

June 9, 1998

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: PLANS TO INCREASE PERFORMANCE-BASED APPROACHES IN REGULATORY ACTIVITIES (WITS - 9700093)

PURPOSE:

To respond to a portion of the Commission staff requirements memorandum (SRM) dated January 22, 1997, on SECY-96-218, "Quarterly Status Update for the Probabilistic Risk Assessment (PRA) Implementation Plan, Including a Discussion of Four Emerging Policy Issues Associated with Risk-Informed Performance-Based Regulation" (Enclosure 1).

BACKGROUND:

This paper addresses the staff's proposed plans for increasing, when appropriate, the use of performance-based approaches to regulation, and focusses on responding to the portion of the staff requirements memorandum of January 22, 1997, on SECY-96-218, "Quarterly Status Update for the Probabilistic Risk Assessment (PRA) Implementation Plan, Including a Discussion of Four Emerging Policy Issues Associated with Risk-Informed Performance-Based Regulation" (Enclosure 1), which states in part:

...The staff should include in the PRA implementation plan, or in a separate plan, how performance-based initiatives will be phased into the overall regulatory improvement and oversight program. As part of the PRA implementation plan, or its separate plan, the staff should include its plan to solicit input from industry on (or develop on its own) additional performance-based objectives which are not amenable to probabilistic risk analysis, but could be ranked according to, for example, a relative hazards analysis, and phase in these initiatives.

The Commission has issued several staff requirements memoranda (SRMs) on applications of risk-informed performance-based regulatory approaches. In response to risk-informed regulations, the staff has already submitted to the Commission SECY-97-221 on Acceptance Guidelines and Consensus Standards for use in Risk-Informed Regulation dated October 21, 1997, and the final regulatory guide and Standard Review Plan sections that address risk-informed decision making. With respect to performance-based inspection activities, the staff discussed such activities and transmitted its results to the Commission in SECY-97-231 dated October 8, 1997, on Performance-Based Inspection Guidance and the Distinction Between Inspecting for Performance and Inspecting Against a Performance-Based Rule.

In the nuclear materials area, the staff has used performance-based concepts in its regulations for many years. For example, a performance-based regulatory approach currently exists in the regulations that govern disposal of high-level radioactive wastes (HLW) in geologic repositories, [10 CFR Part 60](#), and the land disposal of low-level radioactive wastes (LLW), [10 CFR Part 61](#).

With respect to [10 CFR Part 60](#), the relative suitability of a performance-based vs. a prescriptive regulatory approach was an issue that received explicit Commission consideration during its rulemaking phase, and the "Performance Objectives" of [10 CFR Part 60](#) implement the Commission's decision in favor of a performance-based approach. Similarly, in the reactor area, there already exist a number of subparts of NRC's existing regulations with performance-based characteristics such as [Appendix J to 10 CFR Part 50](#) (Containment Testing), [10 CFR Part 55](#) (Operators' Licenses), and the Maintenance Rule ([10 CFR Part 50.65](#)).

In support of this paper, the staff has relied on the staff's white paper, "Risk-Informed, Performance-Based Regulation," and has framed this commission paper to be consistent with that white paper. In addition, the staff has collected background information from a number of programs already in-place. These include the Marginal to Safety Program (SECY-94-090), the National Performance Review effort (SECY-95-123), the Regulatory Review Group effort (SECY-96-024), and the DSI-12, DSI-13 and DSI-23 initiatives.

DISCUSSION:

The staff recognizes that a consistent understanding of what constitutes a performance-based regulatory approach is necessary to facilitate discussions within the agency and with stakeholders. For reactors and, to a lesser extent, material licensees, the staff views the current state of progress on these approaches to be akin to the status of risk-informed approaches before the PRA Policy Statement was issued by the Commission on August 16, 1995. Drawing on the lessons learned from the experience with risk-informed approaches, the Commission may wish to consider whether a separate policy statement on performance-based approaches would be beneficial in light of the information presented in this paper.

