CARD No. 55
Results of Compliance Assessments

55.A.1 BACKGROUND

The Compliance Criteria include two general categories of quantitative requirements on the performance of the WIPP that are intended to ensure its safety. The first category consists of the containment requirements at Section 194.34, which implement the general containment requirements of the radioactive waste disposal regulations, Section 191.13. The containment requirements establish limits on the cumulative quantity of radioactive materials that may migrate beyond the specified subsurface physical boundary that separates the WIPP repository area from the accessible environment. That is, they restrict the amounts of radioactive materials that might escape from the WIPP to very low levels. DOE carried out a Performance Assessment (PA) to demonstrate compliance with the disposal requirements at Section 191.13. The results of the performance assessment are discussed in **CARD 34—Results of Performance Assessments.**

The second category of quantitative requirements consists of the individual and groundwater protection requirements, which implement Section 191.15. The individual and groundwater protection requirements place limitations on both the potential radiation exposure of individuals and the possible levels of radioactive contamination of groundwater due to disposal of waste in the WIPP. The individual protection requirement focuses on the annual radiation dose of a maximally exposed hypothetical person living on the surface just outside the boundary to the accessible environment. In particular, Section 194.55 requires that the WIPP be constructed in such a manner as to provide a reasonable expectation that, for 10,000 years after disposal, undisturbed performance of the disposal system will not cause the annual committed effective dose equivalent (hereafter simply called “dose”) to exceed 15 millirems (150 microsieverts) to any member of the public in the accessible environment. “Undisturbed performance” means that no human activities such as drilling or mining are assumed to disturb the disposal system. Section 194.55 also requires that underground sources of drinking water be protected at least to the extent prescribed by the Safe Drinking Water Act regulations at 40 CFR Part 141.

The containment requirements and individual and groundwater protection requirements are fundamentally different. The containment requirements apply to cumulative releases to the “accessible environment” over the 10,000-year regulatory period. To demonstrate compliance with the containment standards, DOE is required to consider human intrusion, such as deep drilling, shallow drilling, and mining. In contrast, the individual and groundwater protection requirements apply to the doses received by an individual over a human lifespan. Moreover, compliance assessments utilized to demonstrate compliance with the individual and groundwater protection requirements need not consider performance of the repository in the “disturbed” scenario. Thus, whereas releases resulting from human-initiated events such as drilling into the repository must be considered to demonstrate compliance with the containment requirements, such intrusion events are not considered in demonstrating compliance with the individual and groundwater protection requirements.

The Compliance Criteria at Section 194.55 call for DOE to determine:

- The maximum individual radiation dose rate from all pathways for 10,000 years after disposal. This dose rate, hereafter referred to simply as "dose," is called the annual committed effective dose equivalent and is measured in millirems.

- The maximum total radioactivity level for radium 226 and radium 228 in any underground source of drinking water (USDW);

- The maximum gross alpha particle radioactivity level (including radium 226 but excluding radon and uranium) in any USDW; and

- The maximum annual dose equivalent to the total body or any internal organ from beta particle and photon radioactivity in any USDW.

To make a case for a "reasonable expectation" of compliance, DOE has chosen to demonstrate that even a worst-case scenario will meet the regulatory requirements. This approach would prove that any less conservative (i.e., more realistic) case also would fall within compliance (Chapter 8.1.2.2). DOE referred to its approach as a "bounding calculation" because it was intended to identify an upper bound to any possible occurrence of exposure. EPA indicated in the Compliance Application Guidance for 40 CFR Part 194 (CAG) that such a "simplified model" would be acceptable provided that it was more conservative than other, more complex models (p. 68). Requirements for the individual annual committed effective dose equivalent from all pathways, on the individual annual committed effective dose equivalent from the ingestion of contaminated ground water, and on the groundwater purity requirements are referred to in this document as simply as the dose and/or ground water requirements.

55.A.2 REQUIREMENT

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

55.A.3 ABSTRACT

Section 194.55(a) of the Compliance Criteria requires that an assessment of compliance with Section 191.15 and Subpart C of Part 191 address uncertainties in the performance of the disposal system. There are two general types of uncertainty. The first is the subjective uncertainty associated with the absence of complete understanding of the physical conditions within and around the repository. The PA compensates for this type of uncertainty by running 300 different undisturbed-site scenarios, with 300 independent sets of sampled values for the most important parameters. The second type is the uncertainty associated with predicting the ways in which contaminated ground water might be pumped out and utilized by persons living near the site. To compensate for this type of uncertainty DOE employed a bounding calculation of individual doses that was intended to demonstrate compliance regardless of any uncertainties.

55.A.4 Compliance Review Criteria

DOE must adequately evaluate and document uncertainty in the compliance assessment. As stated in the CAG (p. 71), EPA expected the CCA to:

- ♦ Identify where uncertainty is documented.
- ♦ Document uncertainty in the performance of the disposal system for compliance assessment purposes.
- ♦ Discuss how uncertainty was considered in the compliance assessment.

55.A.5 DOE Methodology and Conclusions

Section 194.55(a) requires assessments intended to demonstrate compliance with 40 CFR 191.15 and Subpart C to examine uncertainties in the performance of the disposal system. DOE relied on the undisturbed scenarios of the performance assessment (PA) as the starting point for the analysis of compliance with the dose requirements. As a result, DOE also had to rely in part on the uncertainty evaluation and statistical attributes of the PA in order to show compliance with the requirements of Section 194.55 (Chapter 8.1.4). The uncertainty and statistical evaluations for the PA are addressed in the requirements of Sections 194.34(a), 194.34(c), and 194.34(f) of the Compliance Criteria. EPA's evaluation of these parts of the CCA, including relevant references, is discussed in **CARD 34—Results of Performance Assessments**.

DOE's performance assessment showed that the only possible release to the accessible environment for undisturbed performance consisted of contaminated water flowing through the Salado formation interbeds (Chapter 8, p. 8-3). Such transport could result if there were a significant buildup of gas and fluid pressure within the waste panels. DOE assumed that this water could be available for human use, following treatment, after it reached the boundary to the accessible environment. Water in the interbeds is actually highly concentrated brine, however, so DOE also assumed that users would dilute brine with pure water to reduce the solids and ionic concentrations to levels that EPA considers acceptable for a potential source of drinking water. Assuming that this diluted brine will be consumed at the rate of two liters per day, DOE calculated the resulting dose from the water-ingestion pathway. In response to a request from EPA (Docket A-93-02, Item II-I-01), DOE sent supplemental information (Docket A-93-02, Item II-I-10, Enclosure 2h) describing DOE's evaluation of the dose from all other reasonable exposure pathways. These pathways were irrigation of crops and forage material with contaminated ground water and the subsequent consumption of the crops and animal products, and the inhalation of contaminated dust.

