

WPO 45835



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

MAR 19 1997

OFFICE OF  
AIR AND RADIATION

Honorable Alvin Alm  
Assistant Secretary for  
Environmental Management  
U.S. Department of Energy  
1000 Independence Ave., SW  
Washington, DC 20585

Dear Mr. Alm:

The U.S. Environmental Protection Agency (EPA) received the U.S. Department of Energy's (DOE) Compliance Certification Application (CCA) for the Waste Isolation Pilot Plant (WIPP) on October 29, 1996. The Agency immediately commenced its review pursuant to Section 8(d)(1) of the WIPP Land Withdrawal Act, as amended, to evaluate whether the CCA demonstrates and documents WIPP's compliance with EPA's radioactive waste disposal regulations at subparts B and C of 40 C.F.R. Part 191.

On December 19, 1996, Mary Nichols, Assistant Administrator for the Office of Air and Radiation, sent you a letter identifying certain aspects of the CCA that my staff had preliminarily determined to require additional support or documentation. The purpose of that letter was to provide DOE, as early as possible, with a preliminary assessment of EPA's concerns regarding the CCA. Since we sent that letter, we have had the opportunity to: (1) conduct a more detailed review of the CCA; (2) preliminarily consider numerous public comments received on the CCA during the public comment period; and (3) evaluate DOE's responses to the letter. Based upon careful evaluation of each of these factors, we have developed lists of issues that need to be addressed by DOE in order for EPA to render a compliance certification decision (see Enclosures 1-6). This letter is based on a review of all materials received by EPA by March 12th. Since we continue to receive information from DOE on a regular basis, some of the information received since March 12th may address certain points raised in the enclosures. We will expeditiously review these materials, as well as materials received in the future.

The first issue is the adequacy of certain conceptual models. As you are aware, the Spallings Model predicts the amount of solid material released during a drilling event -- an

SWCF-A: 1.4.3.3: NO REFS **Information Only**

important release scenario. The Spallings Model has been found inadequate by DOE's independent peer review panel. Also, the Chemical Conditions Model, which determines the dissolution of radionuclides in brine found around WIPP, has been deemed inadequate by the same DOE peer review panel. We have been informed by your staff that the peer review panel will be re-convened March 31 to April 4, 1997, to re-evaluate these models. The results of these peer reviews are critical to the Agency's evaluation of the CCA. We request that DOE provide us with the peer review reports and DOE's assessment of the status of the conceptual models. This will enable us to determine the impact on our review of the CCA.

The second area of concern is the derivation of important input parameters, and their associated values, for the performance assessment. This concern is significant because parameters are used as inputs to the computer codes that calculate potential releases from the WIPP. Of the approximately 1,600 input parameters reviewed by EPA, 58 parameters that could have a significant impact on the results of the performance assessment are of concern. I have divided these 58 parameters into three different categories, each of which is listed in a separate enclosure.

The first set of parameters is those for which we have been unable to find supporting data (see Enclosure 2). My staff has been working continuously since November to establish the traceability of the parameter and data record packages that support the input parameter values used in the performance assessment. The Records Center has greatly improved since November. We encourage the Department to continue with these improvements to facilitate retrievability of records. To date, 13 key input parameters are either not supported by experimental or field data, or the data trail is untraceable. The Compliance Criteria, at 40 C.F.R. §194.26(a), clearly indicate that input parameters should be based on actual experimental data. To the extent that certain input parameter values cannot be obtained through data collection or experimentation, DOE may derive such values using "expert judgment." The Compliance Criteria set forth explicit requirements for the proper conduct of elicitation of such expert judgment. Thus, in accordance with the Compliance Criteria, DOE must provide the following support for the critical input parameters that appear to be unsupported by actual data: (1) documentation of actual data collection and/or results of experimentation, or (2) demonstration that EPA's expert judgment procedures were followed in selecting the parameter values.

The second set of five input parameters are those for which EPA has reviewed the supporting information and finds that the information in the record supports a value or range of values different from those selected by DOE (see Enclosure 3). EPA suggests that new values or ranges be selected for these parameters. My staff will be available to meet with DOE to explain these suggested changes.

The final set of 40 input parameters are those for which EPA has reviewed the supporting data and has questions about the value(s) selected (see Enclosure 4). My staff will be available to meet with DOE staff to review the supporting documentation for each of these parameters to see if changes to the value or range selected for each parameter are needed.

The third area of concern relates to specific scenarios that were eliminated from the CCA's performance assessment calculations. As you know, conceptual models represent our understanding of WIPP and include different types of scenarios, such as human activities (e.g., drilling) and geologic processes (e.g., earthquakes), that could occur over the regulatory time frame. EPA has concluded, as have numerous public commenters, that the CCA does not contain adequate justification for eliminating consideration of the occurrence of certain fluid injection scenarios at WIPP. Therefore, EPA requires either additional substantiation to support the elimination of fluid injection scenarios from performance assessment calculations, or revision of the performance assessment to include appropriate fluid injection scenarios.