Performance-Based Regulatory Approaches - Definition, Advantages and Disadvantages**Definition:**

The definition and discussion in the following four paragraphs have been adopted verbatim from the staff's white paper.

Performance-Based: A regulation can be either prescriptive or performance-based. A prescriptive requirement specifies particular features, actions, or programmatic elements to be included in the design or process, as the means for achieving a desired objective. A performance-based requirement relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, but provides more flexibility to the licensee as to the means of meeting those outcomes. A performance-based regulatory approach is one that establishes performance and results as the

primary basis for regulatory decision-making, and incorporates the following attributes: (1) measurable (or calculable) parameters (i.e., direct measurement of the physical parameter of interest or of related parameters that can be used to calculate the parameter of interest) exist to monitor system, including licensee, performance against clearly defined, objective criteria, (2) licensees have flexibility to determine how to meet the established performance criteria in ways that will encourage and reward improved outcomes; and (3) a framework exists in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern. The measurable (or calculable) parameters may be included in the regulation itself or in formal license conditions, including reference to regulatory guidance adopted by the licensee. This regulatory approach is not new to the NRC. The Commission previously has approved performance-based approaches in 10 CFR Parts 20, 60, and 61. In particular, the Commission weighed the relative merits of prescriptive and performance-based regulatory approaches in issuing 10 CFR Part 60.

A performance-based approach can be implemented without the use of risk assessment. Such an approach would require that objective performance criteria be based on deterministic safety analysis and performance history. This approach would still provide flexibility to the licensee in determining how to meet the performance criteria. Establishing objective performance criteria for performance monitoring may not be feasible for some applications and, in such cases, a performance-based approach would not be feasible.

As applied to inspection, a performance-based approach tends to emphasize results (e.g., does the pump work?) over process and method (e.g., was the maintenance technician trained?). Note that a performance-based approach to inspection does not supplant or displace the need for compliance with NRC requirements, nor does it displace the need for enforcement action, as appropriate, when non-compliance occurs.⁽¹⁾

As applied to licensee assessment, a performance-based approach focuses on a licensee's actual performance results (i.e., desired outcomes), rather than on products (i.e., outputs). In the broadest sense, a performance-based approach to regulatory oversight will focus more attention and NRC resources on those licensees whose performance is declining or less than satisfactory.

As mentioned above, not all regulated activity will lend itself to a performance-based approach. Given the diversity of NRC licensees and the broad scope of NRC regulatory activity, the establishment of objective performance criteria for performance monitoring may not be feasible for some applications and, in such cases, a performance-based approach would not be feasible. For example, 10 CFR Part 34 (Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations) is generally viewed as an appropriately prescriptive regulation. This reinforces the importance of evaluating the performance vs. prescriptive orientation of a regulation within the context of the regulated entity. In addition, any individual NRC regulatory activity is not likely to be either fully performance-based or prescriptive. Rather, each activity is likely to contain gray areas, and should provide flexibility where it is appropriate and prescriptive direction where economy and human factors would so justify. For example, many provisions of 10 CFR Part 20 employ performance-based features. These include concepts of "as low as is reasonably achievable" (ALARA), use of analyses to estimate total effective dose equivalent, and objectively developed criteria and provision for corrective action. However, Part 20 also contains relatively prescriptive features such as Appendix A which concerns numerical values for permissible assigned protection factors for respirators.

Further, even if feasible, there may be a number of reasons why a performance-based approach is inappropriate. For example, the added flexibility may be unwelcome or received with indifference by certain licensees because licensees do not have the resources or expertise to initiate a facility-specific response, or licensees may already have committed large capital outlays (sunk costs) to the prescriptive regulatory approach such that the performance-based approach is not cost effective. In addition, shifts to a more performance-based approach may impose higher costs on individual licensees for those cost elements that currently lend themselves to industry-wide generic support. For example, current training modules to support prescriptive requirements are frequently developed industry-wide and made available to individual licensees. The cost efficiencies of such an approach may be compromised if licensees adopt requirements that are tailored to their specific facilities. These issues suggest that although a performance-based approach should be allowed whenever it can ensure an acceptable level of public health and safety, each licensee should have the option of deciding whether it is suitable from its perspective.

