NEI

NUCLEAR ENERGY INSTITUTE

DSI-7

(29)

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SENIOR VICE PRESIDENT
REGULATORY POLICY & REFORM

November 27, 1996

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTENTION: Chief, Docketing and Service Branch

SUBJECT: NRC Strategic Assessment and Rebaselining
(61 *Federal Register* 195; October 7, 1996)
Request for Comments

Dear Mr. Hoyle:

The Nuclear Energy Institute (NEI),[1] on behalf of the nuclear energy industry, has reviewed the Direction Setting Issue (DSI) papers which form a part of the NRC Strategic Assessment and Rebaselining Initiative. The purpose of these papers is to discuss key issues affecting the future strategic direction of NRC and provide options for selection by the Commission. The NRC has requested comments from all "stakeholders" to be considered as part of the Commission's decision making process. Our comments on each DSI paper are organized in the following format:

1. What, if any important considerations have been omitted?

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

[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

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3. Do the Commission's preliminary views respond to the current environment and challenge?

4. NEI Recommendations

The NRC is to be commended for undertaking this effort. It is important to periodically review the overall direction of the agency, particularly given the dynamic circumstances in the nuclear industry today. The DSIs identified through the early phases of this assessment are reasonably complete, highlighting the areas in which strategic decisions are needed. Many of our comments highlight areas where the staff analysis of the issues does not include viewpoints significantly different from the status quo.

We are concerned that insufficient review time will reduce the effectiveness of the stakeholder comment process. The stakeholders had a very limited time to solicit and compile comments from their constituencies. We recognize that the public comment period was extended, but the two week extension was announced too late in the process to affect the collection of comments from NEI's members. It is likely that other "stakeholders" representing large constituencies, including licensees with multiple internal organizational groups, were similarly constrained.

Of greater significance is the amount of time the NRC has indicated will be used to assess the comments. NRC staff indicated during the workshops that "Stakeholder Interaction Reports," compiling the comments, would be forwarded to the Commission for consideration within three weeks after the comment deadline. This schedule would make it very difficult for NRC management to consider the variety and volume of public comments that are likely to be received. It could restrict the ability to revise the thinking that went into the initial papers, to define and flesh out new options which may be suggested by the comments, or to provide analysis of such new options for the Commission's consideration. We encourage NRC to take the time necessary to derive full benefit from this important endeavor.

A significant omission from this strategic assessment is the current enforcement policy. That policy has a pervasive effect on the relationship between the NRC and its licensees and on the message the public perceives regarding the safety significance of problems. Other federal agencies with safety mandates, and many foreign nuclear regulatory authorities, have different approaches to enforcement. Some of these are structured differently specifically to encourage compliance, rather than punish non-compliance. NEI strongly encourages the NRC to subject the enforcement policy to the same type of review, examining options different from the

agency's historical practice, as has been applied to other programs in many of the DSIs.

In many of the DSI papers, past actions of the agency are summarized, but often not critically evaluated. Instead, it appears to be accepted that past regulatory actions were necessary and remain appropriate as continuing regulatory requirements. In fact, many of these actions were in response to specific events and issues, may not have been the most effective means of dealing with the issue, and are inappropriate as continuing burdensome requirements since the causes of the events have been dealt with. A more thorough assessment of previous NRC actions could produce lessons on how the agency could have been, and could be, more effective in addressing issues. Today, the regulatory problems at the Millstone station are the issue of the moment. References to these problems permeate the DSI papers. The papers could well have had a different tone had they been prepared a year earlier. While it is necessary to deal with compliance problems when they are found, it seems inappropriate for individual situations such as Millstone to color so completely the strategic picture for a regulatory agency.

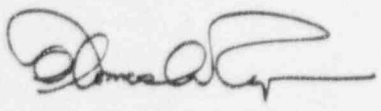
There is agreement between the NRC and industry that safety performance has improved over the last several years. Performance indicators monitored by NRC and industry both demonstrate such improvement. Nevertheless, the total burden imposed by regulatory requirements continues to increase. There is danger that this increasing burden will make it economically infeasible for some nuclear power plants to continue operation, thus depriving the nation of a reliable, clean source of electric power. Such an outcome is not in the public interest if safety is not in question. An improved focus is needed in the nuclear regulatory process on safety significance. We note that Chairman Jackson has often expressed her support for the concept of risk-informed, performance-based regulation. We agree that this is an excellent mechanism for providing the needed focus. It would allow issues to be addressed in their appropriate context, considering both their individual significance and the overall level of safety performance in the industry. It would lead to more efficient means to address those issues that require action. It would appropriately allow for individual variation in the response to an issue, as it is seldom the case that a single specific action is the appropriate, effective response for all members of a class of NRC licensees. The regulatory process needs to recognize this, and allow problems to be addressed in the manner which will be most effective given the circumstances of individual licensees. We encourage the NRC to utilize fully this strategic planning process to further the transition to this more effective and efficient regulatory regime.

