POLICY ISSUE
INFORMATION

November 16, 2001 SECY-01-0205

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: STATUS REPORT ON PERFORMANCE-BASED APPROACHES TO REGULATION

PURPOSE:

To inform the Commission of the status of performance-based activities.

SUMMARY:

The staff plans to institutionalize consideration and use of performance-based concepts in making changes to the regulatory framework. This will be accomplished by issuing guidance for staff in a NUREG/BR which will be referenced in Management Directive (MD) 6.3, "The Rulemaking Process." A communications plan will also be developed on the basis of ongoing pilot-type applications of performance-based concepts.

BACKGROUND:

In SECY-00-191, "High-Level Guidelines for Performance-Based Activities," dated September 1, 2000, the staff provided the Commission with high-level guidelines developed to identify and assess the viability of making elements of the regulatory framework performance-based. A performance-based regulatory approach focuses on results as the primary basis for regulatory decision-making and as such allows licensee flexibility in meeting a regulatory requirement. This in turn, can result in a more efficient and effective regulatory process. Three types of guidelines were developed which, collectively, comprise the high-level guidelines:

CONTACT: N. Prasad Kadambi, RES
(301)415-5896

(i) Guidelines to Assess Viability: These guidelines rely on the four attributes of a performance-based approach as discussed in the Commission's White Paper on "Risk-Informed and Performance-Based Regulation." They are measurable or calculable parameters, objective performance criteria, flexibility, and a performance failure not resulting in an immediate safety concern. These guidelines are useful to evaluate whether a more performance-based approach is feasible to address a regulatory issue. This evaluation would be applied on a case-by-case basis and would be based on an integrated consideration of the individual guidelines within this grouping.

(ii) Guidelines to Assess Change: If a performance-based approach is deemed viable based on the guidelines in (i) above, then the regulatory activity would be evaluated against guidelines that assess whether a more performance-based approach results in opportunities for regulatory improvement (by which is meant a positive contribution to the NRC's performance goals and achieving a net societal benefit).

(iii) Guidelines to Assure Consistency with Other Regulatory Principles: These guidelines assess consistency and coherence with other overriding NRC goals and principles (e.g., the defense-in-depth principle).

The staff informed the Commission of plans to:

- Apply the guidelines in ongoing or future approved rulemakings, as appropriate.
- Apply the guidelines to ongoing regulatory efforts under Option 3 of SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50," December 23, 1998.
- Apply the guidelines to suitable candidates identified as being not appropriate to be risk-informed pursuant to SECY-00-0062, "Risk-Informed Regulation Implementation Plan," March 15, 2000.
- Develop a management directive to support agency-wide implementation of the guidelines in ongoing or future approved rulemakings and other regulatory activities, as appropriate (e.g., the inspection process). Supporting guidance at the office level will occur through office letters.
- Develop a communications plan to promote broader awareness of performance-based approaches on the part of external stakeholders. Wider acceptance of the guidelines should lead to efficiencies and an overall increased level of performance-based activities.
- Provide a report to the Commission on the above activities at the end of FY 2001.

The high-level guidelines were discussed with the Advisory Committee on Reactor Safeguards (ACRS) and the Advisory Committee on Nuclear Waste, and were provided for information to the Advisory Committee on the Medical Uses of Isotopes. On September 8, 2000, the ACRS provided the following conclusions and recommendations to the staff, stating:

1. We support the staff's proposal to apply the guidelines for performance-based activities to an example regulation.

2. The guidelines should explicitly state that the performance levels and reliability parameters should be set at the highest practical level.

3. Guidance should be given on the extent to which multiple performance parameters that provide redundant information should be used to satisfy the defense-in-depth philosophy.

4. Expanded discussions should be provided in the guidelines of the responses to the relevant questions that appeared in the *Federal Register* Notice of May 9, 2000.

DISCUSSION:

The staff is applying the high-level guidelines to selected rulemakings in a pilot-type program with the objective of determining whether a performance-based approach is applicable. Strengths and weaknesses of the high-level guidelines are being identified through these applications. The pilots also provide information on whether there is a need to change some of the guidelines. Sufficient information from this pilot program is expected to be available by mid FY 2002.

