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

July 27, 1995

MEMORANDUM TO: Thomas O. Martin, Chief
Regulatory Development Branch
Division of Regulatory Applications
Office of Nuclear Regulatory Research

FROM: Suzanne C. Black, Chief
Quality Assurance and Maintenance Branch
Division of Reactor Controls and Human Factors
Office of Nuclear Reactor Regulation

SUBJECT: PETITION FOR RULEMAKING (PRM-50-62) 10 CFR 50.54

We have reviewed the petition filed by the Nuclear Energy Institute (NEI) and the draft federal register notice (FRN) prepared by the Office of Administration (ADM). It is our opinion that this petition should not be treated in the fast-track process primarily because of the cursory nature and lack of depth of the regulatory analysis information provided in the NEI petition. The fast-track petition process requires that the petitioner assume a larger burden of developing the needed information than is evident in this submittal.

By way of background, the NRC Regulatory Review Group examined the various change control mechanisms for Final Safety Analysis (FSAR) content. The review pointed out the disparity between 10 CFR 50.59 which addresses changes to the FSAR content and 10 CFR 50.54(a) which governs change control for quality assurance (QA) program descriptions. Further, 50.54(a) was contrasted with the other 50.54 change control process for emergency and security plan content. NRR had deferred action on the 50.54(a) recommendation pending development of the graded QA initiative. It was our expectation that the graded QA initiative would help to identify those elements of the QA program where licensees should have greater flexibility to make changes without NRC pre-review.

A second initiative underway involves the effort to relocate administrative controls from the Technical Specifications (TSs) based upon Commission directive in the "Final Policy Statement on Technical Specifications Improvements for Nuclear Power Reactors," 58 FR 39132 (July 22, 1993) that articulated four criteria for retaining TS provisions. The administrative controls relating to review and audit provisions define an administrative framework to confirm that plant activities have been properly conducted. These provisions are not included in the Commission's criteria for retention in TS. Thus, for a number of plants the TS administrative controls have been relocated to the QA program such that future changes would be controlled by 50.54(a).

Our initial thought is that 50.59 is not conducive for controlling changes to programmatic aspects contained in the QA program. It is not clear how the

description could be changed without triggering the need for NRC pre-review as described in the NEI petition. NRR has contacted NEI to make arrangements for a public meeting where we can obtain further insights into how they envision the revised QA program change control process would function.

With respect to the draft FRN, we request that the attached be included for specific areas for public comment.

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existing guidance (NSAC-125) for implementing 50.59 would be applied for QA program change control. We feel that practically any facet of the QA program description could be changed without triggering the need for NRC pre-review as described in the NEI petition. NRR has contacted NEI to make arrangements for a public meeting where we can obtain further insights into how they envision the revised QA program change control process would function.

With respect to the draft FRN, we request that the attached be included for specific areas for public comment.

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Specific Areas for Public Comment

In addition to commenting on the petition for rulemaking (petition) presented above, the NRC staff is soliciting specific comments on the issues presented below. Because the NRC staff has not yet developed its positions on the petition, it is soliciting these comments to obtain information that it will use to develop its regulatory positions for quality assurance program change control rulemaking.

1. 10 CFR 50.54(a) was issued on January 10, 1983 to correct instances where licensees had changed their programs without informing the NRC which resulted in some unacceptable programs. What assurances exist to prevent a similar situation from recurring if the petition and the revised threshold for reporting QA program changes is adopted?

2. Traditionally, the staff has used a variety of documents such as the NRC Standard Review Plan, NRC Regulatory Guides, and associated industry consensus standards to delineate what QA program elements are necessary to meet Appendix B. Should these standards continue to be used to define acceptable QA programs? Should a licensee QA program change that constitutes a departure from a regulatory position be considered of sufficient importance that the NRC should be notified in advance of implementation?

3. The NRC has allowed licensees to relocate administrative controls for review and audit functions from the technical specifications. Examples include details on safety review committees, audits, and technical review functions. These have been relocated to the QA program based on the existing change control provisions in 50.54(a). Would it be appropriate for activities such as safety review committees, independent technical review groups, and audits to be controlled so that only licensee changes exceeding the threshold of an unreviewed safety question be reported to the NRC for pre-review before implementation? If the revised QA change control mechanism is adopted should aspects of the review and audit functions remain in the QA program or be relocated elsewhere to ensure appropriate NRC review of changes prior to implementation?

4. With respect to maintaining an appropriate balance of QA program change submittals that provide changes of sufficient safety importance for NRC staff review before implementation, and considering the expenditure of both licensee and NRC staff to process and review the changes, what is the most appropriate criteria to judge the necessity for licensees to submit their QA program changes for review in advance of implementation?

5. The NRC Regulatory Review Group (RRG) examined change control mechanisms in 10 CFR 50.54 for control of licensee plans and programs (quality assurance, security, and emergency preparedness). The RRG recommended that licensees should have greater flexibility to make changes in their programs without having to receive prior NRC approval. Currently, QA

program changes that "reduce the commitments in the program" are submitted for NRC staff review before implementation. Similarly, security plan changes that "decrease the effectiveness" are submitted for staff review before implementation. Should the staff consider a revision to 10 CFR 50.54(a) to set the threshold for reporting QA program changes for NRC pre-review that constitute a decrease in effectiveness? Would a "decrease in effectiveness" standard in 10 CFR 50.54(a) provide a sufficiently flexible and technically reasonable criteria for licensees to report QA program changes to the staff before implementation?

6. Should the NRC staff consider retaining the current language of 10 CFR 50.54(a) and to define explicit guidance or identify examples on what types of QA program changes would be considered to "reduce the commitments in the program"? By developing this guidance could sufficient flexibility be afforded to licensees to make changes in their QA program without having to undergo a pre-review by the staff?

7. The petition proposes to apply a 10 CFR 50.59 process to evaluate QA program changes to determine the necessity for pre-review by the staff. Industry guidance for 10 CFR 50.59 exists within NSAC-125 "Guidelines for 10 CFR 50.59 Safety Evaluations." The NSAC document appears to contain little relevant guidance that would be helpful for determining whether QA programmatic changes would constitute an unreviewed safety question that requires NRC pre-review of the change. In particular, Section 4.2 of NSAC-125 deals principally with evaluating changes associated with nuclear plant equipment and not programmatic controls. Is existing guidance for processing 10 CFR 50.59 evaluations sufficient for evaluating QA program changes? What factors or aspects of the existing industry guidance would need to be supplemented? What types of QA program changes <u>would</u> be necessary to report to the NRC if the current 50.59 criteria were applied to QA program changes? What are examples of QA program changes that <u>should</u> be considered as meeting the unreviewed safety question threshold?

8. Adoption of the petition would result in a dramatic reduction in the number of QA program changes that are submitted by licensees for NRC review prior to implementation. This could result in a number of changes which would generally not be questioned until a concern was identified during the course of an NRC inspection. What standard would then be applied by the inspection staff to establish whether the licensee's revised QA program was acceptable? Would the possibility arise that a greater number of licensee changes would result in extensive questioning during on-site inspections to determine the adequacy of the licensee's program and continued conformance to the requirements of 10 CFR 50, Appendix B?

9. The NEI petition asserts that the current rule is an "unwarranted burden" and that granting of the petition will improve the quality assurance program change process, reduce administrative burden, and potentially enhance public health and safety. What are the benefits (costs and otherwise) that would accrue to public health and safety, to licensees, and to regulatory bodies?