



NUCLEAR ENERGY INSTITUTE

DSI-12
(25)

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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?

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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.

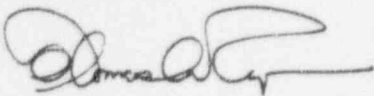
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Several of the DSIs would benefit from a practical definition of an adequate level of protection of public health and safety. It is difficult to discuss how to (1) improve public communication, (2) improve the efficiency and effectiveness of the regulator, 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 12 – Risk-Informed, Performance-Based Regulation

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

- The issue paper gives significant emphasis to reducing the regulatory burden. This can tend to obscure the benefit that risk-informed performance-based practices can have on regulatory implementation efficiency and effectiveness, thereby reducing the resource burden on NRC staff and licensees while maintaining safety. A risk-informed, performance-based regulatory process provides a more realistic method for identifying safety significant matters. It enables licensee and NRC staff to better focus resources on issues of safety significance that will ultimately enhance the protection of public health and safety.
- The NRC should consider internal review material. The Office of Inspector General issued OIG/96E-18 "Better Definition and Planning Needed to Guide NRC's Transition to a Risk-informed, Performance-based Regulatory System", in October 1996 (recognized to be after these DSI papers were finalized). This report, and any similar internal reviews, should be factored into the NRC deliberations.
- The paper should recognize that the current regulatory regime of prescriptive procedural compliance can degrade safety. The current process causes licensee and NRC personnel to focus on a myriad of matters, many of which have no, or minimal safety significance. Replacing the current prescriptive procedural compliance regulatory regime with a risk-informed, performance-based approach would eliminate this potential weakness.
- The paper does not address the following topics:
 - the importance of changing the regulatory culture from a procedural compliance mind-set, to a performance-based assessment perspective;
 - the economic considerations associated with changing the regulatory process;
 - the need for licensee flexibility in adopting risk-informed, performance-based regulation as an option;
 - the importance of being able to benchmark the risk to public health and safety from nuclear plants compared with the risk from other societal activities and events;
 - the potential NRC resource impact from a dual NRC regulatory regime: a risk-informed, performance-based, and a procedural compliance regime; and

- an over-emphasis on the legal matters in the current regime which can dominate and distract licensee and NRC management attention away from matters of safety significance.
- The purpose of the paper is to evaluate the reform of the nuclear regulatory process. It must be recognized that the process involves much more than regulations and related guidance. It includes how regulation is practiced by NRC and its licensees. For over 30+ years the regulatory process has been based on the comparison of documentation and activities against prescriptive procedures; a procedural compliance regulatory process. The practices have become deeply embedded in a rigid and regimented culture. The specific implementing procedures and processes are often considered more important than the regulations. Licensees request exceptions to regulatory implementation commitments. The change process for these implementation commitments is often protracted, resource intensive, and discourages licensees from pursuing improvements. Significant resources and patience are going to have to be dedicated to changing this embedded culture that is pervasive throughout the industry and NRC staff.
- The issue paper does not recognize the development of risk-informed, performance-based implementation practices that already have been established. The extensive discussions on 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants", established the concepts and fundamental implementation practices for a risk-informed, performance-based regime. The Commission allowed a five year period for the industry and the NRC staff to develop appropriate implementation practices for this new regulatory regime. The framework has been established and proven. The concepts and general practices should be applied to other areas without the need for protracted debate on the concepts.
- The option to implement a risk-informed, performance-based approach to satisfying the regulations should apply to all licensees. It is correct that the source term for a reactor is considerably higher than for a fuel fabrication facility, which is higher than a uranium mill. However, risk-informed, performance-based regulatory concepts can still be applied. The specific method of application may vary, e.g., the use of hazards analyses as opposed to probabilistic risk analyses. Such options are not recognized in the paper.
- For material licensees, the assumptions and projects described in the issue paper are incorrect. The industry through NEI has recently filed a petition for rule making for the Part 70 licensees. It would establish a risk-informed, performance-based method of regulation for these licensees. The major issue that the Part 35 licensees have with the quality management (QM) rule is that it is prescriptive and not risk-informed, performance-based regulation.

