January 17, 2002

The Honorable Richard A. Meserve Chairman U. S. Nuclear Regulatory Commission Washington, DC 20555-0001

Dear Chairman Meserve:

SUBJECT: TOTAL SYSTEM PERFORMANCE ASSESSMENT AND CONSERVATISM

As a result of the Committee's vertical slice review of the staff's issue resolution process and sufficiency review, the Committee issued three letters to the Commission (referenced). In all of these letters, the Committee expressed an overarching concern that over-reliance and inconsistent use of "conservative" assumptions in the TSPA-SR prepared by the US Department of Energy (DOE) precludes a risk-informed analysis. In this letter the Committee would like to clarify further what we consider to be a "risk-informed regulatory decision" and what is meant by a "realistic and reasonable risk-informed performance assessment." In part, the motivation for this letter is derived from the Executive Director for Operations' responses to our letters (referenced).

We want to begin by clarifying what the Committee considers to be the distinction between an "evidence-supported" analysis and an "assumption-based analysis" in performance assessment. In an evidence-supported analysis "evidence" is substituted for "assumptions" wherever possible and, where not possible, the assumptions are supported with the best available scientific information. Assumption-based analysis, on the other hand, is based on arbitrary assumptions that are generally not supported by the available evidence and that are sometimes called conservative assumptions and used to avoid conducting a realistic risk analysis. Furthermore, the Committee's position is that the evidence-supported analysis is synonymous with a defensible and realistic risk-informed analysis, but that the assumption-based analysis is not.

With regard to the "risk-informed regulatory decision," the Committee wants to stress that it recognizes that regulatory decisions must be conservative. We strongly believe that what provides confidence that a regulatory decision is in fact conservative is a defensible analysis of what the real risk is; this means an evidence-supported risk assessment that relies more on quantifying uncertainties than on opaque assumptions about them. The identification of the important contributors to risk, together with an assessment of the origins and magnitudes of the uncertainties of critical risk measures, can only be achieved using a "realistic" performance assessment. Such an analysis provides a reference point for arguments about defense-indepth, conservative assumptions, and quantification of safety margins. Without such transparency in the safety assessment, the question, "How safe is the repository?" is unanswerable. The underlying question of "what is the risk?" must be answered if the concept of conservatism in regulatory decisionmaking is to have a scientific basis. It is in this context that we criticized the TSPA-SR — the spirit of calculating the real risk was not evident. We did

note, however, that DOE has recognized this shortcoming and is taking corrective actions subsequent to the TSPA-SR (e.g., Supplemental Science and Performance Analyses or SSPA). Therefore, we remain optimistic that a risk-informed analysis will be available should a license application be submitted.

The Committee believes that assumption-based conservatism in a performance assessment may not provide an adequate basis for making appropriately conservative regulatory decisions. Lessons learned from applying quantitative risk assessment to other systems, such as nuclear power plants have indicated too often the difference between assumption-based conservatism and evidence-supported, risk-informed conservatism. For example, an early assumption in the nuclear industry was that the design-basis accident for nuclear power plants involving *large break* loss-of-coolant accidents was a conservative representation of the risk of a nuclear plant accident. Although this approach resulted in a very safe nuclear power industry, it was not a risk-informed, conservative representation. In fact, risk-informing nuclear power plant safety revealed that the major contributors to risk came from such events as *small break* loss-of-coolant accidents, losses of offsite power, transients, and such external events as fires and earthquakes. What was thought to be a conservative approach led, in fact, to a nonconservative representation of the major contributors to risk. Simply put, decisions that are founded on assumption-based conservatisms are prone to mistakes.

