



NUCLEAR ENERGY INSTITUTE

DSI-11
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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.

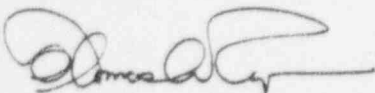
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Several of the DSIs would benefit from a practical definition of an adequate level of protection of public health and safety. It is difficult to discuss how to (1) improve public communication, (2) improve the efficiency and effectiveness of the regulator,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

TDR/RWH/ec
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 11 – Operating Reactor Program Oversight

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

- The issue paper omits discussion of what the NRC should be doing to establish a focus for the oversight program for commercial nuclear power plants. The program should be based on a credible standard which permits a reasoned balancing of the legitimate concerns of the public for "adequate protection of their health and safety" against the significant societal benefits which are provided by commercial nuclear power.

Throughout this paper (and the other papers) there are numerous references to initiatives "to improve the regulatory process and foster an environment that is conducive to continual improvements in the industry performance while achieving NRC's regulatory mission of ensuring safe plant operations." Nuclear power plant safety performance has improved steadily in recent years, above a level which was found adequate (most visibly in the Commission's Policy Statement on Severe Accidents in 1986). NRC's "continual improvements" over that time have served largely to increase the margin of safety of existing plants. NRC must recognize that this ratcheting of required safety level can challenge the economic viability of the nuclear option and that, as a result of its policies and actions, society could be denied the benefits of this important energy source. Since societal risk from the nuclear fuel cycle compares favorably to that from competing forms of electrical generation, such an outcome could actually increase the risk to the public. Unless the standards for adequate protection of public health and safety have changed, or are significantly different for nuclear energy, there is no justification for the increase in burden. There has been no indication that such a change in standard has occurred.

- The closest the NRC has come to addressing the admittedly-difficult question of "what level of safety is sufficient?" was the "Policy Statement on Safety Goals for the Operation of Nuclear Power Plants" which was issued over ten years ago and has not been revised. Those goals were intended to set the threshold of adequacy below which efforts to further reduce risk need not be required.

In the intervening decade since the Policy was issued, the NRC has made little progress in applying the safety goal objectives and developing a practical generic adequate protection standard. During that same decade, plant safety performance has improved demonstrably. Until there is an objective standard which is used to measure the adequacy of the existing body of regulation and the need for additional regulations, power reactor

licensing, oversight, and rulemaking initiatives will continue to place undue emphasis on subjective judgments, non-quantitative criteria, and an apparently never-ending upward spiral of performance expectations for licensees.

- The paper fails to assess the current enforcement policy or possible alternatives. The enforcement program is noted in this paper to be an element of inspection of operating reactors, but it is not critically assessed. It is not apparent that this subject was considered anywhere else in the Strategic Assessment and Rebaselining Initiative. This is a serious omission for a comprehensive strategic planning process. The enforcement program has a pervasive effect on the relationship between NRC and its licensees. It is currently highly punitive and is contributing to the adversarial nature of that relationship. Issues and options which should be considered include:
 - allowance for flexibility / discretion in dealing with noncompliances identified by licensees,
 - timeliness of enforcement action, which in some cases does not occur until years after a noncompliance event, and
 - the punitive effect of the management of press involvement, which can now provide for negative press on two occasions for a single noncompliance (once for the enforcement conference and again if a civil penalty is issued).

Any reassessment of the enforcement program should consider comparisons with the programs of other federal agencies with health and safety missions (e.g., EPA, FAA) and with practices of other Western nuclear regulatory authorities.

- The paper does not identify the present rulemaking process as a potential area for analysis and reform. In addition to the basic problem noted above concerning the lack of an objective adequate protection standard, many other elements of the process could be improved. Generally, the process seems to take too much time. The Regulatory Analyses which are offered in support of proposed rules typically do not adequately address the issues. The credibility of cost estimates could be improved by providing for interaction with stakeholders during its development. Projected safety benefits need to be made less subjective to improve their accuracy and credibility.

For example, the U.S. Department of Health and Human Services (DHHS) published guidelines for drug screening in June 1994. The revised guidance reduces the required specimen from 60ml to 30ml and the number of blind performance test specimens from 10 percent to 3 percent. In a recent article,

the NRC indicated that its final rule that would include these changes won't be out before the summer of next year. Why does it take over three years to get the benefit of guidance that has been finalized by DHHS?

- There needs to be an evaluation of whether the NRC's resident inspection program has been effective. An obvious question is: "Why did the resident inspection program not catch early indications of what were later determined to be "major" problems?" Resident inspectors were added in the aftermath of the Three Mile Island accident, when there was greater concern about the thoroughness of operations safety. All objective indicators of operational safety have improved significantly in the intervening 15 years. It may be that applying scarce resources in this manner is no longer effective. Consideration should be given to elements of inspection programs in place in other Western countries.
 - The paper does not identify the present hearing process as a potential area for reform. It seems that it should be possible to find better, more cost-effective ways for the public to state their views without recourse to the full adjudicatory hearing process. Certainly, the full adjudicatory hearing process is not always commensurate with the degree of risk associated with a specific licensing action. In those instances where the full adjudicatory process is deemed appropriate, standards for intervention and qualifications for expert witnesses should be more rigorously applied.
 - The paper includes a number of citations of the Atomic Energy Act as dictating both the NRC's responsibilities and specific requirements which must be imposed on licensees. There are also numerous other federal laws which define additional NRC responsibilities. The NRC should consider offering legislative proposals as a means of modifying or removing legal requirements which, through experience, have been found to be unnecessary, unduly wasteful of resources, or unduly restrictive.
 - The success of option 2 is not constrained by expanded use of communications technology as indicated in the discussion of this option. Communications technology is a tool that should be used, under any option, where it provides cost effective improvements in the transfer of information.
2. How accurate are the NRC's assumptions and projections for internal and external factors?
- The paper states that it is not unreasonable to expect three to five currently operating reactors to shut down prematurely over the next 10 years because of economic pressures and concerns regarding aging of equipment. This estimate could be overly optimistic due to a number of additional factors such as delays in resolution of the high level waste disposal problem and an

underestimate of the negative economic impact of the regulatory burden. Uncertainty regarding possible future increases in regulatory requirements and unpredictability resulting from the reactor oversight process could contribute to premature shutdown decisions.