Advantages:

An increased reliance on performance-based regulatory approaches is desirable when it allows licensees to take explicit account of system or facility-specific characteristics that translate into a regulatory response that is more efficient and cost effective, yet still protective of the public health and safety. In addition, since performance-based approaches afford licensees greater flexibility in responding to their health and safety responsibilities, it is consistent with the underlying principle that licensees are responsible for the safe and secure use of nuclear materials.

Disadvantages:

A greater reliance on performance-based approaches is likely to result in incremental licensee costs associated with the development of analyses to design and justify performance-based regulatory responses in support of their system or facility-specific characteristics. Similarly, the NRC is likely to incur incremental costs in its review and approval of such responses. Further, given that performance-based approaches are likely to result in less uniformity across licensees, there exists the potential for increased initial costs in NRC's regulatory oversight role, particularly in inspection and enforcement activities, and the potential for higher licensee training costs. In addition, performance-based regulatory approaches in the reactor area may conflict with Commission encouragement to utilize and adopt industry codes and standards in NRC regulations given that these tend to be prescriptive. It should be noted however, that for the disposal of nuclear waste, the use of performance-based approaches is consistent with the international approach as exemplified by ICRP Publication 46.

The staff's plan to increase performance-based approaches in new regulatory initiatives consists of four principal activities. These are: 1) soliciting stakeholder input; 2) internal collection and analysis of relevant information and data; 3) screening analysis to assess feasibility and desirability of applying performance-based approaches to specific regulatory activities; and 4) follow-up activities, such as additional research, guidance development, rulemaking, or other regulatory action for NRC issues that are judged appropriate candidates for performance-based approaches.

Stakeholder Input:

Given the expected divergence in applicability of performance-based regulatory approaches across the broad scope of NRC's licensees and regulated activities, the staff anticipates that stakeholders' views, particularly in identifying candidate regulatory activities, will be essential to the overall planning process.

Consistent with the NRC's overall objective to promote stakeholder involvement, the staff proposes to include a discussion of performance-based regulatory approaches in the DSI-13 stakeholder meetings concerning the role of industry in the regulatory process (SECY-97-303). This stakeholder meeting is being planned for July or August 1998. In response to the ACRS letter of April 9, 1998, and in order to promote a more meaningful dialogue at the meeting, the staff will discuss issues likely to arise in developing performance-based regulations, recognizing that a clearer description of the issues at this time would help structure the proposed solicitation of input from industry. Further, prior to the meeting, the staff will provide stakeholders with advance information on the issues surrounding performance-based regulation, and the type of input being sought by the NRC. It is the staff's intent to utilize the Internet and/or E-Mail to ensure as broad coverage as possible for this information. Stakeholders who cannot attend the meeting will be encouraged to submit written input directly to the NRC. Through this process, it is the staff's expectation that stakeholders will identify candidate regulations and guidance documents that would be amenable to a more performance-based approach. Suggestions received through this process will be considered in the staff's screening of candidate regulatory activities. Further, the staff will encourage the stakeholders to apply the principles and practices articulated in [Regulatory Guide 10.12](#), "Preparation of Petitions for Rulemaking Under 10 CFR 2.802 and Preparation and Submission of Proposals for Regulatory Guidance Documents." Follow-up interactions with stakeholders are also anticipated.

There are many materials licensees who are not likely to participate in the planned meeting. The staff also anticipates using the Internet and/or E-Mail to solicit and obtain the input of these stakeholders. Similarly, the Agreement States are an important stakeholder in the licensing of nuclear materials uses, and similar methods are envisioned to solicit input from these stakeholders.

Internal Collection and Analysis of Information:

Internal data sources will be reviewed to identify a preliminary set of regulatory actions where a more performance-based approach would appear to be beneficial. The internal data sources for regulatory issues include: operating experience, risk information, licensing and inspection information, engineering and scientific information, regulatory initiatives, and nominated issues. In addition, the NMSS effort on developing a risk-informed performance-based framework for materials licensees will be examined after it has been placed into operation to identify projects and information useful to performance-based approaches.

