Department of Energy
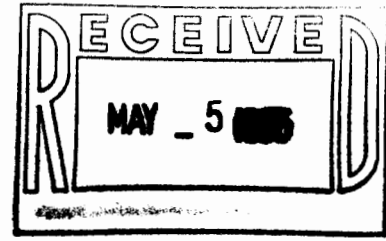Carlsbad Area Office
P. O. Box 3090
Carlsbad, New Mexico 88221

MAY - 1 1995

Lindsay A. Lovejoy, Jr.
Assistant Attorney General
State of New Mexico
P.O. Drawer 1508
Santa Fe, N.M. 87504-1508

Dear Mr. Lovejoy:

Thank you for your comments on the Performance Assessment Methodology Position Paper. Your interest and participation in the Systems Prioritization Method (SPM) is greatly appreciated. Enclosed is the Carlsbad Area Office's response to the questions you have expressed regarding this paper in your letter dated ~~A~~ NO COPY

Thank you for bringing it to our attention that you had not received the responses. Responses were prepared earlier, but were not forwarded to you.

If you have any questions regarding these responses, please contact George T. Basabilvazo of my staff at (505) 234-7488.

Sincerely,

Michael H. McFadden
Assistant Manager
Office of Regulatory Compliance

Enclosure

cc w/o enclosure:
J. Mewhinney, CAO
R. Bills, CAO
C. Wayman, CAO
L. Shephard, SNL #1395
M. Irwin, SNL #1341

Printed on recycled paper

950501

Performance Assessment Methodology Position Paper
Comments and Responses

Question/Comment 1. A key issue in the WIPP PA is the treatment of uncertainty. The position paper states only that DOE will deal with uncertainty by generating only the mean CCDF (p. 10). such an action does not adequately address the issue of uncertainty in public safety decisions. An instructive treatment is contained in Paté-Cornell, Risk Analysis and Relevance of Uncertainties in Nuclear Safety Decisions, in Public Regulation, New perspectives on Institutions and Policies (MIT Press 1987). Briefly, Paté-Cornell argues for full disclosure of the extent and nature of analytical ("subjective") uncertainty as well as observational ("stochastic") uncertainty and a deliberate choice of a high level of certainty in public safety decisions. First, disclosure is required for the following reasons:

a) A regulatory decision is a collective judgment among the regulator, the regulated entity, and affected parties, and various participants will have different levels of confidence in various data sources and uncertainty ranges. The range of uncertainty must be expressed to permit a public dialogue leading to a decision.

b) To display uncertainty makes clear the possibility of reducing the uncertainty by investment in research.

c) In certain instances, whether the regulatory probability limit is met may depend in a nonlinear way upon a frequency (e.g., intrusion) that depends on uncertain parameters, thus calling for reduction of such uncertainty.

d) Public confidence in a regulatory decision depends on the degree of uncertainty of risk assessments.

Further, Paté-Cornell explains, in determining regulatory compliance, there is no theoretical justification for use of the mean, median, or any other element of a distribution:

"The probability distribution of the future frequency of the system's failure is generated by parameter and/or model uncertainties. There is no theoretical framework to justify the use of the mean, the median, or other characteristics of this distribution (fractiles, moments, etc.) to show compliance with any of the probabilistic constraints (risk and plant performance)." (at 247).

Thus, it is erroneous to select the mean or the median and to exclude other elements of the distribution from having effect on the decision.

Paté-Cornell explains that, to ensure that the regulatory limitations of probability and consequence have been met with "reasonable certainty", uncertainties must be explicitly set forth

1

and the judgment of compliance must be made on the basis of a high probability, such as 0.95:

> "Once this analysis has been done, safety decisions must be made to ensure that with a high probability (e.g., 0.95) the plant is in compliance with the maximum acceptable individual risk constraints and with the maximum allowable frequency of failure." (at 249).

The public safety decision is different from an economic assessment made when allocating limited funds; such assessment should be governed by mean values (at 250). But when a safety constraint set forth as a maximum probability and consequences is the goal, assurance at the level of 95% is appropriate:

> "If the goal is to verify that a probabilistic threshold (e.g. individual mortality frequency) is not exceeded, it is reasonable to require that this constraint be satisfied with a probability to be specified (e.g. 0.95). One needs to consider then the probability distribution on the frequency estimates in order to reflect analytical uncertainties." (at 250).