- In a risk-informed performance-based regulatory environment, the emphasis is on satisfying performance standards and goals, not on observing activities. The NRC Inspection Manual, chapter 0610, must be changed. In addition, the paper must emphasize that performance-based regulation is less specific, allowing licensees greater flexibility in implementation.
- The paper does not discuss the potential resource impact from changing the regulatory process. The priority criteria for changes are weighted towards safety benefit and do not appear to take into consideration the cost of implementation. The cost of implementation, including personnel training and indoctrination, could be high. Such costs could become prohibitive for some facilities (e.g., those with a limited number of years of operation remaining) and could themselves, in the extreme, lead to decisions to shut down prematurely. Thus, the adoption of a risk-informed, performance-based regime should be optional for licensees for specific regulations.
- The paper is silent on philosophical issues, such as, regulatory threshold, and the potential adverse effect of regulation on safety. In practice the safety goals are seldom used. Although the safety goal policy is briefly discussed, there is no discussion on the link between PSA, economics and the safety goal policy. The industry began to address this issue through its "PSA Application Guide" (EPRI TR-105396).
- The paper identifies analytical uncertainties as a weakness in probabilistic methodologies. The maintenance rule, and other risk-based pilot studies have used expert panel solicitation and review to address the issue of uncertainties in probabilistic safety analyses (PSA). Through such a process, uncertainties can be accommodated and the important defense-in-depth characteristic maintained. The use of an expert panel of knowledgeable licensee personnel has been proven and generally found acceptable. This aspect is not recognized in the discussion on PSA in this paper.
- NRC should consider previous recommendations for changes in this area. For example, in an internal memorandum dated September 6, 1984, Richard DeYoung, then-Director of the Office of Inspection and Enforcement (IE), recommended consideration of a shift to performance-based inspection of quality assurance (QA). Mr. DeYoung stated, "we believe that a shift of the NRC QA efforts away from a licensing review of QA program descriptions and inspection of programmatic aspects to a review and inspection of actual performance using a performance trend analysis of ongoing activities in key functional areas would improve the attainment and assurance of quality." Discussions between NEI and NRC intended to reach agreement on a performance-based approach to QA foundered in 1995, eleven years after Mr. DeYoung's memo.

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

- The implementation of risk-informed, performance-based regulations will enable the public to better assess and understand the risk perspective from nuclear facilities.
- Recent Administration and Congressional initiatives to improve the federal regulatory process encourage the adoption of a performance-based regime. These initiatives indicate that all federal agencies should be moving to a new regulatory process where practical. In such cases there should be a consistent interpretation, and the NRC has the opportunity to lead since it has a working example of a risk-informed, performance-based regulation in 10 CFR 50.65.
- Where there is dual regulatory jurisdiction on matters associated with radiological hazards and materials, it is essential for the NRC to be the lead agency. A common interagency regulatory framework is central to improving the effectiveness and efficiency of the nuclear regulatory process. Any differences in interagency policy, interpretation, and implementation will result in extended "turf" debates, exacerbating the difficulties of a transition to an improved regulatory regime.
- Many foreign regulatory agencies and utilities look to the NRC as a leader in nuclear regulatory matters. The NRC, working with the nuclear industry, should take the lead in developing standards and guidelines for implementing risk-informed, performance-based regulatory concepts. This would provide an example of practical implementation. It would preclude protracted debate on theoretical topics that can be the hallmark of international consensus activities. It would firmly establish the US in the leadership position of the international nuclear community.
- The paper must recognize the onset of electrical power deregulation. The need for urgency in the pursuit of risk-informed, performance-based improvements to NRC regulations is of paramount importance. The implementation schedule must reflect this urgency.

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

- The Commission's preliminary views do not reflect the need to change the process for assessing regulatory compliance through monitoring the plant (equipment and organizations) against predetermined criteria. The reform of

the regulatory process should build on the 1993 NRC Regulatory Review Group Report recommendations.

- The Commission's preliminary view that materials licensees are not supportive of these concepts does not reflect the current environment. There were several Commission briefings on the regulatory problems of Part 35 licensees in 1995 and 1996. These dealt with the prescriptive nature of the current regulations. The industry indicated that a performance-based rule was preferred. None of this was reflected in the Commission's view.

4. NEI Recommendation

NEI generally concurs with the preliminary views of the Commission, but with the following important qualifications:

- the need for urgency in implementation must be reflected in implementation schedules and activities,
- the implementation of a risk-informed, performance-based regulatory concept, framework, and practices should build on those established through 10 CFR 50.65; there is no need for further protracted debate,
- the need to consider changes to the regulations that would reduce the resource burden without necessarily requiring an improvement in safety to do so. Maintaining already-adequate levels of safety should be sufficient, and
- the need to accept that a new regulatory process will mean changes to NRC and industry assessment practices and culture.

The strategic policy discussions and implementation schedules can only be of benefit if the above factors are included in the Commission's plans for improving and reforming the nuclear regulatory process through a risk-informed, performance-based approach.