There were two primary sources of uncertainty in DOE's compliance assessment. The first source of uncertainty was that associated with the incompleteness of DOE's understanding of the physical conditions within and around the repository. DOE addressed this uncertainty by running the PA for 300 different scenarios for the WIPP in its undisturbed state, using 300 independent sets of values for the 57 relevant sampled parameters. Radionuclides in the interbeds reached the subsurface boundary of the accessible environment in only 9 of the 300 runs. The other 291 undisturbed scenarios led to releases with maximum concentrations of less than a cutoff level of 10^{-18} curies per liter (10^{-6} pCi/L). (DOE considered radionuclides with concentrations less than 10^{-6} pCi/L to have negligible significance relative to those with greater concentrations and did not report them. See Table 8-1, p. 8-7.) The radionuclide concentrations that DOE calculated for the nine scenarios in question are shown in Table 1. DOE's analysis found only four radionuclides to be significant: ^{241}Am, ^{239}Pu, ^{230}Th and ^{234}U (Table 8-1, p. 8-7).

The second major type of uncertainty in the compliance assessment was associated with predicting the ways in which contaminated ground water might be pumped out and utilized by persons living near the site. It is not obvious how best to use the interbed concentrations of radionuclides to calculate doses to humans arising through various exposure pathways. To compensate for this uncertainty, DOE conducted a calculation that makes unrealistically conservative assumptions, which resulted in an upper-bound estimate of the dose that is much higher than would be produced by any "realistic" calculation (Chapter 8.1.2.2). For further discussion of this approach, see **CARD 51/52—Consideration of Protected Individual and Exposure Pathways** and **CARD 53—Consideration of Underground Sources of Drinking Water**.

Based on the combination of the uncertainty analysis done for the performance assessment and the conservatism of the bounding analysis, DOE concluded that the requirement at Section 194.55(a) was met.

Table 1
Concentrations and Doses from Water Ingestion Obtained from the PA

	Maximum Concentration (Ci/L) [a, c]				**Dose (mrem/y)** [b]
Realization Number	**^{241}Am**	**^{239} Pu**	**^{234}U**	**^{230}Th**	**Water Ingestion**
1	1.4×10^{-17}	4.3×10^{-12}	5.8×10^{-13}	2.1×10^{-14}	3.4×10^{-1}
2		5.1×10^{-14}	6.8×10^{-15}	1.9×10^{-17}	4.3×10^{-3}
3		1.4×10^{-15}	1.7×10^{-16}	7.0×10^{-18}	1.1×10^{-4}
4	1.3×10^{-17}	7.2×10^{-14}	9.8×10^{-15}	9.4×10^{-16}	5.8×10^{-3}
5		6.2×10^{-18}			5.1×10^{-7}
6		5.2×10^{-16}	7.4×10^{-17}		4.3×10^{-5}
7	3.5×10^{-18}	3.1×10^{-13}	4.3×10^{-14}	1.1×10^{-16}	2.5×10^{-2}
8	6.0×10^{-17}	7.4×10^{-14}	9.1×10^{-15}	2.3×10^{-15}	6.2×10^{-3}
9	5.4×10^{-17}	5.9×10^{-12}	7.6×10^{-13}	4.7×10^{-15}	4.7×10^{-1}

a. Source: CCA, Chapter 8, Table 8-1, p. 8-7.
b. Source: CCA, Chapter 8, Table 8-2, p. 8-9.
c. Values have been rounded to two significant figures. Values less than 10^{-18} Ci/L were considered to be negligible relative to the other values and were not reported.

55.A.6 EPA Compliance Review

EPA found that DOE considered uncertainty in two ways: 1) by assigning probability distributions to 57 of the key parameters that describe the repository, and sampling from them in carrying out the PA (Chapter 6, pp. 6-21 to 6-23 and 6-173 to 6-199, and Appendix PAR); and 2) by translating from ground water contaminant level to doses by means of the bounding analysis (Chapter 8 and Docket A-93-02, Item II-I-10).

DOE's method of evaluation of uncertainty in the amounts of contaminants transported underground was essentially the same as that for the 300 scenarios involving human intrusion in the PA, as presented in the CCA in Chapter 6.1.2, except that those uncertainties introduced by the borehole drilling process can be ignored. (In addition, the demonstration of compliance with the dose requirements does not involve CCDF curves, so those uncertainties do not appear there.) EPA also thoroughly reviewed of the uncertainty analysis of the PA for the disturbed scenarios presented in Chapter 6 of the CCA and supporting documents. EPA found this aspect of the treatment of uncertainties to be satisfactory, and reported its findings in Section 194.34(b) of **CARD 34—Results of Performance Assessments**. Aspects of uncertainty—in particular, the calculation of confidence intervals on estimates of mean values for contaminant concentrations in ground water and for doses—are discussed further under Section 194.55(f) below.

EPA reviewed the bounding calculation as presented in Chapter 8 and supplementary information (Docket A-93-02, Item II-I-10) and reported the results of that evaluation in **CARD 51/52—Consideration of Protected Individual and Exposure Pathways.** EPA determined that DOE's conceptual model and the use of the GENII-A computer code to calculate radiation doses were appropriate. An independent calculation of doses commissioned by EPA confirmed both DOE's initial estimates of exposure from direct consumption of drinking water and the dose from the consumption of agricultural products and the inhalation of resuspended dust (EPA 1998a). A comparison of the estimated maximum dose from the two assessments is shown in Table 2 of **CARD 51/52--Consideration of Protected Individual and Exposure Pathways**. EPA found this bounding calculation to be acceptable in lieu of further uncertainty analysis.

As noted above, DOE considered only those radionuclides with concentrations greater than a cutoff level of 10^{-18} curies per liter (10^{-6} pCi/L) to have a significant impact on individual dose or dose from ground water. EPA found this cutoff level to be sufficiently low to be acceptable.

55.B.1 REQUIREMENT

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

55.B.2 ABSTRACT

DOE is required in Section 194.55(b) to address subjective parameter uncertainties in the projected future performance of the undisturbed repository. This analysis involved running the PA with 300 independent sets of values for the 57 relevant sampled parameters relevant to the description of the physical conditions within and around the repository. The parameter distributions (i.e., probability distributions for the parameters) that DOE used for the evaluation of groundwater contamination and of individual exposure are the same as those used for the 300 PA realizations that include human intrusion. EPA discusses this analysis in **CARD 23—Models and Computer Codes** and **CARD 34—Results of Performance Assessments.**

55.B.3 COMPLIANCE REVIEW CRITERIA

DOE must develop and document probability distributions for uncertain parameters used in the PA. As stated in the CAG (p. 71), EPA expected the CCA to:

- Identify the probability distributions used for compliance assessments. Cross-reference to performance assessment probability distributions is acceptable, but performance assessment probability distributions that are not used for compliance assessment should be noted.

- Describe the parameters, including units (see discussion under Section 194.23(c)(4) in **CARD 23—Models and Computer Codes**).

- Identify the model(s) and code(s) in which each parameter was used and the computer code (i.e., geologic or other physical material, and parameter) name(s) of the parameter that was sampled (see discussion under Section 194.23(c)(4) in **CARD 23CModels and Computer Codes**).

