



NUCLEAR ENERGY INSTITUTE

1. FSM
→ 2. Yt Sheron
Significant Issues
raised that cross
Division lines, I continue
to support the 4 points in
Michael's letter. Please
Ralph E. Beedle
SENIOR VICE PRESIDENT AND
CHIEF NUCLEAR OFFICIAL
NUCLEAR GENERATION
discuss your approach
w/me. Ashok
10/15

October 10, 1996

Mr. Ashok C. Thadani
Deputy Director
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: Graded QA Project – An Industry Perspective (Project Number: 689)

Dear Mr. Thadani:

The industry has been closely monitoring the "volunteer plant" graded QA activities over the past 15 months. There is a growing concern that these activities may not result in general industrywide improvements in: the QA regulatory regime, the focus on safety, or the effectiveness and efficiency of implementing a QA program. NEI believes it may be beneficial to revisit the application of risk-informed, performance-based regulatory concepts for QA activities as an expedient means for resolving the graded QA issues.

The industry's concerns are linked to the extensive implementation questions and inferred requirements associated with the QA programs for low safety significant structures, systems and components (SSCs), probabilistic safety assessment analyses, and the expert panel process. The focus should be on safety and program output, predominantly for high safety significant SSCs. It should not be on extensive and prescriptive implementation details for low safety significant SSCs. Such details become locked in place by the burdensome Section 50.54(a) change process. They adversely impact a licensee's decision-making process for making improvements in its QA program.

Fifteen months ago, NEI submitted a rulemaking petition to amend 10 CFR 50.54(a). The central purpose of the petition is to improve the change process for a licensee's QA program description by focusing regulatory interactions on the safety implications of a change. A satisfactory conclusion to this petition is a central element for improving the regulatory process for QA.

9610230003 961010
PDR PROJ
689 PDR

PROJECT 689

Mr. Ashok C. Thadani

Page 2

NEI and the volunteer plants believe it would be beneficial to discuss these issues with you and your staff. The enclosure to this letter provides additional information that could be the basis for discussion on improving the regulatory process for QA.

If you have any questions, please contact Tony Pietrangelo at (202) 739-8081 or me.

Sincerely,

A handwritten signature in dark ink, appearing to read 'R. Beedle', with a long horizontal flourish extending to the right.

Ralph E. Beedle

APH/jes
Enclosure

c: Mr. Bruce E. Boger, NRC
Mr. Jerry W. Yelverton, Entergy Operations, Inc.
Mr. James M. Levine, Arizona Public Service Co.
Mr. William T. Cottle, Houston Lighting & Power Co.

Enclosure to NEI Letter Dated October 10, 1996

Graded QA Program Description and its Change Process

Background

The industry and the NRC staff have been discussing and assessing improvements to the QA regulatory process since 1992. The initial industry pilot project, *Implementation of a Graded, Performance-Based Approach to Quality* was deferred in 1994 to allow the risk-informed, performance-based concept, its implementation practices, and regulatory understandings to mature.

The industry had become concerned at the level of detail being suggested for inclusion in a licensee's QA program description that is contained, or referenced in its final safety analysis report. The industry believed that the proposed level of detail would become an additional and unnecessary burden on licensees because of: (1) the addition of a performance-based monitoring regime for assessing QA program adequacy is designed to compensate for, not be in addition to, a procedural regulatory compliance regimen, and (2) the additional impact of increased detail from the burdensome Section 50.54(a) change process. These aspects would have precluded a general, industrywide improvement in the effectiveness and efficiency of implementing licensees' QA programs.

The objective of adding a requirement for performance-based monitoring as the means for assessing the adequacy of a licensee's QA program was to improve implementation effectiveness and efficiency, and enhance regulatory predictability, without degrading safety. As a result, the performance-based monitoring requirement would obviate the need for a very prescriptive QA program description in a licensee's final safety analyses report to support a procedural compliance regime. However, the industry recognizes that the experiences of nonnuclear industries strongly suggest that a vibrant quality program is a vital element in any business plan.

The deferred industry pilot project was based on the concepts and practices established by the maintenance rule. In the deferred pilot project regulatory interactions, there was a general understanding that a risk-informed, performance-based approach to implementing QA (a graded approach) encompassed four essential elements. These elements were initially described in the NRC letter (Milhoan, NRC/Rasin, NEI) dated June 15, 1994.

The elements remain germane and are:

- the categorization of structures, systems and components (SSCs) based on safety (risk) significance, using probabilistic safety assessment (PSA) insights, operational experience, and an expert panel review;
- the application of appropriate quality controls consistent with safety significance;
- the implementation of an effective corrective action program; and
- the incorporation of new information and operational feedback (this could include the monitoring of performance or condition against licensee-established criteria (goals) in a manner sufficient to provide reasonable assurance that the safety functions will be fulfilled).

