September 14, 2000

Dr. B. John Garrick, Chairman
Advisory Committee on Nuclear Waste
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

SUBJECT: TECHNICAL REPORT ON A PERFORMANCE ASSESSMENT METHODOLOGY FOR LOW-LEVEL RADIOACTIVE WASTE DISPOSAL FACILITIES

Dear Dr. Garrick:

I am responding to your August 2, 2000, letter to the Chairman. In that letter you provided the views of the Advisory Committee on Nuclear Waste (ACNW) on the subject technical report. In particular, the ACNW provides some general comments on the report and recommendations in four specific areas (i.e., use of probabilistic analyses, use of conservative assumptions and parameter ranges, compliance demonstration, and engineered barrier performance).

Based on your letter and staff interactions with the ACNW, the staff understands and appreciates the ACNW's overall support for publishing the report. The staff response to the ACNW's comments and recommendations is presented below.

General Comments: The ACNW was disappointed to learn that the document was now scheduled to be released as a "NUREG [technical report]" and not as a Branch Technical Position (BTP). The ACNW interprets this decision as staff's lack of confidence in the positions expressed. The ACNW also thinks that the value of the document would be diminished if issued as a NUREG. The ACNW knows that there are currently no licenses for low-level waste (LLW) facilities pending and that the U.S. Nuclear Regulatory Commission (NRC) involvement in LLW is minimal. There is no guarantee that this minimal involvement will continue indefinitely, however. Thus, the ACNW believes that care should be taken to provide a sound risk-informed, performance-based (RIPB) foundation for any future activity. The ACNW believes that the staff should state its position and stand by it.

Response: As a result of the public comment process, some respondents expressed the concern that the earlier proposed guidance, particularly in the area of recommended policy approaches (Section 3.2), once finalized, would be viewed as *defacto* NRC standards by virtue of them being put forth as staff positions (i.e., a BTP). This was not the staff's intent. Thus, the change in the status of the guidance from a BTP to a technical report recognizes that the current responsibility for implementation of the national LLW program primarily rests with the States, as directed by the *Low-Level Waste Policy Amendments Act of 1985*. In this regard, it is recognized that the Agreement States are responsible for implementing their regulations, based on their own independent technical judgment. In addition, the staff believes that given NRC's currently reduced role in licensing activities for LLW disposal, there is less of a need for providing specific guidance to staff and licensees, which is the primary purpose of a BTP.

However, the staff believes that the document can be used to share with the Agreement States and potential LLW disposal facility licensees some of the staff's experience and insights on conducting performance assessments.

First Recommendation: In the document, the NRC staff indicates that either a deterministic or a probabilistic analysis is acceptable. In fact, the statement in footnote number 3 – that the staff does not recommend a probabilistic, scenario-driven approach – is antithetical to accepted practices of risk analysis. Although the ACNW realizes that there may be situations in which it is possible to bound the risk clearly and convincingly, as a matter of principle a risk-informed finding requires a risk assessment, however simple or complex it may be. Of course, a risk assessment does not have to be any more complicated than is warranted. The ACNW concurs with the staff's recommendation of an iterative approach, starting with simple models and becoming complex only as needed. The ACNW prefers that simplicity be achieved in the scope of the risk assessment rather than by a substitute analysis that is not risk-informed. The staff should indicate in the technical report that a risk assessment is the acceptable method of safety analysis, the scope of which should be commensurate with the complexity of the facility.

Responses: In specific terms, the staff is aware of the issue that the ACNW has identified concerning the statement made in footnote number 3 [footnote no. 2 in the current version]. The staff's intent here was to communicate the view that the siting requirements found at 10 CFR 61.50 generally discourage the siting of potential disposal sites in areas subject to certain types of disruptive events. By avoiding such sites, the need for a comprehensive scenario analysis (including the potential for human intrusion and assignment of probabilities to scenarios) can be generally avoided.

