

November 20, 1996

John C. Hoyle, Secretary
U.S. Nuclear Regulatory Commission
Attn.: Chief of Docketing and Services Branch
Washington, D.C. 20555-0001



Dear Mr. Hoyle:

In response to the Commission's solicitation, the following are my comments on NRC'S **STRATEGIC ASSESSMENT OF REGULATORY ACTIVITIES**. Upon review of the documents, I find this initiative to be a significant effort for improvement in NRC's history, and feel privileged to provide my comments on the major policy issues as a member of the NRC staff. My comments are categorized by Issue Papers, and focused as requested by the Commission.

ISSUE 12 RISK-INFORMED, PERFORMANCE-BASED REGULATION

1. What, if any, important considerations may have been omitted from the issue paper?

This issue paper omitted consideration of the policies and framework for risk-informed, performance-based regulation established for the Regulatory Improvement program. The Commission approved these policies and frameworks in Staff Requirements Memorandum dated, May 18, 1994 in response to the staff's proposals in SECY-94-090, "Institutionalization of Continuing Program for Regulatory Improvement." This issue paper mainly references the P.R.A. Policy Statement which excluded important considerations for a framework of performance-based regulation. The recent risk-informed, performance-based revision of Appendix J of 10 CFR Part 50 was developed consistent with the policies and framework established for the Regulatory Improvement program.

An important consideration for establishing and expanding the scope of risk-informed, performance-based approach is: *What is the most efficient method by which NRC can transition to a risk-informed, performance-based regulatory structure, specifically, should the revised regulations be available for voluntary adoption by licensees, or should NRC mandate their implementation?* The answer to this question obviously depends on whether the revised regulation is promulgated for: (1) Increasing the level of public health and safety; (2) reducing unnecessary burdens; or (3) better using resources by focusing on those activities that are most important to safety (as indicated in the issue paper the safety benefits for this are difficult to quantify). Each of these objectives may be met through a risk-informed, performance-based regulatory framework. Implementation of a revised regulation that results in a substantial increase in public health and safety with justifiable implementation costs can be backfitted (per

10 CFR 50.109(a)(3)), however, it is not clear whether the Commission should, or could, mandate licensee implementation of changes that reduce licensee and staff burdens by eliminating unnecessary burdens or better focus staff and licensee resources on safety significant activities (see 60 FR 9641, and 60 FR 49501 for previous Commission consideration of this issue). Combining actions for (1) with (2) and (3) above may not be justifiable as a backfit, and significant net cost reductions would be necessary to provide licensees incentives to voluntarily adopt such revised regulations. Given these considerations, should the Commission separate regulatory actions toward meeting the objective in (1) from those in (2) and (3) above, and only promulgate revisions aimed toward objectives in (2) and (3) for voluntary adoption by licensees and not as backfits. In the past, the Commission approved the following two policies proposed by the staff for the Regulatory Improvement program in SECY-94-090:

- A. Since the main aim of the Regulatory Improvement program is to increase regulatory efficiency and recognizing that many licensees have technical programs which they may not wish to modify, any revised requirements from this program will be issued for voluntary adoption by licensees that are in compliance with current requirements.
- B. Given the history of difficulty and low success rates for attempts to resolve new safety issues simultaneously with improvements to regulatory efficiency, regulatory actions and programs for new safety issues and those for improving regulatory efficiency will be separate and independent.

The above considerations are important and need to be addressed and reaffirmed to overcome the inherent culture in the regulatory staff that actions that only reduce the regulatory burden for licensees without tangible improvements in safety do not fulfill the mandate of the regulatory staff to protect the public health and safety (this consideration is included in Issue 23 in reverse logic).

Another important consideration related to expanding the scope of risk-informed, performance-based regulation, specifically for reducing prescriptiveness in the regulations and thereby providing flexibility and reducing regulatory burdens, is: *Should the NRC be proactive in establishing the framework in a specific regulatory area such that licensees can use the new regulatory structure without prior staff approval, or should the burden be on industry and licensees to petition the NRC for changes and demonstrate their adequacy.* Since 1991, when the "Marginal to Safety" program was revived, the Commission has alternated between the two approaches. The staff took a proactive approach for the revision to Appendix J of 10 CFR Part 50. Since then the staff positioned itself to be reactive to industry proposals, e.g., a petition to revise NRC's fire regulations was received from industry, however; the staff concluded that the petition did not meet its expectations. More recently, regulatory guides are being prepared for risk-informed, performance-based approaches for licensees to use in submitting requests for regulatory relief. It is not clear at this point how much a burden of proof of adequacy these requests will entail, and whether licensees will be able to address the complexities of the policy issues that arise in the use of such approaches.