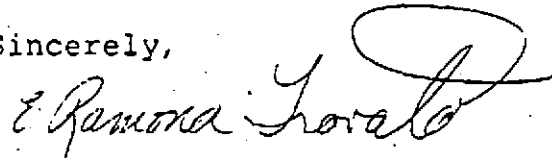
The last item of concern relates to the final results of the performance assessment calculations. Since the performance assessment represents how WIPP is expected to perform in the future, it is critical that site characteristics, conceptual models, computer codes, and input parameters be as representative of the disposal system as possible. EPA believes that final resolution of the three issues identified above may result in different performance assessment input values, as well as revisions to some of the models. Further, EPA is aware that some models have already been changed by DOE and its contractors. Accordingly, DOE will probably need to rerun the performance assessment to demonstrate that the WIPP complies with the disposal criteria using the revised models, input parameters and scenarios. If DOE decides not to rerun the performance assessment, the Department will have to demonstrate why the combined effect of all the changes is not significant enough to require new performance assessment computer runs. An individual impact analysis of each change that does not take into account

the synergistic and holistic effects of all of the changes will not be sufficient. This new performance assessment or demonstration will enable us to complete our review of the CCA.

The above requests, as well as a complete listing of other Agency concerns, are explained in detail in Enclosures 1-6 to this letter. Enclosures 5 and 6 list findings from recent quality assurance and peer review audits conducted to verify conformance with the Compliance Criteria at 40 C.F.R. §194.22(a)(1) and §194.27(b), respectively. The issues described in this letter and enclosures include EPA's outstanding concerns with the CCA. In order to facilitate EPA's decision-making process, please send me a letter describing how, and when, the Department will resolve these concerns.

Thank you for your continued cooperation during our review process. Should you have questions regarding this request, please call me at (202) 233-9320.

Sincerely,



E. Ramona Trovato, Director  
Office of Radiation and Indoor Air

Enclosures

cc: Mary D. Nichols (EPA)  
Tom Grumbly (DOE/HQ)  
George Dials (DOE/CAO)

*Enclosure 1***WIPP Compliance Certification Application Technical Issues Requiring Additional Information Prior to EPA Rendering a Certification Decision***Content of Compliance Certification Applications***194.14(a)(2)**

Section 194.14(a)(2) states that the description of the disposal system shall include a description of the geology, geophysics, hydrogeology, hydrology, and geochemistry of the disposal system and its vicinity and how these are expected to change and interact over the regulatory time frame.

The CCA identifies a new conceptualization of the origin of the hydrogeochemical facies in the Culebra. The explanation of the relationship between the hydrochemical facies and the groundwater basin modeling is not adequate. Section 2.2.1.4.1.2 briefly mentions a potential relationship but does not provide support for the relationship.

*DOE needs to provide a discussion of the origin of the hydrochemical facies that incorporates the modeled Culebra paleoflow directions with geochemical principles.*

*Data Quality Characteristics***194.22(c)**

Section 194.22(c) requires that the compliance application describe, to the extent practicable, how data used to support compliance have been assessed for the five referenced data quality characteristics: accuracy, precision, representativeness, completeness and comparability.

Section 5.3.21.1 of the CCA states that " ...it is not practical to apply data quality characteristics to most scientific investigations used to support a performance assessment in which there is uncertainty in the conceptual models and the resultant ranges of parameters."

*While some information that supports this statement was provided in the CCA, EPA requires additional documentation from DOE that supports the CCA arguments and uses specific measured data points as examples.*

*Models and Computer Codes***194.23(a)(3)(I)**

Section 194.23(a)(3)(I) states that any compliance application shall include documentation that conceptual models and scenarios reasonably represent possible future states of the disposal system.

It is EPA's understanding that after an initial E2 drilling intrusion, subsequent E2 drilling intrusions do not produce releases via spillings or direct brine release. It is not clear whether this is a modeling outcome or an assumption.

*DOE needs to provide a description of the implementation of the E2 scenario that addresses releases when another E2 event occurs.*

**194.23(a)(3)(iv)**

Section 194.23(a)(3)(iv) states that computer models must accurately implement the numerical models; i.e., computer codes are free of coding errors and produce stable solutions.

(1) Testing of the functional requirements for SECOTP2D is not documented in the CCA's validation documents. The information presented in the Analysis Plan (provided in December 1996) addresses this comment from a completeness standpoint; however, the testing of the SECOTP2D is not technically adequate.

*DOE needs to test SECOTP2D with a heterogeneous transmissivity field.*

(2) There appears to be a mass balance problem in SECOTP2D that could cause the computer code to produce calculations with errors and thus inaccurately implement the numerical models.

*DOE needs to provide an analysis of the mass balance in SECOTP2D and its effects on calculations of radionuclide transport in the Culebra.*

(3) Potential errors have been found in the computer codes.

