MEMORANDUM

FROM: J. William Gunter, Director
Criteria and Standards Division

TO: Interested Parties

SUBJECT: Draft Compliance Criteria for the Waste Isolation Pilot Plant (40 CFR 194)

Attached for your review is a draft of the Criteria for the Certification and Determination of the Waste Isolation Pilot Plant's (WIPP) Compliance with Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes. As you are aware, the Environmental Protection Agency (EPA) is developing these criteria pursuant to the WIPP Land Withdrawal Act (LWA) (PL 102-579). Under the WIPP LWA, EPA was granted the authority to certify whether the WIPP facility complies with the 40 CFR 191 radioactive waste disposal standards. These criteria will be used in that process.

In order to gain the insight of those parties that have been key participants in the compliance criteria rulemaking, EPA is soliciting comments on the enclosed draft criteria before they are presented to the Agency for approval or proposed in the Federal Register. In particular, EPA is interested in the views of interested parties on the following questions:

1) Passive institutional controls. To what extent, if any, and for how long can passive institutional controls be relied on to reduce the likelihood of inadvertent, intermittent human intrusion into the WIPP disposal system? Is it appropriate for performance assessments to consider contributions from passive institutional controls? If so, how would one ascertain the validity of the contribution?

2) Quality Assurance. The Agency is seeking additional comment and information on specific quality assurance standards, guidelines, or criteria and their appropriateness for data collection, waste characterization and compliance assessment purposes at the WIPP.
(B) Codes and standards that have been applied to the design and construction of the disposal system.

(3) Results of assessments performed under 40 CFR part 191.

(4) Evidence that disposal of waste will be conducted in accordance with the provisions of section 14 of 40 CFR part 191.

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

(6) An identification and evaluation of the natural resources in the vicinity of the disposal system, including estimates as to undiscovered deposits. Undiscovered deposits of resources characteristic of the area shall be estimated based on geological and geophysical evidence.

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

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

(A) Map scale and date;

(B) Floodplain area;

(C) Surface waters including intermittent streams;

(D) Surrounding land uses, i.e., residential, commercial, agricultural, recreational;
(E) A wind rose i.e., wind speeds and directions;
(F) Orientation of the map, i.e., north arrow;
(G) Boundaries of the controlled area;
(H) Location of proposed active and passive institutional controls;
(I) Location of any active or inactive injection and withdrawal wells in the controlled area and in the vicinity of the disposal system; and
(J) Location of proposed monitoring stations or wells.

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

§ 194. Content of compliance determination application(s).

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

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

(2) Monitoring results;

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

(4) Waste characterization information.

(5) Any changes that depart from the most recent previous application which formed the basis of a certification or determination of compliance.

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

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

Subpart C--Compliance Certification and Determination

GENERAL REQUIREMENTS

§ 194. Inspections.

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

(b) Records kept by the Department pertaining to aspects of the disposal system which could affect the movement of waste
toward the accessible environment shall be made available to the Administrator or the Administrator's authorized representative within 30 calendar days of a request from the Administrator or the Administrator's authorized representative.

(c)(1) The Department shall, upon request by the Administrator or the Administrator's authorized representative, provide rent-free office space for the exclusive use of the Administrator's authorized inspection personnel. The office space shall be convenient and have full access to the disposal system.

(2) The Department shall afford the Administrator's inspection personnel access, equivalent to access provided Department employees, following proper identification and compliance with applicable access control measures for security, radiological protection and personal safety.

(d) The Administrator or the Administrator's designated inspection personnel shall be allowed to obtain samples, including split samples and to monitor any aspects of the disposal system and the waste proposed for disposal in the disposal system.


(a) Compliance application(s) must include quality assurance plans for:

(1) Waste characterization activities and assumptions;

(2) Environmental monitoring, sampling and analysis
activities;

(3) Data from field measurements of geophysical factors, ground water, meteorology, and topography;

(4) Computations, codes, models and methods used to calculate compliance with the disposal regulations;

(5) Results of any expert elicitation used to support applications for certification or determination of compliance;

(6) Measures taken to produce confidence in any data not collected under an approved quality assurance plan;

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

(8) Any other relevant systems, structures, components, and activities relevant to the transport of radionuclides toward the accessible environment.

(b) Quality assurance plans shall address how the following quality indicators have been and will be achieved:

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

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

(3) Data representativeness, i.e., the degree to which data accurately and precisely represent a characteristic of a population, a parameter, variations at a sampling point, or environmental conditions;
(4) Data completeness, i.e., a measure of the amount of valid data obtained compared to the amount that was expected; and

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

(c) The Agency will verify the implementation of quality assurance programs through select observation and audits of quality assurance operating procedures.

