March 17, 1997

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

Dear Chairman Jackson:

SUBJECT: PROPOSED STANDARD REVIEW PLAN SECTIONS AND REGULATORY GUIDES FOR RISK-INFORMED, PERFORMANCE-BASED REGULATION

During the 437th, 438th, and 439th meetings of the Advisory Committee on Reactor Safeguards, December 5-7, 1996, February 6-8, and March 6-8, 1997, respectively, we met with representatives of the NRC staff, industry, and other interested parties to review the proposed Standard Review Plan (SRP) sections, Regulatory Guides, and other matters associated with risk-informed, performance-based regulation. We discussed the staff's approach to codify risk-informed, performance-based regulation into a general guidance SRP section and an associated Regulatory Guide, as well as related documents for technical specifications, inservice testing, and graded quality assurance. We also discussed industry views and initiatives related to these matters. In addition, our Subcommittee on Probabilistic Risk Assessment (PRA) met with the staff and industry representatives to discuss these documents on October 31, November 1, 21, 22, 1996, and January 28, February 20 and 21, 1997. We also had the benefit of the documents referenced.

Conclusions and Recommendations

1. The draft Regulatory Guide DG-1061 (General Guidance) and the associated SRP Chapter 19 that provide guidance for making risk-informed changes to the current licensing basis of individual plants constitute a significant achievement. They, and in particular the stated principles, provide the foundation for risk-informed regulatory philosophy that can better focus resources and can lead to a more coherent regulatory structure. These documents should be issued for public comment. The staff has formulated questions that should elicit the public comments needed to refine and improve these draft documents.

2. The draft Regulatory Guides for application of risk-informed decisionmaking to technical specifications (DG-1065) and in-service testing (DG-1062) have been developed consistent with the principles articulated in the General Guidance (DG-1061). These Regulatory Guides and associated SRP sections should be issued for public comment. The proposed guidelines for acceptability of allowed outage time changes are based on the

incremental conditional probability of core damage and large, early release. Such guidelines could also include limits on the maximum conditional annual core damage frequency (CDF) and large, early release frequency (LERF). This alternative is one of the questions included in the proposed Federal Register notice, and we believe that final resolution of this issue can be postponed until public comments on this matter have been received.

3. The version of the Regulatory Guide that we reviewed for application of risk-informed decisionmaking to graded quality assurance (DG-1064) took an unnecessarily timid approach toward focusing stringent quality assurance activities on highly risk-significant systems, structures, and components (SSCs) and defining adequate, but less exacting, quality assurance demands on areas of low risk significance. There should be a clear justification based on PRA or other compelling reasons for classifying SSCs as belonging to the high-safety-significant category. Issuance of this draft Regulatory Guide in this form for public comment could erroneously reinforce the wide-spread suspicion that risk-informed regulation is simply an additional layer of regulation imposing burden without tangible benefit. The staff is currently working to revise this document, and we are confident that the revised version will, in large measure, address our concerns. Since there is intense industry interest in this Regulatory Guide, we have no objection to the staff's proposal for issuing this document for public comment.

4. The successful implementation of the new regulatory philosophy will require a change in culture for both the NRC staff and the industry. A vigorous program should be established to communicate the risk-informed philosophy through workshops and other means planned by the staff.

5. The Commission should consider issuing a statement inviting licensees to propose new and innovative approaches to risk-informed, performance-based regulation using the concepts articulated in the General Guidance (DG-1061). The review and approval processes may need to be revised to provide timely responses to licensee submittals, which will necessarily cross disciplinary and organizational lines.

6. Appendix B of DG-1061 provides a method for estimating LERF in the absence of a Level 2 PRA. We recommend that some approaches also be developed for estimating the contributions of external events to CDF and LERF, as well as from low-power and shutdown operations when detailed PRAs are not available.

Discussion

It has been about 22 years since the Reactor Safety Study (WASH-1400) introduced PRA to the reactor safety community. During this time, PRA methods, especially those for internal events during power operations, have matured to the point that PRA insights are increasingly being utilized in risk management both by the staff and licensees. However, formal guidance as to how PRA results can

be used in the regulatory arena has been lacking. The documents that the staff has prepared provide such guidance. They constitute a major step forward in the development of a more risk-informed regulatory process.

Formulation of the guidance in terms of a basic set of principles creates a foundation for the new regulatory philosophy. We believe this to be a sound and significant achievement. It provides the starting point for the integration of traditional engineering approaches to safety, such as defense-in-depth, and the new probabilistic approach. The implementation of the General Guidance will evolve as experience is gained. We are confident, however, that a good start has been made.

The efforts to understand how the concepts of defense-in-depth and safety margins can be considered in the context of PRA must be applauded and encouraged. They provide very useful insights regarding the intent of these cornerstones of traditional reactor safety philosophy and the extent to which they are reflected in the PRA results.

We agree with the use of an "integrated" process in risk-management situations. It is clearly recognized that decisionmaking cannot rely solely on numerical results from either the PRA or more traditional approaches. We note that this integrated approach to decisionmaking is akin to the concept of the inclusion of "deliberation" in reaching risk-management decisions, as discussed in a recent report by the National Research Council Committee on Risk Characterization.

A first reading of the proposed SRP sections and associated Regulatory Guides creates the impression that they impose an onerous burden and are difficult to understand. We believe that the potential benefits clearly outweigh this burden and merit the effort to implement the new philosophy.

At this time, many of the staff and the industry may still not believe that risk-informed regulation is real or may have difficulty in making the transition to risk-informed decision-making. We are, therefore, very pleased to hear that the staff plans to organize workshops and public meetings to explain the new regulatory philosophy.

Interaction with industry is needed to ensure that the industry realizes its responsibility to provide the staff with the information needed to make meaningful risk-informed decisions. To a large extent, the benefits of a risk-informed approach will be in proportion to the attention to accuracy and completeness of the industry's PRAs. There probably are licensees that have not yet done enough with their current PRAs to be able to garner significant benefit from a risk-informed approach to regulation. The new approach may, in the beginning, require additional industry effort. This is understandable and should be considered in the context of potential increases in safety and reductions in regulatory burden.

Graded quality assurance is a quintessential subject for

application of risk-informed decisionmaking. Risk information should be the rational basis for adjudicating the level of quality assurance effort needed to provide confidence that SSCs will perform their safety functions reliably. The staff is currently planning to use risk information only to reduce quality assurance requirements for SSCs in the low-safety-significant category. We believe there is a better approach to using risk information to classify SSCs according to quality assurance needs than that described in the draft Regulatory Guide. Greater discrimination among the quality assurance needs will better focus licensee and regulatory attention on risk-important topics. Such a focus may not be achieved by simply using risk information to define reductions in licensee burdens associated with quality assurance for low-safety-significant items.

The approach proposed in Appendix B of DG-1061 for estimating LERF in the absence of a Level 2 PRA needs to be supported with additional documentation. Although this approach may be appropriate for screening purposes, additional probabilistic analyses using plant-specific values may be necessary for plants that do not meet the LERF guidelines.

We express our appreciation for the staff's cooperation during this long process. We have had excellent discussions of both concepts and methods during our meetings. The staff was always willing to listen and debate with us. The frequent interactions between the staff and the Committee were very valuable and constructive.

Sincerely,

/s/

R. L. Seale
Chairman

References:

1. U.S. Nuclear Regulatory Commission, Draft Regulatory Guide DG-1061, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Current Licensing Basis," dated February 28, 1997.
2. U.S. Nuclear Regulatory Commission, Draft Regulatory Guide DG-1062, "An Approach for Plant Specific, Risk-Informed, Decision Making: Inservice Testing," dated February 25, 1997.
3. U.S. Nuclear Regulatory Commission, Draft Regulatory Guide DG-1064, Revision 4, "An Approach for Plant-Specific, Risk-Informed Decision Making: Graded Quality Assurance," dated February 26, 1997.
4. U.S. Nuclear Regulatory Commission, Draft Regulatory Guide DG-1065, Revision 5, "An Approach for Plant-Specific, Risk-Informed Decision Making: Technical Specifications," dated February 24, 1997.
5. U.S. Nuclear Regulatory Commission, Draft Standard Review Plan, Chapter 19, Revision L, "Use of Probabilistic Risk Assessment in Plant-Specific, Risk-Informed Decisionmaking: General Guidance," dated March 3, 1997.
6. U.S. Nuclear Regulatory Commission, Draft Standard Review Plan, Chapter 3.9.7, Revision 2C, "Standard Review Plan for the Review of Risk-Informed Inservice Testing Applications,"

dated February 25, 1997.
7. U.S. Nuclear Regulatory Commission, Draft Standard Review Plan, Chapter 16.1, Revision 12, "Risk-Informed Decision Making: Technical Specifications," dated February 24, 1997.
8. U. S. Nuclear Regulatory Commission, NUREG-75/014, "Reactor Safety Study, An Assessment of Accident Risks in U.S. Nuclear Power Plants," WASH-1400, October 1975.
9. National Research Council report, "Understanding Risk, Informing Decisions in a Democratic Society," 1996.

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