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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 10, 1997

MEMORANDUM TO: Samuel J. Collins, Director
Office of Nuclear Reactor Regulation

FROM: Ashok C. Thadani, Director
for Technical Review 
Office of Nuclear Reactor Regulation

SUBJECT: RECOMMENDED APPROACH FOR RESOLVING THE 50.54(a)
RULE GOVERNING CHANGES TO QUALITY ASSURANCE
PROGRAMS

On June 12, 1995, NRC received a petition filed by the Nuclear Energy Institute (NEI) on behalf of the nuclear power industry to amend the regulatory requirements of 10 CFR 50.54(a) that control licensee-proposed changes to quality assurance programs. The petition was docketed by the Commission on June 19, 1995, and assigned Docket No. PRM-50-62. The petitioner requested that the NRC amend 50.54(a) to broaden the authority for licensees to make certain changes to their quality assurance programs described or referenced in the licensees' SARs without prior NRC approval. NEI proposed to use the 10 CFR 50.59 criteria to determine which changes could be made unilaterally by licensees and which ones needed NRC review and approval prior to implementation (i.e., those that constitute an Unreviewed Safety Question or result in a Technical Specification change).

The NEI petition responds in part to a recommendation by the NRC's Regulatory Review Group (RRG) to permit licensees to make changes to their quality assurance programs without NRC approval providing the program continues to meet the regulations. The RRG intent was to modify the regulations so that quality assurance program changes would be treated in a similar fashion as changes to plans for fire protection, physical security, and emergency response. Changes to the physical security and emergency response plans are controlled under 50.54(p) and (q), respectively, and require an evaluation by the licensee to assure continued effectiveness in order to preclude the need for staff review. Changes to fire protection plans are controlled under 50.48(c)(5) and those that affect requirements to assure safe shutdown capability must be submitted for staff review and approval. Other aspects of the fire protection plans can be changed by licensees without prior staff review and approval.

The current 50.54(a) regulation requires licensees proposing changes to their quality assurance programs to submit those that "reduce the commitments", relative to the previously approved program, for a staff determination of acceptability prior to implementation. Therefore, any program change, including administrative, organizational, or programmatic, that could be interpreted as reducing a quality element must be formally submitted for staff review and approval. Clearly, eliminating a QA control from a previously approved program constitutes a reduction in commitment. It has been reaffirmed recently during an appeal meeting with Entergy Operations on April 3, 1996, regarding a proposed change in the auditing controls in the quality assurance program for Grand Gulf that substitution of a new

control deemed equivalent by the licensee for an existing control also constitutes a reduction in commitment and is subject to staff review. The NEI petition is directed toward eliminating the necessity for licensees to submit QA program changes for staff review providing the 50.59 criteria are met, as determined by the licensee.

NRR, RES, and OGC staff members, including various levels of NRR management, have considered the NEI petition in numerous meetings and discussions. Although the staff agrees that the current regulation is too restrictive, the general conclusion is that the 50.59 criteria are not appropriate for controlling QA program and procedural changes. The 50.54(a) regulation was originally promulgated in January, 1983 because QA programs were being unilaterally changed by licensees under 50.59 to the extent that they were no longer acceptable. NEI provided a draft guidance document to demonstrate how quality assurance programmatic and procedural changes could be evaluated using the 50.59 criteria. The steps include (1) an initial screening to determine if a USQ exists, (2) a comparison of the new QA requirement relative to the existing requirement to determine whether the same activities are performed and the same functions achieved, (3) an evaluation of the safety implications of the change to determine whether there is any reduction in QA program adequacy that affects safety, and finally, (4) assessment of whether the proposed change affects any licensing commitments as a result of a notice of violation within the last 2 years. Although these evaluation steps appear to consider the appropriate type of questions, the staff believes more evaluation is required. The NEI proposal involves the subjective analysis of the safety merits of the proposed change versus the continued implementation of pertinent QA elements. Furthermore, as part of the PRA implementation plan, the staff is considering the impact of QA on plant performance. The results of that work may be useful in formulating a revision to 50.54(a). It appears that the types of questions that NEI proposed may be more amenable to incorporation in the regulation, versus being in the guidance document only. Accordingly, the staff recommends denial of the NEI petition.

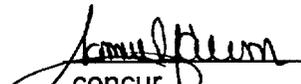
The staff met with NEI representatives in a public meeting held in the NRC offices on April 30, 1996, to discuss the concerns with using the USQ threshold for QA program changes. The staff told NEI at that meeting that the reason that 50.54(a) was adopted in January 1983 was to restrict unilateral changes to QA programs by licensees that had been subsequently determined by the staff to be unacceptable. However, the staff agrees that the current 50.54(a) language may be too restrictive. Based on FY 95 data, the staff could save at least 1/2 FTE per year if the regulation was made less restrictive (based on the number of QA program changes that were accepted as proposed by licensees). In addition, licensees would save the cost associated with NRC review.

The staff believes that changes to the 50.54(a) regulation are warranted. As a minimum, licensees should be permitted to make unilateral changes that are administrative, organizational, incorporate newly endorsed consensus standards, or adopt new QA positions previously approved by the staff provided these changes result in programs that continue to meet applicable regulations. In addition, the staff plans to continue its interactions with NEI to identify potential alternative criteria to use, such as "maintain the effectiveness" in lieu of the "reduction in commitment" criterion currently used in 50.54(a). Once we have developed criteria that will allow licensees more flexibility to change their QA programs without prior NRC review and approval, but assure continued program effectiveness, we plan

to develop a User Need memorandum asking RES to prepare a revision to 10 CFR 50.54(a). The rulemaking would reflect the changes discussed above, and would further consider risk-informed, performance-based standards that are developed through the PRA implementation plan.

RECOMMENDATION:

The staff recommends that RES be informed of the decision to deny the NEI petition for rulemaking. The staff will continue its interactions with NEI with the objective of identifying criteria that could be used to allow licensees to make changes to their QA programs without prior NRC review and approval. Following completion of these interactions, the staff will prepare a rulemaking request to RES to revise 10 CFR 50.54(a). RES should inform NEI of the NRC decision to deny its rulemaking petition after obtaining Commission concurrence.


concur

3/7/97
date