- Identify any correlations between sampled parameters (see discussion under Section 194.23(c)(4) in **CARD 23CModels and Computer Codes**).

- Discuss how correlations between sampled parameters are addressed in performance (hence in compliance) assessments (see discussion under Section 194.23(c)(4) in **CARD 23CModels and Computer Codes**).

- Identify the functional form of the probability distribution (e.g., lognormal, uniform) used for the sampled parameters (see discussion under Section 194.34(b) in **CARD 34—Results of Performance Assessments**).

- Fully describe the statistics of each probability distribution, including the values for the lower and upper ranges, mean (geometric mean when appropriate), and median (see discussion under Section 194.34(b) in **CARD 34CResults of Performance Assessments**).

- Identify the importance of the sampled parameter relative to final releases, and to the intermediate results calculated by the codes that use this parameter. For example, a parameter may have an important role in a particular process, but may not have as significant an effect on the results of compliance assessments. The EPA recommends that this information be presented in a table, as well as briefly discussed in the text (see discussion under Section 194.34(b) in **CARD 34CResults of Performance Assessments**).

- Demonstrate that the data used to develop the input parameter probability distribution have been qualified and controlled in accordance with the quality assurance requirements of Section 194.22 (see discussion under Section 194.34(b) in **CARD 34CResults of Performance Assessments**).

- Discuss the linkage between the input parameter information and the data used to develop the input information (see discussion under Section 194.23(c)(4) in **CARD 23—Models and Computer Codes**).

55.B.4 DOE METHODOLOGY AND CONCLUSIONS

DOE is required in Section 194.55(b) to address the subjective uncertainties in the projected future performance of the undisturbed repository that arise out of a lack of complete understanding of the physical conditions within and around it. DOE addressed this requirement by running the PA for 300 different scenarios with no intrusions, with 300 independent sets of values for the 57 relevant sampling parameters.

The selection of appropriate parameter distributions was of critical importance to this process (Chapter 8.1.5, p. 8-10; Chapter 6.1.5.1, p. 6-31, and Appendix PAR). The 57 parameters that DOE employed in the CCA PA were discussed in Chapter 6 and presented in more detail in Appendix PAR. The documentation for the various computer models and codes also considered the parameters in some detail (see discussion under section 194.23(c)(4) in **CARD 23—Models and Computer Codes**). The parameter records at SNL Record Center include WIPP parameter entry forms (464 Forms), Parameter Records Packages, Principal Investigator Records Packages, Data Records Packages, and Analysis Packages (also in Docket A-93-02, II-G-3). The parameter distributions that DOE used for the evaluation of groundwater contamination and individual exposure are the same as those employed for the 300 realizations that involve involving human intrusion, as presented in Chapter 6.1.2 (pp. 6-21 to 6-23).

55.B.5 EPA COMPLIANCE REVIEW

The probability distributions for uncertain disposal system parameter values used for demonstrating compliance with the individual dose and ground water requirements of Section 194.55 are identical to those used for the containment requirements. EPA extensively reviewed the parameters and supporting data used in the performance evaluation, including the technical basis presented in the CCA, Appendix PAR, and the parameter discussions in the documentation of the various models (see discussion under Section 194.23(c)(4) in **CARD 23—Models and Computer Codes**).

Based on these reviews, EPA found several fixed parameters for which it believed a variable range of values would be more appropriate. EPA requested that DOE incorporate this potential variability into its analysis. Similarly, EPA requested that the central values and/or distribution selected for some of the extant parameters be changed. These changes are discussed in detail in EPA Technical Support Document for Section 194.23: Parameter Justification Report (EPA 1998e). The results and implications of this parameter evaluation affected the PA, as is discussed under Section 194.34(b) in **CARD 34—Results of Performance Assessments**. Following the changes, EPA found the probability distributions to be acceptable for compliance with both Sections 194.55(b) and 194.34(b).

Of the ten items listed under “Compliance Review Criteria” above for Section 194.55(b), four of the requirements are equivalent to those for Section 194.34(b): identifying the functional form of the probability distribution used for the sampled parameters; describing the statistics of each probability distribution; identifying the importance of the sampled parameter relative to final and intermediate releases; and demonstrating that the data used to develop the input parameter probability distribution were qualified and controlled in accordance with Section 194.22. These criteria are discussed under Section 194.34(b) in **CARD 34—Results of Performance Assessments**. EPA concluded that DOE provided general information on probability distributions, data sources for parameter distribution, forms of distributions, bounds, and importance of parameters to releases. EPA's initial concerns about the parameter documentation were addressed.

As a result of the parameter review, EPA required DOE to perform additional PA modeling that included parameter value and distribution modifications. At the request of EPA, DOE incorporated these parameter value and distribution modifications, expressed several additional parameters as variables, and evaluated them for their impact in the Performance Assessment Verification Test (PAVT). (See EPA 1998d and Docket A-93-02, Items II-I-17, II-I-25, and II-I-27).

Five of the ten items listed under "Compliance Review Criteria" above are the same as requirements for Section 194.23(c)(4): describing the parameters; identifying the model(s) and code(s) in which each parameter was used and the computer code name(s); identifying any correlations between sampled parameters; discussing how correlations between sampled parameters are addressed in performance assessments; and discussing the linkage between the input parameter information and the data used to develop the input information. DOE's methodology and EPA's compliance review are discussed further under Section 194.23(c)(4) in **CARD 23—Models and Computer Codes**.

EPA initially raised concerns about the completeness of the list of CCA PA parameters, the description and justification that support the development of some code input parameters, and the traceability of data reduction and analysis of parameter records. DOE improved the documentation in the Sandia National Laboratories (SNL) Record Center in Albuquerque, New Mexico, of the basis of parameters, and also developed better "roadmaps" that link parameter documentation and parameter development. Upon subsequent review of records in the SNL Record Center, EPA determined that DOE adequately provided the required information for probability distributions of code input parameters.

55.C.1 Requirement

(c) "Computational techniques which draw random samples from across the entire range of values of each probability distribution developed pursuant to paragraph (b) of this section shall be used to generate a range of:

> (1) Estimated committed effective doses received from all pathways pursuant to §194.51 and §194.52;
>
> (2) Estimated radionuclide concentrations in USDWs pursuant to §194.53; and
>
> (3) Estimated dose equivalent received from USDWs pursuant to §194.52 and § 194.53."

55.C.2 ABSTRACT

The statistical technique that DOE used to select subjective parameter values in the analysis of the disturbed scenario (i.e., Latin Hypercube Sampling) also was employed in DOE's calculations of radionuclide concentrations in ground water and individual doses for the undisturbed scenario. For the disturbed scenario, the PA produced a set of 300 CCDF curves that were necessary to assess compliance with the containment requirements at Section 194.34 with statistical reliability. For the undisturbed scenario, the PA generated 300 values of contaminant concentration in ground water at the boundary to the accessible environment, as well as individual doses used to assess compliance with Section 194.55.

