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Everett A. Wick
High Level Waste
Licensing Management Branch
Division of Waste Management
Mail Stop SS 965
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Wick:

Attached are discussions of comments received from DOE on the DTP on reliability.

You should have received an advanced copy of the memo to P. Soo through the FAX.

Sincerely,

C Sastre

C. Sastre

CS:cp
enc.
cc. T. Johnson, NRC
M. S. Davis
W. Kato
H. Kouts
C. Pescatore
D. Schweitzer
P. Soo
NRC Docket Control

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: July 31, 1984

TO: P. Soo

FROM: C. Sastre CS

SUBJECT: Comments from DOE on DTP on Reliability.

I have reviewed the comments on the DTP on Waste Package Reliability conveyed in a letter fom J. W. Bennett to R. W. Browning of June 22, 1984.

The letter itself includes some comments and an appendix includes the bulk of the comments.

COMMENTS IN THE LETTER

It should be noted that the comments offered by DOE are based on the May version of the draft and some objections have been corrected in the November version of the DTP.

COMMENTS IN THE APPENDIX

General Comments

Comment #1.

"Many of the comments center around the absence in the technical positions of explicit allowance for other methodologies to determine reliability estimates of the waste package."

Response

It was not the intent of the authors to claim that there is only one methodology to calculate probabilities of failure of the waste package to comply with the NRC criteria.

It is the intent of the authors to show that at least one method exists to treat the probability of failure of waste packages.

Alternative methods that account for uncertainties in the basic data about the processes involved in the identified failure modes and that also account for uncertainties in the models used for prediction of performance can of course be used in place of the suggested methods, as long as they are technically sound.

This is covered at the end of Section 2.1.5 of the November version of the DTP, and in Section 1.3, Item 5.

Comment #2

"In some cases, lack of data may prevent the formulation of probability functions, for some parameters.."

Response

In some cases the data involved will have limited impact on the results of calculations or predictions of repository performance, which can be shown by sensitivity studies. In those cases, good engineering judgement could be used to either take a point value estimate since the parameter is not important anyway or good engineering judgement could be used to select a broad enough distribution that covers all credible values of the parameter.

But, if data is lacking on a parameter that sensitivity studies show that is important or dominant in determining the performance of the waste package, even if the functional form of the probability density function can not be determined rigorously, the DTP calls for a conservatively broad distribution that experts can agree that represent their best conservative estimate.

If the prediction of the performance of a waste package is really sensitive to the value of some property or parameter then it is imperative that an effort be made to explicitly show the range of values that are credible.

General Comments

1. The calculational and analytical examples given propose methodologies that may not represent the best or most appropriate approach for repository licensing. The technical position should not limit the approach, but rather allow the use of techniques most appropriate to the particular problem. While the use of a series of Monte Carlo runs based upon Latin Hypercube Sampling in which parameters are treated as random variables has many good features, the NRC should clearly delineate the limitations as well as the strengths of these techniques in the position.

Response

The DTP recognizes that other methodologies may be equivalent in estimating the uncertainties on the predicted performance of a waste package. In particular this is stated at the end of Section 1.3 Step 5 and at the end of Section 2.1.5.

2. The position should include the use of in-depth sensitivity analyses to identify key parameters affecting degradation and possible failure of the waste package. Techniques such as stepwise regression and/or partial correlation are available to do this.

Response

Yes, it was implicit in the process of development of the models, and it is briefly addressed at the end of Section 1.3 of the November version, but it could be made more explicit in the text.

3. The use of "relatively simple algorithm" (p.14) may introduce more uncertainty than is desired. In performance assessment analyses, simple models are often used so that Latin Hypercube Sampling may be used. In this case, it appears that the models are being forced to fit a desired statistical technique.

Response

There is nothing wrong with selecting the models to facilitate the use of techniques as long as the models are adequate and are justified. The last sentence applies also to schemes of error propagation which involve linearization of the models.

4. The rigor required in reliability analyses may not be possible with present models and with anticipated limits on the availability of data. The number of runs required to achieve useful results using the sample reliability analysis given in the technical position could be unattainable. It will probably not be possible to analyze available corrosion data with the rigor assumed in the position. Also, available leaching data may be far too few, too scattered, and show the effect of too many variables to enable this type of reliability analysis. It should be noted that many existing computer programs are set up such that calculations using probability distributions of the input data would not be economical. For example, the Latin Hypercubes Sampling (LHS) is not suitable for a computer program with many variables such as WAPPA. This program has too many parameters for LHS to handle directly. Therefore, this position should be revised to explicitly state that the methods presented are an approach, and other analytical approaches to relaibility analyses that are more appropriate for the available data and analytical models being used are allowed.