Nevertheless, to avoid the potential for future confusion in this area, the staff agrees with the ACNW's recommendation and has modified the footnote in question (see bold type) to now read as follows:

> Probabilistic approaches encompass a wide range of analysis techniques and methods. For the purposes of this technical report, the probabilistic approach being recommended refers to the use of a formal, systematic uncertainty analysis to quantify the uncertainty in performance estimates caused by uncertainty in models and parameters. **Although LLW disposal facility developers are free to screen scenarios and assign them probabilities (which is characteristic of some probabilistic approaches), the PAWG [Performance Assessment Working Group] believes that the siting guidelines found at Section 61.50 obviate the need for this step.**

Regarding the specific recommendation that the technical report should indicate that the scope of the risk assessment should be commensurate with the complexity of a candidate site and design, the staff also agrees with this recommendation. Consistent with the Commission's *Final PRA Policy Statement* (NRC, 1995), the following paragraph has been added to the end of Section 2 ("LLW Performance Assessment Process") of the *Executive Summary* and the end of Section 1.8 ("Use of this Technical Report by Other Regulatory Entities") of the main report:

> Finally, consistent with the Commission's views regarding the use of probabilistic risk assessment, the application of the performance assessment techniques to LLW disposal facility designs outlined in this technical report should be tempered according to the complexity of the disposal system, uncertainties associated with system performance, and the estimated risks due to the types and kinds of wastes being disposed.

In addition, to reflect current knowledge about probabilistic performance assessments, a list of updated references supporting the views and recommendations of the staff can now be found in Section B-2 of Appendix B. Section B-2 describes where the new references have been introduced and in many cases, additional text has also been added to the technical report. These additions and updates, as well as some recent editorial revisions, do not change the recommendations and advice provided earlier by the staff.

Second Recommendation: The staff recommends the use of conservative assumptions and ranges of parameters that could effectively bound the reference geologic setting for the site. The ACNW does not agree with this approach in the context of a probabilistic risk assessment. A performance assessment should aim to display the best information available, including uncertainties, about how the system will perform. Conservatism should enter at the point of deciding what it means to "meet the standard." The staff should provide guidance to the applicant to use realistic ranges and distributions of parameter values and conceptual models when conducting [probabilistic] risk analyses.

Response: The staff agrees with this ACNW recommendation. Earlier, in the draft BTP, the staff had generally recommended the use of "...conservative assumptions and ranges of parameters," with the intent of avoiding the potential of underestimating doses to potential receptors. Regardless of whether a deterministic or probabilistic approach is used, the staff believes that an applicant will have to demonstrate, and staff verify, that sufficient technical bases are provided to support the models, that the parameter ranges and distributions are technically defensible, and that uncertainty is adequately addressed. Therefore, consistent with the Commission's general view that probability risk assessments should be realistic, the staff has substituted the word "realistic" for "conservative" in the technical report, when appropriate.

Third Recommendation: For a probabilistic analysis, the staff recommends that the dose standard be evaluated by requiring that the peak of the mean doses (the mean taken across multiple realizations of the model with randomly sampled parameters) be less than 0.25 millisievert (mSv) (25 millirem) and that the 95th percentile be less than 1 mSv (100 millirem). Although this approach aims to incorporate uncertainty in the evaluation, it disregards all information about the distribution of the results except the mean and 95th percentile. A more satisfactory approach is to use the complementary cumulative distribution function. This distribution, when presented as a family of percentile curves, shows all aspects of the uncertainty and is extremely useful for deciding how to employ conservatism into regulating exposures. For example, the standard could be set by requiring that there be less than 1 chance in 10, or 1 chance in 100, or 1 chance in 1000, that the dose will exceed 0.25 mSv (25 millirem) over the compliance period. The staff should consider recommending a complementary cumulative distribution function approach to treating uncertainty in a probabilistic interpretation of the dose standard.

Response: The staff disagrees that the proposed approach for addressing uncertainty disregards all information about the distribution, except the mean and the 95th percentile. Section 3.2.4.3 of the report states that the whole distribution of results should be evaluated to gain insights into the possible disposal facility performance. As explained in Section 3.3.2.3.2 of the report on conducting sensitivity analyses, it is envisioned that the whole distribution curve would be considered, in that the recommended approach calls for looking at both the spread of doses at the time of the peak of the mean dose and also the spread in peak doses. The staff agrees that it may be useful for the regulatory agency to see the whole distribution of results

before making a finding on the compliance demonstration; however, in comparing such a distribution of results against a single dose criteria (i.e., 25 mrem), guidance must be provided on what specific part(s) of the distribution should be used for this purpose. The use of the mean value does take the entire distribution into consideration. Furthermore, to ensure that the high end of the distribution is not unacceptably high, the 95th percentile of the distribution is used to compare to the public dose limit of 1 mSv/year (100 mrem/year).