The 300 calculated sets of concentration values roughly span the range of radionuclide concentrations in underground sources of drinking water (USDWs) pursuant to Section 194.53 (Consideration of USDWs). DOE found that concentrations in all but 9 of the 300 cases were negligible. When water from a hypothetical contaminated USDW is diluted appropriately and drunk at the rate of 2 liters per day, the resulting doses cover the range of dose equivalents received from USDWs. DOE's consideration of additional pathways—ingestion of contaminated water by animals, irrigation of crops with contaminated water, the subsequent consumption by humans of these plants and animal products, and inhalation of resuspended dust contaminated by irrigation water—resulted in a comprehensive range of dose equivalents from all pathways.

55.C.3 COMPLIANCE REVIEW CRITERIA

Variable parameters must be sampled with computational techniques that draw random samples across the entire range of values of each probability distribution. As stated in the CAG (p. 72), EPA expected that the CCA would:

- Indicate the methodology used to estimate committed effective doses received from all pathways in accordance with Sections 194.51 and 194.52.
- List and discuss estimated committed effective doses.
- Identify underground sources of drinking water in the vicinity of the WIPP.
- Discuss potential pathways by which radionuclides could travel to an underground source of drinking water.
- Discuss why any underground sources of drinking water in the vicinity of WIPP would not be expected to be affected.
- Identify the radionuclide concentrations in the USDWs in the accessible environment that are expected to be affected by the disposal system over the regulatory time frame.
- Discuss the method for estimating the dose from any USDW that is expected to be affected by the disposal system.

- ♦ Identify the estimated dose.

- ♦ Provide sufficient information for EPA to confirm the analysis.

55.C.4 DOE METHODOLOGY AND CONCLUSIONS

The use of parameter distributions in the evaluation of the individual committed effective dose equivalent from all pathways, the committed effective dose equivalent from the ingestion of contaminated ground water, and the contaminant concentrations in ground water are discussed above in this CARD. Section 194.55(c) calls for statistical techniques to be used to sample values from these distributions for generating ranges of concentrations of radionuclide contaminants in possible underground sources of drinking water, doses from ingestion of that water, and doses from all exposure pathways.

The 300 PA realizations for undisturbed scenarios were produced at the same time as the 300 for disturbed scenarios (i.e., those involving human intrusions), and the same sets of sampled parameter values were used. Uncertain parameters were sampled using Latin Hypercube Sampling (LHS) (see Chapter 6.1.5.2 of the CCA and EPA Technical Support Document for Section 194.23: Parameter Report EPA (1997d)). LHS and random sampling were both used, for different purposes, for sampling for human intrusion scenarios, but only LHS for the undisturbed scenarios is relevant to compliance with Section 194.55. The process of sampling with LHS is discussed under Section 194.34(c) in **CARD 34—Results of Performance Assessments**.

The first aspect of DOE's analysis with relevance to Section 194.55(c) was the calculation in the PA of 300 sets of contaminant concentrations at the site boundary for the undisturbed repository. The nine cases that were non-zero, shown in Table 1 above, served as the starting point for DOE's individual annual dose calculations. DOE calculated a maximum dose due only to drinking water for each of the nine cases where radionuclides reached the boundary of the accessible environment in the Salado interbeds (CCA Table 8-2, p. 8-9). The diluted water was assumed to be consumed as drinking water, with no further treatment, at the rate of two liters per day as prescribed in Section 194.52 (CCA Chapter 8.1, p. 8-2). The calculated doses ranged from a high of 4.7×10^{-1} millirem per year to a low of 5.1×10^{-7} millirem per year. These doses are also listed in Table 1 above. (The individual protection requirement is that the dose be less than 15 millirem per year.) Finally, DOE submitted an estimate of the maximum dose from all pathways other than direct ingestion of water of 4.6×10^{-1} millirem per year (Docket A-93-02, Item II-I-10, Enclosure 2h). DOE's maximum estimated individual dose from all exposure pathways was under 1 millirem per year.

DOE's method of calculating ingestion and all-pathways doses is discussed in **CARD 51/52—Consideration of Protected Individual and Exposure Pathways** and EPA Technical Support Document for Sections 194.51, 194.52, and 194.55: Dose Verification Evaluation (EPA 1998a). See Docket A-93-02, Item II-I-10, Enclosure 2h, for a discussion of DOE's method of dose calculation. Issues related to USDWs are considered in **CARD 53—Consideration of Underground Sources of Drinking Water**.

DOE concluded that it had employed computational techniques that draw random samples from across the entire range of values for each stochastic parameter in carrying out the PA for the undisturbed repository. Based on the results of that analysis, DOE estimated doses from the ingestion of drinking water and doses from all pathways and found them to be in compliance with the requirements of Section 194.55.

55.C.5 EPA Compliance Review

EPA examined DOE's use of the Latin Hypercube Sampling procedure and prepared a report on EPA's successful testing of the LHS code (Appendix A of EPA Technical Support Document for Section 194.23: Models and Computer Codes (EPA 1998c)). As discussed under Section 194.34(c) in **CARD 34—Results of Performance Assessments**, EPA found that the LHS technique draws samples from the entire range of each sampled parameter, is appropriate for use in assessing the concentrations of radionuclides in ground water, and was implemented correctly by DOE.

DOE's evaluation of individual doses and ground water radionuclide contamination and assessment of underground sources of drinking water were described in Chapter 8 of the CCA. EPA evaluated the conceptual model that DOE used to estimate a maximum individual exposure in its bounding calculation (see Section 1 of EPA Technical Support Document for Section 194.23: Models and Computer Codes (EPA 1998c)). EPA determined that DOE's conceptual model and the use of the GENII-A computer code to calculate the radiation doses were appropriate.

55.D.1 Requirement

(d) "The number of estimates generated pursuant to paragraph (c) of this section shall be large enough such that the maximum estimates of doses and concentrations generated exceed the 99th percentile of the population of estimates with at least 0.95 probability."

55.D.2 Abstract

Because of the uncertainties involved in PA, DOE must rely on statistical arguments to demonstrate compliance with Section 194.55. It is therefore important that enough undisturbed-site scenarios are generated so that conclusions drawn are statistically justified. Section 194.55(d) places a requirement on the minimum number of scenarios: there must be enough so that the maximum estimates of doses and concentrations exceed the 99th percentile of the population estimates with at least 0.95 probability.

EPA evaluated this determination of the number of estimates in conjunction with the performance assessment and presents its findings under Section 194.34(d) in **CARD 34—Results of Performance Assessments**.

55.D.3 COMPLIANCE REVIEW CRITERIA

The number of estimates of doses and concentrations must be large enough so the maximum estimate exceeds the 99th percentile of the population of estimates with 0.95 probability. As stated in the CAG (p. 72), EPA expected the CCA to:

- Discuss the method used to calculate that the maximum estimates of doses and concentrations exceed the 99th percentile of the population of estimates with at least 0.95 probability.
- List and discuss the sample size used for the analysis.
- Identify the estimate of doses and concentrations at the 99th percentile in the calculated sample.
- Provide sufficient information for EPA to confirm the analysis.