Screening of Candidate Regulatory Activities:

As noted earlier, not all regulatory activities are expected to be suitable candidates for performance-based approaches. This will necessitate an assessment of the values and impacts including a preliminary consideration of feasibility for each candidate regulatory activity.

Feasibility:

The feasibility of applying a performance-based approach to a given candidate regulatory activity will be assessed in terms of its ability to meet each of the following.

- Measurable (or calculable) parameters exist or could reasonably be expected to be developed to monitor system or licensee performance. The measurable (or calculable) parameters may be included in the regulation itself or in formal license conditions, including guidance adopted by the licensee. The relationship of the measurable parameters to the performance of interest may be direct or indirect.
- Objective criteria have been or could reasonably be expected to be developed for assessing performance based on risk insights, hazards analysis, performance history, or safety considerations based on results of deterministic analyses.
- Licensees have flexibility to determine how to meet established performance criteria; once the particular criteria are selected and formally committed to by the licensee, they would become regulatory requirements (e.g. license conditions) for that licensee.
- A framework exists in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern.

The consideration of feasibility is an integral part of a value-impact analysis and would be considered within the value-impact analysis discussed below.

Value-Impact:

The net societal value of applying a performance-based approach to a candidate regulatory activity must be evaluated from a value-impact perspective wherein all meaningful consequences are considered. The consequences of most notable interest would include public health and safety consequences, licensee costs, and NRC costs. In addition, on the benefit-side of the equation there may be other noteworthy attributes. For example, in a recent presentation to the Advisory Committee on Reactor Safeguards, the National Fire Protection Association stated that the benefits they expect from performance-based standards documents are achievement of the desired levels of safety with equal or reduced cost, specification of levels of safety, better direction of research efforts, improved transfer of technology, increased design freedom, and increased confidence in non-prescriptive methods. The staff agrees that, in certain applications, these are also potential desired outcomes that one could attribute to NRC's increased use of performance-based approaches to regulation. On the cost-side of the equation, the staff is particularly sensitive to the resource requirements associated with the NRC's implementation of performance-based approaches. These efforts would typically include additional research in defining appropriate performance criteria and/or meaningful performance parameters for specific regulatory actions, and perhaps additional rulemaking. Given that NRC's resources will

probably decrease over the foreseeable future, any increased NRC activity associated with adding performance-based approaches to regulatory activities will require shifting resources away from other worthwhile endeavors. The benefits that have been foregone because of such a shift may well exceed the dollar cost of NRC's resources, and may represent a truer measure of the cost of the implementation of a performance-based approach. It is questionable whether foregone benefits can be identified at the preliminary value-impact stage. However, before resources are committed to a given activity, as part of its budgeting process, the staff does evaluate the relative merits of proceeding with that activity from among competing needs for NRC's resources.

Follow-up Activities - Leading to and Including Resolution:

Candidate regulatory activities that pass the feasibility and value-impact screening criteria become candidates for performance-based regulatory approaches. These regulatory initiatives may take the form of additional rulemakings, additional research, or other regulatory action, and will be submitted to their respective programmatic office for resolution. Mechanisms exist to establish priorities from among competing needs within each program office and through the Planning, Budgeting, and Performance Management process (PBPM) involving the Program Review Committee (PRC). In this way, recommended regulatory initiatives resulting from this plan would be undertaken on a schedule and level of effort consistent with the programmatic offices' priorities and resource availability.