§ 194. Models and codes.

(a) Compliance application(s) shall include:

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

(2) Model and code verification. Compliance application(s) must demonstrate that:

(A) conceptual models reasonably represent the disposal system;

(B) mathematical models incorporate equations and boundary conditions appropriate to the conceptual models;

(C) computer codes provide satisfactory solutions to the mathematical models, i.e., codes produce accurate results and are free of coding errors;

(D) a high degree of agreement exists between the model and measured data, if observational data are available for model
validation; and

(E) models, codes, and data used to support models and codes have been subjected to peer review according to § 194.XX of this subpart;

(3) Software coding, user’s manuals, programmer’s manuals, and any necessary licenses.

(b) Models and codes used to support compliance applications shall be fully and clearly documented in a manner compatible with NUREG 0856 “Final Technical Position on Documentation of Computer Codes for High Level Waste Management.”

(c) Documentation shall include:

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

(B) Detailed descriptions of the structure of each code and complete listings of the source codes;

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

(D) Necessary licenses.
(d) The Administrator or the Administrator's authorized representative may verify the results of computer simulations used to support compliance applications by performing independent simulations. All data files, source codes, executable versions of computer software for each model, anything else needed to permit the Administrator or the Administrator's authorized representative to perform independent simulations, and access to any necessary hardware to perform such simulations, shall be provided upon the request of the Administrator or the Administrator's authorized representative.

§ 194. Waste characterization.

(a) Compliance application(s) shall include a detailed chemical, radiological and physical characterization of waste proposed for disposal in the disposal system. Such waste characterization shall be used in assessing compliance with 40 CFR part 191.

(b)(i) Waste characterization information provided under (a) shall quantify the following characteristics for existing and to-be-generated waste:

(1) Species and curie quantity of each radionuclide;
(2) Solubility of each radionuclide species under disposal system conditions;
(3) Waste pH and Eh under disposal system conditions;
(4) Waste form;
(5) Free liquid content and initial liquid saturation;
(6) Pyrophoric or explosive materials; and
(7) Any other characteristics that could affect the transport of radionuclides toward the accessible environment including, but not necessarily limited to, those affecting the solubilization of radionuclides, formation of colloidal suspensions containing radionuclides, production of gas from the waste, nuclear criticality, and generation of heat in the disposal system.

(ii) The method(s) used to quantify each waste characteristic and its associated uncertainty shall be identified and described in any compliance application(s).

(c) Compliance application(s) shall include information demonstrating that:
(1) Physical sampling to verify waste characterization of the existing inventory of waste has been conducted and the extent of sampling is sufficient for results to be statistically representative of the total inventory of existing waste proposed for disposal in the disposal system; or
(2) In assessing compliance with 40 CFR part 191, the characteristics of the existing inventory of waste proposed for disposal in the disposal system shall be assumed to consist of a combination of chemical, radiological, and physical characteristics of such waste that would maximize the transport of radionuclides toward the accessible environment; and
(3) Waste characterization information provided under (b) for to-be-generated waste accurately quantifies the total inventory of
to-be-generated waste proposed for disposal in the disposal system; and

(4) Waste emplaced in the disposal system will not differ from information provided under (b) such that the chemical, radiological, or physical characteristics of such waste increases the mobility of radionuclides.

(d) Compliance application(s) shall describe the chemical, radiological, and physical characteristics of the existing inventory of waste proposed for disposal in the disposal system that would maximize the transport of radionuclides toward the accessible environment, if the requirements under (c)(2) are used to support compliance application(s).

(e) The Administrator will use audits and inspections to verify waste characterization data and assumptions.

§ 194. Future state assumptions.

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


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

(b) Compliance application(s) shall clearly identify any expert judgments used to support the application(s), shall describe the process of eliciting expert judgment, and shall document the results of expert judgment elicitation processes and the reasoning behind those results. Documentation shall be provided of interviews used to elicit judgments from experts, deliberations among and formal interactions among experts, background information provided to experts, and the questions or issues presented for elicitation of expert judgment.

(c) The following restrictions and guidelines shall pertain to any selection of individuals used to elicit expert judgments:

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

2. Individuals shall not be selected who maintain a supervisory role or who are supervised by (directly or indirectly) those who will utilize the judgment;

3. At least one-half of the membership of any expert panel shall consist of individuals who are not employed, directly or indirectly by the Department;

4. When assembling an expert panel, individuals shall be selected such that collectively they represent a diversity of scientific and technical viewpoints, including all areas of
expertise directly required to address the question or issue presented; and

(5) Individuals shall not be selected who maintain a personal or economic interest in the results of the elicitation.