Since December 1994, the industry and the NRC staff have gained additional and significant experience in risk-informed, performance-based approaches to implementing the NRC's regulations through the maintenance rule's implementation activities. A performance-based approach for QA could assist in overcoming NRC concerns, and industry apprehension, with regard to graded QA implementation.

Discussion

The "volunteer plant" graded QA activities have built on the practices discussed in the deferred industry pilot project: the use and incorporation of industry operational experiences, PSA insights, and expert panel review. However, progress has been frustratingly slow. There is a growing industry concern that any industrywide benefits from this project, improvements in the regulatory process, improvements in safety, and improvements in efficiency would be minimal, with limited economic benefit.

From an industry observer's perspective, it appears that the "volunteer plant" graded QA activities are experiencing similar difficulties as the deferred industry pilot project. The volunteer plants and the NRC staff are struggling unnecessarily through protracted discussions on level of detail issues for low safety significant structures, systems, and components. The emphasis and discussion should be focused on the QA program for high safety significant SSCs.

On the use of probabilistic safety assessment analyses and insights in the implementation of graded QA, there is confusion. In meetings, some NRC staff have questioned whether PSA should be used as input into the decision process for graded QA. In contrast, changes in NRC personnel have resulted in repetitive detailed questions and discussions on PSA. To observers and participants, it is a confusing scenario. It breeds uncertainty, resulting in a reluctance to pursue

potential improvements. It results in incorrect assumptions that the licensees' responses have been insufficient and inadequate, that progress is minimal, and that the cost of implementing graded QA is uncertain and could be significant. These unfortunate conclusions undermine the hard work of all participants (NRC and industry) that are striving to improve the regulatory process and safety.

Additionally, the NRC staff is requesting very detailed and specific information, often beyond that currently included in the "volunteer plant" licensees' PSA models. There are few licensees that could supply such information, without an extensive expenditure of resources. The industry agrees that PSA alone cannot be the basis for regulatory change or action unless significant additional resources are expended. The incorporation of an expert panel into the process provides the appropriate mechanism to balance analytical uncertainties and assure "defense-in-depth" is maintained.

NEI agrees with NRC staff statements made in recent ACRS presentations that the reviews of PSA implementation pilot projects, and maintenance rule implementation activities indicate that licensees' expert panels can offset, and compensate for, the limitations of the PSA. In view of these statements, and those in SECY 95-265, *Response to August 9, 1995, Staff Requirements Memorandum Request to Analyze the Generic Applicability of the Risk Determination Process used in Implementing the Maintenance Rule*, and the statements in the NRC Regulatory Review Group Report on PSA applications, the industry is struggling to understand the need for additional, detailed, and complex PSA analyses as a prerequisite to implementing graded QA, even for pilot applications.

In a risk-informed, performance-based approach to QA, the assessment of QA program adequacy is encompassed by the operational feedback and corrective action elements. The adequacy of the program is determined in a more objective, effective and efficient means, through the monitoring (trending) of performance and condition against licensee-established criteria (goals), rather than through a prescriptive procedural compliance regimen.

The current change process for QA program descriptions is burdensome. A simple change request often takes months to process and approve. In the NEI June 8, 1995, rulemaking petition to amend 10 CFR 50.54(a), it was emphasized that often licensees are discouraged from pursuing improvements to their QA program descriptions because of the resource burden associated with the Section 50.54(a) process and requirements. The NEI petition focuses the need for regulatory interaction on the impact on safety resulting from a change. The industry strongly believes that the regulatory process for QA could be significantly improved by changing the Section 50.54(a) focus from procedural commitment to one of impact on safety.

The NEI petition, when coupled with a risk-informed, performance-based approach to implementing QA, could provide the vehicle for resolving the graded QA concerns with minimal impact on project activities. In addition, such a process would provide more objective and realistic input into the resolution of any emerging policy issues, rather than the usual protracted and theoretical interactions on draft project implementation guides.

The industry acknowledges that the above proposal is a significant departure from the traditional nuclear industry QA regulatory practices. However, similar concepts and practices have been proven in nonnuclear industries, such as semiconductor, aerospace, and automotive. In piloting any new approach, NEI recognizes the importance of coordinating industry and NRC activities to assure optimum management of resources. More importantly, a combined pilot project approach reduces the potential for misunderstanding and miscommunication.

Conclusion

The monitoring of plant condition or performance against licensee-established goals coupled with a change in Section 50.54(a) to focus on the safety significance of a change to a licensee's QA program description, would significantly increase the effectiveness and efficiency of implementing regulations. It would reduce the degree of debate on graded QA projects, and reduce unnecessary NRC and industry resource burdens associated with implementing and regulating QA. A performance-based approach provides for an increased focus on safety, increased licensee flexibility, a more objective and predictable regulatory regime, and increases licensee and NRC attention and resources on safety significant matters.