*DOE needs to identify errors that have been found in the computer codes since the PA calculations were run for the 10/29/96 CCA submission. DOE needs to describe the impact of those errors on the results of PA.*

(4) While the type of testing for the SECO3D code appears to be appropriate, the most relevant tests (listed in Record 25, WPO 43367) are only briefly described, and test results are not presented.

*The tests mentioned in Record 25 need to be fully described and the results provided.*

**194.23(c)(2)**

Section 194.23(c)(2) requires that the CCA include detailed instructions for executing the computer codes, including hardware and software requirements, input and output formats, listings of input and output files from a sample computer run, etc.

NUTS Validation Document, page 1205: EPA commented in the December 1996 letter that there is no obvious physical reason for oscillations in the concentration profile and there are concerns about the adequacy of the testing. DOE responded that the "apparent oscillations" are actually concentration accumulations due to the velocity field and coarse grid that was used. DOE also stated that no attempt was made to actually solve the problem described in the test, but instead, the purpose was to determine whether NUTS could track the results computed by an independent technique (i.e., MT3D) given the velocity field. This may be true, although it raises two issues: (1) Since MT3D is known to have problems producing accurate solutions, an essentially perfect match of the NUTS results to these inaccuracies does not produce confidence that the NUTS code is providing accurate solutions; and (2) the fact that the same degree of grid coarseness leads to exactly the same level of inaccuracy in both codes is unusual behavior for two independently formulated codes.

*DOE should use the computer code SWIFT to benchmark NUTS for the same problem, with the exception that the grid be made fine enough to provide an accurate solution.*

#### 194.23(c)(4)

Section 194.23(c)(4) states that detailed descriptions of data collection procedures, sources of data, data reduction and analysis, and code input parameter development must be documented in the CCA.

(1) Concerns regarding anhydrite marker beds still need to be addressed. Specifically, the information on the incorporation of the anhydrite behavior is very general and does not provide the detailed information necessary to reproduce DOE's results regarding the incorporation of permeability and porosity.

*DOE needs to provide information that explains the methodology by which the permeability versus pressure curves and porosity versus pressure curves were developed. DOE needs to explain the permeability and porosity curves generated by Mike Lord (attached to the February 26 response as the 1/29/96 memo to Margaret Chu and the 1/24/96 memo from Kurt Larson to Mike Lord and others).*

(2) Concerns regarding a low transmissivity feature still remain. A low transmissivity region appears consistently in the calibrated transmissivity fields in the northeastern portion of the site where there are little data. Care must be taken with model interpretations in regions where there are little data to corroborate the interpretation. Low transmissivity produces long travel times and could produce an overly optimistic PA.

Information provided by M. LaVenue at a DOE meeting on 17 and 18 September 1996 at Sandia originally indicated that the low transmissivity region is due to a single very low transmissivity data point at P-18. From the histogram of Culebra transmissivity data, the

P-18 data point could be argued to be a statistical outlier. Given the large variation of transmissivity data over the wider region, the P-18 data point could also be valid. But the geostatistical methods in GRASP\_INV should not allow the data point at P-18 to produce low transmissivity in the northeastern portion of the site that is far separated from P-18.

The DOE response to EPA's request of December 19, 1996 stated that there are no independent data to confirm the P-18 data point. But it is stated that the P-18 data point is consistent with the geological conceptual model. Further, it is stated that the P-18 data point has a minor effect because of the geostatistical methods used in GRASP\_INV.

While the above DOE response is reasonable, the original question still remains as to why there is a low transmissivity feature in the eastern portion of the site where there are little data to confirm the feature.

*DOE needs to provide the transmissivity field that results from kriging the transmissivity data and which does not show the low transmissivity region in the northeastern part. DOE needs to provide several typical transmissivity fields calibrated to steady-state head data that show the appearance of the low transmissivity feature in the northeastern part of the site. These plots need to be accompanied with an explanation as to the reasons why the calibration causes this low transmissivity feature in the northeastern part of the site.*

(3) "Legacy" parameters were developed and used in the 1992 PA calculation and in the CCA PA calculations without alteration. Current parameter packages simply reference "Legacy" parameters without explaining how they are developed or providing traceability to source documents.

*DOE needs to document the development of "Legacy" parameters to show traceability.*

### Waste Characterization

#### 194.24(a)

Section 194.24 requires the CCA to include a description of the chemical, radiological, and physical composition of all existing waste (and, to the extent practicable, to-be generated waste) proposed for disposal in the WIPP.

1) The BIR indicates that the Department has collected more recent information on the waste inventory of the generator sites, in particular, information were collected during the January 1996 data call.

*If the Department would like this information considered as part of the application, then it should provide that to the Agency. Otherwise, EPA will assume that the waste inventory*



information submitted with the October, 29, 1996 application is that on which we will base our certification decision.

#### 194.24(b)

Section 194.24(b) requires the CCA to include a complete discussion of all waste characteristics that influence disposal performance, including but not limited to solubility, formation of colloids suspensions, gas generation, shear strength, compatibility, and other waste-related input to model parameters.

