside of the controlled area are to be identified on the date of compliance certification approval. It is incumbent upon the Department to provide information on USDWS around WIPP. Therefore, the Department should include in the compliance application submittal information that identifies, locates (via maps that show information such as a cross-section and plan view with township, range and estimated latitude and longitude of the center of the USDW) and characterizes the water quality and estimated size of any USDWs in the accessible environment that may be affected by releases from the disposal system over the 10,000 year regulatory time period. The application should discuss the assumptions and approach used (e.g., modeling ground-water flow) used by the Department in its consideration of underground sources of drinking water. Expected radionuclide concentrations and potential doses from the affected USDWs should be provided along with a discussion of the uncertainties associated with the analysis. Enough information should be provided by the application so that EPA can recreate the analysis.

In determining whether or not a USDW is likely to be affected, the Department is directed in 40

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[5]From 40 CFR 191.22 and New Mexico Water Quality Control Commission regulations relating to the Underground Injection Control Primacy Program.

CFR section 194.53 to consider interconnections linking surface and other ground waters to USDWs. Such interconnections outside the controlled area could provide pathways through which contaminants may travel from the disposal system to a USDW in the accessible environment. Where interconnections are identified, the Department should examine the current and potential groundwater flow rates and direction to determine if the interconnection could result in the migration of radionuclides from the disposal system to the accessible environment within the 10,000 year regulatory time period.

As an example, the Ogallala Aquifer is an example of an aquifer which is not likely to be affected by the disposal system. The Ogallala Aquifer, which extends throughout the High Plains, is generally considered to be comprised of fresh to slightly brackish water. Given the geographical and geophysical separation between this aquifer and a disposal system located in the Delaware Basin, it is unlikely that the aquifer would be impacted by a release from the disposal system during the 10,000 year regulatory time period. Should the Department determine that this aquifer is not located in an area of hydrogeologic influence to the disposal system and that there exist no interconnections between the aquifer and the disposal system, then the Ogallala Aquifer would need not be included in the identification of USDWs provided in the compliance application.

As another example, the Dockum Group is considered to be the chief source of water for both domestic and livestock uses in eastern Eddy and western Lea counties, New Mexico (SAND89-7147). This water-bearing unit is located within the Delaware Basin. If it were determined that interconnections existed between this unit and the disposal system such that a release from the system could reach the unit within the 10,000 year regulatory time period, then the compliance application would need to include the Dockum Group as a USDW.

If the application demonstrates that, for the regulatory time frame, there are no predicted releases under undisturbed conditions to the accessible environment or to any USDWs via the ground-water pathway, then the application should state that the repository does not exceed the applicable maximum contaminant levels (MCLs), and no further consideration of USDWs is necessary.

Section 194.54 Scope of compliance assessments

Compliance assessments, used to determine compliance with the individual and ground-water protection requirements of 191, use a process similar to that used for the performance assessment except that compliance assessments:

1. Are limited to undisturbed performance, where 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;

2. Should, where there are predicted releases to the accessible environment, focus on estimated radiation doses and the radionuclide concentrations in the accessible environment instead of using the allowable performance assessment release limits; and

3. Do not have an established definition for "unlikely natural events" and therefore the application should discuss the reasoning behind the Department's selection and omission of natural events considered for compliance assessments.

The application should list the potential process, events or sequences of processes and events that may occur over the regulatory time frame. If these processes, events or sequences of processes and events are subsets of those identified for the performance assessment (see section 32), and the discussion is suitably written for both performance assessment and compliance assessment purposes, the application should 1) list the process, events or sequences of processes and events under the compliance assessment discussion and 2) reference the appropriate discussion in the performance assessment section. Otherwise, the compliance assessment discussion of potential processes, events or sequences of processes and events that may occur over the regulatory time frame will have to be independent of the performance assessment discussion.

After the application discusses the potential process, events or sequences of processes and events that may occur over the regulatory time frame, there should be a discussion of the processes, events or sequences of processes and events that were kept for the compliance assessment calculations, and the reasons why particular events or sequences of processes and events were omitted. It is expected that the Department will use a process similar to the screening process used for the performance assessment, but the Department will need to account for the use of "unlikely natural events" instead of the probability cutoff of 1 chance in 10,000 over 10,000 years required for performance assessments. Though not required, bounding analyses or other analyses of the effects of processes and events could provide useful information in substantiating the omission of particular processes and events from further analysis. The discussion should include the uncertainties associated with this process. For example, if gas generation is identified as a potential process, the uncertainties associated with the gas generation process and their potential impact on compliance should be discussed.

