November 2, 2000

MEMORANDUM TO: Thomas L. King, Director
Division of Risk Analysis and Application
Office of Nuclear Regulatory Research

FROM: Farouk Eltawila, Acting Director **/RA/**
Division of Systems Analysis and Regulatory Effectiveness
Office of Nuclear Regulatory Research

SUBJECT: UPDATED MEDIA BRIEFING PAPER ON RISK-INFORMED AND PERFORMANCE-BASED REGULATION

The attachment to this memorandum is the updated media briefing paper on risk-informed and performance-based regulation. The concepts and discussions are derived from the recent SECY-00-0191, “High-Level Guidelines for Performance-Based Activities.”

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Risk-Informed and Performance-Based Regulation

The NRC has established its regulatory requirements, in both reactor and materials applications, to ensure that "no undue risk to public health and safety" results from licensed uses of Atomic Energy Act (AEA) materials and facilities. Most of NRC's regulations were developed without the benefit of quantitative estimates of risk. There have been significant advances in and experience with risk assessment methodology since 1975. Thus, the Commission is advocating certain changes to the development and implementation of its regulations through the use of risk-informed, and ultimately performance-based, approaches.

The transition to a risk-informed regulatory framework is expected to be incremental. Many of the present regulations are based on deterministic and prescriptive requirements that cannot be quickly replaced. The perceived benefits of the deterministic and prescriptive regulatory requirements were based mostly on experience, testing programs and expert judgment, considering factors such as engineering margins and the principle of defense-in-depth. The current requirements will have to be maintained while risk-informed and/or performance-based regulations are being developed and implemented.

It is important that the NRC, the regulated community, and the public at large have a common understanding of the relevant terms and concepts involved; an awareness of how these concepts (in both reactor and materials arenas) are to be applied to NRC rulemaking, licensing, inspection, assessment, enforcement, and other decision-making; and an appreciation of the transitional period in which the agency and industry currently operate.

Risk and Risk Assessment: The risk 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 and/or conditions that could occur) or a set of scenarios. 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 probability and the uncertainties involved. In some situations, there may be little or no data and a predictive approach for analyzing probability and uncertainty will be required. The third question, "What are the consequences?" can be answered for each scenario by assessing the probable range of outcomes (e.g., dose to the public) given the uncertainties.

Deterministic and Probabilistic Analyses: The current body of regulations, guidance and license conditions is based largely on deterministic analyses and is implemented by prescriptive requirements. The deterministic approach involves implied, but unquantified, elements of probability in the selection of the specific accidents to be analyzed as design basis events. A deterministic analysis explicitly addresses only two questions of the risk triplet. Probabilistic analysis explicitly addresses a broad spectrum of initiating events and their event frequency. It then analyzes the consequences of those event scenarios and weights the consequences by the frequency, thus giving a measure of risk. There is now the opportunity to enhance the traditional approach by more explicitly addressing risk and incorporating the insights thus gained.

Risk Insights: The term "risk insights" refers to the results and findings that come from risk assessments. Risk insights have been incorporated successfully into numerous regulatory activities, and have proven to be a valuable complement to traditional deterministic approaches.

Risk-Based Approach A "risk-based" approach to regulatory decision-making is one in which such decision-making is solely based on the numerical results of a risk assessment. The NRC does not endorse an approach that is "risk-based". For example, it may not be appropriate to consider issues related to steam generator performance in a risk-based framework.

Risk-Informed Approach: A "risk-informed" approach to regulatory decision-making represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety.

Risk-Informed Approach and Defense-in-Depth: The concept of defense-in-depth[1] has always been and will continue to be a fundamental tenet of regulatory practice in the nuclear field. Risk insights can make the elements of defense-in-depth more clear by quantifying them to the extent practicable. Quantified elements and uncertainties can aid in determining how much defense-in-depth makes regulatory sense.

Performance-Based Approach: A regulation can be either prescriptive or performance-based. A performance-based regulatory approach is one that establishes performance and results as the primary basis for regulatory decision-making. A performance-based requirement relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, but provides more flexibility to the licensee as to the means of meeting those outcomes. A performance-based approach can be implemented without the use of risk insights.

Risk-Informed, Performance-Based Approach A risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment including the principle of defense-in-depth and the incorporation of safety margins, and performance history are used, to (1) focus attention on the most important activities, (2) establish objective criteria for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, (4) provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes, and (5) focus on the results as the primary basis for regulatory decision-making.

CONTACT: N. Prasad Kadambi

REFERENCE: These definitions are contained in the Commission White Paper on this subject, which can be located at <www.nrc.gov/NRC/COMMISSION/SRM/ 1998-144srm.html>.

[1]Defense-in-depth is an element of the NRC's Safety Philosophy that employs successive compensatory measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges.