

July 27, 2000

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

**SUBJECT: DEVELOPMENT OF RISK-INFORMED REGULATION IN THE OFFICE  
OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS**

Dear Chairman Meserve:

The Joint Subcommittee of the Advisory Committee on Reactor Safeguards (ACRS) and the Advisory Committee on Nuclear Waste (ACNW) met with representatives of the NRC staff on May 4, 2000, to discuss development of risk-informed regulation in the Office of Nuclear Material Safety and Safeguards (NMSS). The staff presented its activities and proposed actions to address the issues noted in the ACRS/ACNW joint report dated November 17, 1999, concerning the risk-informed framework in SECY-99-100 [References 1 and 2]. This matter was subsequently discussed at the 120<sup>th</sup> meeting of the ACNW on July 25-27, 2000. Although the ACNW has the responsibility for providing advice to the Commission on this subject, it should be noted that ACRS members Drs. Apostolakis and Kress (members of the Joint Subcommittee) participated in writing this report.

Specific topics addressed by the Subcommittee at the meeting on May 4 included risk-informed fuel cycle programs, integrated safety assessments (ISAs), byproduct material risk analysis, dry cask storage risk analysis, results of a public workshop on the use of risk information in regulating the use of nuclear materials, and related matters. Some of these issues relate to proposed modifications to 10 CFR Part 70 [Reference 3]. The ACNW and the Joint Subcommittee members from the ACRS have no objections to the proposed modifications to 10 CFR Part 70. We intend to interact with the staff to address our concerns regarding implementation of the revised rule.

The Subcommittee was impressed with the work being performed by NMSS in addressing the challenges in developing a risk-informed regulatory process. We were pleased to see progress in many areas, including the application of ISA to fuel cycle facilities, the completion of the byproduct material risk analysis, the beginning of probabilistic risk assessment (PRA) work on dry cask storage, and the transportation package performance risk studies. We were encouraged by the recent interactions between the NMSS staff and stakeholders on risk issues and believe that public workshops such as the one held in April of this year contribute to the information base needed to implement effective risk-management practices. These types of activities are important to obtain stakeholder input and to assure stakeholders that their concerns are being properly addressed.

## Discussion and Recommendations

A general observation of the Subcommittee was that while several risk-assessment activities are underway in NMSS, a strong commitment and a clear vision are necessary regarding the direction to be taken in future implementation of risk-informed and performance-based regulatory practices. We recognize that there is a great diversity of nuclear material activities being regulated, covering such broad areas as fuel cycle facilities, byproduct materials, fuel storage, and transportation. Although, in general, the implementation of risk-informed regulatory practices needs to be different for different activities, it also needs to be guided by a stated overall policy or mission statement and an articulation of a set of fundamental principles.

### Recommendation

- NMSS should establish a stated overall policy or a clear mission statement with supporting principles for the implementation of risk-informed and performance-based practices. The principles adopted should be consistent with the high-level principles used in reactor safety applications [Reference 4].

The proposed rulemaking amending 10 CFR Part 70 with emphasis on ISA does facilitate increased use of risk assessment in the licensing activities associated with special nuclear materials. We have some concern with the lack of visibility in the guidance documents as to the use of the agency's expertise and experience in risk assessment. We believe that the implementation guidance would benefit from input from the NRC staff with experience in formulating risk-acceptance criteria.

### Recommendation

- NMSS should seek assistance from NRR and RES staffs with experience in the implementation of risk-assessment practices and the development of risk-acceptance criteria while revising the Standard Review Plan. These interactions should be conducted in a manner that solicits external stakeholder participation and feedback.

ISA has its roots in chemical safety analysis, not in nuclear safety analysis. The bulk of experience in the nuclear field is with PRA. The principal differences between ISA and PRA are in the methods of analysis and in the language and terminology employed. By taking advantage of the agency's experience with the use of PRA, NMSS could expedite the task of risk-informing the licensing activities of special nuclear materials. Inefficiencies stemming from starting anew with ISA could be avoided. The use of common terminology would contribute to the understanding and the coherent application of the risk-informed regulatory philosophy to all of the agency's activities. The Commission's White Paper on the use of PRA provides clear definitions, and there is no need to introduce different terminology [Reference 5]. The use of ISA, as compared to the use of PRA, is new to the nuclear industry. We doubt that ISA has been sufficiently tested on issues critical to nuclear regulation, such as applicable standards, peer review, quality control, ownership of analysis, validity of databases, and completeness of scope.

### Recommendation

- The NMSS staff should take full advantage of the agency's experience in PRA in its application of ISA to ensure ISA's evolution to risk-informed practices of safety analysis. A common language based on the Commission's White Paper should be adopted.

The study, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems," is a significant step in answering the earlier questions that were raised by the Joint Subcommittee about how NMSS applies its own expertise to rank various risks [Reference 6]. Although the study was limited to byproduct material and did not consider a number of important issues, such as uncertainty, defense in depth, and, in the case of medical applications, patient risk, it does represent an important start to prioritizing risks.

We consider the application of PRA methods to dry cask storage to be reasonably straightforward. The study has not advanced to the point where there are specific questions about how the PRA methods were applied.

### Recommendation

- A risk-informed approach of prioritizing contributors to risk should be applied to the other nuclear material categories within NMSS' area of regulatory responsibility.

### Future Meetings

We look forward to meeting with the staff to discuss NMSS' vision on the underlying principles and motivation for pursuing the ISA approach. We believe that the best and most efficient way to continue discussions with NMSS on the use of ISA would be to discuss an important application. We are also interested in following the progress being made on decisions that will lead to safety goals of the different categories of nuclear material activities. Of particular interest on safety goals is the selection of risk measures. As indicated above, the Subcommittee is interested in following the development of the Standard Review Plan for special nuclear materials. Finally, because actuarial data can contribute to a risk-informed understanding of byproduct materials and devices, we are interested in learning more about the practices for recording and archiving data, for example, how the Nuclear Material Events Database is operated.

Sincerely,

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B. John Garrick  
Chairman, ACNW

References:

1. Report dated November 17, 1999, from B. John Garrick, Chairman, ACNW, and Dana A. Powers, Chairman, ACRS, to Richard A. Meserve, Chairman, NRC, Subject: Implementing a 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, for the Commissioners, Subject: Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards.
3. SECY-99-147, Memorandum dated June 2, 1999, from William D. Travers, Executive Director for Operations, NRC, to The Commissioners, Subject: Proposed Rulemaking - Domestic Licensing of Special Nuclear Material.
4. 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.
5. 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.
6. U.S. Nuclear Regulatory Commission, NUREG/CR-6642, Vol. 1-3, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems."