NUCLEAR ENERGY INSTITUTE

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Mr. Thomas O. Martin
Chief, Regulation Development Branch
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Martin:

In the April 30, 1996, NEI/NRC staff meeting on the NEI petition to amend 10 CFR 50.54(a), we indicated that we would inform you of alternative approaches that would achieve our mutual objective: an improved change process for licensee QA program descriptions that provides a better focus on safety matters.

The industry's main concern is that, in the existing process, licensee and NRC resources are being expended on matters that have minimal, or no safety significance. We agree that the rule needs clarification to focus licensee and NRC attention on potential safety issues. The existing process has resulted in the diversion of diminishing licensee and NRC staff resources to matters that have minimal or no safety significance. This increases the potential for distracting licensee and NRC attention and resources from matters of real safety significance. As such, the industry believes that the rule governing the process for changing licensee QA commitments should include language that permits a licensee to make a change to its QA program description included or referenced in its Safety Analysis Report, providing the change does not degrade safety.

In our response to the *Federal Register's* request for additional information and comment on the NEI Section 50.54(a) petition, we provided a draft guidance document for implementing the amended regulation. There are other options, which we have outlined below.

Guidance Options

NEI's preliminary options for providing guidance to the industry on assessing whether safety is being degraded through a change to a QA program description are:

1. Further develop the draft guideline included in the NEI response to the *Federal Register* request (60 Fed. Reg. 47716 - September 14, 1995) for additional information and comment on the NEI petition. The draft guideline was developed by the NEI Appendix B Working Group and based on the industry's experiences in implementing programmatic changes through NSAC-125, *Guidelines for 10 CFR 50.59 Safety Evaluations*. We believe this provides an initial basis for guidance implementing the petition.

2. As part of the efforts to improve the Section 50.59 implementation guidance, the industry will be developing more appropriate guidance for programmatic changes that are being implemented under Section 50.59. Such activities would be applicable to changes to a licensee's QA program that is included or referenced in its Safety Analysis Report, and provide an alternative method for implementing the proposed regulation.

3. The process described and endorsed in SECY 95-300 for managing NRC commitments. In this process the emphasis is on safety, with clear guidance on when to seek NRC review and approval prior to implementation. More importantly, regulatory consistency would be improved by having one process for managing NRC commitments, whether they are associated with QA, or other commitments such as design or operations.

4. Perform a safety evaluation on the differences in the new and proposed QA program amendment. In such a process the licensee would:

   (a) Define the safety functions or purpose of the elements in the QA program description that are being changed.
   (b) Describe how those elements, or functions, or purpose are being addressed in the amended program.
   (c) If the functions or purpose are not being addressed, perform a safety evaluation of the potential safety degradation by assessing the impact against the following criteria:

      (i) Would the omission of the QA activity increase the probability of occurrence of an accident previously evaluated in the Safety Analysis Report?
      (ii) Would the omission increase the consequences of an accident that is evaluated in the Safety Analysis Report?

(iii) Would the omission increase the possibility of an accident of a different type than previously analyzed in the Safety Analysis Report?
(iv) Would the omission result in a decrease in the margin of safety as defined in the basis of the Technical Specifications?
(v) Would the omission result in a change to the Technical Specifications?

A positive response to any of the above criteria would indicate that there is the potential to degrade public health and safety and NRC review and approval would be required prior to implementation. This method is very similar to the method described in Option 1.

The above ideas are some of the options that can be used to improve the current regulatory change process for QA program descriptions. We emphasize the safety benefits of having a consistent change process for licensee commitments, or matters described in the Safety Analysis Report, and a process that focuses on safety.

In recent months there have been several protracted licensee/NRC staff interactions on proposals for improving the efficiency and effectiveness of implementing QA programs that would have allowed more appropriate allocation of resources on safety matters, and would have resulted in a general improvement in safety. The proposed amendment to Section 50.54(a) would provide licensees with the regulatory flexibility to implement such improvements devoid of the administrative burden associated with the current change process, as demonstrated in some of the recent regulatory interactions.

The industry will continue to work with the NRC staff on developing appropriate guidance to implement improvements in the current regulatory process associated with QA; one that achieves the mutual objectives of improving efficiency and our focus on safety matters.

If you have any questions please contact Adrian Heymer (202-739-8094) of the NEI staff or me at (202) 739-8078.

Sincerely,

Stephen D. Floyd

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APH/jes

c: Mr. Bruce E. Boger, NRC
Ms. Suzanne Black, NRC