



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

October 28, 1996

MEMORANDUM TO: Frank J. Miraglia, Jr., Acting Director
Office of Nuclear Reactor Regulation

FROM:  Brian W. Sheron, Acting Associate 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 permit 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 staff review and approval 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. Further, 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 to 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. The general conclusion reached by the staff was that using the criteria of 50.59 would provide excessive leeway for licensees to implement major program changes and, further, would not be amenable for the evaluation of programmatic QA changes. Depending upon how 50.59 would be implemented by licensees, the staff envisioned that major changes could be made to a QA program that would not be deemed by licensees to constitute an Unreviewed Safety Question (USQ), and thus would not require NRC review prior to implementation. Examples of such changes, provided in NEI's response (draft industry guideline to assist licensees to implement and interpret the petition) to the Federal Register notice of the NEI petition published on September 14, 1995, included:

- Change specific qualification standards (experience and education) for line or section supervisors to one based on licensee management's assessment of the candidates' abilities to perform the duties, responsibilities and tasks.
- Transfer of receipt inspection activity and oversight from the QA department to the line organization.
- Change offsite review committee reporting relationship for Site #1 from the Executive Vice-President - Power Supply, to the Senior Site Manager - Site #2.
- Create a matrix-type organization that allows for maintenance personnel to perform QC inspections of work performed by other maintenance personnel.

The staff is of the opinion that using a threshold of a USQ to judge whether staff review is required provides too great a relaxation of staff control that could readily lead to situations where QA programs could be changed to an extent that they might not continue to meet Appendix B, which was the original reason for the promulgation of 50.54(a). With regard to whether the 50.59 regulation encompasses programmatic changes, the staff believes that current industry guidance (NSAC-125) for implementing the 50.59 regulation does not adequately address QA programmatic changes. Rather, it focuses primarily on hardware and structural changes and staff experience to date has likewise also focused in these areas. NEI, on the other hand, claims that licensees routinely use the 50.59 criteria to evaluate non-hardware related changes to procedures and programs, with quality assurance programs being the exception.

As noted above, NEI provided a draft guidance document to demonstrate how quality assurance programmatic changes can be evaluated using the 50.59 criteria. The guidance document presents the steps to determine the acceptability of a QA program change without the need for NRC review. 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. Based on its review of this draft document, the staff has concluded that, while the evaluation steps for a proposed change appear to be widely encompassing, considerably more evaluation and development by the staff is required before it could be found acceptable for use in controlling QA programmatic changes under 50.59.

The staff expressed its concerns with using the USQ threshold to evaluate QA program changes to NEI representatives in a public meeting held in the NRC offices on April 30, 1996. At this meeting, it was also indicated that the reason the present change control criteria ("reduce the commitments") language in 50.54(a) was adopted in January 1983 was to restrict unilateral changes by licensees because extensive modifications were resulting in some unacceptable QAPs.

To provide further insights regarding staff experience in processing QA program changes requested by licensees, FY 95 data from the regional offices were analyzed as shown in the enclosure. The total number of QAP changes requested by licensees averaged less than 20 per region. The data indicates that only one change request per region, on the average, was denied (5%). About 1/2 of the changes involved staff and licensee interactions to arrive at a satisfactory change. For about the same number of changes, the staff accepted the change without finding a need for any interaction with the licensee.

This latter group of changes raises the issue of whether there is any merit in modifying the current 10 CFR 50.54(a) rule to permit licensees to make and implement limited QAP changes unilaterally. The types of changes permitted could be limited to ones such as administrative, organizational, correction of typographical errors, and to provisions that the staff has previously found acceptable (for other licensees or through regulatory guide endorsement). These are the types of changes the staff previously has accepted without a need for any interaction with licensees. The benefit of modifying current 10 CFR 50.54(a) as indicated above would be that, based on FY 95 data, minimal NRC resource savings would result if staff review of the limited changes indicated above did not have to be performed; any licensee savings would be in addition to that. There would be little or no safety benefit from this limited change to the regulation. The disadvantage is that the relatively modest resource savings would come at a cost of engaging in a rulemaking activity that likely would be opposed by industry as not giving them all they requested in their petition for rulemaking.

Accordingly, the following three options can be considered for the disposition of the NEI petition:

1. Make no change to 10 CFR 50.54(a). Advise NEI that its petition for rulemaking, assigned Docket # PRM-50-62, is denied.

The staff would justify the rejection of the petition based upon the excessive leeway for making changes permitted by the 50.59 threshold and the shortcomings of 50.59 criteria to evaluate programmatic material.

2. Modify 10 CFR 50.54(a) in accordance with the NEI petition and advise NEI that its petition request is granted.

3. Make a limited modification to 10 CFR 50.54(a) that is consistent with the following guidelines:

The staff would further articulate examples of types of changes that would be representative of a reasonable threshold regarding whether changes need to be submitted for staff review. This would include an assessment as to whether the changed quality elements, including alternative approaches, continue to result in a functionally acceptable program. Further, the staff would provide examples of criteria which are deemed appropriate to evaluate whether a change would need to be submitted (presuming 50.54(a) were revised accordingly) such as: continued conformance to industry QA standards that are endorsed by NRC regulatory guides; evaluation by the licensee that the proposed unilateral change results in "continued effectiveness"; and revisions limited to specific areas such as administrative, organizational, correction of typographical errors, and use of previously approved NRC positions. The licensee would also need to periodically evaluate the adequacy and effectiveness of the changed QAP (per Criterion II of 10 CFR 50, Appendix B). In part, this could be accomplished by trend monitoring of quality-related parameters to demonstrate that the necessary level of plant safety and equivalence to prior commitments is maintained.

However, since there is minimal, if any, safety benefit to licensees, based on what would be permitted under this limited revision, and the staff resource savings are minimal as noted above, the priority assigned to making this modification to the regulation would be extremely low and the staff would not plan to devote any effort to it in the near or even far future.

Selection of this option would result in advising NEI that its petition for rulemaking has been granted in part and revised in part.

As noted above, the staff does not favor Option 2, granting the NEI petition in full, due to the staff's belief that using the criteria of 50.59 would provide excessive leeway for licensees to

implement major program changes and, further, would not be amenable for the evaluation of programmatic QA changes. However, a general staff consensus appears to have evolved regarding the need to permit some changes to be made by licensees to their QAPs where: (a) the changes are noncontroversial and have required minimal interaction between staff and licensee for the staff to accept the change and (b) the changes do not result in any reduction in effectiveness of the licensees' QAPs. Notwithstanding this view, as noted above, the staff has determined that NRR resource savings would be minimal, there is little or no safety benefit, and the rulemaking activity would be assigned a low priority. Given the priority assigned (low) for this activity, it is highly doubtful that the staff would devote resources to it because of other, higher-priority work and the level of resources available. Thus, we conclude that Option 3 should not be pursued. As a result, it is recommended that Option 1 be adopted. In this way, if the industry determines that the potential savings warrant continued pursuit of rulemaking, then NEI could restructure their petition for a future resubmittal.

RECOMMENDATION:

NRR should inform RES of its decision to recommend rejection of the NEI petition. In turn, RES should inform NEI of the NRC decision.

concur

date

REGIONAL STATISTICS

Review of Quality Assurance Program (QAP) Changes

	<u>Region I</u>	<u>Region II</u>	<u>Region III</u>	<u>Region IV</u>
Number of QAP changes submitted	17	10	22	20
Number of QAP changes approved w/o comments	8	6	9	9
Number of QAP changes approved with comments	8	4	10	9
Number of QAP changes denied	1	0	1	1
FTEs used	0.2	0.1	0.303	0.3