The staff plans to implement the guidelines by considering and using performance-based concepts in making changes to the regulatory framework (e.g., rulemaking, regulatory guidance, Technical Specifications, etc.). Eventually, an integrated process is expected that, in accordance with the Commissions's White Paper, combines the "risk-informed" and "performance-based" elements to regulatory decision-making. The staff is developing guidance on implementing the high-level guidelines for performance-based activities. This guidance would address selection of performance thresholds, collection and treatment of data, and frequency of measurement of the performance parameters selected. The guidance will also address the ACRS recommendations and include enhancements, such as check lists, to implement performance-based approaches.

The status of ongoing performance-based efforts is described below.

Pilot test the guidelines in ongoing or future approved rulemakings, as appropriate.

The staff is in the process of applying the viability guidelines, which is the first component of the high-level guidelines, in pilot projects involving the following three Office of Nuclear Materials Safety and Safeguards (NMSS) rulemaking plans:

- 10 CFR Part 34 – Options for Use of Associated Equipment for Gamma Radiography (PRM-34-05)

During the development of the rulemaking plan, the viability guidelines have been applied. Based on this preliminary assessment, it is likely that a performance-based regulatory framework could be developed for this rulemaking.

- 10 CFR Part 36 – Requirements on Attendance During Irradiator Operation (PRM-36-01)

  During the development of the rulemaking plan, the viability guidelines have been applied. Based on the preliminary assessment, it is likely that a performance-based regulatory framework could be developed for this rulemaking. Therefore, during development of the proposed rule, the staff will apply the high-level guidelines to determine whether it is appropriate to continue with a performance-based approach.

- 10 CFR Part 72 – Geological and Seismological Characteristics for Siting and Design of Dry Cask Independent Spent Fuel Storage Installations

  The staff will consider the high-level guidelines during development of a proposed rule.

In addition, the staff has used the viability guidelines in the following proposed NRR rulemaking.

- SECY-01-0113, "Fatigue of Workers at Nuclear Power Plants," June 22, 2001

  The characteristics of one of the options in this SECY, Option 4, were determined by considering the viability guidelines. This option requires licensees to assess and manage risks associated with fatigue of workers.

<u>Apply the guidelines to ongoing regulatory efforts under Option 3</u>.

The Commission approved rulemaking to risk-inform 10 CFR 50.44, "Standards for Combustible Gas Control System in Light-Water-Cooled Power Reactors," as described in SECY-00-198, "Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.44 (Combustible Gas Control)," dated September 14, 2000. As part of this effort, the staff is following the intent of the high-level guidelines to consider performance-based approaches that may be appropriate for some aspects of the rulemaking. In addition, the staff informed the Commission of how they plan to use performance-based approaches SECY-01-133, "Status Report on Study of Risk-informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-informed Changes to 10 CFR 50.46 (ECCS Acceptance Criteria)," dated July 23, 2001.

<u>Apply the guidelines to suitable rulemaking candidates identified as being not appropriate to be risk-informed</u>.

The staff recognizes the need to ensure the consideration of performance-based approaches so that when rulemakings are proposed, they are assessed for being amenable to a performance-based approach. In this way, even if a risk-informed approach cannot be taken,

a performance-based approach will still be considered. The staff will accomplish this via ongoing programs as described in the Appendix to Part 2 of SECY-00-0213, "Risk-Informed Regulation Implementation Plan," October 26, 2000. The staff's efforts to reduce unnecessary regulatory burden in the reactor safety arena will be described in a paper to be submitted to the Commission by the end of CY 2001. In this activity, the viability guidelines will be used to evaluate whether the appropriate level of licensee flexibility is being provided by the regulation. If not, unnecessary regulatory burden is likely to exist, and consideration will be given to improvement of the regulatory framework to make it more performance-based.

Develop a management directive to support agency-wide implementation of the guidelines.

The staff had originally planned to develop a management directive to support agency-wide implementation of the high-level guidelines for performance-based approaches to regulation. A new management directive would provide the guidance necessary to address all three arenas of agency activity, reactors, materials, and waste. Since issuing SECY-00-191, the staff has determined that there is a more efficient way to implement the necessary guidance by issuing a NUREG/BR which will be referenced in MD 6.3, "The Rulemaking Process." This course of action is more effective and efficient than preparing a new management directive because it avoids duplication and improves accessibility of needed guidance to the staff.

Develop a communications plan to promote broader awareness of performance-based approaches.