Several of the DSIs would benefit from a practical definition of an adequate level of protection of public health and safety. It is difficult to discuss how to (1) improve public communication, (2) improve the efficiency and effectiveness of the regulator, and (3) properly focus a regulatory oversight program without defining the baseline against which effectiveness can be measured. Without a more objective definition of adequate safety levels, one cannot determine when programs are successful or address a perception that more needs to be done. The NRC needs to develop means for applying the safety goals in a practical manner in order to provide a benchmark that is useful for determining when and how much additional action is required to assure safety.

Significant management attention will be required to implement any changes that result from this strategic planning process. The experience with risk-informed performance-based regulation is instructive in that regard. The Commissioners and senior staff management repeatedly have made comments supportive of such approaches to regulation. There appears to be an understanding, at the policy level, that it is appropriate to deal with issues in their particular safety context. This policy has not been effectively transferred to the working level of the staff. Inspectors and reviewers, whose actions impact NRC licensees on a daily basis, remain focused on detailed, prescriptive approaches. They continue to be concerned with how the "requirements" of NRC guidance documents are met, regardless of the safety objective and inherent flexibility of guidance. It will be very important for the Commission and staff management to devote considerable effort to translating any policy changes resulting from this rebaselining to changes in practice at the working level, so that they may indeed improve the effectiveness of the regulatory process.

We appreciate the opportunity to comment on these issues. We are willing to meet with the Commission or staff to discuss our comments or the related broader issues. Please contact me at (202) 739-8013 if there are any questions regarding our comments.

Sincerely,



Thomas D. Ryan

TDR/RWH/ec
Enclosure

c: Hon. Shirley Ann Jackson, Chairman
Hon. Kenneth C. Rogers, Commissioner
Hon. Greta J. Dicus, Commissioner
Hon. Nils J. Diaz, Commissioner
Hon. Edward McGaffigan, Jr., Commissioner
Mr. James M. Taylor, EDO

Nuclear Energy Institute Comments

on

Direction Setting Issue Papers

from

NRC Strategic Assessment and Rebaselining Initiative

November 27, 1996

DSI 7 – Materials/Medical Oversight

1. What, if any, important considerations may have been omitted?

   - The paper did not address the materials licensee program for source or special nuclear material. It focused only on the by-product licensees.

   - The NRC should consider the role of other regulators (e.g., Agreement States and FDA) and the radiation risks that these agencies are regulating. The NRC should focus on the material licensees that are required to have an Emergency Plan and defer to Agreement States all other material licensees. NRC should maintain its role of establishing national radiation regulations but defer to the Agreement States the inspection activity for the facilities not required to maintain an Emergency Plan. The NRC should defer to FDA the role of approval of new radioactive material uses and devices for medical applications, and to Agreement States for industrial, consumer product applications. NRC should retain the regulation of the major material licensees. These are the facilities that are required to maintain Emergency Plans as determined by the quantities of radioactive material they are licensed to possess.

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

   The NRC's assumptions for internal and external factors appear to be correct. The paper correctly identified the quality management (QM) rule as a major issue in the community, but failed to recognize that this is only one of the many issues facing the material licensees. Although the QM rule affects only a small portion of the materials licensees, most materials licensees believe the NRC regulations are too prescriptive and enforcement is based on compliance to paperwork rather than safety performance.

3. Do the Commission's preliminary views respond to the current environment and challenge?

   The Commission's preliminary view is responsive to the current environment and challenges only for by-product licenses. The NRC needs to expand its thinking and consider all materials licensees and the associated regulations.

4. NEI Recommendation

NEI recommends a blend of the options.

- The concept of having all federal regulatory responsibility within one agency is appropriate. Implementation of standards for low-risk activities by Agreement States provides the ability to focus federal resources on issues of most safety significance.

- The combination of X-ray, accelerators, and naturally occurring and accelerator-produced radioactive materials (NARM) with by-product, source and special nuclear materials would result in uniform and consistent regulation of radiation regardless of the source. The NRC should take on the role of establishing the national radiation protection standards applicable to all materials.

- The NRC should encourage states to become Agreement States and have them provide regulatory oversight of the facilities and activities that do not require an emergency plan while the NRC focuses on the major material licensees.

- The NRC should discontinue regulation of all medical activities, cede to the FDA regulatory approval of devices and radionuclide applications in medicine, and cede to state authority regulatory approval of devices and radionuclides used in industrial and consumer products.

- The NRC should retain the regulatory authority over major material licensees, regardless of the type (i.e. source, by-product, or special nuclear materials). The defining factor between the state authority and the NRC authority would be the source term and if an emergency plan is required for licensing the facility.