These considerations are provided for the Commission's review for developing criteria to be used in expanding the scope in applying risk-informed, performance-based regulatory approaches and overcoming obstacles that lie ahead. They are also important for the subsumed issue: *What should be NRC's strategy and philosophy with respect to changing NRC's responsibilities and authority in areas of little public risk?*

2. How accurate are NRC's assumptions and projections for internal and external factors discussed in the issue paper?

The history of performance-based regulation dates back to the early '80s when some work in this area was conducted by the Administrative Conference. More recently, President Clinton's Council on Sustainable Development issued a report entitled, "Sustainable America - A New Consensus for Prosperity, Opportunity, and a Healthy Environment for the Future" (February 1996). This report documents more than two years of efforts by the Council (which included representatives from environmental groups, industry, and government agencies) to obtain a consensus on a new approach to environmental regulation. A consensus was reached on performance-based regulation to provide flexibility to reduce regulatory burdens on the industry while providing incentives for cost-effective safety improvements that could be implemented on a voluntary basis. Several pilot projects have been conducted by EPA and industry to demonstrate that implementation costs could be reduced concurrent with improvements in safety. The report provides insights of initiatives related to this issue paper, and there is potential that the results of the Council may be pursued by President Clinton and the new Congress next year. Recently, an agreement signed by EPA and Intel Corporation in a pilot program known as Project XL has been welcomed by many corporate leaders, regulatory specialists, and members of Congress searching for new regulatory paths.

3. Do the Commission's preliminary views associated with the issue paper respond to the current environment and challenges?

In general, the Commission's preliminary views and emphasis are responsive to the current economic status of the nuclear industry and the declining federal budget by emphasizing the need to transition to a risk-informed, performance-based regulatory structure in order to focus staff and industry resources commensurate with risk significance. However, given the issues discussed above which could become obstacles to the transition, and the lack of a framework for performance-based regulation in the P.R.A. Policy Statement, a new Policy Statement that includes all aspects of risk-informed, performance-based regulation should be issued by the Commission to provide guidance to the staff and industry and ensure an efficient transition. This consolidated Policy Statement would be based on the P.R.A. Policy Statement, other earlier staff initiatives (e.g., Regulatory Improvement program, Regulatory Review Group), issues discussed above and other considerations brought to the Commission's attention through public comments on this solicitation.

ISSUE 23 ENHANCING REGULATORY EXCELLENCE

1. What, if any, important considerations may have been omitted from the issue paper?

In the past, the staff has adopted the policy that activities related to regulatory improvement would be conducted in a reactive manner to industry petitions and proposals. However, experience has shown when improvements to the regulatory structure involve major policy issues, e.g., for revisions to NRC's fire protection regulations, industry petitions have not been acceptable to the NRC staff (see SECY-96-134). This comment is also related to Issue 12.

As indicated in the issue paper, over the last several years the NRC staff has undertaken several initiatives for achieving regulatory excellence. The relationship and integration of activities for this strategic issue to others, e.g., for Issue 12, is an important consideration for efficient use of resources and consistency.

The discussion above for Issue 12 on consideration of potential conflicts between activities for achieving regulatory excellence and efficiency is applicable here.

I believe motivational factors of the NRC staff (discussed in the issue paper) is probably the most important consideration for this issue. Staff involvement in the decision making, and empowerment to make these enhancements, will be critical to achieving success. Organizational streamlining and the reduction of multiple layers of managements are essential in order to empower, involve, and motivate the staff. An example of a good motivational factor is the recent initiative in RES for Improving Individual Performance by allowing the staff time and latitude to involve themselves in activities that expose them to the latest technologies and thereby enhance their skills and knowledge.