Communication is key to building support and awareness for performance-based approaches to regulation. The staff has been active in promoting a broader awareness of performance-based activities as exemplified by the following:

- A special session was organized at the 2001 national summer meeting of the American Nuclear Society (ANS) on the topic of performance-based regulation. A panel that included NRC, university, and National Institute of Standards and Technology staff addressed various aspects of performance-based approaches and responded to comments and questions from a national audience.

- The staff is leading a working group in the ANS's standards development structure to adopt the concepts in the high-level guidelines to make consensus standards more performance-based.

- The staff notes that the General Accounting Office has provided supportive comments on the high-level guidelines in GAO-01-259, "Major Management Challenges and Performance Risks, Nuclear Regulatory Commission," January 2001.

- Stakeholder workshops have been held (e.g., those on the Reactor Oversight Program) on specific performance-based initiatives and activities.

- Communications activities focused on internal stakeholders are also being conducted. For example, NMSS has developed a Communication Plan for the Revised Fuel Cycle Facility Oversight Process (ML003758749) that specifically addresses the need to inform and engage internal stakeholders and communicates the performance-based inspection elements of the process.

The staff has provided information to the Commission in SECY-00-191 regarding earlier interactions with stakeholders and the public on performance-based concepts.

Sufficient experience is needed in communicating to internal stakeholders the concepts in the high-level performance-based guidelines and actually applying them before a reliable communications plan can be developed. Such experience is being accumulated from the pilot program. The staff will integrate the lessons from the experiences of the pilot program and feedback received from internal and external stakeholders into a comprehensive communications plan.

FOLLOW-ON ACTIVITIES:

The staff plans to:

1. Continue to apply performance-based concepts, including the high-level guidelines, in ongoing or future rulemakings, as appropriate.

2. Complete the proposed NUREG/BR by the end of FY 2002. The supporting guidance will incorporate the lessons learned from any pilot projects and other experience.

3. Complete a communications plan incorporating the experience with performance-based activities by mid FY 2002. The response to the ACRS recommendations will be incorporated into the plan.

4. Provide a status report to the Commission on the above activities at the end of FY 2002. The status report will include the recommended performance based approach comprised of the final high-level guidelines as well as the supporting guidance. The decisions that staff needs to make to know that the recommended approach is effective will be based on successfully achieving the expected benefits of a performance-based approach in the pilot program, i.e., that performance and results are the primary basis for the regulatory decisions associated with each application of the guidelines and staff guidance. The staff will provide a recommendation to the Commission to endorse the performance-based approach consistent with the White Paper on "Risk-Informed and Performance-Based Regulation."

RESOURCES:

Resources for the guidance document and communication plan are included in the RES budget for FY 2002.

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.

/RA/

William D. Travers
Executive Director
for Operations

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.

/RA/

William D. Travers
Executive Director
for Operations

Distribution:

OEDO R/F	REAHFB R/F
WITS199900019	JCraig, AO
RES2000234	JLarkins, ACRS
DSARE R/F	PNorian, RES

C:\Program Files\Adobe\Acrobat 4.0\PDF Output\SP01-0205.wpd
*See previous concurrence
OAR in ADAMS? (Y or N) Y ADAMS ACCESSION NO.: ML012750021 TEMPLATE NO. EDO-004
Publicly Available? (Y or N) Y DATE OF RELEASE TO PUBLIC _____ SENSITIVE? No
To receive a copy of this document, indicate in the box: "C" = Copy without enclosures **"E"** = Copy with enclosures **"N"** = No copy

OFFICE	OGC	
NAME	STreby by EJensen by e-mail	
DATE	09/27/01*	

OFFICE	REAHFB		C:REAHFB		D:DSARE		D:DRAA		D:DET		DD:RES		D:RES	
NAME	NKadambi:mtb		JFlack		TKing		SNewberry		MMayfield		RZimmerman		AThadani by RZimmerman	
DATE	09/17/01*		09/17/01*		09/19/01*		09/27/01*		09/27/01*		10/01/01*		10/01/01*	
OFFICE	C:RDB		D:NMSS		D:NRR		CFO		DEDR		DEDMRS		EDO	
NAME	MLesar		MVirgilio by MFederline w/ comments		SCollins by WBorchardt w/comments		JFunches by KFitch by e-mail		WKane		CPaperiello		WTravers	
DATE	09/24/01*		09/24/01*		09/24/01*		09/27/01*		11/15/01		11/15/01		11/16/01	