Thus, DOE's proposed methodology, which does not set forth the distribution of CCDF's which represents subjective uncertainty, and which selects the mean as decisive, is erroneous.

> *Response. We are familiar with the reference cited by Paté-Cornell, and we agree with the discussion concerning the treatment of uncertainty. We will not make the judgment about which summary curve (or curves) should be compared to the Containment Requirements criteria. EPA will make that choice. Their guidance in Appendix C of 40 CFR 191, as quoted in the paper, is to "to incorporate (effects of the uncertainties) into a single such distribution function". Obviously, to generate the mean curve requires evaluating the full range of uncertainty.*

Question/Comment 2. The paper does not present any methodology for dealing with conceptual model uncertainty. It is not sufficient to state that conceptual model has previously been dealt with by running ceteris paribus analyses (p. 10), since the target of PA is to express risk, which such analyses do not do. Further, some conceptual model uncertainties have been dealt with in other ways (e.g., relative permeability and capillary pressure; see 1991 PA vol. 4, at 5-9).

PA requires a valid structure for displaying risk, including uncertainty as to risk -- thus including conceptual model uncertainty. It must be recognized that uncertainty in conceptual models does not imply a parameter that varies in linear fashion. Further, it may be difficult to justify the assignment of probability estimates to different conceptual models or to generate a probability distribution function. However, it remains DOE's responsibility to develop a coherent and structured approach to incorporation of conceptual model uncertainty into PA.

> *Response. Conceptual model uncertainty is a difficult issue that must be dealt with by any risk assessment program for waste disposal. It has been the focus of both NEA PAAG and SEDE working groups, and the WIPP Project has given considerable attention to this issue. In our view, we must deal with CMU on a case by case basis rather than trying to*

2

impose one approach on all cases. What we choose to call CMU is, in itself, a subjective judgment. Some would always include CMU as parameter uncertainty, and we chose to take that approach by sampling on an index parameter between Parker-van Genuchten and Brooks-Corey characteristic curves to be used in BRAGFLO. The ⅓ - ⅔ weighting was a subjective judgment of the PI in this area. Some would always include CMU with scenario construction when identifying FEPs. We chose this approach with Castile pressurized brine in defining E1 and E2, including material-property parameters as subjective uncertainty and area for probability calculations as stochastic uncertainty. These are all subjective decisions that are made when structuring the system analysis. We believe that the reasonable approach is to make these judgments on a case by case basis in a way that helps to provide clear understanding of the calculated results.

Question/Comment 3. The paper contains references (pp. 5, 16-17) to the related problems of aggregation, resolution, and computational efficiency. However, to state that these issues exist and are related does not quantify them and resolve the issues. These discussions are lacking.

Response. These issues are discussed in the cited references, especially Helton, et al. which has been added to this paragraph.

Question/Comment 4. Discussing the conceptual basis for scenario development, the paper indicates (p.11) that certain scenarios are excluded from consideration by regulatory directive, referring to what is now Appendix C. Appendix C is expressly nonbinding, and DOE does not regard itself as bound by certain other aspects of Appendix C, such as the assumption that the likelihood of drilling should be taken to be 30 boreholes per square kilometer per 10,000 years.

DOE should incorporate the category of scenarios termed regulatory exclusions into its risk analysis. Incorporation of the previously excluded category will mean that intrusion probabilities will need to be estimated for future human actions such as resource development, mining, archeological investigation and the like, which have previously been left out of PA.

Similarly, any separate treatment of so-called low-probability high consequence scenarios must be questioned. The source of this exclusion is in Appendix C, whose status is at best uncertain. As the paper (p. 13) notes, it is possible to exclude any category of events by narrowing scenario definitions.

Response. Point 1 - We will continue to follow the guidance concerning the probability cut off provided in Appendix C until final guidance is written for the Certification Application. Point 2 - The message in this comment is apparently that scenarios (FEPs) should be screened on risk, not just probability as stated in Appendix C. However, the containment Requirements are expressed in terms of probability, not risk in the sense of human dose and health effects. The EPA has made the determination that risk derived from FEPs with probabilities less than their cutoff is unimportant compared to risk derived from FEPs with likelihoods above that cutoff.