RECOMMENDATIONS:

The staff proposes a plan with the following elements:

- (1) As part of DSI-13 meetings, staff will solicit input from stakeholders;
- (2) As part of NRC's commitment to improve its regulatory framework, staff will collect and analyze relevant information to support the identification of regulatory activities where a more performance-based approach would appear to be beneficial;
- (3) As part of NRC's commitment to improve its regulatory framework, staff will evaluate regulatory initiatives from a value-impact perspective which would include a preliminary consideration of the feasibility of achieving a more performance-based approach;
- (4) Staff will recommend appropriate agency action for those issues that pass the analysis in item (3). Recommendations will be made to the appropriate programmatic office and the Program Review Committee;
- (5) Any recommendations for additional rulemakings, additional research, or other regulatory action resulting from this plan will be initiated by the appropriate programmatic office based on its priorities and available resources, and agency approval. All new rulemakings will be performed in accordance with Management Directive 6.3, and will be tracked in the Rulemaking Activity Plan; and
- (6) All new rulemaking plans and regulatory analyses will include at least a qualitative evaluation of performance-based alternatives. Management Directive 6.3 will be modified to reflect this additional consideration.

RESOURCES:

The developmental, justification, and notification aspects of this plan (items 1 through 4) will largely rely on RES and AEOD resources already directed towards NRC's commitment to improve its regulatory framework. However, about six staff-months of effort, over and above these levels, may be necessary for planning and coordination efforts such as for conducting the workshops, and the offices will reprogram the staff as necessary. If specific recommendations for increased performance-based approaches (Item 5) are forthcoming, these recommendations will be evaluated by the appropriate programmatic office subject to their existing resources and priorities. The staff will identify resource impacts associated with implementing rule changes resulting from the performance-based regulatory approach. Consideration of performance-based approaches in new rulemakings (item 6) will be conducted with existing resources. In addition, if the Commission determines that a separate policy statement on performance-based approaches is appropriate, an additional level of effort on the order of one year would be necessary.

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 and finds no resource related issues. The Office of the Chief Information Officer has reviewed this Commission Paper for resource implications and has no objections. A draft of this paper was discussed with the ACRS and their letter dated April 9, 1998, is enclosed (Enclosure 2).

Hugh L. Thompson, Jr., for
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Enclosures: As stated

April 9, 1998

Mr. L. Joseph Callan
Executive Director for Operations
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Callan:

SUBJECT: PLANS TO INCREASE PERFORMANCE-BASED APPROACHES IN REGULATORY ACTIVITIES

During the 451st meeting of the Advisory Committee on Reactor Safeguards, April 2-4, 1998, we met with representatives of the NRC staff to discuss the proposed Commission paper entitled "Plans to Increase Performance-Based Approaches in Regulatory Activities." Our Subcommittee on Reliability and Probabilistic Risk Assessment met with the staff on November 13, 1997, and February 20, 1998, to discuss issues related to performance-based regulation. We also had the benefit of the documents referenced.

The proposed Commission paper provides early input to the development of Strategy 5 of the NRC Excellence Plan. Strategy 5 is intended to develop a process and identify candidate issues for improving the effectiveness and efficiency of rules, regulatory guidance and their application. We believe that the staff should identify and define the issues likely to arise in developing performance-based regulations in the absence of quantified risk information. Examples include: how and by whom performance parameters are to be determined and deemed acceptable, and how to place the acceptance limits on them. A clearer description of the issues at this time would help structure the proposed solicitation of input from the public and interested stakeholders.

We recommend that the staff provide the above information to us prior to proceeding with the solicitation of input. We look forward to working with the staff as it develops the strategy.

Sincerely,
/s/

R. L. Seale
Chairman

- References:
1. Draft Commission paper for the Commissioners from L. Joseph Callan, Executive Director for Operations, NRC, Subject: Plans to Increase Performance-Based Approaches in Regulatory Activities, received March 25, 1998 (Predecisional).
 2. Draft Commission paper for the Commissioners from L. Joseph Callan, Executive Director for Operations, NRC, Subject: FY 1998 NRC Excellence Plan, received March 13, 1998 (Predecisional).

1. Not every aspect of licensed activities can or should be inspected using this approach. For example, if a licensee is unsuccessful in meeting the criteria defined by a performance-based regulation, the inspector should then focus on the licensee's process and method, to understand the root cause of the breakdown in performance, and to understand how future poor performance may be avoided.