



NUCLEAR ENERGY INSTITUTE

DSI-23

(14)

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SENIOR VICE PRESIDENT
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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.

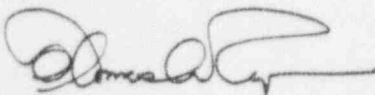
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Several of the DSIs would benefit from a practical definition of an adequate level of protection of public health and safety. It is difficult to discuss how to (1) improve public communication, (2) improve the efficiency and effectiveness of the regulator, 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

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Enclosure

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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 23 – Enhancing Regulatory Excellence

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

- The paper fails to consider that any past actions of the NRC may have been incorrect or inappropriate. Instead, it equates action with improvement. We believe the agency should adopt a questioning, self-critical attitude in its assessment of past initiatives, similar to what is expected of licensees.
- The paper does not factor in previous internal studies. For example, the Office of the Inspector General issued a report in May, 1995, entitled, "Now is the Opportune Time to Re-examine NRC's Organizational Structure." It addressed significant topics related to DSI 23 including eliminating duplication, reducing management layers, and consolidating activities to reduce program inconsistency. It included recommendations which appear more aggressive than the options considered in this paper.
- The paper focuses on regulatory effectiveness which "denotes a regulatory framework for ensuring public health and safety that is clear, coherent, logical, consistent, reliable, and technically sound." It then provides, in the appendix, a description of "improvements" that have been made over the years to the regulatory framework. When examined together, the litany of improvements falls far short of being clear, coherent, logical, consistent, reliable, or technically sound. For the most part, we see adoption of specific prescriptive regulatory approaches and requirements, without apparent reference to a consistent or coherent safety standard. The most notable exception is the performance-based maintenance rule, although its ultimate effect will depend on the NRC's inspection and enforcement practices, which are still in their infancy.
- NRC activities are highly reactive, driven by specific events. The response to those events becomes institutionalized as part of the ever-increasing set of regulatory "requirements". In the end, this leads to a dilution of NRC and industry resources, rather than a focus on issues of true safety significance. The paper does not consider this problem or the apparent need for an underlying basis for the regulatory framework. Such a basis (e.g., an application of the existing safety goals) could help focus NRC's activities and temper response to non-safety-significant events.

For example, the NRC's recent report on spent fuel pool action plan issues concludes that existing designs and operating activities provide adequate protection of public health and safety. The report also notes that, based on available risk analyses, spent fuel pool issues are a small fraction of overall plant risk. For the majority of plants, spent fuel pool operations are

currently addressed in plant technical specifications with regard to criticality and inventory control. In its August 1, 1996, briefing for the Commission, the staff concluded that they had not found "fundamental weaknesses in any of the safety functions with respect to the spent fuel safety functions." An AEOD study, briefed for the Commission in November, reached similar conclusions.

NRC's report, however, states that it is the staff's intent to include spent fuel pool operations in the proposed shutdown rule. We believe this action would be inconsistent with the efficiency principle embodied in NRC's Principles of Good Regulation, as well as with the Commission's policy statement and pronouncements on PRA and risk-informed regulation. Notwithstanding the report's conclusions that spent fuel design and operation provide for adequate protection, are of minor risk significance, and are addressed in technical specifications, another layer of regulation is proposed in the form of a performance-based shutdown rule. This action would not achieve any further risk reduction, and will divert resources and attention away from more safety-significant activities. If the existing risk analyses are accurate, it is highly unlikely that this action could be supported under the regulatory analysis guidelines. It is being pursued only because of the current environment.

- The current scope and complexity of NRC power reactor activities is too broad to achieve regulatory excellence. Nuclear power plant safety performance has been good and is improving, but significant resources are being devoted by both NRC and industry to issues which go beyond assuring safety. While optimizing existing rules and regulatory programs is important and necessary, focusing the NRC regulatory program is more important so that NRC staff can concentrate on their fundamental regulatory responsibility (which, as noted above, can benefit from more concise expression). During the last decade, NRC has been devoting many resources to operational assessment programs that go well beyond regulations, and duplicate, in large part, the industry's own efforts to achieve operational excellence. This had been documented by review groups and in regulatory impact surveys by NRC and industry, yet the activities have not changed. In effect, NRC's focus on operational assessment has diverted its resources from its most fundamental regulatory responsibilities, such as review of licensing applications/amendments and verifying compliance with regulations.
- NRC still spends significant resources on items of low safety significance, and needs to be more performance based in their inspection activity. This results, at least in part, from the lack of performance measures for evaluating NRC activities. Recent Regulatory Information Conferences have included discussion of timeliness of NRC regulatory response, but, at best, this measures only efficiency. It assumes that everything that NRC does is

equally necessary and thus avoids the question of effectiveness. Metrics for measuring effectiveness are needed, and the views of "customers", including the regulated industry and the public, should be sought in their establishment.