Response

See response to #1 above. If the performance of the package can only be predicted with very large computer programs, and if the complex computations are really needed, then other methods may be available to satisfy the spirit of the DTP. If the problem is that the data has uncertainties that can not be estimated or bounded, and the uncertainties impact significantly the prediction of performance, then no statistical technique can cure the situation and the problem should perhaps be designed away. If the data is bad, then simple models should suffice. For example if the uncertainty of prediction of corrosion rates is equivalent in the best model available to a change in temperature of several tens of degrees, it may not be justified to run in the system model a 3D calculation on package temperature, or a transport calculation for the radiation module.

5. Although the NRC regulations are based on failure of the engineered system, this technical position is directed only to the reliability of the waste package. There is no indication of how to factor this analysis into an engineering system failure analysis.

Response

A basic assumption was made that failure of the package is equivalent to failure of the engineering system. If the DOE thinks that there is a substantial containment in the rest of the engineering system outside the package,

then the spirit of the DTP could be satisfied by developing a performance model including all the components of the engineering system and treat the resulting system model as suggested in the DTP or by other equivalent statistical methodology.

6. Statistical issues and concepts are not treated as rigorously and precisely as they should be. One example of this is the weakness of definitions in Section 1.2. Suggested alternatives are given under specific comments. Other important statistical concepts such as significance level and confidence level should be more clearly defined and characterized. The concept of confidence level associated with a reliability estimate should be presented in terms of parameter estimation. To do this, reliability estimates should be defined as estimates of percentiles of life distributions. Similiarly, tests of significance (hypothesis testing) should carefully be defined in the context of their application in this judgement.

Response

It was not the intention to provide a self contained manual, since the methodology is not mature enough and alternatives are quite acceptable if technically sound. In the illustration the results are not presented as percentiles of life distributions since the uncertainties of the data are not individual variations.

7. References to "possible" and "impossible" failure modes are not appropriate for reliability analyses. Failure modes may be significant or insignificant, or probable and improbable.

Response

Possible and impossible are used in the common engineering usage. Possible means probable and impossible means quite improbable.

8. The methods proposed in this technical position may have application to the site and seal subsystems, and ultimately to the entire isolation system. A separate technical position, or an expansion of this technical position extending this methodology to these areas as one of several acceptable approaches, is recommended.

Response

Yes.

SPECIFIC COMMENTS

Page	Section	
1	1.1	The first paragraph states in part "...the waste package will contain the waste for 300 to 1,000 years (depending on the thermal load to the geologic repository)..." The parenthetical statement appears to relate waste package life solely to the thermal environment. The intent of this statement should be clarified.

Response

The statement serves no essential purpose in the DTP and should be removed.

1	1.1	The third paragraph refers to EPA standards for overall reliability of the repository system which may have been established for guidance in determining waste package reliability. As the overall reliability has not been determined in the EPA standard, there is no guidance for waste package reliability.

Response

The EPA standard has not been issued yet, and the text says "... standards which may have been established by the Environmental..."

2	1.2	"Confidence Parameter" appears to be a term created for this technical position that is unfamiliar to the DOE. Either clarification or deletion is recommended.

Response

The issue of the confidence parameter appears to have created the most difficulties. In fact, in the work of Aerospace for NRC, there is confusion in this area.

The term has been created for this application but is justifiable.

The most useful solution would be to write an appendix to the DTP, perhaps including some illustration. This is not a trivial job.

2	1.2	As indicated in general comment six, the definitions should be strengthened. The following modified definitions are suggested alternate definitions to those given in the position that would strengthen and clarify the statistical concepts. These definitions are typical of those to be found in standard text book or reference books on probability and statistics. Sample Space: The set of all possible outcomes of an experiment or trial. Event: Any subset of the sample space.

Random Variable: A numerical-valued function defined on a sample space, or a variable whose values are predicted by probabilistic means (either for convenience in modeling or because a deterministic model for its variation is unavailable).

Probability (of an event): There are different philosophies regarding the appropriate definition of probability. The following is a widely accepted standard definition of what is meant by the probability of an event. Let A be an event of sample space S and suppose the experiment which generates the outcome in S is rpeated n times (n independent trials). Let Y be the number of times that A occurs in the n trials. Then the probability of the event A, P(A), is defined as...

Response

It was clear at the time of the preparation of the draft that including definitions of statistical terms would create confusion and controversy. At the insistance of NRC the definitions were included. For any set of definitions there will be a set of statisticians who object.