1) Adsorption of actinides by immobile mineral surfaces or metal corrosion products can retard the migration of actinides relative to the flow of brine through the repository. Adsorption of actinides onto colloids can enhance actinide migration. The CCA apparently does not account for the adsorption of actinides onto colloids in determining the releases during cuttings/cavings.

*The Department needs to provide a description of how adsorption of actinides was accounted for in releases of cuttings/cavings. If adsorption not taken into account, the Department needs to show how this would lead to a conservative release estimate.*

2) The effects of organic complexants on actinide solid solubilities within a brine system has not been well documented through experimental or modeling studies.

*The Department needs to provide more detail discussion on the use of HYDRAQL code, especially in respect to quantity of organic complexants used in the calculation.*

#### 194.24(c)(1)

Section 194.24(c)(1) requires DOE to demonstrate that for total inventory of waste proposed for disposal, WIPP complies with the numeric requirements of section 194.34 for the upper and lower waste limits, including their associated uncertainties.

It is not evident in the CCA how the Department is treating the associated uncertainties for the upper and lower limit for each waste component.

*The Department needs to identify the method by which the uncertainties associated with the upper and lower limits for each waste component are being incorporated into the results of the performance assessment.*

#### 194.24(c)(3)

Section 194.24(c)(3) requires the Department to provide information which demonstrates the use of process knowledge to quantify waste components.

Acceptable knowledge plays a key role in identifying the origin or generation of TRU wastes. This information is used to help inform the non-destructive assay (NDA) process in the selection of the appropriate correction or calibration factors. The operational history of a site indicates many important details of the waste matrix. Each TRU generator site considers acceptable knowledge in choosing measurement equipment, designing analytical protocols and establishing the types and ranges of correction and/or calibration factors for NDA measurement systems. However, the CCA is not clear on what the protocol is for determining this information when no acceptable knowledge information is available.

*The Department needs to provide the protocol for determining the NDA measurement equipment, designing analytical protocols and establishing the types and ranges of correction and/or calibration factors for NDA measurement systems when no acceptable knowledge information is available.*

#### 194.24(c)(4)

Section 194.24(c)(4) requires the CCA to provide information which demonstrates that a system of controls has been and will continue to be implemented to confirm that the total amount of each waste component that will be emplaced in the disposal system will not exceed the upper limit or fall below the lower limit.

The CCA discusses the WIPP Waste Information System (WWIS) which the Department proposes to use for the purpose of tracking the quantity of waste emplaced in the WIPP. It is not clear what information will be collected regarding the location of drums in the repository. In addition, the WWIS Software Design Description contains the internal details of each design entity including a description of the data elements associated with each entity. Although the WWIS lists the data elements, it is not clear which data elements are active or inactive and are functioning as placeholders.

*EPA will soon be conducting an audit of the WWIS system. The Department should be prepared to address the above issues during the conduct of that audit.*

#### 194.24(d)

Section 194.24(d) requires the Department to provide a waste loading scheme, or else the performance assessments shall assume random placement of waste in the disposal system.

The CCA assumed that the containers of waste would be emplaced randomly for the 569 waste streams tracked in the TWBIR. The CCA also assumes that the sampling of 10,000 futures was large enough that the relatively low probability combination of three of the waste streams with higher activity loading occurring in a single drilling event was captured in the CCDFs. However, the assumption that containers will be randomly placed in the WIPP does not take into account likely "real world" scenarios where a specific generator sends a large shipment of a particular

waste stream at one particular time (e.g. RF-Residues from Rocky Flats which is estimated to represent 15 percent of the total curies emplaced in the WIPP at 2133).

*The Department needs to address how it is planning to achieve random loading of waste drums at WIPP. If the Department cannot achieve random loading they need to analyze the effect of non-random loading.*

#### Scope of Performance Assessments

##### 194.32(a)

Section 194.32(a) states that performance assessments shall consider natural processes and events, mining, deep drilling, and shallow drilling that may affect the disposal system during the regulatory time frame.

The CCA does not provide adequate information as to the behavior of short-term brine flow to the surface if a brine pocket is hit.

*DOE needs to document the modeling results that support the current approach, which assumes that brine flow to the surface from hitting a brine pocket does not result in releases.*

##### 194.32(c)

Section 194.32(c) specifically requires that the PA include an analysis of the effects on the disposal system of any activities that occur in the vicinity of the disposal system prior to disposal and are expected to occur in the vicinity of the disposal system soon after disposal system. These activities include boreholes and leases that may be used for fluid injection activities.

The process for solution mining for extraction of brine is distinctly different from other resource extraction techniques. The fluid injection activities used in solution mining can potentially induce alterations, which may not be limited to subsidence and caving, in the host rock (Salado).

*DOE needs to consider in the PA existing boreholes in which solution mining can reasonably be expected to occur in the near future.*

##### 194.32(e)

Section 194.32(e) states that compliance application(s) shall include information which: (1) Identifies all potential processes, events or sequences and combinations of processes and events that may occur during the regulatory time frame and may affect the disposal system; (2) Identifies the processes, events or sequences and combinations of processes and events included in performance assessments; and (3) Documents why any processes, events or sequences and combinations of processes and events identified pursuant to paragraph (e)(1) of this section were not included in performance assessment results provided in any compliance application.