Section 194.55 Results of compliance assessments

Compliance assessments should consider uncertainty in the undisturbed performance of the disposal system. Discussions of uncertainty should include a qualitative discussion of the uncertainty (e.g., processes and events, confidence in an input parameter's probability distribution) and a quantitative measure of uncertainty where possible. Bounding analyses or analyses of the effect (on potential doses and releases of radionuclides to the accessible environment) of individual input parameters and processes and events should provide useful information on the uncertainty of the undisturbed performance. Whatever type of uncertainty analyses used must be clearly and thoroughly discussed. Any method(s) of uncertainty analysis should be presented so that EPA can readily recreate the analysis.

Probability distributions for uncertain disposal system parameter values should be developed in a manner similar to those developed for purposes of 40 CFR section 194.34. If the computational techniques (e.g., Monte Carlo) used for 40 CFR section 194.34 are used for the purposes of this section, it is not necessary to discuss the techniques again (page numbers should be provided). If different computational techniques are used, they should be fully and clearly described in detail.

However, there are differences between this section's requirements and those of 40 CFR section 194.34. First, the sample size should be large enough such that, for the radiation doses to individuals and radionuclide concentrations in ground water, the maximum generated values exceed the 99th percentile of the population of estimates for the doses and for the radionuclide concentrations. The application should discuss the method used to achieve this value.

Second is the requirement to estimate the full range of 1) radionuclide concentrations released to the accessible environment, and 2) doses. In keeping with section 51, the estimated radiation doses should be for the individual who would be expected to receive the highest exposure from radionuclide releases from the disposal system.

In addition, both the mean and the median results are required to be presented. The 99th percentile is required and must be presented also. The application should provide information which demonstrates that there is at least a 95% level of statistical confidence that the mean and the median of the range of estimated radiation doses and the range of estimated radionuclide concentrations meet the 15 millirem annual committed effective dose requirement of the individual protection requirements and the environmental standards for ground-water protection of 40 CFR part 191. The application should discuss the method used to develop the 95% confidence level in such a manner that EPA can recreate the analysis.

Appendix A Definitions From 40 CFR parts 191 and 194

The following definitions have been excerpted from the respective portions of 40 CFR parts 191 and 194. They are reproduced here for convenience. Definitions from 40 CFR part 191 are listed first, followed by definitions from the proposed 40 CFR part 194.

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 under section 8(d) of the WIPP LWA.

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

Compliance assessment(s) means the analysis conducted to determine compliance with section 15 and subpart C of 40 CFR part 191.

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

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

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

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

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

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

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

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

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

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

Revocation means any action taken by the Administrator to terminate or withdraw the effectiveness of a certification under section 8(d) of the WIPP LWA or to terminate or withdraw the effectiveness of a determination under section 8(f) of the WIPP LWA.

Secretary means the Secretary of the Department of Energy.

Suspension means any action taken by the Administrator to withdraw, for a limited period

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

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

WIPP means the Waste Isolation Pilot Plant project authorized under section 213 of the Department of Energy National Security and Military Applications of Nuclear Energy Authorization Act of 1980 (Public Law 96-164; 93 Stat. 1259, 1265).

WIPP LWA means the Waste Isolation Pilot Plant Land Withdrawal Act (Public Law 102-579, 106 Stat. 4777).

Appendix B Source Code Documentation and Sample

The following description and example are included to provide a consistent format for the preamble documentation of each PA code module, program, subroutine, or function. This is type of information that is needed, although the code should have as much detail as possible. It is not necessary to follow this example exactly, but the code information should be similar. Please remember that the actual source code should also include sufficient detail to allow a reviewer to follow the code execution step by step.

LEVEL 1 NAME

Place the name of this operation here.

LEVEL 2 PURPOSE

Provide a brief, one or two line statement of the purpose of this subroutine.

LEVEL 3A SUBROUTINE DESCRIPTION

The description should be detailed enough for a reviewer to understand the inputs, outputs and operation of this subroutine.

LEVEL 3B CALL SEQUENCE

Show the subroutine or function call used. For example, CALL SUBXXX (var1,var2,var2, ..., IERROR).

LEVEL 3C DESCRIPTION OF ARGUMENTS

Briefly describe the input arguments used in this subroutine or function. Values passed in program COMMON should also be described.

1. *var1* - ...
2. *var2* - ...
3. *var3* - ...

LEVEL 3D RANGE LIMITATIONS

Variable range limitations should be explained.

LEVEL 3E ERROR CONDITIONS

Abnormal error conditions should be described with examples shown.

LEVEL 3F ACCURACY

Any accuracy considerations should be discussed and clearly explained that may effect this subroutines operation.