Page	Section	
3	1.3	The first full sentence on page 3 indicates that all the probabilities, and any sensitivities that could be developed, are scenario dependent. In statistical jargon, this fact should be emphasized in terms of conditional probabilistics in the conclusion on page A.20. Otherwise, it may result in a misunderstanding of the 2 percent failure probability presented.

Response

The sentence referred to in the comments appears in a previous version. The point that the probabilities computed are conditional on a scenario is well taken, however any probability estimation involves assumptions and in that sense implies conditional probabilities. The point might be stressed in future issues.

4	1.3	In item 4 and other locations throughout the report, emphasis is given to the development of probability densities for the inputs. The data that will be available may be too sparse or scattered and thus make this impractical. It may not be possible to decide with an confidence which probability density best fits the available data. Rigorous probability densities should be developed only when necessary.

Response

For some input data, if the results are insensitive to the value, a rigorous PDF may not be necessary and a point value or bounding PDF might suffice. But for those data that are crucial to the results an at least bounding PDF is necessary. Another approach would be to take a conservative point

value such that the probability of exceeding or not exceeding (as the case may be) the point value is negligible. This is done constantly in reactor safety. But this approach is nothing else than assigning to the value a conservative PDF, in the form of a unit step function. One advantage of recognizing this is that it brings to light that a conservative value has associated with it the idea of a negligible probability.

Page	Section	
5	2.1	Adequate alternatives to failure mode and effects analysis (item 4) are available and their use should be allowed in the position.

Response

If the alternatives are adequate in the sense of identifying failure mechanisms and describing the failures, then they are acceptable.

5	2.1	In item 2 (and under 2.1.2, page 6) "bind" should be "bound".

Response

Yes.

6	2.1.2	Ground-water flux and flow mechanisms should be added to the list of environmental factors of concern. This is necessary to account for sealing failures in shafts and boreholes.

Response

Yes.

7	Table 1	The inclusion of leaching assumes saturation under the general usage of the term. Degradation modes and environmental factors for the unsaturated conditions are also needed. For instance, other degradation modes may become operative under the expected environmental conditions. The "D" factor (pressure and stress fields) is only important with regard to the waste form condition after the containment period in the unsaturated setting, and/or if a canister failure occurs coinciding with collapse of emplacement hole walls or flooding of the hole so that lithostatic or hydrostatic stresses can be transmitted to the canister and waste form.

Response

Leaching here is used in the broad sense of chemical attack leading to dissolution.

9	Table 2	Is "resilience" to hydrothermal alteration the intended word?

Response

Resistance would be a better word.

Page	Section	
11	2.1.7	Design reliability specifications, although useful, are not required by 10 CFR 50 Appendix B, ANSI N 45.2 or ANSI NQA-1.

Response

The text may be altered to say that "...are an integral part of many good QA programs."

12	3.0	The first and last paragraphs on the page refer to the completeness of the review of reliability considerations and completeness of phenomena considered in failure mode anlaysis. Even after completion of design and formulation, it will never be possible to prove that all failure modes have been considered by repeated review by competent technical persons because of the possibility of the unknown, never-before-thought-of phenomenon. Potential failure modes must continually be scrutinized by such persons. Also, the energy and thought focused on completeness must not detract from that needed to examine the more probable failure modes.

Response

This comment agrees with the spirit of the DTP.

13	3.1	Introduction of an extra random variable to account for model uncertainty seems to be an unrealistic means for approaching this problem. It would be simply a "fudge factor" that would carry little information and be difficult to qualify and/or defend in terms of the desired answer. Analytical treatment of uncertainty by developing an equation/model to describe and test components of the overall model uncertainty would provide more useful information because components of uncertainty associated with various parts of the system model could be identified. If retained, the important statistical properties of the extra random variable should be described and demonstrated in the example.

Response

This point has been raised by other reviewers. A method is needed to account for uncertainties of the applicability of the model itself. In the sense that safety factors are used in design. At the time of development of the DTP, this issue was handled through the introduction of a new random variable. It would be desirable to spend some effort developing this concept some more.

13	3.2	Paragraph 3 could be interpreted to allow a Monte Carlo simulation as an alternative process to the introduction of the extra random variable described in the previous paragraph. This should be clarified.

Response

The present wording does not lead to that interpretation.

Page	Section	
14	3.2.1	(First paragraph) To obtain significance levels of the regression coefficients, one must assume the errors are normally distributed. So if one does study the distribution of the errors and determines they are non-normal, then the significance levels are not valid. In other words, what is being requested may not be appropriate. Some equations will be developed as "conceptual models" for processes where only a few actual data points are known, or perhaps are known for conditions outside the range of conditions expected in the repository. In this case, a complete descriptive statistical analysis would not be justified, but rather non-parametric assessments could be used to establish some degree of confidence in the results.