(1) The Stoelzel and O'Brien features, events and processes (FEP) analysis (Reference 611) provides information on how fluid injection may effect the disposal system. This approach does not appropriately model this event.

*DOE needs to:*

- (a) Use a 150-year period as the period of simulation.*
- (b) Identify the extent to which the initial conditions (i.e., conditions before an intrusion event) of the repository could change with the longer period of fluid injection.*
- (c) Analyze the effects of a human intrusion event subsequent to fluid reaching the repository via a fluid injection event.*
- (d) Increase the transmissivity of Bell Canyon to allow higher volumes of brine to be injected.*
- (e) Reduce, by one-half, the DRZ volume.*
- (f) Estimate the frequency of fluid injection wells that have failed or appear to have failed.*
- (g) Substantiate why a two-dimensional cross-sectional modeling approach is appropriate for this analysis.*

(2) DOE has not analyzed (screened) the potential effects of solution mining of halite in the CCA. Section 194.32(c) requires that performance assessments include an analysis of the effects on the disposal system of such activities in its vicinity prior to disposal or that can reasonable be expected soon after disposal.

*DOE needs to provide an analysis of the effects of solution mining for halite. Since the mining of the halite is associated with the production of oil, the time frame for the modeling study may be limited to the potential life of oil production around WIPP (i.e., 150 years).*

Enclosure 2

**WIPP Performance Assessment Parameters Lacking Supporting Evidence**

No.	ID #	Material ID	Parameter ID	Description
1	3245	BLOWOUT	CEMENT	Waste cementation strength
2	3246	BLOWOUT	PARTDIA	Waste particle diameter in Cuttings Model for direct brine release
3	198	DRZ_1	PRMX_LOG	Log of intrinsic permeability, X-direction; disturbed rock zone; time period 0 to 1000 yrs
4	2177	S_MB_139	DPHIMAX	Incremental increase in porosity relative to intact conditions in the Salado Marker Bed 139
5	2180	S_MB_139	PF_DELTA	Incremental pressure for full fracture development
6	586	S_MB_139	PI_DELTA	Fracture initiation pressure increment
7	2178	S_MB_139	KMAXLOG	Log of max permeability in altered anhydrite flow model
8	3134	BH_OPEN	PRMX_LOG	Log of intrinsic permeability x - direction borehole unrestricted
9	2158	S_ANH_AB	DPHIMAX	Incremental increase in porosity relative to intact conditions in the Salado anhydrite beds A and B
10	214	EXP_AREA	PRMX_LOG	Log of intrinsic permeability, X-direction, experimental area
11	3473	BLOWOUT	THICK_CAS	Thickness of the Castile formation, direct brine releases
12	3456	BLOWOUT	RE_CAST	External drainage radius for the Castile formation, direct brine releases
13	3194	CASTILER	GRIDFLOW	Index for selecting brine pockets

Enclosure 3

**WIPP Performance Assessment Parameters Where the Record Supports Values Other Than Those Selected by DOE**

No.	ID #	Material ID	Parameter ID	Description
1	3493	GLOBAL	PBRINE	Probability of Encountering Pressurized Brine
2	2254	BOREHOLE	TAUFAIL	Waste Shear Strength
3	3184	BH_SAND	PRMX_LOG	Log of Intrinsic Permeability, x-direction
4	2918	CASTILER	VOLUME	Total Reservoir Volume
5	61	CASTILER	COMP_RCK	Bulk Compressibility

Enclosure 4

**WIPP Performance Assessment Parameters Not Explicitly Supported  
by the Relevant Data/Information**

No.	ID #	Material ID	Parameter ID	Description
1	27	BOREHOLE	DOMEGA	Drill String Angular Velocity
2	64	CASTLER	POROSITY	Effective Porosity
3	66	CASTLER	PRESSURE	Brine Far-field Pore Pressure
4	259	PAN_SEAL	PRMX_LOG	Panel Seal Permeability
5	528	S_ANH_AB	POROSITY	Effective Porosity
6	567	S_MB138	POROSITY	Effective Porosity
7	588	S_MB139	POROSITY	Effective Porosity
8	651	WAS_AREA	ABSROUGH	Absolute Roughness of Material
9	653	WAS_AREA	COMP_RCK	Bulk Compressibility
10	1992	WAS_AREA	DIRNCCHW	Bulk Density of Iron Containers CH Waste
11	1993	WAS_AREA	DIRNCRHW	Bulk Density of Iron Containers RH Waste
12	2040	WAS_AREA	DIRNCCHW	Average Density of Iron-Based Material in CH Waste
13	2041	WAS_AREA	DCELLCHW	Average Density of Cellulosic in CH Waste
14	2274	WAS_AREA	DCELLRHW	Average Density of Cellulosic in RH Waste
15	2907	STEEL	CORRMCO2	Inundated Corrosion Rate for Steel w/o CO2 Present
16	3147	CONC_PLG	POROSITY	Effective Porosity
17	3185	CONC_PLG	PRMX_LOG	Log of Intrinsic Permeability, x- direction
18	3256	BLOWOUT	FGE	Gravity Effectiveness Factor
19	3259	BLOWOUT	APORO	Waste Permeability in CUTTINGS Model
20	3429	PHUMOX3	PHUMOX	Proportionality Constant Humic Colloids
21	3471	BLOWOUT	MAXFLOW	Maximum Blowout Flow
22	3472	BLOWOUT	MINFLOW	Minimum Blowout Flow