(d) Compliance application(s) shall demonstrate that the expertise of any individual(s) involved in expert judgment elicitation is consistent with the level of knowledge required by the question or issue presented to that individual(s).

(e) The results of any expert judgment processes shall be peer-reviewed according to § 194.XX of this subpart. The report of the proceedings and findings of peer-review processes shall be attached to the documentation required under (b).

(f) A relationship between the information presented, the questions asked, the judgment of any expert panel or individual and the purpose for which the expert judgment is being used shall be demonstrated.

(g) The results of any elicitation resulting in a range of potential values with upper and lower bounds for a specific parameter shall be used such that the bounding value that would result in the largest estimated releases of radionuclides is incorporated into the compliance assessment.

(h) The elicitation process shall include an opportunity for presentation to the expert(s) of the scientific and technical views of groups and individuals other than those affiliated with the Department.
§ 194. Peer review.

(a) Compliance application(s) shall include information which demonstrates that peer review has been conducted to evaluate the adequacy of the results of any expert elicitation, consideration of processes and events, quality assurance programs and plans, models and codes, and waste characterization.

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

§ 194. Consideration of controlled area.

Certification or determination(s) of compliance with the disposal regulations shall assume the controlled area encompasses no more than the area authorized under section 3 of the WIPP LWA.

CONTAINMENT REQUIREMENTS

§ 194. Scope of performance assessments.

Performance assessments need not consider categories of processes and events that are estimated to have less than one chance in 10,000 of occurring over 10,000 years.

§ 194. Consideration of human-initiated processes and events.

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

(b) Performance assessments need not consider intentional
intrusion into the disposal system.

(c) The following process shall be used in assessing the likelihood and consequences of human-initiated processes and events:

(1) The record of exploratory activities in the Delaware Basin of New Mexico over the past 50 years shall be examined. A separate analysis for each type of exploratory activity shall be conducted.

(2) The rate of intrusion (expressed in intrusions per square kilometer per year) into the controlled area shall be assumed to be the average rate of drilling (per square kilometer per year) for each specific type of exploratory activity in the entire Delaware Basin over the last 50 years. The total rate of human intrusion shall be the sum of the rates of all the different types of human-initiated processes and events which may affect the disposal system.

(3) In determining the consequences of human-initiated processes and events, human-initiated processes and events shall be assumed to occur at random intervals in time and space in the controlled area throughout the regulatory time frame. The consequences of each human-initiated process and event shall be calculated. Performance assessments shall take into account the cumulative effects of all human-initiated processes and events, if any, on the disposal system.

(4) In determining the consequences of human-initiated
processes and events, assumptions pertaining to the characteristics of human-initiated processes and events including, but not limited to, the type and amount of drilling fluids, borehole depth and diameter, and the characteristics and presence of borehole seals shall be based on the technology used in current practice.

§ 194. Compliance.

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

(b) At least 300 CCDFs shall be generated and included in applications for certification or determination of compliance. In cases where parameter values are imprecisely known, mathematical techniques which consider the full range of potential values shall be used in calculating CCDFs.

(c) The mean CCDF, of the total number of CCDFs generated, must meet the requirements of 191.13(a).

ASSURANCE REQUIREMENTS

§ 194. Active institutional controls.

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

(b) Performance assessments that assess isolation of the waste from the accessible environment shall not consider any contributions from active institutional controls for more than 100 years after disposal.

§ 194. Monitoring.

(a) Compliance application(s) shall include a detailed plan for monitoring the performance of the disposal system. At a minimum, such plan shall:

(1) Identify parameters that will be monitored;

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

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

(b) Monitoring programs shall be designed to detect movement of radionuclides toward the accessible environment at the earliest practicable time and shall be consistent, to the extent practicable, with monitoring required under applicable federal hazardous waste regulations.

(c) To the extent practicable, monitoring of parameters which may affect the transport of radionuclides toward the accessible environment shall be conducted. Monitored parameters shall include:

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

(2) Gas quantity and composition;

(3) Temperature distribution;

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

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

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

(7) Any other parameters which could affect the transport of radionuclides toward the accessible environment.

§ 194. Passive institutional controls.

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

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

(2) Placement of records in the archives and land record systems of local, State, and Federal government agencies, and international archives, that would be likely to be consulted by potential human intruders. Such records shall identify:

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

(iii) The nature and hazard of the waste;

(iv) Geologic, geophysical, geochemical, hydrologic, and other site data pertinent to the containment of radionuclides in the disposal system; and

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

(b) Compliance application(s) shall include detailed descriptions of the proposed passive institutional controls, their location, and the period of time the controls are expected to endure and be understood.