Response

As indicated before, for variables shown to be noncrucial, their variability could be ignored or bounded, but for crucial variables means are needed to bound the uncertainty.

14	3.2.1	(Second paragraph) One-dimensional temperature models may not be adequate to simulate the temperature profile. This is another example of forcing the model to fit a desired statistical technique. Models should not be simplified without sufficient justification.

Response

The text offers one-dimensional models as an illustration of simplifications that might be used but specify that such simplifications need to be validated.

16	3.2.3	Something is missing in the second sentence, first paragraph.

Response

Not in the present version, but it could be rephrased.

A-1	App. A	The illustrative example utilizes different methods of establishing input data for the Monte Carlo sampling approach, ranging from rigorous statistical analysis of experimental data to subjective consensus. These methods are chosen on the basis of judgement of the adequacy of the data base and of the behavior of a particular input variable. The position should contain more definitive guidance with respect to the acceptability of this approach.

Response

At the present time, it would be advisable to retain flexibility

Page	Section	
A-2	A.3.1	Although codes such as HEATING 6 are too complicated to use in a Monte Carlo type simulation, they could be useful. A comprehensive adjoint sensitivity analysis could be performed on HEATING 6 to determine the key parameters needed in the simplified model and to provide a defensible means of evaluating the simplified model.

Response
Yes.

A.9	A.3.2.2	The linear regression that relates uniform corrosion to time may be too simple.

Response
Of course it is too simple. The analysis was offered as a simplified illustration of some of the concepts.

A.20	A.3.3.1	(Last paragraph) The assumption of a near stagnant solution source term should be considered in future corrosion tests.

Response
The calculations are offered as elementary illustration of concepts and techniques only.

A.21	A.3.3.1	The comments on leaching rate should include consideration of individual isotopic and synergistic effects.

Response
In the section call there is a call for better models and better data.

A.30	A.5	In the first major paragraph, the number of coincident failures, both canister and release rate, should be noted and discussed. The duality of failure mode has been observed previously in the review of the Sandia studies and is a weakness in this approach. Also, in using the approach of randomly selecting parameter values over assigned ranges, it is possible that two or more parameters could be given values which ar physically incompatible (e.g., high porosity and low flow rate). Consequently, results from such single calculations would not be valid. In particular, some apparent (calculated) failures may in fact be impossible or at least highly improbable.

Response
The reason for the failure of the canister on both counts is that in many cases in the illustration used, the failure on controlled release is prevented by survival of the canister, based on the data used.

It should be noted that the Latin Hypercube allows the proper representation of correlation between variables. If the variables are independent there is no problem. If the variables are correlated, the Latin Hypercube Technique can account for it. If the variables are so strongly coupled that one is function of the other, this should be reflected in the model.

Page	Section	
A.30	A.5	(Second paragraph) The point is made that 2 percent failure probability means that there is a 2 percent chance that all canisters will fail. This would be a very serious failure for a repository and may be unacceptable. Consequently, this failure analysis needs to be examined and discussed in greater detail.

Response

The analysis presented as an illustration treats only the uncertainties on the data not the variability from canister to canister. So that a failure in this illustration is a common-mode failure. The extension to canister to canister variability is feasible. It was not the object of the illustration to present a definitive result.

A.32	Table A.5.1	Hydraulic conductivity is represented here by a uniform distribution. The DOE believes that a log-normal distribution is more appropriate.

Response

Yes, it is probably more appropriate.

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: August 1, 1984

TO: P. Soo

FROM: C. Pescatore, C.P.

SUBJECT: Resolution of DOE's Comments on the DTP on Waste Package Reliability.

The DOE has recently forwarded to the NRC its own comments on the NRC Draft Technical Position on Waste Package Reliability. These are contained in a letter from Mr. J. W. Bennett (DOE) to Mr. R. W. Browning (NRC). The letter also contains two enclosures encompassing general comments and specific comments, respectively. A review and a reply to these comments is presented hereafter.

Letter from Mr. Bennett to Mr. Browning

While indicating that the DTP "presents a logical approach for determining the reliablity of the waste package" and that "such guidance is particularly welcome", Mr. Bennett summarizes DOE's criticism in three basic points:

1. The DTP lacks explicit allowance for probabilistic methodologies other than the implemented LHS-Monte Carlo simulation;

2. The suggested approach is too rigorous as in some cases lack of data may prevent the formulation of probability distribution functions (PDF's);

3. The simplified "advocated" models are not sufficient in some cases to obtain accurate results.

In response to Item 1, the DTP does not claim the proposed technique to be the preferred or unique one for reliability analysis. As it is recognized in Section 1.3 (Item 5) and in Section 2.1.5 "other probabilistic schemes may be acceptable as well. Indeed a preferred scheme cannot be identified at this time due to the fluid state of high level waste repository design." This position still reflects the state of the art.