**WIPP Performance Assessment Parameters Not Explicitly Supported  
by the Relevant Data/Information**

No.	ID #	Material ID	Parameter ID	Description
23	3433	PHUMOX3	PHUMSIM	Proportionality constant of actinides in Salado Brine with humic colloids, inorganic
24	3470	BLOWOUT	GAS_MIN	Gas Rate Cutoff
25	3317	PU	PROPMIC	Microbial Proportionality Constant
26	3405	SOLMOD6	SOLCIM	U(VI) Solubility Limits - Castile
27	3406	SOLMOD6	SOLSIM	U(VI) Solubility Limits - Salado
28	3402	SOLMOD3	SOLCIM	Oxidation State +III Model
29	3403	SOLMOD4	SOLCIM	Oxidation State + IV Model
30	3407	SOLMOD4	SOLSIM	Oxidation State +IV Model
31	3404	SOLMOD5	SOLCIM	Oxidation State +V Model
32	3408	SOLMOD5	SOLSIM	Oxidation State +V Model
33	3311	AM	PROPMIC	Microbial Proportionality Constant
34	3482	AM+3	MKD_AM	Matrix Partition Coefficient for Am
35	3480	PU+3	MKD_PU	Matrix Partition Coefficient for Pu
36	3481	PU+4	MKD_PU	Matrix Partition Coefficient for Pu
37	3479	U+4	MKD_U	Matrix Partition Coefficient for U
38	3475	U+6	MKD_U	Matrix Partition Coefficient for U
39	656	WAS_AREA	GRATMICH	Gas Production Rate - Microbial Humid Conditions
40	657	WAS_AREA	GRATMICI	Gas Production Rate - Microbial Inundated Conditions



*Enclosure 5***EPA Quality Assurance Audits: Findings & Observations**

Since the Department submitted its WIPP Compliance Certification Application on October 29, 1996, EPA has performed quality assurance audits of DOE's Carlsbad Area Office (CAO), Sandia National Laboratory (SNL) and Westinghouse Corporation pursuant to 40 CFR Part 194.22(e). The purpose of these audits was to verify the appropriate execution of the requirements of 40 CFR 194.22(a)(1), which addresses quality assurance for activities associated with the Waste Isolation Pilot Plant (WIPP).

The Agency's findings and observations from the CAO and SNL quality assurance audits are listed below. There were no findings or observations from the audit of the quality assurance program of the Westinghouse Corporation. A finding is a specific nonconformance with an applicable NQA element or the element's implementing procedure. An observation is not a nonconformance, but does require a response.

***Findings and Observations From EPA's Quality Assurance Audit of the Carlsbad Area Office***

On December 9-13, 1996, EPA performed an audit of DOE's CAO quality assurance program pursuant to 194.22(e). The purpose of the audit was to verify the appropriate execution of the requirements of 40 CFR 194.22(a)(1). The audit team identified four findings of relatively minor and isolated consequences during the audit.

**Finding No. 1**

NQA-1, Requirement 2 states that the management of those organizations implementing the quality assurance program shall regularly assess the adequacy of that part of the program for which they are responsible and shall assure its effective implementation.

However, CAO's MP 9.1, which implements this NQA requirement, contained no provision for regular assessments. At the time of the audit, MP 9.1 was under revision and was to be changed to address this finding.

**Finding No. 2**

Team Procedure TP 10.5, Requirements 3.4.2(a) and (c) require documentation of orientation of peer review team members.

However, documentation was not available to demonstrate orientation training for one of the panel members for Peer Review No. 3.

#### Finding No. 3

Team Procedure TP 10.5 (Rev. 0), Requirement 3.1.3(a), requires that the peer review selection committee shall be impartial and have no conflict of interest, including financial gain.

However, the chair of the peer review selection committee, which chose the panel for Peer Review No. 3, is the executive vice president of the firm where one of the selected panel members is employed. It was not clear from the information presented during the audit whether the chair of the selection committee may have been in a position in which his own personal interest was conflicted with the independent performance of the Peer Review panel No. 3.

#### Finding No. 4

The audit team identified some documentation that was missing from the DRR files for TP 10.5 (Rev. 0 and Rev. 1).

Copies of the missing information were found and placed in the DRR files during the audit.