LEVEL 3G EXCEPTIONS TO STANDARDS

Any source coding exceptions should be noted and clearly explained.

LEVEL 3H MACHINE DEPENDENT INFORMATION

Machine dependent concerns should be discussed and clearly explained. For example, system compiler dependent switches.

LEVEL 3I MISCELLANEOUS

Include other important information about the execution of this code.

LEVEL 3J AUTHORSHIP AND UPDATE HISTORY

List authorship and update information starting with most recent first.

LEVEL 3K EXAMPLES

Provide typical INPUT and OUTPUT values for this subroutine or function.

INPUT -

USAGE - CALL ... (...)

OUTPUT -

LEVEL 3L DICTIONARY OF TERMS

Define special terms or names used.

LEVEL 3M REFERENCES

Reference important textbooks or articles.

LEVEL 4 SUBPROGRAMS

List all subroutines called "directly" or "indirectly."

----------SUBROUTINES----------
DIRECTLY CALLED INDIRECTLY CALLED

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C                 3. INCV        - Incremental value to round of
C               velocities ...
C                 4. MAXOUT  - Maximum number of velocities to
C               calculate ...
C                 5. ...
C
C                 x. IERR        - Error Parameters/Conditions
C
C     LEVEL 3D            RANGE LIMITATIONS
C
C           'MAXOUT'   Must be .GE. 2 .AND. .LE. 120
C           'VMIN'     Must be .GT. 0
C           'VMAX'     Must be .GT. VMIN ...
C           ...
C
C     LEVEL 3E            ERROR CONDITIONS
C
C                 1. IERR = 1 If 'MAXOUT' is less than 1 or greater C
                   than 120
C                 2. IERR = 2 If 'VMAX' less than 0
C                 3. IERR = 3 If 'Vmax' less than VMIN
C
C     LEVEL 3F            ACCURACY
C
C                 NONE
C
C     LEVEL 3G            EXCEPTIONS TO STANDARDS
C
C                 NONE
C
C     LEVEL 3H            MACHINE DEPENDENT INFORMATION
C
C                 ENTRY POINT              -      VELLIS
C
C                 LANGUAGE                 -      FORTRAN V
C
C                 SUBROUTINE LENGTH        -      520 WORDS
C
C                 EQUIPMENT                       -      CRAY
C
C                 TIMING                   -      0.3 SECS PER TABLE
C
C     LEVEL 3I            MISCELLANEOUS
C
```

```
C                 NONE
C
C     LEVEL 3J          AUTHORSHIP AND UPDATE HISTORY
C
C                 VERSION 3-01/94 I. AM. GOOD AND U. R. RIGHT.
C                       Expanded the error exceptions and fixed bug
C                       in table generator.
C
C        VERSION 2-06/92 U. R. RIGHT.
C                       Added expanded table generation.
C
C                 VERSION 1-03/91 I. DID IT.
C
C     LEVEL 3K          EXAMPLES
C
C                 INPUT       -     VMIN   = 5000.0
C                                   VMAX   = 15000.0
C                                   INCV   = 20.
C                                   MAXOUT = 120
C                                   ...
C
C                 USAGE       -     CALL VELLIS (VMIN,VMAX,INCV,MAXOUT,
C                                         ... ,IERR)
C
C                 OUTPUT      -     DT   = .00054654
C                                   NOUT = 120
C                             IVOUT = 5000. 5020. 5040. ...
C                                     5140. 5160. ...
C                                     5280. ...
C                                     ...
C     LEVEL 3L          DICTIONARY OF TERMS
C
C                 NONE
C
C     LEVEL 3M          REFERENCES
C
C                 Journal of the Geophysical Industry
C                 "Velocity Calculations for Subsurface Processing"
C                 Volume 6.25, May 19, 1990, page 626-635.
C
C     LEVEL 4           SUBPROGRAMS
C
C           -------------SUBROUTINES-------------
C                       DIRECTLY CALLED        INDIRECTLY CALLED
```