55.D.4 DOE METHODOLOGY AND CONCLUSIONS

Section 194.34(d) requires that the number of CCDF curves generated in the PA be statistically sufficient by requiring that at least one of those curves exceed the 99th percentile curve of the CCDF population. DOE's approach to this requirement is discussed further under Section 194.34(d) in **CARD 34—Results of Performance Assessments**. Section 194.55(d) requires essentially the same approach regarding the number of undisturbed scenarios to be considered in assessing compliance with the dose requirements of Section 194.55(f). As discussed in **CARD 34—Results of Performance Assessments**, DOE determined that 300 undisturbed scenarios were sufficient to demonstrate compliance with Section 194.55(d).

55.D.5 EPA COMPLIANCE REVIEW

The number of estimates generated must be large enough so that the probability is at least 0.95 that at least the maximum estimate exceeds the 99th percentile of the population of estimates. If the 300 realizations were statistically independent, then the probability that the maximum estimate exceeds the 99th percentile of the population of estimates would equal $1 - (0.99)^{300} = 0.951$, and the Section 194.55(d) criterion would be satisfied. The LHS method is designed to cover the wide range of possible parameter values better than simple random sampling. On that basis, the probability that the maximum LHS estimate exceeds the 99th percentile of the population of estimates should also exceed 0.95, and the Section 194.55(d) criterion should be satisfied.

The determination of the groundwater concentration and individual dose is based on the performance assessment (PA) analysis of releases to the Salado interbeds. Therefore, the number of estimates of concentrations and doses due to releases to the interbeds is the same as the number in the PA and is dependent on the same calculations. EPA's evaluation of the adequacy of DOE's number of estimates is discussed in Section 194.34(d) of **CARD 34—Results of**

Performance Assessments. (Note that the discussion in CARD 34 of the use of a beta distribution does not apply to compliance assessment.)

55.E.1 REQUIREMENT

(e) "Any compliance application shall display: (1) The full range of estimated radiation doses; and (2) The full range of estimated radionuclide concentrations."

55.E.2 ABSTRACT

The performance assessment calculations generated the full range of estimated radionuclide concentrations and radiation doses resulting from undisturbed conditions. The bounding analysis employed by DOE was based on the upper end of the range of estimated radiation doses.

55.E.3 COMPLIANCE REVIEW CRITERIA

The CCA must display the full range of estimated radiation doses and radionuclide concentrations. As stated in the CAG (p. 73), EPA expected the CCA to:

- List the lower and upper values of the estimated doses; along with other descriptive statistics, such as the mean, median, and standard deviation.

- List and discuss the sample size used to develop the full range of estimated doses.

- Identify the time period for which the doses apply.

- List the lower and upper values of the estimated radionuclide concentrations, along with other descriptive statistics, such as the mean, median and standard deviation.

- List and discuss the sample size used to develop the full range of estimated radionuclide concentrations.

- Identify the time period for which the radionuclide concentrations and doses were calculated.

- Identify the location (estimated spatial coordinates) for which the estimates apply.

- Provide sufficient information for EPA to confirm the analysis.

55.E.4 DOE METHODOLOGY AND CONCLUSIONS

As discussed above, DOE used the undisturbed-performance scenarios of the PA to calculate 300 sets of contaminant concentrations at the boundary of the accessible environment beneath the earth's surface. The adequacy of the number of samples with respect to the groundwater and individual dose calculations is discussed in Chapter 8.1.4 of the CCA. The nine estimates that were non-zero, shown in Table 1 above, served as the starting point for DOE's individual annual dose calculations. The maximum concentrations of radionuclides within the Salado interbeds at the disposal system boundary are presented in Table 8-1 (p. 8-7) of the CCA.

These concentrations were used in the calculation of annual committed effective doses from drinking water, as presented in Table 8-2 of the CCA (p. 8-9). The calculated doses ranged from a high of 4.7×10^{-1} millirem per year to a low of 5.1×10^{-7} millirem per year, also listed in Table 1 of this CARD. In a subsequent DOE response to an EPA request for an expanded analysis, DOE estimated the dose from all pathways combined. DOE added the estimated maximum dose from pathways other than direct ingestion of ground water, 4.6×10^{-1} millirem per year, to the values of dose from the ingestion of ground water. This yielded an upper bound on the amount from all pathways combined. The method of calculating ingestion and all-pathways doses is discussed in **CARD 51/52—Consideration of Protected Individual and Exposure Pathways** and in EPA Technical Support Document for Sections 194.51, 194.52, and 194.55: Dose Verification Evaluation (EPA 1998a). DOE arrived at ranges for both radionuclide concentrations and for individual doses (in both cases, from the maximum value down to zero). DOE concluded that this analysis satisfied Section 194.55(e).

55.E.5 EPA COMPLIANCE REVIEW

Section 194.55(e) requires DOE to display the full ranges of estimated doses and concentrations. EPA found that:

- The estimated doses caused by ingesting water from the USDW were reported in Table 8-2 of the CCA. The maximum estimated dose rate from the other relevant pathways (0.46 mrem/year) was reported in a DOE response document (Docket A-93-02, Item II-I-10, Enclosure 2h). The all-pathway individual doses were obtained by adding 0.46 mrem/year to those values. The maximum annual dose obtained in this fashion was less than 1 mrem/year (0.93 mrem/year).

- The CCA, Section 8.2.3, p. 8-15, states that the maximum estimated radium concentration across the nine non-zero realizations is 2.0 pCi/L.

- Table 8-1 of the CCA contains the 300 estimated concentrations for the five radionuclides ^{241}Am, ^{239}Pu, ^{238}Pu, ^{234}U, and ^{230}Th, of which only nine were not vanishingly small. The nine ^{226}Ra concentrations were not separately recorded, but the maximum gross alpha particle concentration, including radium and excluding radon and uranium, was reported as 7.81 pCi/L. The confidence interval analysis described below under Section

194.55(f) used a more conservative approach that added the total radium concentration bound (2.0 pCi/L) to the total of the five radionuclide concentrations, including uranium.

- The 300 USDW dose estimates were reported in Table 8-2 of the CCA.

EPA conducted an independent assessment of the potential radiation dose. In their dose verification analysis, EPA independently estimated and tabulated the all-pathway and USDW doses. EPA found DOE's calculations to be conservative (e.g., the anhydrite layers in the Salado are actually much thinner than the aquifer assumed in the modeling). However, EPA's assessment generally agreed with the DOE analysis (see EPA 1998a). Since DOE did not undertake a statistical analysis of its results, as called for in Section 194.55(f) and in the CAG for Section 194.55(e), EPA developed the necessary descriptive statistics for doses and concentrations (see Section 194.55(f) below). EPA's consideration of the number of estimates in the PA is presented in Section 194.34(d) of **CARD 34—Results of Performance Assessments**.