### ***Findings and Observations From EPA's Quality Assurance Audit of Sandia National Lab***

On January 13-24, 1997, EPA performed an audit of the Sandia National Laboratory Quality Assurance Program pursuant to 194.22(e). The purpose of the audit was to verify the appropriate execution of the requirements of 40 CFR 194.22(a)(1). The audit team identified six findings and six observations during the audit.

#### Finding 1

NQA-1, Supplement 1S-1, states "quality achievement is verified by persons or organizations not directly responsible for performing the work." However, QAP 1-1 states "line management is responsible for verifying the quality."

#### Finding 2

NQA-3, Requirement 2.4, states "Management assessments of the quality assurance program shall be conducted regularly and reported at least annually."

However, the last management assessment was performed in April 1995.

### Finding 3

Several CAR files requested from the Records Center were found to be incomplete, i.e., referenced documents were not included in the files, or listed on the Record Package Table of Contents.

<u>CAR</u>	<u>Missing Documents</u>
EA96-15-QAF-1	Original log sheet and correction
EA96-15-QAF-5	Attachment documenting sample identification scheme
EA96-26-QAF-1	Corrective Action Request form, initial proposed resolution of CAR (determined to be unacceptable), and revised proposed resolution of CAR (acceptable)
W97-003	Summary memo, including Statement of Impact

### Finding 4

Section 4.1, Step 4, of QAP 5-1 requires the use of the format described in Appendix A.

QAP 5-1 does not conform to its own requirements for procedure format.

### Finding 5

NQA-3, Supplement 3SW-1 states "All data shall be recorded so that they are clearly identifiable and traceable to test experiment, study, or other source from which they were generated."

However, the supporting documentation for the following parameters analyses do not meet traceability requirements:

Parameter No. Id. 34, Borehole PRMX\_LOG is listed as a placeholder parameter. The parameter value listed in Form 464 is not traceable.

Parameter No. Id. 3148, CONC\_PLG COMP\_RCK, listed two sets of parameter values. There is no traceability documentation provided for the first set of data, which has a parameter value of "0." The second set of data has a parameter value of 1.2E-09, which was listed in Form 464 and is traceable, but has never been used. Instead, the parameter value of 2.64E-09 was used, but this value has never been entered into Form 464.

Although 2.64E-09 is the wrong value to use in the analysis, traceability documentation must still be provided with Form 464.

#### Finding 6

QAP 5-1, Revision 2, Section 4.2, Step 1, Note 1 states that QAPs are allowed to carry ICN changes for up to one year before they are revised and reissued.

QAP 2-4 has two ICNs that exceed the one-year limitation. ICN 01's effective date is 10/27/95 and ICN 02 has an effective date of 11/17/95. QAP 20-3 has an ICN with an effective date of 10/13/95. ICN 01 for QAP 5-1 rescinds the one-year limitation on the incorporation of ICNs through QAP revision. However, this ICN was not effective until December 18, 1996.

#### Observation 1

CAR W97-013 was issued due to a deviation from NQA-3, Requirement 2.4, which requires the annual performance of management assessments. The corrective action for this CAR provided for the scheduling of a management assessment in April 1997. The corrective action was accepted by SNL WIPP QA and the CAR was closed out on January 9, 1997. The audit team is concerned that this corrective action is inappropriate and that the CAR should not be closed until the management assessment is completed.

#### Observation 2

CAO CAR 96-039 was issued due to deviations from SNL QAPs 13-1 and 13-2, which prescribe sample control and chain-of-custody, respectively. Numerous samples were transferred without proper chain-of-custody. The corrective action performed included revision of existing chain-of-custody forms for several samples. In addition, chain-of-custody forms were filled out for those samples which had been transferred without maintaining chain-of-custody. The audit team is concerned that the chain-of-custody forms were improperly used and, as a result, the data generated from the subject samples is legally inadmissible.

#### Observation 3

The software disaster recovery process does not readily describe the procedure by which the software configuration management system and the PA software will be restored with adequate assurance that superseded software versions will not be recreated as "current" versions.

#### Observation 4

The Validation Document Reviewer's Form should explicitly require the reviewer to confirm that the executed test cases are the same as the test cases listed in the Validation Plan document.

Observation 5

The definition of gradation provided in QAP 19-1 is not clearly stated. For example, if software is exempt from QAP 19-1, it will be qualified under QAP 9-1. This optional means of approving software demonstrates that gradation has a different meaning than the definition of grading set forth in NQA-1.

Observation 6

NQA-1, Requirement 5, requires procedures for activities which affect quality to have quantitative or qualitative acceptance criteria.

However, the format specified by QAP 5-1 for developing QAPs does not clearly include a section for acceptance criteria. No QAPs contain acceptance criteria.

*Enclosure 6*

### EPA Peer Review Audit Findings & Observations

On February 10-12, 1997, EPA performed an audit of DOE's documentation of its peer review processes conducted in support of the WIPP Compliance Certification Application to establish that they were conducted in a manner compatible with NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories," as required by 40 CFR Part 194.27(b). The audit team identified seven findings of relatively minor and isolated consequences during the audit. A finding is a specific nonconformance with an applicable NQA element or the element's implementing procedure. An observation is not a nonconformance, but does require a response like a finding. The findings and observations resulting from this audit are listed below.