2. How accurate are NRC's assumptions and projections for internal and external factors discussed in the issue paper?

A key factor that may affect the Commission's initiatives in this area is the influence of the employees' union in controlling staff involvement. Past experiences have shown that the union will attempt to control staff involvement in improvement activities, and the interests of the union are narrowly focused and not necessarily in the best interest of the agency or its employees. Processes that allow employee involvement without the union, will need to be maximized in order to overcome these obstacles.

3. Do the Commission's preliminary views associated with the issue paper respond to the current environment and challenges?

I believe the Commission's views are very responsive to the administration's effort to improve the morale and productivity of federal employees.

ISSUE 22 RESEARCH

1. What, if any, important considerations may have been omitted from the issue paper?

I believe consideration of expanding international cooperative research programs (discussed in the paper) is most important to meet NRC's research needs given smaller research budgets and the need to focus efforts. An essential element for success in this expansion is a more liberal policy for involvement of the technical staff in international activities. This will help the staff develop cooperative programs to focus on exchanges of information that more directly benefit work being conducted by the technical staff. This will also enhance regulatory excellence (Issue 23) by developing a strong technical knowledge base.

As indicated in the issue paper, the agency's efforts for risk-informed, performance-based regulation will require research support. The existing policy that industry should conduct the necessary research for revisions to the NRC's rules and guides that are aimed at reducing regulatory burdens should be revisited and the need to modify this policy should be evaluated.

Related Issue: *How should international cooperative research programs, either bilateral or multilateral, involving both industry and governmental agencies, be best utilized and in what areas to leverage resources and technical expertise?*

The research that will be necessary to support development of a risk-informed, performance-based fire regulation (see SECY-96-134) is an area where there is an interest from both the U.S. industry, and international industries (nuclear and building) and governmental agencies and has the potential for serving as a pilot for such cooperative programs to reduce NRC costs.

3. Do the Commission's preliminary views associated with the issue paper respond to the current environment and challenges?

Yes. I also believe Commissioner Rogers proposal for building a sound technical knowledge base at the NRC, and organizational considerations in order to achieve maximum efficiency will be useful in implementing the Commission's decisions.

ISSUE 20 INTERNATIONAL ACTIVITIES

1. What, if any, important considerations may have been omitted from the issue paper?

As discussed in response to Issue 22 - Research, international cooperative programs allow increased efficiency for conducting research with limited budgets. Increased priority consideration to this international activity will be necessary compared to other activities that may be less directly related to NRC's mandate for the safety of domestic reactors. Increased

opportunity for participation of the technical staff in international activities and work groups related to staff duties will be necessary in order for the technical staff to establish an international network of contacts for information exchange.

3. Do the Commission's preliminary views associated with the issue paper respond to the current environment and challenges?

Yes. International activities that directly provide benefit toward regulatory products for NRC's domestic mission should receive priority, e.g., for activities to support transition to a risk-informed, performance-based regulatory structure if the Commission's preliminary views on Issue 12 are finalized.

ISSUE 13 ROLE OF INDUSTRY

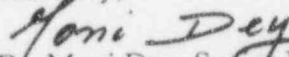
1. What, if any, important considerations may have been omitted from the issue paper?

Although industry has played a major role in developing guidance documents for implementing NRC's regulations in the past, it has recently submitted documents on several occasions that have not been acceptable to the NRC staff. Processes that would enhance early interaction between the industry and NRC staff during industry efforts to develop guidelines should be considered to increase the efficiency of the regulatory process and ensure fruition of efforts. Currently industry is expected to conduct research activities in support of regulatory actions to decrease regulatory burdens. Consideration should be given to using NRC-industry, cooperative research programs in lieu of this policy. This should lead to increased efficiency resulting from closer cooperation and mutual understanding between the industry and NRC staff.

3. Do the Commission's preliminary views associated with the issue paper respond to the current environment and challenges? Yes.

I hope my comments will be useful to the Commission in its deliberations for final decisions on the issue papers, and in the implementation of the results of the strategic assessment in the near future. I am enthusiastic of the many positive changes that will take place at the NRC as part of this initiative.

Sincerely,



Dr. Moni Dey, Senior Nuclear Engineer
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission

cc: Dave Morrison
Bill Morris