55.F.1 Requirement

(f) "Any compliance application shall document that there is at least a 95 percent level of statistical confidence that the mean and the median of the range of estimated radiation doses and the range of estimated radionuclide concentrations meet the requirements of § 191.15 and Part 191, Subpart C of this chapter, respectively."

55.F.2 Abstract

DOE calculated a maximum annual committed effective dose from all pathways and leading from underground sources of drinking water (USDWs) for all relevant radionuclides. DOE also calculated the total radioactivity concentration for Ra-226 and Ra-228 in USDWs. DOE determined the gross alpha particle radioactivity concentration for six alpha-emitting radionuclides. The maximum annual committed effective doses were calculated to be an order of magnitude less than the required limits. The maximum radionuclide concentrations were approximately half of their respective limits. DOE found that the maximum annual dose equivalent to the total body or to any internal organ from both beta particles and gamma rays met the requirements of Subpart C of Part 191.

EPA performed an independent analysis of doses and concentrations determined through compliance assessment. The analysis calculated mean, median, and 95 percent confidence interval values. The Agency confirmed that all mean, median, and 95 percent confidence intervals were below the dose and radioactivity concentration limits of Section 191.15 and Subpart C of Part 191.

EPA required DOE to perform a Performance Assessment Verification Test (PAVT) using modifications to the parameters and codes used in PA. DOE performed additional compliance assessment calculations of individual dose and radioactivity concentration as part of the PAVT. The mean dose calculated in the PAVT from all pathways was an order of magnitude below the limit of Section 191.15. Because all radionuclides contributing to the dose were alpha-emitting, the PAVT also indicated compliance with the annual dose equivalent to the total body or any internal organ from beta particle and photon radioactivity in USDWs. The mean radionuclide concentrations calculated in the PAVT for alpha-emitting radionuclides (including radium 226 but excluding radon and uranium) and for radium 226 and radium 228 were below the limits of Subpart C of Part 191.

55.F.3 COMPLIANCE REVIEW CRITERIA

DOE must demonstrate that the mean and the median of the range of the doses and concentration meet the requirements of Section 191.15 and Subpart C with a 95 percent level of statistical confidence. The limits incorporated by Section 191.15 and Subpart C are as follows:

- Annual committed effective dose from all pathways: 15 mrem/year.
- Total radioactivity concentration for radium 226 and radium 228 in any underground source of drinking water (USDW): 5 pCi/L.
- Gross alpha particle radioactivity (including radium 226 but excluding radon and uranium) in any USDW: 15 pCi/L.
- Annual dose equivalent to the total body or any internal organ from beta particle and photon radioactivity in any USDW: 4 mrem/year.

As stated in the CAG (p. 73), EPA expected the CCA to:

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

55.F.4 DOE METHODOLOGY AND CONCLUSIONS

As required by Section 194.55(f), the compliance assessment shall document that the mean and median estimated doses and concentrations do not exceed the maximum allowable dose or concentration with a 95 percent confidence.

DOE’s demonstration of compliance with Section 194.55(f) was not presented in a single place in the CCA. For the 15 mrem per year limit on annual committed effective dose from all pathways in Section 191.15, DOE provided calculations for the direct ingestion of groundwater alone in the CCA in Table 8-2 (p. 8-9). DOE obtained 4.7×10^{-1} mrem/y for the realization that yielded the largest dose from the direct ingestion of groundwater, as indicated in Table 2 of this CARD (see also Docket A-93-02, Item II-I-10, Enclosure 2h, p. 9). In a subsequent Analysis Package on Dose Calculations of Other Pathways (DOE 1997e), DOE obtained a largest value of 4.6×10^{-1} mrem/y for the remaining pathways of consumption of livestock and produce that used contaminated water and of direct inhalation of suspended dust. For the statistical analysis of data, DOE added 4.6×10^{-1} mrem per year to each of the drinking water doses from Table 8-2 (Chapter 8, p. 8-9). The maximum bounding value for all pathways combined for a single realization was thus 9.3×10^{-1} mrem per year, more than an order of magnitude less than the Compliance Criteria require for the *mean* of all 300 realizations.

For the radium concentration in drinking water, DOE calculated a maximum value, 2 pCi/L (Chapter 8, p. 8-17). It was assumed that all nine realizations that showed material getting to the accessible environment boundary are at this maximum radium, and the other 291 realizations had zero radium since no contaminants reached the accessible environment.

For gross alpha particle concentration, DOE determined the maximum concentration of each of the relevant radionuclides for all of the three hundred realizations. Only nine of the realizations had significant concentrations (that is, greater than 10^{-18} curies/liter). The maximum concentrations for the five most significant radionuclides in these realizations—^{241}Am, ^{239}Pu, ^{238}Pu, ^{234}U, ^{230}Th, and ^{226}Ra— are displayed in Table 8-1 (Chapter 8, p. 8-7). (All of these maxima occurred at year 10,000.) DOE summed the radionuclide concentrations for each realization and found that the largest of these total values, including uranium, was 6.6 pCi/L. DOE added to this largest concentration the maximum radium concentration, 2 pCi/L, resulting in a maximal dose from alpha emissions of 8.6 pCi/L. Finally, DOE compared this largest grand total concentration for a single realization to the 15 pCi/L limit on the mean value for all 300 imposed by Section 194.55(f).

Table 2
Maximum Doses (mrem/year) Calculated in the CCA and PAVT by DOE and EPA

	CCA - DOE	CCA - EPA	PAVT - DOE	PAVT - EPA
Number of Realizations:	9		13	
EDE, all emissions (15 mrem / y limit)				
all pathways	9.3×10^{-1}	6.5×10^{-1}	6.3×10^{-2}	3.1×10^{-1}
water pathway	4.7×10^{-1}	4.9×10^{-1}	3.2×10^{-2}	2.3×10^{-1}
other pathways	4.6×10^{-1}	—	3.1×10^{-2}	—
beta, electron, photon (4 mrem / y limit)				
total body	2.3×10^{-4}	—	1.5×10^{-5}	—
organ	4.2×10^{-3}	—	2.9×10^{-4}	—

The Safe Drinking Water regulations at 40 CFR 141.15 state:

The following are the maximum contaminant levels for radium-226, radium-228, and gross alpha particle radioactivity:

(a) Combined radium-226 and radium-228 — 5 pCi/l.
(b) Gross alpha particle activity (including radium-226 but excluding radon and uranium) — 15 pCi/l.

Section 141.16(a) requires that “the average annual concentration of beta particle and photon radioactivity from man-made radionuclides in drinking water shall not produce an annual dose equivalent to the total body or any internal organ greater than 4 millirem/year.”

DOE asserted in Chapter 8.2.3.4 that if the body dose for all radionuclides together from the ingestion of water was only 4.7×10^{-1} mrem/y, then the dose from beta, electron, and photon emissions alone (i.e., excluding doses from alpha-particle emissions) must be far less than 4 mrem/y.

