ACRSR-1865

November 17, 1999

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

Dear Chairman Meserve:

SUBJECT: IMPLEMENTING A FRAMEWORK FOR RISK-INFORMED REGULATION IN THE OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

During the 113th meeting of the Advisory Committee on Nuclear Waste (ACNW), October 12-13, 1999, and the 467th meeting of the Advisory Committee on Reactor Safeguards (ACRS), November 4-6, 1999, the Committees considered the staff's proposed framework for risk-informed and performance-based regulation in the Office of Nuclear Material Safety and Safeguards (NMSS), as articulated in SECY-99-100 and an associated Staff Requirements Memorandum dated June 28, 1999. A meeting of the ACRS/ACNW Joint Subcommittee was held on May 11, 1999, to discuss these matters. We had the benefit of the documents referenced.

Recommendations

1. NMSS should develop a set of principles and a safety goal approach for each of its regulated activities to guide its implementation of risk-informed and performance-based regulation.

2. NMSS should identify the analytical methods to be applied to implement risk-informed and performance-based regulation on an application-specific basis.

Discussion

The NMSS staff is examining the use of risk information in four major categories of regulated activities: (1) long-term commitment of a site to the presence of nuclear material (e.g., high-level waste disposal); (2) use of engineered casks to isolate nuclear material under a variety of conditions (e.g., transportation and storage); (3) physical and chemical processing and possession of nuclear material at a large-scale facility (e.g., fuel fabrication); and (4) use of sealed or unsealed byproduct material in industrial and medical applications. The objectives of

this examination are to focus regulatory activities on matters that are important to safety and avoid unnecessary burdens on licensees and the NRC staff.

The diversity of the four categories of activities listed above indicates that the risk assessment methods for material licensees are likely to be different from those for nuclear power plants. While quantitative risk assessment is a well-developed and utilized tool for nuclear power plant licensees, it may be unnecessarily complex for the NMSS regulated activities. The performance assessments (PAs) done for waste repositories are conceptually similar to probabilistic risk assessments (PRAs) for reactors. Recently, there have been developments for simplified approaches to quantitative risk analysis, e.g., integrated safety assessments (ISAs), that are less rigorous than PRAs or PAs.

The staff must address two crucial issues as it considers risk methods in the regulation of material licensees:

1. What criteria should be used to decide whether the regulations for a specific nuclear materials activity should be changed to a risk-informed regulation? Can the current deterministic criteria, accounting methods, or proposed approaches such as ISA accomplish risk-informed objectives?

2. What risk analysis methods (and scope) and risk acceptance criteria should be applied to the operations that merit risk-informed regulation?

To address the first question, we believe that the staff will need to develop a set of principles for risk-informed regulation. Such a set of principles is important to guide the need for and change from a prescriptive form of regulation to a less prescriptive, but risk-informed, method of regulation. In developing these principles, the staff should take full advantage of the knowledge base unique to materials and waste disposal regulation, as well as the staff's experience in developing principles for other regulatory applications, such as Regulatory Guide 1.174.

Some of the characteristics of nuclear materials regulation that differ from reactor regulation include: (1) experience in regulating to radiation exposure standards, as opposed to surrogate measures such as facility damage, (2) diversity of types of licensee activities involving major differences in materials, facilities, and practices, (3) activities not dominated by a clear-cut feature such as core damage, and (4) activities where the operational risk, as opposed to the accident risk, may be the central issue of risk regulation. Although these characteristics distinguish materials regulation from reactor regulation, the Committees believe that the approach to regulatory decisionmaking for the NMSS activities should have a basis that is consistent with the approach for reactor regulation.

An important element introduced in Regulatory Guide 1.174 and that should be investigated in the present context of materials regulation is that regulatory decisionmaking should be based on an analytic and deliberative process. Analytical results from risk assessments and other engineering analyses are only part of the input to this process. Qualitative inputs, e.g., the preservation of the defense-in-depth philosophy, may be considered by an expert panel or other decisionmaking entity. In developing the new principles, the staff should consider this approach and its applicability to the various NMSS activities. If qualitative information is to be used in the

decisionmaking process, then the reason(s) should be explained. If there is a need for an expert panel for some activities, its form and composition should be discussed.[1]

Consideration should be given to developing variations on the safety goal approach to risk acceptance. One variation may be to include uncertainty directly in the risk acceptance criteria via required confidence levels in their determination. Another may be to define acceptance criteria that are either met or not, i.e., the range of risk is partitioned into two regions, the acceptable and unacceptable regions. Another might be to adopt a three-region approach. In this concept, there is a range of acceptability with an upper and lower bound. The lower bound constitutes the level below which no further action is required. The upper bound constitutes a level above which definitive action to control the risk is required. The middle region is the region in which cost-benefit tradeoffs can be made. These are a few concepts that should be investigated by the staff for materials regulation. There may be others.

The Committees believe that, just as "guiding principles" are important to establishing a well-founded philosophy of risk-informed regulation, so are certain risk assessment concepts. The representation of risk as a triplet set is such a guiding concept. The triplet consists of accident scenarios (what can go wrong?), probabilities of these scenarios (how likely is each scenario?), and the consequences (what are the consequences?). We view the various risk (or safety) assessment methods that exist in the literature as dealing with these three elements of the risk triplet in different ways. PRAs for reactors and PAs for HLW repositories offer the most complete treatment of the triplet, and they require the most resources. We believe that the staff should clarify how any chosen method deals with the risk triplet (either quantitatively or qualitatively) and justify the appropriateness of the selected scopes as differentiated among the four major categories of NMSS licensees. If methods that are less rigorous than PRAs or PAs are judged to be appropriate for certain applications, their treatment of the triplet should be explicitly identified. The reasons for resorting to these less rigorous methods should be carefully justified. We are especially concerned about the completeness of the scenario list and the analysis of uncertainties.

We look forward to reviewing staff activities on these matters during future meetings.

Sincerely,

/s/	/s/
B. John Garrick	Dana A. Powers
Chairman, ACNW	Chairman, ACRS

[1] This concept of an expert panel refers to the discussion on integrated decisionmaking in Regulatory Guide 1.174. The purpose of such an expert panel is to evaluate multiple sources of information to make decisions in an integrated manner. This is different from the guidance in the "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program," NUREG-1563, that refers to a specific formalized process for developing information and "data" to be used in a performance assessment.

References:

1. Memorandum dated June 28, 1999, from Annette Vietti-Cook, Secretary, NRC, to William D. Travers, Executive Director for Operations, NRC, and John T. Larkins, Advisory Committee on Reactor Safeguards, Subject: Staff Requirements - SECY-99-100 - Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards.
2. SECY-99-100, Memorandum dated March 31, 1999, from William D. Travers, Executive Director for Operations, NRC, to the Commissioners, Subject: Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards.
3. Memorandum dated February 24, 1999, from Annette Vietti-Cook, Secretary, NRC, to William D. Travers, Executive Director for Operations, NRC, Subject: Staff Requirements - SECY-99-144 - White Paper on Risk-Informed and Performance-Based Regulation.
4. Report dated April 19, 1999, from Dana A. Powers, Chairman, Advisory Committee on Reactor Safeguards, to Shirley Ann Jackson, Chairman, NRC, Subject: Status of Efforts on Revising the Commission's Safety Goal Policy Statement.
5. U.S. Nuclear Regulatory Commission, Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," July 1998.
6. U.S. Nuclear Regulatory Commission, NUREG-1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program," November 1996.