SECY-99-176

July 12, 1999

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: PLANS FOR PURSUING PERFORMANCE-BASED INITIATIVES

PURPOSE:

To obtain Commission approval of plans for pursuing performance-based initiatives consistent with the direction in the Staff Requirements Memorandum (SRM) to SECY-98-132, "Plans to Increase Performance-Based Approaches in Regulatory Activities."

BACKGROUND:

In the SRM to SECY-98-132 issued on February 11, 1999, the Commission directed the staff to provide it with the staff's plan for pursuing performance-based initiatives, including those that are not amenable to probabilistic risk analysis (PRA). The Commission's direction in the SRM included the following elements:

(A) All program offices should be responsible for the identification of candidates for performance-based regulatory activities.

(B) The staff should participate in pilot projects to further develop its understanding and maturity in applying performance-based regulation.

(C) The staff should hold stakeholder meetings before preparing the plans.

(D) The plans should incorporate experience from existing performance-based regulatory activities (e.g., The Maintenance Rule, Appendix J to Part 50, Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors).

(E) The plans should incorporate comments from the Commission, the Advisory Committee on Reactor Safeguards (ACRS), as well as participants from the Direction Setting Issue-13 (DSI-13), "Role of Industry," meeting.

(F) The staff should consider providing more guidance on identifying candidate regulatory activities and simplifying the screening and reviewing process for selecting performance-based regulatory activities.

(G) The staff should consider looking for performance-based opportunities in new rulemakings, including routinely requesting comments on proposed rules as to whether there are elements of the rule that are unnecessarily prescriptive; the staff would deal with those comments in adjusting the final rule, as appropriate.

As described in SECY-98-132, an important part of the staff's approach to increasing performance-based activities was to use the opportunity presented by the DSI-13 meetings to solicit input from stakeholders. The staff met with a large number of stakeholders on September 1, 1998, in a series of meetings in Chicago, Illinois. A discussion of performance-based initiatives was on the agenda, along with other topics associated with supporting the use of codes and standards in regulatory activities. This meeting represents one example of many such meetings, which are part of a significant stakeholder outreach program in which all offices are involved and which comprise an integral part of the staff's performance-based initiatives. In this effort, the staff uses the Commission's definition of "performance-based" provided in the SRM to SECY-98-144, "White Paper on Risk-Informed, Performance-Based Regulation," (March 1, 1999).

The Office of Nuclear Regulatory Research (RES) has included its activities on performance-based initiatives (including proper coordination among the program offices) as an aspect of implementing strategies for regulatory effectiveness. Consistent with the direction in the SRM, initiatives not amenable to PRA have been included. As further reflected in this paper, NRR and NMSS are continuing with development of performance-based initiatives on a variety of fronts. The program described in this paper is intended to complement those ongoing efforts.

The staff recently completed a research project designed to improve the understanding and implementation of performance-based approaches to regulations. The research project consisted of a literature search for promising approaches and developing a modeling framework for applying a performance-based approach to regulation. The results of the project are in NUREG/CR-5392, "Elements of an Approach to Performance-Based Regulatory Oversight," January 1999. The staff established an Internet technical conference site to involve a broader community in exploring the ideas associated with performance-based approaches to regulation. This is a continuing effort and the staff will use input from the site to the extent applicable as the plans for pursuing performance-based initiatives are further developed and refined.

On April 14, 1999, the staff conducted a public meeting with a number of stakeholders in a discussion forum at the NRC headquarters in Rockville. Participants included representatives from the Nuclear Energy Institute (NEI), the Union of Concerned Scientists, and Public Citizen, and their comments have been taken into account in the staff's planning. Again, this represents an example of on-going interaction with stakeholders involving all offices on

topics that include performance-based initiatives.

On April 21, 1999, the staff met with the ACRS subcommittees on Reliability and PRA, and Regulatory Policies and Practices, and on June 2, 1999, met with the full committee to obtain their input and ideas for developing a plan for pursuing performance-based initiatives. The staff has incorporated the input received into the plans provided herein.