§ 194. Engineered barriers.

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

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

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

(1) the long- and short-term environmental benefit and detriment;

(2) the ability of the engineered barrier to prevent or substantially delay the movement of water or radionuclides toward the accessible environment;

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

(4) the increased ease or difficulty of removing the waste;

(5) the increased or reduced transportation risks;

(6) the increased or reduced uncertainty in compliance assessment;

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

(8) the increased or reduced total system costs;

(9) the impact, if any, on other waste disposal programs from the incorporation of engineered barriers;

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

(c) In considering the benefit and detriment of incorporation
of engineered barriers, the benefit and detriment of engineered barriers for existing waste already packaged, existing waste not yet packaged or in need of re-pakaging, as well as waste to-be-generated shall be considered separately and described.

(d) The evaluation shall consider engineered barriers alone and in combination.

§ 194. Consideration of the presence of resources.

(a) Compliance application(s) shall include:

(i) descriptions of the favorable characteristics of the disposal system; and

(ii) descriptions of the likelihood of human intrusion into the disposal system that take into account the presence of resources.

(b) Compliance application(s) shall include information which demonstrates that the favorable characteristics of the disposal system compensate for the likelihood of future human intrusions into that system.

(c) In evaluating compliance with 40 CFR part 191.13, compliance application(s) shall consider human intrusion into the controlled area in search for all known resources.

§ 194. Removal of wastes.

Compliance application(s) shall include a plan for removal of wastes from the disposal system. The plan shall incorporate the best technology available, at the time of application, for removing such waste.
§ 194. Consideration of protected individual.

Certifications or determinations of compliance with 40 CFR part 191.15 and Subpart C, shall assume that an individual resides at the location in the accessible environment where that individual would be expected to receive the highest exposure from radionuclide releases from the disposal system.

§ 194. Consideration of exposure pathways.

In certifying or determining compliance with 40 CFR part 191.15 and Subpart C, all potential exposure pathways, associated with undisturbed performance, from the disposal system to individuals shall be considered. Certifications or determinations of compliance with 40 CFR part 191.15 and Subpart C shall assume that individuals consume 2 liters per day of drinking water from any underground source of drinking water in the accessible environment.

§ 194. Consideration of underground sources of drinking water.

In certifying or determining compliance with Subpart C of 40 CFR part 191 Subpart C, all underground sources of drinking water in the accessible environment likely to be affected by the disposal system over 10,000 years shall be considered. In determining whether underground sources of drinking water are likely to be affected by the disposal system, interconnections between bodies of surface water, ground water and underground
sources of drinking water shall be considered.

§ 194. Consideration of undisturbed performance.

In certifying or determining compliance with 40 CFR part 191.15 and Subpart C of 40 CFR part 191, categories of events or processes that are estimated to have a one in 10 chance or greater of occurring over 10,000 years shall be considered.

§ 194. Compliance.

When the uncertainties in undisturbed performance of a disposal system are considered, the mean of the appropriate distribution of estimated radiation exposures and radionuclide concentrations must meet the requirements of 40 CFR part 191.15 and Subpart C.

Subpart D--Public Participation


(a) Upon receipt of an application for certification of compliance, the Agency will publish in the Federal Register an advance notice of proposed rulemaking announcing that an application for certification of compliance has been received, soliciting comment on such application, and announcing the Agency's intent to conduct a rulemaking to certify whether the WIPP facility will comply with the disposal regulations.

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

(c) The notice will provide a comment period of at least 120 days.
(d) A public hearing concerning this notice will be held if a written request for such a hearing is received within 30 calendar days of the date of publication. Written requests shall be directed to the Administrator and the Administrator’s authorized representative.

(e) Any comments received on such notice will be made available for inspection in Agency dockets.

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


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

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

(c) The notice will announce the opportunity for public hearings in New Mexico and provide information on the timing and location of such hearings and procedures for registering to testify.

(d) Any comments received on such notice will be made available for inspection in Agency dockets.
(e) A document summarizing major concerns and issues arising from comments received on such notice as well as the Administrator's response to such concerns and issues will be prepared and will be made available for inspection in Agency dockets and upon request.


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

§ 194. Documentation of continued compliance.

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

(b) Copies of documentation of continued compliance will be made available for inspection in Agency dockets.

(c) The notice will provide a comment period of at least 30 days after publication.

(d) Any comments received on such notice will be made available for public inspection in Agency dockets.
(e) Upon completion of a review of documentation of continued compliance with the disposal regulations, the Administrator will publish a notice in the Federal Register announcing the Administrator's decision determining whether or not the WIPP facility continues to be in compliance with the disposal regulations.

§ 194. Dockets.

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