```
C                                   SQRT          NONE
C                                   ABS
C                                   ROUND
C*****************************************************************
```

Draft Checklist for the proposed 40 CFR part 194 rule

§194.3 Communications

☐ Signed by the Secretary of Energy

§194.11 Completeness and accuracy of compliance applications

☐ Application is complete

☐ Application is not complete

§194.12 Submission of compliance applications

☐ 30 paper copies of the compliance application have been submitted to the Administrator

☐ Alternative submission method is used

§194.13 Submission of reference materials

☐ 10 copies of any material referenced within the compliance application

☐ Alternative submission method is used

§194.14 Content of compliance certification application

☐ Description of the use of vicinity

☐ Description of the disposal system and features that may affect performance

☐ Location of the disposal system and controlled area

- ☐ physical setting
- ☐ size
- ☐ county
- ☐ township and range
- ☐ transportation routes
- ☐ longitude and latitude
- ☐ adjacent property owners
- ☐ appropriate graphics (at least maps)

☐ Description of the geology, geophysics, hydrogeology, hydrology, and geochemistry of the disposal system and its vicinity

- ☐ geologic history (e.g., depositional history)

- ☐ stratigraphy (e.g., form, arrangement, geographic distribution, chronological sequence, contact zones, age, thickness,)

- ☐ lithology (e.g., rock composition, homogeneity in composition, color, mineralogical components, grain size, texture, laminations, degree of cementation, etc.)

- ☐ structural geology, seismology, geotectonics (e.g., geologic structure, tectonic history,

present and past stress regimes, lineaments, fault or fracture zones, earthquake occurrence, location of epicenters, relation of epicenters with geologic structures and/or geologic setting, seismic compressional and shear velocities, ground motion duration; processes, such as tectonism, metamorphism, plutonism, volcanism, hydrothermal, folding, faulting, tilting, jointing, deformation, density foundering, fracturing, uplift, sink, subsidence)

☐ geomorphology and topography (e.g., geomorphic units, features and processes, such as secondary topographic features caused by erosion)

☐ soil characteristics in the controlled area (e.g., bulk density, profile, porosity, permeability, hydraulic conductivity, particle size distribution, potential evapotranspiration, infiltration capacity)

☐ natural resources (e.g., type, occurrence, location, extent of minerals, hydrocarbons and water, such as potash, oil, gas, irrigation water. See Section 194.45 for more detail.)

☐ fracturing (geometry, orientation, filling, cementation, and roughness)

☐ 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

☐ regional and site-specific recharge and discharge areas (deep percolation, net infiltration, springs, seeps, stream baseflow)

☐ ephemeral and permanent water bodies including active and inactive karst features (breccia pipes, sinkholes, etc.)

☐ surficial drainage patterns, current and historical fluctuations (the historical drainage pattern should include information regarding the Ancestral Pecos River). This may include: location or waterway course, gradient, effect on geologic formations, and projection of effect of high water level on geologic formations (pluvial period effects)

☐ general physical characteristics such as porosity (total, effective, interstitial, fracture) and saturated thickness

☐ general hydraulic characteristics such as hydraulic conductivity, storage coefficients, transmissivity, permeability (intrinsic and relative), matrix and fracture characteristics, hydraulic gradients

☐ general transport characteristics such as longitudinal 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 and each water bearing unit

☐ geochemistry and geochemical history of different geologic units (water quality, mineral content and distribution, fluid density, salinity, evidence of dissolutioning etc.)

☐ identification of Underground Sources of Drinking Water (USDW) as defined in 40 CFR

section 191.22 (this applies for undisturbed performance when there are expected releases outside the Land Withdrawal Act boundary)

☐ withdrawal rates (consumption) and other usage for aquifers currently producing water (e.g., Dewey Lake Redbeds)

☐ brine pockets and their potential distribution in the controlled area

☐ Discussion of how the geology, geophysics, hydrogeology, hydrology, and geochemistry are expected to change and interact

☐ The presence and characteristics of potential pathways

☐ Projected geophysical, hydrologic and geochemical conditions due to waste

☐ Description of the disposal system design

☐ Construction information: materials, dimensions

☐ Codes and standards that have been applied

☐ Results of assessments conducted pursuant to the disposal regulations

☐ Description of input parameters

☐ Evidence that the disposal system meets 191.14

☐ Description of waste acceptance criteria and actions taken to assure adherence to criteria

☐ Description of background radiation in air, soil, and water in the vicinity of the disposal system.

☐ Topographic maps

☐ Scale and date
☐ Floodplain area
☐ Surface waters
☐ Surrounding land uses
☐ Wind rose
☐ Orientation of the map
☐ Boundaries of controlled area
☐ Location of institutional controls
☐ Location of injection and withdrawal wells in the controlled area and vicinity
☐ Location of proposed monitoring stations or wells

☐ Description of past and current climatologic and meteorologic conditions and how theses conditions are expected to change and interact