DISCUSSION:

Recently, the staff has undertaken several performance-based initiatives that meet the intent of the Commission to incrementally improve the efficiency, consistency, and coherence of the regulatory framework by using such approaches. Specific examples are identified below to illustrate the ongoing characteristics of the process into which the plans described in this paper will be integrated. The examples cover both the reactor and materials arenas.

Nuclear Reactor Regulation

The Office of Nuclear Reactor Regulation (NRR) has initiated a significant effort (SECY-99-007A, "Recommendations for Reactor Oversight Process Improvements [a follow-up to SECY-99-007]) to revise the reactor regulatory oversight process. Many elements of this process are performance based. Licensee performance will be assessed on a combination of performance indicators (PI) and findings from risk-informed, performance based inspections. These will be evaluated against risk-informed thresholds when feasible. This initiative is being tested at nine pilot plants, the pilots having commenced on May 30, 1999.

The staff is pursuing a broad-based initiative to implement risk-informed revisions to 10 CFR Part 50 (SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50"). Although the primary focus of the initiative is to incorporate risk-informed modifications to Part 50, this initiative will also include performance-based elements as appropriate. The Commission approved the staff initiative in an SRM dated June 8, 1999. The insights gained from the effort to revise the reactor regulatory oversight process will likely play a role in the rulemaking for the risk-informed revisions to 10 CFR Part 50.

The staff is working with NEI to implement a risk-informed, performance-based regulatory framework for steam-generator tube integrity. The objective of the initiative is to revise the steam-generator technical specifications (via a generic change request from NEI) to support implementation of NEI 97-06, "Steam-Generator Program Guidelines."

The staff is finalizing revisions to Subpart H of 10 CFR Part 20, "Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas". In demonstrating compliance with ALARA, licensees will have flexibility in how they meet regulatory requirements. Licensees are to perform analyses to determine whether issuing respirators to prevent a small intake of radioactive material is the optimal choice given other considerations. These considerations include: 1) possibility of increasing external dose, 2) subjecting the worker to other non-radiological hazards, or 3) other stresses such as heat or lowered visibility.

Nuclear Materials Safety and Safeguards

In the Office of Nuclear Materials Safety and Safeguards (NMSS), significant efforts are ongoing to use performance-based concepts for regulation development, licensing, inspection and enforcement activities. Examples are provided below:

Proposed 10 CFR Part 63, which would apply to a geologic repository for high-level radioactive wastes at Yucca Mountain, includes two requirements that have the attributes of performance-based regulation that are identified by the Commission in its "White Paper." First, performance objectives for the repository operations area through permanent closure are stated in 10 CFR 63.111. They require that any doses during normal operations and for certain design basis events be within specified limits. Such doses are calculable from measurable parameters that would be used in designing the facility and establishing radiation protection programs. Moreover, they are monitorable. The specified limits are objective criteria based on risk insights and the prospective licensee has flexibility to determine how to meet them. The limits are sufficiently conservative that, while failure to meet them would be undesirable, such failure would not be an immediate safety concern. Second, the performance objective for the geologic repository after permanent closure is stated in 10 CFR 63.113. It requires (in part) that the expected annual dose resulting from repository releases be within a specified limit. Like the pre-closure performance objectives, this post-closure performance objective also has the attributes of performance-based regulation that the Commission identified in its "White Paper."

The proposed Part 70 rule, currently being considered by the Commission (SECY-99-147), would require licensees and applicants to conduct an integrated safety analysis. The results obtained from the analysis would be compared to the performance requirements in proposed 10 CFR 70.61. If the performance requirements were not met, preventive or mitigative actions would have to be taken by the licensee or applicant. The proposed Part 70 rule contains measurable parameters such as dose values, and chemical exposure values, in the performance requirements. Licensees would have flexibility to determine how to meet the performance criteria. The rule would not prescribe how the performance requirements are to be met. Actions necessary to meet the performance requirements would be determined by the licensee or applicant. Failure to meet a Part 70 performance criterion would not automatically result in an immediate safety concern.