#### Finding 1

NUREG-1297 states that Peer Reviewers should have sufficient freedom from funding considerations to assure the work is impartially reviewed.

To address this issue, the DOE's Carlsbad Area Office (CAO) included conflict of interest forms which require financial disclosure to identify whether a conflict exists. Mr. Evaristo Bonano and Ms. Patricia Robinson, members of the Waste Characterization Peer Review, checked that they had conflicts of interest but did not complete the required disclosure form.

#### Finding 2

NUREG-1297 states that in cases where total independence cannot be met, the peer review report should contain a documented rationale as to why someone of equivalent technical qualifications and greater independence was not selected.

A Non-Selection Justification form was included for the Waste Characterization Peer Review. Ms. Patricia Robinson, a Nuclear Engineer with a Master of Science Degree pending, was selected for the Waste Characterization Peer Review Panel. Ms. Robinson is currently employed by a DOE contractor. The form lists Dr. Peter K. Mast, a Nuclear Engineer with a Ph.D., and notes that other equally or more qualified individuals are available. From the form, it appears that persons of equivalent technical qualification were available but not selected. However, the Non-Selection Justification form does not document the rationale.

#### Finding 3

CAO Team Procedure TP 10.5 (Rev. 1), Section 3.1.3(c), requires peer review panel members be selected from a predetermined list of personnel. However, Section 5.4, the responsibilities

section of this procedure, states that the Peer Review Selection Committee shall generate a list of qualified Peer Reviewers using its knowledge of university contacts, professional organizations, and qualified industry professionals. A conflict exists within the procedure and should be revised.

Additionally, with the exception of the Engineered Alternatives Peer Review, neither a predetermined list nor a list generated from university contacts, professional organizations, and qualified industry professionals was located in the files reviewed.

#### Finding 4

CAO Team Procedure TP 10.5 (Rev. 1), Section 5.7, requires Peer Review Panel Members to complete and document the necessary training prior to the start of the Peer Review process.

Training forms for Mr. Chuan-Mian Zhang and Mr. Paul Cloke, members of the Natural Barriers Peer Review Panel, are dated May 15, 1996, while the meeting minutes of May 14, 1996, show them already in attendance.

#### Finding 5

CAO Team Procedure TP 10.5 (Rev. 1), Section 3.4.2, requires that all Peer Review Panel Members receive an orientation prior to the start of the Peer Review process. At a minimum, the orientation shall cover subjects or documents related to the Peer Review process, including administrative requirements, the applicable Peer Review Plan, a brief summary of the Peer Review technical subject matter, an overview of the requirements of TP 10.5, and any other appropriate topic.

Records indicate that Mr. David Sommers did not receive administrative orientation prior to the start of the Peer Review process.

#### Finding 6

CAO Team Procedure TP 10.5 (Rev. 1), Section 3.4.2, requires that all Peer Review Panel Members receive an orientation prior to the start of the Peer Review process.

There is no evidence that Mr. Florie Caporuscio received orientation when the Conceptual Models Peer Review Panel reconvened in January 1997.

### Finding 7

CAO Team Procedure TP 10.5 (Rev. 1), Section 3.4.4, requires minutes for all meetings, activities, and deliberations.

Minutes for the Natural Barriers Orientation Meeting conducted on May 14, 1996, were not included in the Peer Review file.

### Observation 1

CAO Team Procedure TP 10.5 (Rev. 1), Section 3.1.3a, requires that the Selection Committee shall be impartial and have no organizational conflict of interest.

The appearance of a conflict of interest exists for both Peer Review Managers. The CAO Technical Assistance Contractor (CTAC) was tasked by CAO to contract for the management of the Peer Review process. Informatics, Inc., was selected. Mr. John Thies, Executive Vice President of Informatics and Peer Review Manager, selected Mr. Leif Errikson of CTAC to serve on the selection committee. Mr. Thies also selected Informatics employees as Peer Reviewers.

Dr. Abbas Ghassemi, Manager of Peer Review for Engineered Alternatives and Director of Special Programs for WERC, selected Dr. Ron Bhada, Administrative Director of WERC, to serve as Peer Review Panel Leader.

### Observation 2

NUREG-1297 states that a rationale as to why someone of equivalent technical qualification and greater independence was not selected should be documented.

Several of the Engineered Alternative Peer Review panel members disclosed, in their Determination of Independence forms, current or previous affiliation with DOE. However, a documented rationale as to why someone of equivalent technical qualification and greater independence was not selected was not included with the support documents.

### Observation 3

The Peer Review Selection Committee is required to document the rationale for selection of Peer Review Panel Members on a Peer Review Panel Selection, Size and Composition Justification/Decision Form.

A form was completed for each peer review, however, the form only repeats the requirements and does not provide a rationale for the selection of peer review panel members.