3

Question/Comment 5. Much of the discussion in the position paper is conclusory and qualitative. In describing the scenario development process, for example, it is said that the first step involves "compiling or adopting a 'comprehensive' list of events and processes that potentially could affect the disposal system." (p.15). It is difficult to argue with this objective. However, to state the objective is not to describe a methodology. The paper continues, noting that the "determination of both scenarios and scenario probabilities is a complex process with significant uncertainties," and it refers the reader to Hora et al. (1991), the documentation of the expert panels on human intrusion, which has been criticized on numerous grounds. (See our comments on the 1992 PA, April 8, 1994, at 11-13). It is difficult to determine whether DOE is seeking comment on the position paper, which is a summary of PA methods, or on the cited works which report on the application of such methods. If DOE is calling for response to the application rather than the method, we refer it to our previously-cited comments.

Response. Description appears in the Scenario Position Paper.

Question/Comment 6. Similarly, the discussion of the calculation of scenario consequences contains a general discussion of method and refers broadly to the lengthy documentation of the application of that method. It is unclear on what materials DOE is seeking comment (particularly when DOE suggests that comments may include "ideas and justifications for variations in our technical assumptions regarding modeling parameters"). In any case, we will reserve our comments on specific parameters for the meetings which concern those technical issues.

Response. Previous consequences modeling is described in the cited documents. Future consequences modeling depends on the baseline set of assumptions described in the various position papers.

Question/Comment 7. The description of the method of selection of variable parameters and determination of their ranges and distributions is inadequate. Indeed, the paper does not describe a method at all. The paper merely states that "information about the ranges and distributions of possible values is drawn from a variety of sources" and that the "review process that leads from the available data to the construction of the cumulative distribution functions ... is unavoidably subjective, and involves some judgment of the investigators and performance assessment analysts." (at 21). This is not a description of a scientific process; this language would describe random selection. Further, there is no discussion at all of how particular parameters were selected as variables.

Response. The text referred to previous PA documents instead of attempting to reproduce that lengthy discussion. Since the set of sampled parameters changes somewhat with changes in modeling assumptions (e.g. baseline assumptions), a lengthy discussion does not seem appropriate here. Some additional general material will be added.

Question/Comment 8. The descriptions of the generation of samples and propagation of samples through the analysis are likewise very general and refer broadly to much more detailed

4

discussions of the performance assessment. What would be more appropriate in a position paper, for example, is a theoretical discussion of the method which led to the decision that a sample size of 70 is correct for a model with 49 variables and similar decisions.

Response. Comment #7 remarks apply here too. The decisions made for interim PAs that were intended to provide guidance to the experimental program do not carry over to an analysis that would form the basis for a Certification Application. Specifically, the reasoning that led to a sample size of seventy would not be appropriate for a final analysis.

Question/Comment 9. There is no discussion of the method for identifying correlated variables and dealing with the correlations in sampling and other stages.

Response. Except for generating conditional simulations of the Culebra transmissivity fields, we have used few correlations in previous PAs because we had insufficient information for PA to assign correlations. The baseline established by these position papers will need to address possible correlations.

Question/Comment 10. The paper contains no reference to the State-DOE agreement as they affect performance assessments and compliance demonstration. DOE should state whether it intends to comply with the State-DOE Consultation and Cooperation Agreement and the Working Agreement, as they have been amended over time. Specifically, DOE should make reference to the Working Agreement provision which requires DOE to consult with the State in selecting radionuclide retardation factors and to select "a range of values to be conservative, but reasonable, based on the lowest reasonable values experimentally obtained." (1988 Modif. to Working Agreements, at 9).

Response. Reference added.

Question/Comment 11. It is not clear why the paper contains a discussion (albeit brief) of uncertainty analysis, sensitivity analysis, and systems prioritization (pp. 23-27). There is as yet no method to connect these exercises to a demonstration of compliance.

Response. Uncertainty and sensitivity analyses enter through qualitative judgments , e.g., your concern regarding the display of the full range of uncertainty. We agree with your comment concerning Systems Prioritization. Systems Prioritization is a management tool and does not relate to compliance, therefore, this paragraph has been deleted.