Additionally, NMSS's program-specific consolidated guidance documents in the NUREG-1556 series reflect a more performance-based approach to licensing. The approach allows licensees more flexibility in managing programs without having to amend licenses in certain circumstances. In the licensing process for renewals, NMSS is also considering approaches that focus on licensee performance and the development of PIs to evaluate that performance.

For inspection and enforcement, NMSS is undertaking an initiative to focus inspection and enforcement on radiation safety performance and outcomes, in order to maintain safety and ensure compliance with NRC programs while also reducing licensee and NRC burdens. PIs are being developed to aid in this

effort. For example, in a medical pilot project, for nuclear medicine program inspections, six PIs have been developed to streamline the process.

With respect to 10 CFR Part 72 storage licenses and cask renewal beyond the initial term of the license or certificate of compliance, the staff plans to derive measurable cask performance objectives based on engineering analyses and related risk information to ensure that the storage arrangements will remain safe for the renewal term. Licensees will be allowed to meet the performance objectives in a suitable manner consistent with the regulatory framework while maintaining safe storage of spent nuclear fuel.

Agency-Wide

A performance-based approach is currently being proposed for all new rules, when appropriate. Those ongoing or planned rules that are performance-based are identified in the NRC's Rulemaking Activity Plan (RAP), issued semiannually. At present, rulemakings are listed in the RAP as "risk-informed, performance-based," "risk-informed, less-prescriptive," or "not a risk-informed, performance-based" rulemaking. Insights on the latest RAP (SECY-99-036) suggest that a rulemaking can also be just "risk-informed" or, if need be for safety-related rulemakings, "risk-informed, more prescriptive." The RAP is an ongoing NRC effort that does not require any additional resources; therefore, we will continue to implement the Commission's directives on an ongoing basis.

Additionally, when NRC solicits public comments on proposed rules, the staff will include language (in appropriate proposed rules) that will request specific comments on whether the proposed rule is unnecessarily prescriptive or can be more performance-based. This will assist the NRC in identifying and assessing whether a rule is a candidate for a more performance-based approach.

Acceptable approaches to meeting regulatory requirements are provided in guidance documents such as regulatory guides and Standard Review Plan sections. The Committee To Review Generic Requirements (CRGR) reviews new criteria before they are issued. CRGR will evaluate whether it should increase its emphasis on performance-based concepts.

Performance-based approaches in the regulatory framework were addressed by participants at the stakeholders meeting with the staff on April 14, 1999. The staff solicited ideas and specific proposals on performance-based initiatives by considering a set of questions (Attachment 1). No specific proposals were offered regarding rules or guidance documents for a more performance-based approach. However, the feedback provided some useful clarifications, including the view that most of the existing rules themselves are not viewed as overly prescriptive. The prescriptiveness may arise from other sources such as guidance documents. A number of ongoing activities (pilot projects, as low as reasonably achievable implementation, etc.) were felt to offer important lessons that the staff should incorporate into the performance-based activities.

In addition, two written submittals were provided subsequent to the meeting. An attendee at the stakeholders meeting provided some supportive suggestions that may fall into the category of initiatives not based on PRA insights. Also, a stakeholder organization, NEI, expressed the perspective that no further performance-based regulatory research effort is needed beyond the two significant initiatives covering the revision to the reactor regulatory oversight process and the risk-informed changes to 10 CFR Part 50.

Useful input was also obtained during the ACRS meetings on April 21, 1999 and June 2, 1999. In a letter to the Executive Director for Operations on June 10, 1999, (Attachment 2) the ACRS recommended that the current performance-based initiatives program should document the lessons learned from current NRC activities in order to focus the diverse NRC activities related to performance-based regulation, and that it would be useful to develop a set of principles and recommendations for future programs from the collection of the lessons learned. The objective of the current program described in this paper is to document these results.

STAFF PLANS:

The staff has considered all the comments and inputs received from the sources cited above and proposes the following plan:

(1) INCORPORATE EXPERIENCE FROM EXISTING ACTIVITIES

Significant information regarding the workings of performance-based requirements in the field may be available from the implementation of the Maintenance Rule and Appendix J to Part 50. The Maintenance Rule was the subject of considerable discussion during the stakeholder meeting of April 14, 1999. There was general agreement that implementation of the rule, which until now has been focused on programmatic reviews, is entering a phase in which valuable data will be accumulated by industry on the performance-based aspects. Appendix J to Part 50 has had a performance-based set of requirements in Option B since October 1995. At last count, 102 nuclear power plant units had adopted this option.

Without duplicating work that has been accomplished or is ongoing, the staff will assimilate the knowledge from these experiences, and others in NMSS, to get a better understanding of the licensees' and other stakeholders' perspectives. RES will create and maintain a database of ongoing performance-based activities, perform regulatory effectiveness reviews without impacting the efforts of other offices, and disseminate the results agency-wide after coordinating appropriately with the concerned offices. Staff in NRR and NMSS are involved in numerous performance-based pilot projects, as stated above. The regulatory effectiveness team in RES will identify pilot projects from among the examples for observation in progress and to learn lessons on applying performance-based approaches. The emphasis will be on making the most effective use of limited resources. Being mindful of the NEI comments, the staff will focus on how application of research insights have benefitted the projects and to assure that future research insights will provide high value.

(2) DEVELOP GUIDELINES TO IDENTIFY AND ASSESS CANDIDATE PERFORMANCE-BASED ACTIVITIES

Consistent with the recommendation by the ACRS, the focus of the current program will be to develop principles and recommendations, with guidelines to follow, if appropriate, as part of future programs. Observations from pilot projects will be shared among offices and evaluated for insight regarding candidates for performance-based activities. The initiative to risk-inform 10 CFR Part 50 would potentially provide such insights. A simplified screening and reviewing process would also be expected to be included in the future program, if needed.

(3) STAKEHOLDER MEETINGS

The success of performance-based initiatives can best be achieved with industry and other stakeholder support. As NRR and NMSS continue to take advantage of stakeholder involvement, RES will follow the work and identify lessons learned.

(4) INSTITUTIONALIZE OR TERMINATE AS NORMAL AGENCY ACTIVITY

The staff plans to review and evaluate these activities after a period of time, and make recommendations to the Commission at the appropriate time, regarding continuation or termination.

RESOURCES:

RES currently has about 1 FTE allocated to activities related to performance-based approaches to regulation, which is considered to be sufficient to undertake the RES activities described in this paper. Resources are already included for NRR and NMSS activities described above.

RECOMMENDATIONS:

The staff recommends that the Commission approve the staff activities described above.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objection. The Office of the Chief Information Officer has reviewed this Commission Paper for information technology and information management implications and concurs in it.

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Attachments:
1. Questions for Stakeholders
2. ACRS Letter to EDO of June 10, 1999

ATTACHMENT 1

QUESTIONS FOR STAKEHOLDERS

- There have been significant difficulties in applying risk methods to rules and regulations that address areas such as quality assurance, security, and fitness-for-duty. Can a performance based approach provide a more cost-effective way to address these regulations? Are there other regulatory areas not readily amenable to PRA which could likewise be addressed using a performance-based approach?
- How can performance based approaches be used to address non-reactor regulatory areas such as the licensing of radioactive materials and radiation devices?
- Is there sufficient infrastructure (methods, tools and data) in the NRC and licensee community to apply performance-based approaches effectively? If not, what additional work needs to be done? Will work in the quest of performance-based regulations be cost-beneficial?
- Are there any additional regulatory areas where performance information could be used to support rule changes? If possible, identify the specific rule, the general approach, and criteria that could be used to assure that the intent of the rule is met.
- Are there any regulatory areas in addition to rule changes where a performance-based approach could be effective? If possible, please identify such areas with sufficient specificity that NRC can follow through with an action plan.
- How should the activity on improving the application of performance-based approaches be related to the efforts to risk-inform 10 CFR 50 or the on-going efforts to revise the reactor regulatory oversight process?