☐ Current climatologic and meteorologic conditions

☐ recorded annual and monthly precipitation averages
☐ recorded monthly temperature averages and extremes
☐ wind speed and direction
☐ evaporation data

☐ atmospheric stability distributions

☐ Past climatologic and meteorologic conditions

☐ climate changes, including past glaciation events
☐ estimated historical precipitation averages and variability
☐ estimated historical temperature averages and variability

☐ Address how conditions are projected to change during the regulatory time period

☐ Information on how projections relate to the conceptual models used in the performance and compliance assessments.

☐ potential changes and rates of change in precipitation, air temperatures, and potential evapotranspiration from the present

☐ potential regional wind flow and precipitation patterns that may evolve in the future as a result of climatic and geologic changes

☐ potential for glaciation

§194.15 Content of Compliance Determination Application(s)

☐ List and discussion of changes since the initial compliance application

☐ Updated performance and compliance assessments if there are changes

☐ Update geologic, geophysical, geochemical, hydrologic, and meteorologic information.

☐ Update monitoring results.

☐ Design conformance information

☐ Waste emplacement information

☐ location and distribution of emplaced waste by waste types as detailed in the information required for waste characterization (Section 194.24);

☐ confirmation that the location and distribution of waste conform to assumptions used in performance assessment or are shown to comply in a new assessment as part of the recertification;

☐ waste characteristics of waste emplaced and a demonstration that they continue to fall within the requirements established under the waste characterization section.

☐ Continuing documentation and code listings (when changes are made to computer codes)

☐ Description of updates and new versions

☐ Updated software summaries

☐ Documentation revisions

☐ Error reporting

☐ Updated computer files

☐ Paper listing

§194.22 Quality Assurance

☐ Implement governing documents. 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)).

☐ Implementation information for the following

☐ Waste characterization activities and assumptions
☐ Environmental monitoring, monitoring the performance of the disposal system, sampling, and analysis activities
☐ Field measurements of geological factors, ground water, meteorology, and topography
☐ Models and computer codes used for compliance
☐ Expert judgment elicitations
☐ Disposal system design and actions taken to ensure compliance with design specifications
☐ The collection of data and information used to support compliance application(s)
☐ Other systems, structures, components and activities important to the containment of waste in the disposal system

☐ Demonstration that all data and information used in the compliance application which was collected prior to implementation of the Quality Assurance program required under 40 CFR part 194.22(a) be qualified by a Quality Assurance program equivalent in scope and implementation to ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda (part 2.7) to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c)).

☐ Quality assurance program claimed to be equivalent in scope to the ASME NQA-1989 and 1990 standards is substantiated

☐ information is cross referenced to the appropriate Quality Assurance documents required of the ASME

§194.23 Models and computer codes

☐ Complete listing and description of the models approach, analysis, underlying assumptions.

☐ Description and documentation of conceptual models used and not used

☐ Information which demonstrates

☐ Conceptual models reasonably represent the disposal system
☐ Mathematical models incorporate equation and boundary conditions which reasonably represent the conceptual models
☐ Numerical models obtain stable solutions
☐ Computer models accurately implement the numerical models

- ☐ Models, computer codes, and observed and measured data are peer reviewed

☐ Models and computer codes are fully and clearly documented according to Quality Assurance requirements specified in 40 CFR 194.22.

- ☐ Description and documentation of mathematical models
- ☐ Description and documentation of numerical models
- ☐ Structure of the system model
- ☐ Description of general numerical procedures
- ☐ Component model information
  - ☐ purpose
  - ☐ flowchart (where applicable)
  - ☐ assumptions and limitations
  - ☐ notation
  - ☐ derivation
  - ☐ application
  - ☐ numerical method type
  - ☐ derivation of numerical model
  - ☐ location of component model (e.g., subroutine) in the code
  - ☐ numerical stability and accuracy
  - ☐ list of alternatives to component model; with discussion

☐ User's manual (including a software summary)

- ☐ Software summary
- ☐ Program considerations
  - ☐ program options
  - ☐ program paths
  - ☐ data structures
  - ☐ initialization
  - ☐ restart procedures
  - ☐ error processing
  - ☐ input data
  - ☐ screen output during execution
- ☐ Data files
  - ☐ content
  - ☐ use by program
  - ☐ auxiliary programs
- ☐ Input data
  - ☐ general considerations
    - ☐ techniques
    - ☐ consecutive cases

- ☐ defaults
- ☐ individual input records
  - ☐ record identifier
  - ☐ format
- ☐ input variables
  - ☐ identification of input variables
  - ☐ need for variable (optional or necessary)
  - ☐ repetition
  - ☐ dimensional units
  - ☐ default values listed
  - ☐ description of each variable
  - ☐ range of acceptable limits
  - ☐ origin of each variable

☐ System interface

- ☐ system dependent features
- ☐ compiler requirements
- ☐ hardware requirements
- ☐ control, input, or command files

☐ Output

☐ Sample/Test problems

☐ Programmer's manual

- ☐ Software summary (can be same as in User's manual)
- ☐ Theoretical Background
- ☐ Program listing
- ☐ Block diagram
- ☐ Program flowchart
- ☐ Data structures
- ☐ Error reporting
- ☐ Software verification and validation

☐ Code assessment

☐ Model peer review

☐ Software verification and validation evidence

- ☐ validation (using one or more of the methods below)
  - ☐ simulation of laboratory experiments
  - ☐ field experiments
  - ☐ analogy with a similar and previously validated model
  - ☐ peer review
- ☐ dynamic and static verification
  - ☐ interrelated program components
  - ☐ interrelated groups of program subroutines and functions
  - ☐ individual subprograms

☐ line-by-line evaluation

☐ Technical contact(s) identified for assisting EPA in the use of the computer codes

☐ Explanation of covariance included

§194.24 Waste characterization

☐ Description of the waste that includes a list of all types of waste intended for disposal at WIPP

☐ physical characteristics
☐ chemical characteristics
☐ radiological characteristics

☐ Study of waste characteristics

☐ Defensible screening process has been applied in identifying important waste characteristics

☐ Consideration of all reasonable characteristics of TRU waste proposed for WIPP
At a minimum:
☐ waste form
☐ free liquid content and liquid saturation
☐ pyrophoric and explosive content
☐ factors affecting solubility
☐ factors affecting mobility, such as forming colloidal suspensions)

☐ Considerations of the processes related to the performance of the disposal system

☐ Documentation which justifies the decision to include or exclude a waste characteristic for use in performance assessment

☐ Identification of important waste characteristics

☐ Description of the waste envelope established for WIPP wastes

☐ demonstration that the WIPP complies with the containment, individual, and ground-water protection requirements of 40 CFR part 191

☐ Overall description of the waste detailing the physical, chemical and radiological properties of each waste category

☐ Identification of the waste analysis methods used

☐ Description of the system of controls to be used for the waste

☐ identifies and describes the accountability system developed to track waste to be emplaced in the disposal system

☐ the system is able to identify non-compliance waste before emplacement

☐ the unit of waste to be tracked

☐ implementation plan includes a discussion of safeguards in the system

☐ analysis of the uncertainty associated with the administrative controls used in the accountability system

☐ tracking system is of sufficient accuracy to ensure that waste placed in the WIPP falls within the approved waste envelope; and

☐ assurance that the tracking system has the ability to separately track contact-handled and remote-handled waste.

☐ Waste characterization activities meet the requirements specified in 40 CFR section 194.22 Quality Assurance and 40 CFR section 194.27 Peer Review.

§194.25 Future States Assumptions

☐ Incorporate into assessments changes in geologic, hydrologic and climatic conditions (see section 194.14 information)

☐ Physical characteristics of average human being are listed

☐ Discussion of living habits assumed

☐ Discussion of the technology assumed

§194.26 Expert Judgment

☐ Identification of the topics for which expert judgment is used

☐ Process of eliciting expert judgment described

☐ Process of eliciting expert judgment documented

☐ Restrictions on panelist selection have been applied

☐ Restrictions on the expert judgment solicitation have been applied

☐ Expert judgment panel members meet or exceed that required for the material reviewed

§194.27 Peer Review

☐ Areas in which peer review has been used is identified

☐ Information is presented to demonstrate that the peer review conforms to the guidelines in NUREG 1297 "Peer Review for High-Level Nuclear Waste Repositories"

☐ Peer review has been used to evaluate engineered barrier study

☐ Peer review has been used to evaluate adequacy of the selection criteria used to screen features, processes, and events

☐ Peer review has been used to evaluate the process of qualifying "existing data"

☐ Peer review has been used to evaluate the adequacy and suitability of conceptual, mathematical and numerical models

☐ Peer review has been used to evaluate major PA program modules

☐ Peer review has been used to evaluate input parameter probability distributions

☐ Peer review has been used to evaluate the adequacy of data to confirm models

☐ Peer review has been used to evaluate the waste characterization study

☐ Peer review has been used to evaluate the adequacy of categories of wastes

☐ Peer review has been used to evaluate the adequacy of values or ranges of values for waste characteristics

☐ Peer review has been used to evaluate DOE's process to obtain these values (e.g., waste characterization methods)

☐ Peer review has been used to evaluate the adequacy of the waste control/tracking system

§194.31 Application of release limits

☐ Release limits are based on 40 CFR part 191

☐ Release limits are calculated using curie activity 100 years after disposal

§194.32 Scope of performance assessments

☐ Identify and discuss an initial comprehensive list of potential features, events and processes that could potentially affect repositories;

☐ Identify and discuss the source of the comprehensive list and discuss the method by which it was developed;

☐ Discuss the screening criteria and procedure for initially eliminating processes and events in the comprehensive list;

☐ List and discuss the features, events and process and the combinations of FEPs that, at the WIPP site, could have an effect on radionuclide transport to the accessible environment and discuss the rationale for excluding those events and processes that have been screened out. Calculations are presented as part of this process.

☐ Specify and discuss the combination of features, events and processes retained for consequence analysis.

☐ Quantitative analyses have been conducted where appropriate

☐ Logical argument to support the lack of a quantitative analysis

☐ Physical reasonableness is appropriately addressed

☐ The application lists and discusses the probability of the events and processes that could occur at WIPP

☐ discussion includes the method(s) used to determine the probability of events and processes

☐ discussion addresses the uncertainty associated with trying to estimate probabilities

☐ Events and processes have been appropriately screened according to regulatory guidelines and requirements

☐ Consequences have been examined using appropriate methodologies and quality assured computer code (where computer code is used)

☐ Methodology has been applied consistently

☐ As part of performance assessment analyzed the effects (including brine injection and water flooding) of potential wells drilled under Federal Oil and Gas Lease No. NMNM02953 and 02953C and the methodology used is discussed

§194.33 Consideration of human-initiated processes and events

☐ Human activities have been addressed
- ☐ human activities have been identified
- ☐ rate of human activities have been appropriately calculated

☐ Human intrusions have been addressed
- ☐ human intrusions have been identified
- ☐ rate of human intrusions have been appropriately calculated

§194.34 Results of performance assessments

☐ Results of performance assessments are presented in CCDFs

☐ All input parameters are listed for each computer code

Constant input parameters
- ☐ values for each constant input parameter are tabulated
- ☐ discussion of why constant input parameters are considered constant
- ☐ each constant input parameter is described, including units
- ☐ each input parameter is linked to the codes in which it is used

Variable input parameters
- ☐ variable input parameters are described, including units
- ☐ the probability distribution type and the information used in its determination (e.g., data collected by the WIPP project, literature search, etc.) and the process used to review the data are discussed
- ☐ the lower and upper bounds of the sampled data range, the median, the geometric mean and geometric standard deviation, arithmetic mean and standard deviation of each input parameter are included
- ☐ cumulative probability plots with the associated data tabulated are included

- ☐ correlations between parameters are included
- ☐ variable input parameters are linked to the codes in which they are used
- ☐ The impact of each parameter on releases (sensitivity analyses) is included

☐ Input parameters are available in a documented computer format that EPA can use

☐ Evidence of peer review

☐ Sampling method(s) have been discussed

☐ The number of CCDFs generated are large enough that the maximum CCDF generated exceeds the 99th percentile of the population of CCDFs with at least a 0.95 probability.

☐ A full range of CCDF realizations has been generated

☐ Behavior of individual CCDFs can be discerned in plots presented

☐ CCDF curves are generated for the mean, the median, the 10th, 90th and 99th quantiles.

☐ Information has been provided on the use of the 95 percent confidence limit of the mean probability of exceeding the release limits of 40 CFR part 191.

§194.41 Active institutional controls

- ☐ Description of planned use of active institutional controls has been provided
- ☐ Location of active institutional controls
- ☐ Procedures necessary to implement the proposed controls
- ☐ Amount of credit expected from active institutional controls and discussion of assumptions used

§194.42 Monitoring

☐ Plan for monitoring the disposal system
- ☐ post-closure information
- ☐ pre-closure information

☐ Pre-closure monitoring information

☐ Post-closure monitoring information:

identifies:
- ☐ the parameters to be monitored
- ☐ how the baseline for each parameter will be determined
- ☐ how the monitoring results of each parameter will be used to evaluate the performance of the disposal system
- ☐ how long each parameter will be monitored

discusses/describes:
- ☐ the environmental media to be monitored
- ☐ the proposed monitoring network

☐ Study of the effects of disposal system parameters

- ☐ includes backfilled mechanical state
- ☐ extent of deformation of the surrounding roof, walls, and floor
- ☐ initiation or displacement of major brittle deformation features in roof or surrounding rock
- ☐ subsidence and other effects of human activity in the vicinity of the disposal system

☐ Substantiation of decision not to monitor a particular disposal system parameter

§194.43 Passive Institutional Controls

☐ Detailed descriptions of measures to preserve knowledge about the location, design and contents of the disposal system

- ☐ identification of the controlled area by markers
- ☐ placement of records in the archives and land record systems of local, State and Federal governments, and international archives

  Records identify:
  - ☐ the location of the controlled area and disposal system
  - ☐ the design of the disposal system