Fourth Recommendation: The technical report suggests that a 500-year lifetime for engineered barriers may be appropriate. The ACNW previously questioned this particular issue in a letter dated June 28, 1995, and still believes that 500 years is too prescriptive. An RIPB approach would allow a license applicant to establish a case for whatever lifetime was defensible and place the responsibility of evaluating the claim on NRC. An implied requirement for any specific lifetime is inconsistent with existing and draft regulations for high-level waste (HLW). The staff should consider eliminating the suggestion of a 500-year engineered barrier lifetime.

Response: The staff agrees with the basic thrust of the ACNW recommendation that the repository developer can rely on more robust engineered barrier materials, such as those being considered for a HLW geologic repository, and thereby justifying longer periods of performance (i.e., on the order of 100 years or more). In establishing the time period of performance for engineered barriers, the repository developer will need to support his/her design decision with an adequate technical justification that will be evaluated on a case-by-case basis. As noted in the staff's response to *Commonwealth of Pennsylvania Specific Comment No. 2,* found earlier in Appendix B, the technical report has now been modified in a number of places to express this view; however, we are reminded that the LLW regulations themselves explicitly impose a specified lifetime on engineered barriers owing to the waste classification and near-surface disposal concepts described in 10 CFR 61.7(b). For example, the requirements found at 10 CFR 61.7(b)(2) require that waste forms or containers for higher-activity wastes, such as Classes B and C wastes,[1] to the extent practicable, should be "...designed to be stable, i.e., maintain [their] gross physical properties and identity, over 300 years...." In addition, the regulations set forth in 10 CFR 61.7(b)(5) require that human intruder barriers, such as concrete covers, may be necessary for Class C wastes and that the "...effective life of these intruder barriers should be 500 years...." To meet the requirements of 10 CFR 61.7(b)(2, 5), it is still incumbent on the repository developer to support his/her design decision with an adequate technical justification (that will be evaluated on a case-by-case basis).

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[1] As defined by 10 CFR 61.55.

In addition, staff believes that statements on the 500-year performance period are useful guidance. Generally, 500 years will be sufficient for the short-lived radionuclides, in LLW, to decay to insignificant levels. Because of the diminished radiological hazard at about 500 years and because of limitations in data and experience in the performance of engineered barrier materials beyond about 100 years, the staff believes that it is not necessary for LLW disposal facility developers to spend large resources trying to justify engineered barrier performance over periods beyond 500 years. However, decisions regarding engineered barrier performance rest initially with the LLW disposal facility developer, and will be evaluated by the regulatory authority on the basis of the evidence presented.

Finally, the ACNW suggests as a possible resolution of arguments about an appropriate time frame for the performance assessment analysis to decide this issue on a case-specific basis as recommended in a letter from the ACNW to the Commission dated February 11, 1997. The staff did consider the advice of the ACNW, offered in the February 11, 1997 memorandum. In that memorandum, the ACNW recommended the use of a two-part approach to addressing the time-of-compliance issue. The first part would require compliance with the numerical standard over a specified period, and the second part would allow a qualitative evaluation of the robustness of the facility over longer time periods. Use of a such a two-part approach, is consistent with the approach recommended in the technical report. The technical report simply goes one step further by recommending a specific time for use in the first part of the approach. The staff still feels that it is important to specify a specific timeframe in order to provide meaningful guidance on determining compliance with the regulations.

In conclusion, I wish to thank the ACNW not only for its comments on the subject report, but also for all its thoughtful guidance in the past in the development of the report. The ACNW comments and recommendations, along with the staff responses will be included in the final version of the technical report when it is published.

Sincerely,

/RA by Frank J. Miraglia Acting For/

William D. Travers
Executive Director
for Operations

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
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/RA by Frank J. Miraglia Acting For/
William D. Travers
Executive Director
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cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
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