In response to Item 2, the rigor with which the PDF of a piece of data should be formulated depends on the relative importance of that piece of data in the overall performance model. If performance is little sensitive to that data, only a few measurements may be sufficient to define the PDF, whose uncertainty may still be acceptable to the specific, subsystem reliability goals set by the reliability specialist. Thus a PDF can be just as accurate as it is justified by its importance in the overall picture. This is implied by the stated position on page 5 and in Sections 2.1.7 and 3.0 of the November version.

In response to Item 3, it should be remarked that the DTP does not expressly "advocate" usage of any simplified model. This is made particularly clear in the November version of the DTP which incorporated the comments from the NRC internal review.

General Comments

1. The calculational and analytical examples given propose methodologies that may not represent the best or most appropriate approach for repository licensing. The technical position should not limit the approach, but rather allow the use of techniques most appropriate to the particular problem. While the use of a series of Monte Carlo runs based upon Latin Hypercube Sampling in which parameters are treated as random variables has many good features, the NRC should clearly delineate the limitations as well as the strengths of these techniques in the position.

Response

As indicated earlier, the DTP does allow the use of techniques which the license applicant may consider most appropriate. Indeed techniques other than Monte Carlo simulations are acceptable as well, as long as they conform to the general acceptance criteria set forth in the DTP. (Section 1.3, Item 5; Section 2.1.5).

At the time the DTP was written, Monte Carlo simulation based on Latin Hypercube sampling was the best developed technique available. It probably still is.

2. The position should include the use of in-depth sensitivity analyses to identify key parameters affecting degradation and possible failure of the waste package. Techniques such as stepwise regression and/or partial correlation are available to do this.

Response

Sensitivity is addressed briefly in the November version of the DTP (page 5). It is agreed that extra references to sensitivity analysis could be added to the body of the DTP.

3. The use of "relatively simple algorithms" (p.14) may introduce more uncertainty than is desired. In performance assessment analyses, simple models are often used so that Latin Hypercube Sampling may be used. In this case, it appears that the models are being forced to fit a desired statistical technique.

Response

"Relatively simple algorithms" should not be adopted blindly in order to use a sampling technique. The DTP indicates rather than "when such simplifications are needed, the models will require further validation of the simplifying assumptions by comparison against detaled calculations accepted to serve as benchmarks", (Section 3.2.1). This should remove most of the uncertainty.

4. The rigor required in reliability analyses may not be possible with present models and with anticipated limits on the availability of data. The number of runs required to achieve useful results using the sample reliability analysis given in the technical position could be unattainable. It will probably not be possible to analyze available corrosion data with the rigor assumed in the position. Also, available leaching data may be

far too few, too scattered, and show the effect of too many variables to enable this type of reliability analysis. It should be noted that many existing computer programs are set up such that calculations using probability distributions of the input data would not be economical. For example, the Latin Hypercubes Sampling (LHS) is not suitable for a computer program with many variables such as WAPPA. This program has too many parameters for LHS to handle directly. Therefore, this position should be revised to explicitly state that the methods presented are an approach, and other analytical approaches to relaibility analyses that are more appropriate for the available data and analytical models being used are allowed.

Response

This comment addresses items which have been dealt with separately earlier. In particular, the comment is imbued with pessimism about the feasibility of a reliability analysis with the requested rigor. To that effect it should be remarked that "much of the value received from performing a reliability analysis is derived from the act of doing the analysis" as stated in Ref. [1]. Thus, an attempt at a reliability analysis by the DOE can be beneficial in determining areas where further work is required and how such work should be prioritized. An attempt such as this would also provide an answer to the above pessimistic views.

5. Although the NRC regulations are based on failure of the engineered system, this technical position is directed only to the reliability of the waste package. There is no indication of how to factor this analysis into an engineering system failure analysis.

Response

This DTP was written on the specific assumption (page 2) that the applicant will rely primarily on the waste packae portion of the engineered barrier system to achieve controlled release. This appears to be the DOE's position, which has concentrated most of its efforts in this area on the waste package. The methods and principles set forth in the DTP would be applicable to the engineered barrier systems as well.

6. Statistical issues and concepts are not treated as rigorously and precisely as they should be. One example of this is the weakness of definitions in Section 1.2. Suggested alternatives are given under specific comments. Other important statistical concepts such as significance level and confidence level should be more clearly defined and characterized. The concept of confidence level associated with a reliability estimate should be presented in terms of parameter estimation. To do this, relaibility estimates should be defined as estimates of percentiles of life distributions. Similiarly, tests of significance (hypothesis testing) should carefully be defined in the context of their application in this judgement.