As for the Committee's position on a "realistic and reasonable risk-informed performance assessment," we note that DOE's approach in its TSPA-SR presumed that a large number of assumption-based conservatisms embedded in a very complex analysis would lead to a demonstration of conservatism in the overall performance of the repository. The Committee questions this premise. For example, assumptions about complex coupled processes are not obviously conservative from a risk perspective — at least they are not obviously conservative to the Committee. In preparing its TSPA-SR, DOE's strategy has been to make conservative or bounding analyses of many of the coupled processes to simplify their treatment. The Committee agrees that where it is possible to screen an issue by doing a simple bounding analysis, it should be done. The problem arises in identifying which conservative or bounding analyses are reasonable. For the TSPA-SR, the supporting evidence for many assumptions is often obscure. Thus, a finding of conservatism from a risk perspective is often difficult to conclude. We believe that coupled processes and their sometimes nonlinear behavior could be underrepresented contributors to risk. Our position is that the contribution to risk from coupled processes should be quantified and made transparent. The quantification should include an uncertainty analysis and the identification of risk contributors based on the evidence.

The evaluation of risk depends on both the likelihood of an event and its consequences. Thus, an assumption-based, "conservative" performance assessment can be doubly wrong in terms of representing risk. This can result in unnecessary expenditures, increased worker exposure, and unjustified burdens on society. In addition, while it is the NRC's primary responsibility to protect the health and safety of the public and the environment, it is also the Commission's responsibility to enable society to receive the benefits of the nuclear industry (energy, medicine, and industrial processes). Numerous assumption-based conservatisms can underestimate — as well as overestimate — the actual risk, just as it can unintentionally deny society important benefits. Our view is that the appropriate way to introduce conservatism into regulatory decisions is to base safety margins on a realistic assessment of risk, where risk includes the guantification of uncertainty.

SUMMARY

- The Committee believes that risk-informed regulatory decisionmaking should be conservative, but be based on realistic and reasonable analyses.
- A risk-informed performance assessment should be a realistic representation of the risk, including a quantification and importance ranking of the sources of uncertainty. That is, the performance assessment should represent the best attempt of the experts at quantifying the risk, and it should not be obscured by assumption-based conservatisms.
- The use of the assumption-based conservative analysis for performance assessment compromises the regulator's ability to quantify defensible safety margins.
- Assumption-based modeling conservatisms can be wrong in both the likelihood and consequences of events and may not result in the best risk-informed regulatory decisionmaking.

Sincerely,

/RA/

George M. Hornberger Chairman

References:

- 1. Letter dated September 18, 2001, from George M. Hornberger, Chairman, ACNW, to Richard A. Meserve, Chairman, NRC, Subject: Total System Performance Assessment-Site Recommendation.
- 2. Letter dated November 29, 2001, from William D. Travers, Executive Director for Operations, NRC, to George Hornberger, Chairman, ACNW, Subject: Response to the ACNW Letter Dated September 18, 2001, on Total System Performance Assessment --Site Recommendation (TSPA-SR), Which Provided Recommendations to the US NRC Staff.
- 3. Letter dated September 28, 2001, from George M. Hornberger, Chairman, ACNW, to Richard A. Meserve, Chairman, NRC, Subject: ACNW Comments on NRC Staff's Issue Resolution Process for Risk-Informing its Sufficiency Review of DOE's Technical Basis Documents for the Yucca Mountain Site Recommendation.
- 4. Letter dated November 20, 2001, from William D. Travers, Executive Director for Operations, NRC, to George M. Hornberger, Chairman, ACNW, Subject: Response to the Advisory Committee on Nuclear Waste Letter dated September 28, 2001.
- 5. Letter dated August 13, 2001, from George M. Hornberger, Chairman, ACNW, to Richard A. Meserve, Chairman, NRC, Subject: Review of Chemistry Issues and Related NRC Staff Capability for the Proposed High-Level Waste Repository at Yucca Mountain.
- 6. Letter dated October 16, 2001, from William D. Travers, Executive Director for Operations, NRC, to George M. Hornberger, Chairman, ACNW, Subject: Review of Chemistry Issues and Related NRC Staff Capability for the Proposed HLW Repository at Yucca Mountain.