Since DOE took this approach, EPA asked that the Department pursue it for the doses to critical organs, as required by 40 CFR Part 191, Subpart C, and Section 141.16(a). DOE responded to this request in the Analysis Report of an Evaluation of the Dose Contributions from Beta, Electron, and Photon Emissions to Critical Organs Related to Drinking Water Consumed for the Undisturbed Performance Supporting the CCA (DOE 1997d, Table 1). Using a highly conservative bounding calculation on the amounts ingested, as discussed above, and the methodology developed and endorsed by the International Commission on Radiological Protection (ICRP), DOE calculated the largest organ dose to be 4.2×10^{-3} mrem/y (bone surface). DOE also demonstrated that the maximum effective dose equivalent (EDE; see ICRP 1991, Sections 2.3 and 2.3) from beta, electron, and photon emissions is 2.3×10^{-4} mrem/y.

All concentration and dose values that DOE calculated were below the levels in 40 CFR Part 191. Coupled with the very conservative nature of the bounding calculation, DOE concluded that this analysis was adequate for compliance with Section 194.55(f). DOE stated in Chapter 8 (p. 8-10), "Because the DOE has developed a bounding analysis, it is not meaningful to calculate and present mean and median dose values. Instead, the bounding analysis provides 100-percent confidence that all potential doses will be below the 4.7×10^{-1} millirem value."

55.F.5 EPA Compliance Review

DOE was required to demonstrate that there is at least a 95 percent level of statistical confidence that the mean and the median of the range of estimated radiation doses are less than 15 millirem per year, and that the range of estimated radionuclide concentrations are compatible (after dilution, as discussed above) with the regulations developed under the Safe Drinking Water Act. DOE's bounding analysis indirectly verified these requirements by showing that the maximum estimated dose or concentration was always lower than the maximum allowable value.

To provide added assurance of the adequacy of the methodology, EPA commissioned an independent analysis (see EPA 1998a). This evaluation adopted the initial premise of the CCA that brine at the point of the accessible environment (i.e., at the boundary line indicated in the Land Withdrawal Act) in the interbed would be available for human use. EPA's analysis confirmed both DOE's initial estimate of exposure from direct consumption of drinking water and the dose from the consumption of agricultural products and the inhalation of resuspended dust. EPA calculated that the maximum dose from drinking contaminated water was 4.9×10^{-1} millirem per year. The maximum dose from all pathways totaled 6.5×10^{-1} millirem per year. A pathway-specific comparison of the estimated mean, 95-percent confidence interval, and maximum dose from the two assessments is shown in Table 3 of this CARD. The differences between DOE assessment and the independent analysis may be due to such factors as ingestion dose conversion factors or assumptions on the consumption of agricultural products.

DOE estimated the doses from electron, beta, and photon emissions and obtained maximum values of 4.2×10^{-3} mrem/y to the critical organ (bone surface) and 2.3×10^{-4} mrem/y EDE, both orders of magnitude less than the 4 mrem/y limit (see DOE 1997d, Table 1, and DOE 1997c, Table 3). The dose methodology used by DOE to calculate critical organ doses (i.e., the currently accepted ICRP methodology) was not consistent with that specified for use in the groundwater standard (i.e, NBS Handbook 69) in 40 CFR Part 141. Nonetheless, EPA believes that it was appropriate for DOE to use the approach it did in place of the methodology indicated in Section 141.16(b). In 40 CFR Part 141, Appendix B, EPA presented the basis for the interim final drinking water regulations for radionuclides, which are still in effect. The discussion of the beta dose limits states that EPA considered establishing the limits in terms of concentration, but decided on dose limits instead because “presently available dose conversion factors for ingested radioactivity are obsolescent, and the ICRP is developing new dose models.” Thus, EPA acknowledged that the NBS Handbook 69 methodology was becoming obsolete as long ago as 1977.[1]

EPA recognizes that the bounding pathway transport calculation that DOE has performed is highly conservative. The ICRP methodology and parameters for computation of doses from ingested or inhaled contaminated materials may not lead to an entirely bounding calculation, however, since there are some instances where the more up-to-date methodology is less conservative than that in the NBS Handbook 69 (although in many instances, the ICRP methodology is more conservative). In evaluating the beta/photon doses submitted by DOE, EPA did not calculate precisely how much more or less conservative the ICRP methodology is compared to doses that would result from using the NBS Handbook 69 methodology. Instead, the Agency increased DOE’s estimated doses (calculated as best-estimates of dose using the ICRP methodology) per unit intake by a factor of 100. EPA believes that this “safety factor” would, in effect, easily bound the uncertainties introduced by not using the NBS Handbook 69 dose methodology. With this change, DOE’s maximum dose values become 4.2×10^{-1} mrem/y and 2.3×10^{-2} mrem/y, both of which still are far below the limit. With this alteration, EPA finds the DOE approach to be highly conservative and adequate for compliance with the ground water protection limits for beta and photon radioactivity.

DOE did not calculate the statistical parameters of the mean, median, and standard deviation called for by Section 194.55(f). However, this failure does not necessarily invalidate DOE’s compliance. To ensure that such statistical parameters would be consistent with DOE’s bounding analysis, EPA performed an independent evaluation (EPA 1998b). This evaluation addressed the information called for in the CAG. EPA’s confirmatory assessment dealt first with the mean releases and then the median, as discussed below.

Table 3
Confidence intervals for the means of concentrations and doses

[1] Revised Primary Drinking Water Regulations for Radionuclides proposed in 1991 (56 FR 33049-33127, July 18, 1991 more current methodology endorsed by the International Commission on Radiation Protection ("ICRP") and used by DOE in its proposal, EPA also partitioned radionuclides into two general categories, to be treated separately. Separate tables provided radi concentrations corresponding to 4 mrem/year effective dose equivalent for "Beta Particle and Photon Emitters" (Appendix B) ar Emitters" (Appendix C); no radionuclide is found in both tables, nor is required to be analyzed in conjunction with both alpha ar limits. For alpha-emitting radionuclides, the incidental photon (and in the very rare cases in which they occur, beta and electror several orders of magnitude less energetic than the alpha emissions, and occur much less frequently. The only radionuclides pre the WIPP boundary in the undisturbed scenarios of the CCA or PAVTCnamely ^{241}Am, ^{239}Pu, ^{238}Pu, ^{234}U, and ^{230}ThCare all alpha (and are listed as alpha emitters in Table Appendix C in the Proposed Drinking Water Regulations of 1991). Consequently it is relevant to consider these radionuclides for compliance with Section 141.16, so long as they are included in the alpha dose limit 141.15(b). Nonetheless, EPA required DOE to comply with the plain language of the regulations currently in effect, and to eval doses from alpha emitters for the WIPP.