Response

This comment needs further consideration. In principle, it is agreed that other definitions could be given.

7. References to "possible" and "impossible" failure modes are not appropriate for reliability analyses. Failure modes may be significant or insignificant, or probable and improbable.

Response

This comment refers to terminology used in Section 1.3. The exact terms, however, are "physicaly possible" vs. "physically impossible" "... in the sense of not violating physical laws." This appear to be an acceptable use of the terms in common engineering practice.

8. The methods proposed in this technical position may have application to the site and seal subsystems, and ultimately to the entire isolation system. A separate technical position, or an expansion of this technical position extending this methodology to these areas as one of several acceptable approaches, is recommended.

Response

We fully agree.

SPECIFIC COMMENTS

Page	Section	
1	1.1	The first paragraph states in part "...the waste package will contain the waste for 300 to 1,000 years (depending on the thermal load to the geologic repository)..." The parenthetical statement appears to relate waste package life solely to the thermal environment. The intent of this statement should be clarified.

Response

This paragraph could be changed by using the specific wording of the rule, or by just removing the insert on the thermal load to the repository.

1	1.1	The third paragraph refers to EPA standards for overall reliability of the repository system which may have been established for guidance in determining waste package reliability. As the overall reliability has not been determined in the EPA standard, there is no guidance for waste package reliability.

Response

True. However, the DTP does not claim the contrary as it refers to reliability requirements which "<u>may have been</u> established" by the EPA.

2	1.2	"Confidence Parameter" appears to be a term created for this technical position that is unfamiliar to the DOE. Either clarification or deletion is recommended.

Response

Clarification will be needed and can be given. However it will not be a trivial task. See also response to comment about "uncertainty factor".

2	1.2	As indicated in general comment six, the definitions should be strengthened. The following modified definitions are suggested alternate definitions to those given in the position that would strengthen and clarify the statistical concepts. These definitions are typical of those to be found in standard text book or reference books on probability and statistics. <u>Sample Space:</u> The set of all possible outcomes of an experiment or trial. <u>Event:</u> Any subset of the sample space. <u>Random Variable</u>: A numerical-valued function defined on a sample space, or a variable whose values are predicted by probabilistic means (either for convenience in modeling or because a deterministic model for its variation is unavailable).

Probability (of an event): There are different philosophies regarding the appropriate definition of probability. The following is a widely accepted standard definition of what is meant by the probability of an event. Let A be an event of sample space S and suppose the experiment which generates the outcome in S is rpeated n times (n independent trials). Let Y be the number of times that A occurs in the n trials. Then the probability of the event A, P(A), is defined as...

Response

The above definitions could indeed be used; however, this would require some additional consideration.

Page	Section	
3	1.3	The first full sentence on page 3 indicates that all the probabilities, and any sensitivities that could be developed, are scenario dependent. In statistical jargon, this fact should be emphasized in terms of conditional probabilistics in the conclusion on page A.20. Otherwise, it may result in a misunderstanding of the 2 percent failure probability presented.

Response

Probability is the limiting value of the relative frequency with which some events occur under stated conditions (Section 1.2). Thus, probability estimates presented in the DTP do depend on the failure modes selected, but they still fulfill the definition of "probability" given above. The extent to which these probability estimates are acceptable, i.e., the extent to which the "stated conditions" are the right ones, is the subject of confidence analysis.

4	1.3	In item 4 and other locations throughout the report, emphasis is given to the development of probability densities for the inputs. The data that will be available may be too sparse or scattered and thus make this impractical. It may not be possible to decide with an confidence which probability density best fits the available data. Rigorous probability densities should be developed only when necessary.

Response

See reply to analogous comment by Mr. Bennett.

Page	Section	
5	2.1	Adequate alternatives to failure mode and effects analysis (item 4) are available and their use should be allowed inthe position.

Response

As long as the applicant lists "all possible, identified failure modes of each waste package component and their retention or dismissal for further analysis," (Section 2.1.4) the spirit of the DTP will be satisfied. One may call such qualitative analysis differently; the DTP simply states that such an analysis is "generally called Failure Mode and Effects Analysis - FMEA".

5	2.1	In item 2 (and under 2.1.2, page 6) "bind" should be "bound".

Response

Yes.

6	2.1.2	Ground-water flux and flow mechanisms should be added to the list of environmental factors of concern. This is necessary to account for sealing failures in shafts and boreholes.