- While it is clear that safety is being achieved, the cumulative effect of NRC's regulatory activities is challenging the economic viability of continued operation of many existing nuclear power plants. At the same time, analyses comparing nuclear power plant risk to the existing Commission-approved safety goals continue to show current nuclear power plants in a favorable light. Given this, the real test of effective regulation is whether the regulated industry can thrive while achieving goals of safety and protection of the public. The agency needs to ask itself if its goals are consistent with that test. It should be considered unacceptable for the regulatory burden to deprive the U.S. economy of any option for production of electric power if the safety performance does not justify the burden.
- The paper gives no consideration to an outside review of NRC activities. NRC should at least consider the option of a critical outside review of its regulatory programs, perhaps including representatives of other federal agencies with safety mandates (e.g., FAA). Such a review should also explicitly consider the human factors effect on licensees and their performance of the totality of NRC requirements and activities.
- The paper makes no mention of the importance of the knowledge, skills, and abilities of NRC managers and staff, the impact on licensees when one or more of these characteristics is lacking, and how performance of NRC managers and staff can be objectively judged. The question of objective assessment of individual performance also raises the obvious question of assessment of the performance of the organization as a whole and the performance of its component elements, e.g., Office of Nuclear Reactor Regulation (NRR), Office of Nuclear Material Safety and Safeguards (NMSS), etc. The paper covering DSI 11 cites numerous examples of how licensee performance is judged; clearly, the means of the NRC assessing its own performance should be discussed in more detail than is currently provided in this paper.
- The paper does not address the problem of "regulation by enforcement," the tendency by the NRC staff to use the enforcement process (in its broadest sense) to impose new interpretations of regulatory requirements and guidelines.

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

- The paper includes several references to a concern that changes "may be misinterpreted by the staff as a basis for relaxing NRC safety vigilance with a negative effect on enhancing the effectiveness aspects of regulatory excellence". No basis is provided for this concern. It appears to be an inherent assumption, and a reason for not changing or changing only incrementally. The assumption is untenable. Proper management of change can and should preclude such interpretations. Change which is obviously intended to focus on what is safety significant (i.e., important) rather than what is non-safety-significant (i.e., unimportant) could equally well be interpreted by staff as a need to enhance vigilance. It is management's job to produce such an outcome. (It should be noted that there is similarly no basis for the presumption of positive consequences with respect to reducing the probability of error or instilling an appropriate safety culture which are attributed to Option 2).
- The paper presumes that all past enhancements to the regulatory framework have been necessary, appropriate, and continue to be needed. This assumption is inappropriate, and as noted above reflects a lack of a questioning, self-critical attitude.
- The discussion of external factors notes, "Licensees have not emphasized changes specifically focused on enhancing regulatory effectiveness". We object to this characterization. On the contrary, the industry proposed NEI 96-04, "Enhancing Nuclear Plant Safety and Reliability Through Risk-Based and Performance-Based Regulation". The goal of this initiative is specifically to focus the NRC and industry on more risk-significant issues, thereby improving the effectiveness of the regulatory process.
- Much recent attention has been directed to implementation of the maintenance rule and comments have been made by the Chairman, and others, on the value of risk-informed, performance-based regulation. Given this background, we are concerned to find the NRC's consideration of risk-informed and performance-based regulation relegated to a background discussion of recent initiatives, as opposed to being the cornerstone of a new regulatory framework.

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

The Commission's preliminary views favor a "more proactive approach to improvement" (Option 2) which would be "broadened to improve the way the NRC does its job". This is obviously responsive to the need for improvement and

reflects an appropriate sense of urgency. We suggest that this broader approach consider the issues and comments summarized above.

4. NEI Recommendation

NEI considers that regulatory excellence requires a solid, objective standard of what is required to assure adequate safety. Without such a baseline, it is impossible to know whether individual activities are contributing to accomplishing the agency's mission -- a fundamental element of excellence -- or are distracting staff and licensees from those activities which contribute directly to adequate safety. NRC should develop a practical, objective standard and use it in its assessment of individual staff activities. Achieving excellence should require that activities not contributing to assurance of adequate safety be terminated.