  - ☐ the nature and hazard of the waste
  - ☐ site data (e.g., geologic) pertinent to the containment of waste in the disposal system
  - ☐ results of tests, experiments and other analyses pertinent to containment

☐ Detailed descriptions of the proposed passive institutional controls

☐ Period of time passive institutional controls are expected to endure and be understood

☐ Proposed credit for reducing the rate of human-initiated processes and events

☐ Method used to determine proposed credit for reducing the rate of human-initiated processes and events

§194.44 Engineered Barriers

☐ Application states that the disposal system will incorporate engineered barriers

☐ Engineered barrier evaluation included, but not limited to:

- ☐ cementation
- ☐ shredding
- ☐ supercompaction
- ☐ incineration
- ☐ vitrification
- ☐ improved waste canisters
- ☐ grout
- ☐ bentonite backfill
- ☐ melting of metals
- ☐ alternative configurations of waste emplacement
- ☐ alternative disposal system dimensions

☐ Engineered barrier evaluation considered:

- ☐ 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
☐ the increased or reduced public confidence in the performance of the disposal system
☐ the increased or reduced total system costs;
☐ the impact, if any, on other waste disposal programs from the incorporation of engineered barriers (i.e., the extent to which the incorporation of engineered barriers affects the volume of waste); and
☐ the effects on mitigating the consequences of human-initiated processes and events.

☐ Justification for excluding each of the engineered barriers evaluated

§194.45 Consideration of the presence of resources (also see information for sections 194.14 and194.15)

☐ Information which demonstrates that the favorable characteristics of the WIPP compensate for the presence of resources and the likelihood of human-initiated activities as a result of the presence of those resources.

☐ Currently exploited and potential resources present are described

☐ The profit oriented extractibility of the resources is discussed.
☐ nature
☐ location
☐ extent
☐ numerical confidence of the resource estimates.

☐ Effects of current and potential future exploration and exploitation (e.g., subsidence, effect on aquifer water levels) should also be addressed.

§194.46 Removal of waste

☐ Plan is included

§194.51 Consideration of protected individual

☐ Maximally exposed individual resides at the location in the accessible environment where that individual would be expected to receive the highest exposure from radionuclide releases

☐ There are predicted releases to the accessible environment under undisturbed conditions

☐ Compliance assessments indicate that no predicted releases to the accessible environment under undisturbed conditions

§194.52 Consideration of exposure pathways

☐ All potential exposure pathways are identified

☐ For the water pathway, analyses assume that individuals consume two liters of water per day from any underground source of drinking water

☐ There are predicted releases to the accessible environment under undisturbed conditions

☐ Compliance assessments indicate that there are no predicted releases to the accessible environment under undisturbed conditions

§194.53 Consideration of underground sources of drinking water

☐ All underground sources of drinking water in the accessible environment likely to be affected by the disposal system over the regulatory time frame have been considered

☐ Interconnections between bodies of surface water, ground water, and underground sources of drinking water have been considered

☐ There are predicted releases to underground sources of drinking water under undisturbed conditions

☐ Compliance assessments indicate that there are no predicted releases to underground sources of drinking water under undisturbed conditions

§194.54 Scope of compliance assessments

☐ Limited to undisturbed conditions

☐ Potential processes, events or sequences of events that may occur over the regulatory time frame have been identified

☐ these have been identified in the application for purposes of section 194.32, scope of performance assessment

☐ these have been documented in the application for purposes of section 194.32, scope of performance assessment

☐ Potential processes, events or sequences of events included in compliance assessment results are provided

☐ There is documentation of why potential processes, events or sequences of events that may occur over the regulatory time frame were not included in compliance assessment results

§194.55 Results of compliance assessments

☐ Compliance assessments consider uncertainty in the undisturbed performance of the disposal system

☐ Probability distributions for uncertain disposal system parameter values used in compliance assessments are used

☐ Computational techniques which draw random samples from across all of the probability distributions were used to generate a range of:

☐ Estimated radiation doses; and
☐ Estimated radionuclide concentrations.

☐ Ranges derived from the uncertain disposal system parameter values is large enough such that the maximum estimate generated exceeds the 99th percentile of the population of estimates with at least a 0.95 probability
☐ The full range of estimated radiation doses are presented

☐ The full range of estimated radionuclide concentrations are presented

☐ Information has been provide which demonstrates that there is at least a 95% level of statistical confidence that the mean and the median of the range of estimated radiation doses and the range of estimated radionuclide concentrations meet the individual and ground water requirements