Response

They have been added in the November version (page 7, footnote). Furthermor·, in order to account for conditions in the unsaturated zone, "air composition and flow rate" should be added.

7	Table 1	The inclusion of leaching assumes saturation under the general usage of the term. Degradation modes and environmental factors for the unsaturated conditions are also needed. For instance, other degradation modes may become operative under the expected environmental conditions. The "D" factor (pressure and stress fields) is only important with regard to the waste form condition after the containment period in the unsaturated setting, and/or if a canister failure occurs coinciding with collapse of emplacement hole walls or flooding of the hole so that lithostatic or hydrostatic stresses can be transmitted to the canister and waste form.

Response

The list of degradation modes in Table 1 does not appear to be limiting. It is possible, however, that other environmental factors will be operative in the unsaturated zone, such as the composition of the gas and steam phase next to the canister.

Page	Section	
9	Table 2	Is "resilience" to hydrothermal alteration the intended word?

Response

"Resistance" would be a better word.

11	2.1.7	Design reliability specifications, although useful, are not required by 10 CFR 50 Appendix B, ANSI N 45.2 or ANSI NQA-1.

Response

This is true. However, "reliability requirements of structures, systems, and components including their interactions, which may impair functions important to safety" are suggested by the ANSI/ASME NQA-1-1983 Edition, in its Appendix 3A-1 "Nonmandatory Guidance on Design Control." According to this NQA, design reliability specifications is an item which the nuclear industry has found desirable to consider in the past. Furthermore, it should be noted that component reliability specifications are more to the applicant's advantage than the NRC's, which is only interested in the final, overall reliability of the system. However, the comment could be accomodated by modifying the last sentence as follows: "The level of rigor of the reported distribution functions should reflect design reliability specifications. The latter are integral components of any advanced QA program."

12	3.0	The first and last paragraphs on the page refer to the completeness of the review of reliability considerations and completeness of phenomena considered in failure mode anlaysis. Even after completion of design and formulation, it will never be possible to prove that all failure modes have been considered by repeated review by competent technical persons because of the possibility of the unknown, never-before-thought-of phenomenon. Potential failure modes must continually be scrutinized by such persons. Also, the energy and thought focused on completeness must not detract from that needed to examine the more probable failure modes.

Response

Yes. The DTP, however, does not state the contrary.

13	3.2	Introduction of an extra random variable to account for model uncertainty seems to be an unrealistic means for approaching this problem. It would be simply a "fudge factor" that would carry little information and be difficult to qualify and/or defend in terms of the desired answer. Analytical treatment of uncertainty by developing an equation/model to describe and test components of the

overall model uncertainty would provide more useful information because components of uncertainty associated with various parts of the system model could be identified. If retained, the important statistical properties of the extra random variable should be described and demonstrated in the example.

Response

According to "PRA Procedures Guides" (NUREG/CR-2300, Vol. 1) "There are basic uncertainties with regards to how well the models are able to represent the actual conditions associated with the plant's design, operation, and response to accident conditions. There are obvious limitations in the ability to faithfully represent the real world by analytical models. ...Model uncertainties are acknowledged and addressed by efforts to make models as realistic as possible with compensating assumptions and modeling contraints." The uncertainty factor referred to in the DTP is thus a "safety factor" on model applicability because the model may be based on a theory whose applicability or comprehensiveness may be uncertain or because the model is extrapolated from data whose representativeness may be uncertain, etc. The DTP suggests that this factor be determined based on a Delphi-type method, i.e., polling professionals who have extensive experience in the area where the model should be applied. This process is not rigorous, and, at present, we agree that it is not clear whether it ought to be a point value or a random variable with its own PDF. However, the presence of this uncertainty factor, would add credence in the applicability of the model to the situation at hand by addressing a basic problem in model uncertainty. The DTP should carry some extra clarification regarding this point. This will require extra consideration.

Page	Section	
13	3.2	Paragraph 3 could be interpreted to allow a Monte Carlo simulation as an alternative process to the introduction of the extra random variable described in the previous paragraph. This should be clarified.

Response

I do not see how.

14	3.2.1	(First paragraph) To obtain significance levels of the regression coefficients, one must assume the errors are normally distributed. So if one does study the distribution of the errors and determines they are non-normal, then the significance levels are not valid. In other words, what is being requested may not be appropriate. Some equations will be developed as "conceptual models" for processes where only a few actual data points are known, or perhaps are known for conditions outside the range of conditions expected in the repository. In this case, a complete descriptive statistical analysis would not be justified, but rather non-parametric assessments could be used to establish some degree of confidence in the results.

Response

This will require further consideration.

