UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON NUCLEAR WASTE
WASHINGTON, D.C. 20555

March 26, 1998

The Honorable Shirley Ann Jackson
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Chairman Jackson:

SUBJECT: RISK-INFORMED, PERFORMANCE-BASED REGULATION IN NUCLEAR WASTE MANAGEMENT

The Advisory Committee on Nuclear Waste (ACNW) welcomes the opportunity to provide input to the Commission on its draft white paper on risk-informed, performance-based regulation (RIPBR) and to clarify the issues and concepts associated with implementing a risk-informed regulatory process. The ACNW supports the development of a basic document that provides a common terminology for the RIPBR approach and that elucidates how the associated concepts can be applied to both reactor and materials regulation across the agency. Moving to an RIPBR approach will help to develop more efficient and effective regulatory measures that focus directly on public safety and will provide a basis for optimizing the regulations.

The ACNW believes that it is essential to develop a broad understanding of RIPBR throughout the agency. Because of the fundamental technical and regulatory differences among reactor systems, waste management and disposal systems, and nuclear materials management systems, it is important that the concepts articulated in the white paper be sufficiently general to encompass all of these activities and regulations. Many of the concepts in the paper are oriented toward reactor applications. The ACNW believes that the context or framework should be broadened for applying RIPBR to the management of radioactive waste and nuclear materials. The ACNW's recommendations and comments that follow are intended to help provide such a framework.

Comparisons Between Nuclear Waste Disposal and Reactor Applications

The primary differences between nuclear power plants and waste disposal facilities are the type of facilities involved and the nature and timing of the events that can lead to a threat to public safety. The events in the nuclear plant risk scenarios are related primarily to short-term equipment and human error problems, while in waste disposal facilities, they are related primarily to long-term physical processes. Waste release events generally take place over hundreds and thousands of years, while times of concern in a nuclear plant may be fractions of a second or a day. Containment in a nuclear waste facility is provided by both natural and generally passive engineered systems, while in a nuclear plant, except for basic structures and atmospheric dispersion, active systems and short-term operator response dominate the mitigation of accidents. Monitoring capability differs greatly between the two. In general,

monitors for reactor performance are on-line with short response times. For waste facilities, there are extreme limitations on monitoring reliability because of the very long times involved and the general difficulty in measuring parameters affecting an eventual threat to public safety. Differences between nuclear plants and waste disposal facilities point to the need for sufficiently fundamental concepts and definitions that embrace the full spectrum of activities regulated by the NRC.

Definitions of Terms and Concepts

Risk and Risk Assessment

The Committee believes that the definition of risk in Section 3, page 2 of the white paper is too narrow. Risk measures need to be interpreted in terms of a fundamental set of principles that serve the broad scope of activities regulated by the NRC. The ACNW recommends adoption of the *triplet definition of risk*[1] because it defines risk at a sufficiently fundamental level to apply to the wide variety of nuclear materials applications that the NRC regulates. This definition may be incorporated in a section added to the white paper before the numbered paragraphs. The triplet definition takes the view that when one asks, "What is the risk?" one is really asking three questions: "What can go wrong?" "How likely is it?" and "What are the consequences?"

The first question, "What can go wrong?" is usually answered in the form of a "scenario" (a combination of events that could occur) or a set of scenarios. Examples in the nuclear materials field include events causing early failure of the engineered barrier system in a waste repository or loss of a sealed source.

The second question, "How likely is it?" can be answered in terms of the available evidence and the processing of that evidence to quantify the uncertainties involved. In some situations, data may exist on the frequency of a particular type of occurrence or failure mode (e.g., actuarial data on losses of sealed sources or accidental overexposures). In other situations, there may be little or no data and a Bayesian approach for analyzing uncertainties will be required.

The third question, "What are the consequences?" assesses, for each scenario, the probable range of outcomes (e.g., radionuclide release rates or dose to the public) given the uncertainties. From this assessment, the important scenarios can be identified. The outcomes or consequences are the "end states" of the analyses. The choice of consequences, that is, the measures of risk, can be whatever seems appropriate for reasonable decisionmaking in a particular regulated activity. The choice could involve combinations of end states or even non-safety consequences, such as technical feasibility, cost, and schedule (i.e., programmatic risk).

Traditional and Probabilistic Approaches

The triplet definition of risk and risk assessment provides a clear framework for distinguishing between what many practitioners and regulators refer to as *deterministic* and *probabilistic*

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[1] Kaplan, S., and B. J. Garrick, "On the Quantitative Definition of Risk," *Risk Analysis,* Vol. 1, No. 1, March 1981.

analyses. The ACNW recommends that Sections 1 and 2 in the white paper be modified to incorporate the concepts discussed below. In particular, traditional deterministic safety analysis addresses only two of the three risk questions in an explicit manner (i.e., "What can go wrong?" and "What are the consequences?"). Such questions have always been the building blocks of so-called deterministic safety analysis, even in arriving at the design-basis accident. Thus, safety analysis is seen to be a subset of risk analysis. It is not a matter of deterministic analysis versus probabilistic analysis, but more a question of expanding the scope of the analyses to include consideration of likelihood in a direct manner. In simple, well-understood systems, likelihood may be easy to establish with reliability. In more complex situations, such as a waste repository analysis, the definition of likelihood becomes the central challenge.