Description	Mean	95 percent confidence interval	Maximum Allowable Value
All pathways dose (mrem/yr): CCA Table 8.2 + 0.46 iff > 0[1]	0.017	0.005 - 0.028	15
All pathways dose (mrem/yr): EPA 1998a, Table 3-2	0.004	0.000 - 0.009	15
Radium concentration (pCi/L): 9 values of 2.0 from CCA, 291 values of 0.0	0.060	0.021 - 0.099	5
Gross alpha concentration (pCi/L): CCA Table 8.1 + 2.0 iff > 0[2]	0.100	0.020 - 0.181	15
USDW dose (mrem/yr): CCA Table 8-2	0.003	0.000 - 0.007	4
USDW dose (mrem/yr): EPA 1998a, Table 3-1	0.003	0.000 - 0.007	4

[1] The value of 0.46 mrem/yr is added for additional pathways other than the ingestion of drinking water. This value is added to the dose from CCA Table 8.2 only for the nine non-zero calculations.

[2] The value of 2.0 pCi/L is added to account for the radium concentration. This value is added to the concentration from CCA Table 8.1 only for the nine non-zero calculations.

Assuming that the 300 realizations were approximately independent, EPA used the central limit theorem of statistics to verify that the sample *mean* (of the 300 values including the 291 zero values) was approximately normally distributed. The well-known 95 percent confidence interval for the mean is the sample mean plus or minus 1.96 times the sample standard deviation divided by the square root of the sample size. The requirement at Section 194.55(f) is met if the upper bound is no more than the maximum allowable value. The relevant statistical formulae are:

N = sample size = 300
X_i = estimate for i-th realization ($i = 1, 2, 3, ..., 300$)
μ = mean = $\Sigma\ X_i / N$ (sum over i)
σ = standard deviation = $\{ \Sigma\ (X_i - \mu)^2 / (N-1) \}^{½}$
95% confidence interval = $\mu \pm 1.96\sigma / \sqrt{N}$

Negative lower bounds are replaced by zero, since the mean must be non-negative. EPA interprets the requirement of Section 194.55(f) to mean that ($\mu \pm 1.96\sigma / \sqrt{300}$) must be less than the specified maximum allowable concentration or dose value.

The results of the analysis of the means are summarized in Table 3. For each case EPA reported the lower and upper bounds of the derived 95 percent confidence intervals and showed that the upper bound is lower than the maximum allowable value, so that the Section 194.55(f) criterion is met.

The 95 percent confidence intervals for the population *median* are derived as follows. The dose or concentration is zero with some probability p, and is non-zero with probability 1-p. The non-zero values can be assumed to have a continuous distribution. The population median equals zero if and only if the probability of a zero dose or concentration, p, is greater than or equal to 0.5.

When the probability of a zero dose or concentration, p, is less than 0.5, the population median is positive. The probability that a single estimate is less than the population median equals 0.5. Regarding the 300 estimates, there is an interval between a minimum estimate, r, and a maximum estimate, s, that defines the lower and upper 95 percent confidence intervals around the mean (r=1 is the minimum possible value; s is larger than r). The probability P(Median) that the population median lies within the 95 percent confidence intervals (between the r-th and s-th highest estimated value) equals the probability of between r and s-1 values less than or equal to the population median. The probability of values less than or equal to the population median in 300 independent Bernoulli trials is 0.5. (A Bernoulli trial is one of a series of trials in which there are two possible outcomes, all trials in the series are independent of each other, and the probability of a particular outcome is the same in each trial. An example is the toss of a coin, where the two outcomes are heads or tails.). One can select a value of s=301-r so that s will fall symmetrically between the maximum estimated value and r, the lower 95 percent confidence limit. P(Median) is at least 0.95 if $p < 0.5$, r=133, and s=168.

When the probability of a zero dose or concentration, p, is greater than or equal to 0.5, then the population median equals zero. The probability that a single estimate is less than or equal to the population median then equals p. Therefore, P(Median) equals the probability of r or more zero values for dose or concentration. The probability of zero values equals p for 300 independent Bernoulli trials. When $p \geq 0.5$, this probability is obviously at least as large as when the probability of a zero value equals 0.5. Also, the probability of at least r zero values is no more than the probability of between r and s-1 zero values (if $s > r$). P(Median) is at least 0.95 if $p >= 0.5$, r=133, and s=168.

It follows that the interval from the 133rd to the 168th highest estimated dose and radioactivity concentration values is a 95 percent or greater confidence interval for the population median based on the 300 realizations. Since there were 291 zero values, all the median confidence intervals are 0 and do not exceed the maximum allowable value.

As discussed under Section 194.34(b) in **CARD 34—Results of Performance Assessments**, EPA required DOE to make modifications in a number of the probability distributions for the subjective parameters undergoing Latin Hypercube Sampling (LHS) in the performance assessment (PA). Also, DOE independently found and corrected some errors in modeling and coding. DOE performed three additional replications of one hundred realizations each on the Performance Assessment Verification Test (PAVT).

As with the CCA, the PAVT involved groundwater modeling simulations for the undisturbed repository. The results of this modeling projected non-zero groundwater concentrations for only 13 of the 300 modeling simulations (as opposed to 9 in the CCA PA). The projected groundwater concentrations from the PAVT are found in “Summary of EPA-Mandated Performance Assessment Verification Test (Replicate 1) and Comparison with the Compliance

Certification Application Calculations, July 25, 1997" (DOE 1997a) and “Supplemental Summary of EPA-Mandated Performance Assessment Verification Test (All Replicates) and Comparison with the Compliance Certification Application Calculations” (DOE 1997b). EPA found that the mean and median radionuclide concentrations in ground water calculated in the PAVT complied with the requirements of Subpart C, Part 191, both for gross alpha particle radioactivity (including radium-226 but excluding radon and uranium) and for radioactivity concentration for radium-226 and radium-228 (EPA 1998b).

Drinking water and all-pathways doses corresponding to projected ground water concentrations in the PAVT were estimated using the modeling methodology established for the CCA. DOE initially submitted results for the drinking water pathway only, where the largest dose value was 3.2×10^{-2} mrem/y (DOE 1997f, Table 3). Later, in its “Summary of the EPA-Mandated PAVT Results for Individual Protection Requirements,” DOE calculated 3.1×10^{-2} mrem/y for all other pathways combined (DOE 1997c, Table 5). This calculation again resulted in a value orders of magnitude less than the 15 mrem/y requirement. EPA’s calculation of the total body dose from DOE’s concentrations for the 13 non-zero realizations yielded a maximum value of 3.1×10^{-1} mrem/y (EPA 1998a).

DOE’s PAVT analysis of beta, electron, and photon doses to the whole body and to individual internal organs is shown in its “Summary of the EPA Mandated PAVT Results for Individual Protection Requirements” (DOE 1997c, Table 3). DOE demonstrated that the largest organ dose is 2.9×10^{-4} mrem/y on the bone surface. The analysis also showed that the maximum effective dose from beta, electron, and photon emissions is 1.5×10^{-5} mrem/y.

Results of the PAVT thus showed that the mean dose contributions from both alpha-emitting radionuclides and from photon and beta-emitting radionuclides are below the limits in 40 CFR 191.15 and Subpart C.

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