- The paper states "Should past improvements in safety continue, the number of new NRC mandated regulatory requirements requiring license amendments or licensee action is expected to remain at a relatively low level." The presumption that new requirements must be imposed is questionable if plant performance (i.e., safety) remains constant, much less if it improves.
- The paper implies that certain NRC initiatives to eliminate unnecessary regulatory burdens were more successful than was the case. The Marginal to Safety Program is a case in point. The rulemaking which allowed licensees to adopt an optional approach to containment leak rate testing appears to be the single success of this program. This was identified in 1986 as the highest priority for change, yet it took 9 years to effect a change. There seems to be little or no visible progress in reforming other burdensome requirements that were identified as legitimate candidates for change in the early stages of this program. One such candidate was the current body of fire protection requirements, for which there was agreement between NRC and industry that the safety needs do not justify the burden of existing requirements.

At the same time, changes to the reactor oversight program have increased the burden on licensees. For example, during the 1996 Regulatory Information Conference, Harold Ray, Southern California Edison, noted that the Integrated Plant Assessment Program (IPAP) inspection at San Onofre represented approximately \$350,000 in direct NRC costs. This should be contrasted with the \$250,000 spent to develop the on-line safety monitor used at the same plant, which made a major contribution to increased safety.

- The paper states that the current program policy is that industry should play a major role in initiating regulations for appropriate changes and makes the assertion: "Efforts in this area will result in improved regulations and reduce unnecessary regulatory burden." These improvements can only be realized if NRC accepts the appropriateness of changes which might appear to reduce requirements. NRC needs to recognize the significant margin that now exists between many current requirements and adequate protection. NRC also must respond to industry initiatives in a timely manner.

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

In general, yes, however the current challenge differs for each utility depending on the local political/economic environment, the age of its nuclear plants and the percent of total production from nuclear power. Licensees currently are faced with significant uncertainties and impacts which are likely to ensue from deregulation. Regardless of the option selected, the Commission must be extremely sensitive to the need to find the most cost-effective solutions to issues and to ensure that the focus of the Commission is on those issues that are truly safety significant.

4. NEI Recommendation

We do not believe that the options presented in the paper are mutually exclusive. Each option has points to be considered and discounted.

- Option 1 would continue the regulatory process along its present course in all three areas (licensing, inspection and performance assessment), with a review of the reactor oversight processes in the context of lessons learned from current issues. This is attractive but carries the risk of biasing the processes to account for problems found at only a few plants. The problems uncovered must be corrected, but the philosophy of "one solution fits all" should not be applied indiscriminately. Already-burdensome NRC oversight processes could be compounded with additional inspection overtures which would add cost without a commensurate safety benefit. This option would do nothing to halt the spiral of increasing cost to both the NRC and the industry.
- Option 2 seeks new approaches within the existing reactor oversight framework to improve effectiveness while also encouraging industry and public interaction and involvement. This option offers the best means for both the NRC and industry to achieve common goals in the most efficient fashion. It will require a major culture shift in accepting that the industry can maintain the current level of safety under a different system of oversight. However, the need for "continued improvements in [safety] performance," as stated in this option, is questionable given the demonstrated safety record of current plants.
- Option 3 is a creative approach to operating reactor program oversight but involves a large cost to conduct a business process reengineering (BPR) of the reactor oversight program. NRC should explore Option 3 by selecting functional areas as pilot programs to test the utility of the business process reengineering approach. To be successful, such pilot programs would have to

lead to a workable, cost-effective alternative providing focused oversight processes and structures grounded in risk significance.

- The major focus should be on the implementation of a modified Option 2 to include features that:
 - 1) Promote an NRC effort to develop a connection between the Safety Goal Policy and regulatory requirements, i.e., an objective standard for the adequate protection of the health and safety of the public.
 - 2) Encourage the NRC to develop necessary methodologies to permit the establishment and implementation of regulations which are truly risk-informed and performance-based. Also, modify NRC's hearing process to determine the need for formalized hearings based on the risk significance of the licensing action, not the nature of the action.
 - 3) Provide for improvement of the effectiveness and understanding of the performance assessment process, i.e., the development of objective criteria for assessing short term and long term performance.
 - 4) Establish a system to draft regulatory guides, standard review plans, and inspection modules in a parallel manner that would permit both the NRC's Committee to Review Generic Requirements (CRGR) and the public to ascertain if the guidance for implementation is consistent and suitably comprehensive. Also, provide more timely review of industry-developed generic guidelines which could be endorsed by the NRC.
 - 5) Pursue realignment of regional and headquarters resources to make more efficient use of special expertise within the NRC and to promote more consistency in the conduct of business and in the interpretation of regulatory requirements. Eliminate the site resident N+1 policy to allow for better resource allocation.
 - 6) Continue programs such as the Cost Beneficial Licensing Action initiative which will allow individual licensees to optimize their regulatory regime.