Risk Assessment and Defense in Depth

The white paper discusses *defense in depth* (DID) in footnotes 1 and 4. The ACNW specifically endorses the Advisory Committee on Reactor Safeguards' (ACRS) recommendations[2] to modify footnote 1 and delete footnote 4. As currently drafted, footnote 4 does not recognize the difficulty in assessing the performance of multiple-barrier systems in the waste management licensing arena. The ACNW recommends that the DID concept be discussed in the main body of the paper with respect to the following issues. The white paper should make the point that a "risk-informed" approach implies quantification of all elements of defense. Although the uncertainties of some elements of defense may be substantial, the fact that they have been identified can greatly aid in deciding how much defense makes regulatory sense.

The concept of DID has always been, and should continue to be, a fundamental tenet of regulatory practice in the nuclear field. In a risk-informed era, the opportunity exists to make DID transparent. In particular, the tools of probabilistic risk assessment (PRA) and performance assessment (PA) should be challenged to expose the capability of all elements of defense. Good decisions on the adequacy or the necessity of elements of defense can be made only through identification of the individual performance of each defense system in relation to overall performance. A clear display of the uncertainties associated with each defense system is essential. The connection between elements of defense and overall performance measures, including their individual uncertainties, allows implementation of the DID concept.[3]

Risk Based and Risk Informed

The Committee agrees in principle with the distinction made in Sections 4 and 5 of the white paper between *risk based* and *risk informed,* whereby the former implies that decisions must be

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[2] Letter dated March 11, 1998, from R. L. Seale, Chairman, ACRS, to Shirley Ann Jackson, Chairman, NRC, Subject: ACRS Comments on Draft Paper on Risk-Informed, Performance-Based Regulation.

[3] Letter dated October 31, 1997, from B. John Garrick, Chairman, ACNW, to Shirley Ann Jackson, Chairman, NRC, Subject: Recommendations Regarding the Implementation of the Defense-in-Depth Concept in the Revised 10 CFR Part 60.

based *exclusively* on risk assessment results, while the latter implies that decisions are based on risk in conjunction with other information. The Committee believes that a risk assessment is not a decision analysis, per se, and that risk-based approaches to decisionmaking must consider other factors, such as costs, benefits, and socio-political issues, in addition to risk.

The Committee does not agree, however, with the implication in the white paper that factors such as "the basis for current regulations, engineering analysis and judgment, and the defense-in-depth philosophy" are outside the boundaries of risk assessment. These factors affect the uncertainties of the risk measures — uncertainties that should be part of a complete risk assessment. There is nothing about the triplet definition of risk that implies that risk assessment cannot include these factors.

Performance Based

Section 6 of the white paper titled "Performance-Based" needs to be rewritten to reflect a much broader use of the term in all NRC regulations. The current waste regulations, including 10 CFR Part 60, high-level waste (HLW); 10 CFR Part 61, low-level waste; and the decommissioning rule, contain performance objectives and criteria, which are generally based on calculated dose, as key regulatory requirements. These are *performance-based* approaches. The discussion in Section 6, pages 4-6 of the white paper, does not appear to recognize that dose-based approaches are fundamentally *performance based.*

The ACNW believes that one of the major differences between materials and reactor licensees occurs in the case of performance-based regulations. For example, the first and third attributes of performance-based regulations mentioned in the white paper fail in the case of HLW regulations (10 CFR Part 60). The first attribute indicates that monitoring is essential, but the assessment of performance by monitoring of closed geological repositories is an unresolved issue. The third attribute might be taken to imply that subsystem requirements are a necessary part of the regulations. Such an interpretation runs counter to RIPBR.[4] The white paper does acknowledge these differences in footnote 4, but because possible misinterpretation of the definition of "performance-based regulations" may create an ambiguity in the HLW licensing process, the definitions should be more explicitly stated.

Regulatory Burden

The white paper, which discusses the issue of regulatory burden in Section 5 on page 4, should be augmented to address the following issue. The Committee is concerned that the spirit of the PRA Policy Statement is compromised if *risk-informed* continues to be interpreted (in the regulatory field) as *in addition to*, rather than as a *substitute for* outdated regulations. The Committee agrees that a careful transition to greater use of risk methods in regulatory decisionmaking is necessary. Although the PRA Policy Statement promises a reduced burden on licensees, the commitment by the NRC to address this issue is weak. What appears to be missing is a clear indication of how and when the regulatory relief implied in the PRA Policy

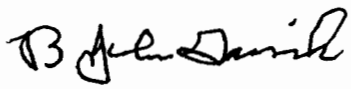
[4] See footnote 3

Statement will occur. The ACNW recognizes that the white paper is not the place to establish policy, but there is an opportunity to clarify this issue by addressing "reduction in licensee burden" explicitly in the paper.

Closing Comments

This letter has discussed RIPBR primarily in relation to geological repositories and nuclear waste isolation. Risk assessment is the essential basis upon which the overall safety of a potential repository will be judged. While very different in detail, PRA of nuclear power plants and PA of geological repositories are similar in terms of system complexity and the application of probabilistic methods to the determination of safety. The PA experience base of Yucca Mountain and the Waste Isolation Pilot Plant, together with the extensive PRA experience with nuclear power plants, provides a varied and extensive risk assessment landscape for considering the applicability of basic definitions and concepts. In simpler situations, the risk may be relatively well defined. Examining the definitions and concepts recommended in this letter against such a wide spectrum of applications gives the Committee high confidence in their applicability to all the nuclear materials regulated by the NRC. However, this conclusion presumes an extremely flexible framework for the implementation of RIPBR across the full spectrum of the materials, processes, and facilities regulated by the NRC. This is the underlying point of our recommendations. We believe such a framework is necessary and feasible. We appreciate the opportunity to offer our views on how to make the subject white paper serve this extremely important purpose.

Sincerely,



B. John Garrick
Chairman