Page	Section	
14	3.2.1	(Second paragraph) One-dimensional temperature models may not be adequate to simulate the temperature profile. This is another example of forcing the model to fit a desired statistical technique. Models should not be simplified without sufficient justification.

Response

Quite the contrary. The same paragraph also states that "In cases where such simplifications are needed, the models will require further validation of the simplifying assumptions by comparison against detailed calculations accepted to serve as benchmarks."

16	3.2.3	Something is missing in the second sentence, first paragraph.

Response

Nothing seems to be missing.

A-1	App. A	The illustrative example utilizes different methods of establishing input data for the Monte Carlo sampling approach, ranging from rigorous statistical analysis of experimental data to subjective consensus. These methods are chosen on the basis of judgement of the adequacy of the data base and of the behavior of a particular input variable. The position should contain more definitive guidance with respect to the acceptability of this approach.

Response

This paragraph has been improved in the November version of the DTP. The purpose of the limited scope analysis performed there should be more clear in the new, improved version.

A-2	A.3.1	Although codes such as HEATING 6 are too complicated to use in a Monte Carlo type simulation, they could be useful. A comprehensive adjoint sensitivity analysis could be performed on HEATING 6 to determine the key parameters needed in the simplified model and to provide a defensible means of evaluating the simplified model.

Response

Comprehensive, adjoint sensitivity analysis is certainly allowed by the DTP. However, its usefulness can be questioned for several reasons: 1.) Adjoint sensitivity analysis can be hard to apply to codes which can switch from one process to another, e.g., WAPPA; 2.) The adjoint analysis gives sensitivity values around a single design point only. Extrapolation to other points may require redoing the analysis many times depending on the nonlinearity of

the response function; 3.) Each adjoint sensitivity calculation requires storage of the forward solution in both time and space, which can add much to computational complexity and running times; 4.) Model-by-model adjoint sensitivity analysis may hardly give the answers sought for, as sensitivity depends on the overall problem at hand.

Page	Section	
A.9	A.3.2.2	The linear regression that relates uniform corrosion to time may be too simple.

Response

It was not in the purpose of this appendix to obtain the best possible regression.

A.20	A.3.3.1	(Last paragraph) The assumption of a near stagnant solution source term should be considered in future corrosion tests.

Response

Yes.

A.21	A.3.3.1	The comments on leaching rate should include consideration of individual isotopic and synergistic effects.

Response

These are referred to indirectly in Section A.3.3.0.

A.30	A.5	In the first major paragraph, the number of coincident failures, both canister and release rate, should be noted and discussed. The duality of failure mode has been observed previously in the review of the Sandia studies and is a weakness in this approach. Also, in using the approach of randomly selecting parameter values over assigned ranges, it is possible that two or more parameters could be given values which ar physically incompatible (e.g., high porosity and low flow rate). Consequently, results from such single calculations would not be valid. In particular, some apparent (calculated) failures may in fact be impossible or at least highly improbable.

Response

(a) Agreed that something should be said on coincident failures. However, this will not change our results.

(b) Since the Latin Hypercube Sampling plan allows correlation between sampled variables, the problem of assigning values which are physically incompatible can be resolved.

Page	Section	
A.30	A.5	(Second paragraph) The point is made that 2 percent failure probability means that there is a 2 percent chance that all canisters will fail. This would be a very serious failure for a repository and may be unacceptable. Consequently, this failure analysis needs to be examined and discussed in greater detail.

Response

The paragraph does say that this is a common failure mode. This arises from the fact that one is sampling on the possible environment around a canister, and this environment is common to all canisters.

A.32	Table A.5.1	Hydraulic conductivity is represented here by a uniform distribution. The DOE believes that a lognormal distribution is more appropriate.

Response

It may well be that hydraulic conductivity should have a lognormal distribution. Appendix A is for illustration purposes only. This is more clear in the November version of the DTP.

Recommendations

Most of the comments presented by the DOE can be resolved easily by adding a few clarification sentences in the DTP. Indeed some of those comments were already resolved in the November version of the DTP (the DOE's review refers to the May version).

A few other comments require additional consideration. These refer to the initial set of definitions, further clarifications of the concepts of confidence parameter, uncertainty factor, and significance level of a regression analysis coefficient. It may require a few months of man work to resolve these issues satisfactorily.

The comments by the DOE were particularly welcome. We also welcome the DOE's proposal of organizing a reliability meeting. In case such a meeting is called for, we suggest the NRC give BNL enough advance notice to prepare for it.

References

1. J. T. Reilly, 1978. A review of Methods for the Integration of Reliability and Design Engineering, GA-A14748/UC-77, General Atomic Company, San Diego, California.

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