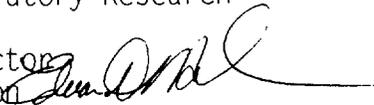




UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 3, 1997

MEMORANDUM FOR: Malcolm R. Knapp, Acting Director
Office of Nuclear Regulatory Research

FROM: Edward L. Halman, Director
Office of Administration 

SUBJECT: OFFICE CONCURRENCE ON FEDERAL REGISTER NOTICE ENTITLED,
"CHANGES TO QUALITY ASSURANCE PROGRAMS; DENIAL OF PETITION
FOR RULEMAKING SUBMITTED BY THE NUCLEAR ENERGY INSTITUTE"

The Office of Administration concurs on the package that contains the Federal Register notice that denies the petition for rulemaking submitted by the Nuclear Energy Institute regarding changes to quality assurance programs. We have attached a copy of the package that presents our comments.

When these documents are forwarded for publication, please include a 3.5 inch diskette that contains a copy of the documents in WordPerfect 5.1 or 6.1 as part of the transmittal package. The diskette will be forwarded to the Office of the Federal Register and the Government Printing Office for their use in typesetting the documents.

In order to assist you in preparing the list of documents centrally relevant to this package that is required by NRC's regulatory history procedures, you should place the designator "PRM-50-62" in the upper right-hand corner of each document concerning the package that you forward to the Nuclear Documents System.

If you have any questions, please contact David L. Meyer at 415-7162 (DLM1), or Michael Harrison at 415-6865 (PMH), of the Office of Administration.

Attachment: As stated

FOR: The Commissioners

FROM: L. Joseph Callan
Executive Director for Operations

SUBJECT: DENIAL OF PETITION FOR RULEMAKING SUBMITTED BY THE NUCLEAR
ENERGY INSTITUTE (PRM-50-62)

PURPOSE:

To obtain Commission approval to publish in the Federal Register a notice of denial of the petition for rulemaking submitted by the Nuclear Energy Institute (NEI) for proposed amendments to 10 CFR 50.54.

CATEGORY:

This paper covers a major policy question requiring Commission consideration.

BACKGROUND:

By letter dated June 8, 1995, NEI petitioned the NRC to amend its regulations controlling changes to quality assurance (QA) programs. The petition was docketed by the Commission on June 19, 1995, and assigned Docket No. PRM-50-62 (Enclosure 1). The petitioner requested that the NRC amend 10 CFR 50.54(a) to change the criteria that nuclear power plant licensees are to use to make changes to QA programs without prior NRC approval. The petitioner proposed that only QA changes involving unreviewed safety questions would require NRC review and approval prior to implementation under the provisions of 10 CFR 50.59.

Under 10 CFR 50.54(a)(3), the licensee has the flexibility to change its QA program without NRC approval provided no prior commitment is reduced. In its petition, NEI argued that 10 CFR 50.54(a)(3) is sometimes interpreted by the staff as requiring NRC approval

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NOTE: TO BE MADE PUBLICLY AVAILABLE
WHEN THE FINAL SRM IS MADE AVAILABLE

for any changes in the QA program, regardless of the safety significance associated with the change. As a consequence, prolonged and sometimes unnecessary regulatory interactions often occur. NEI argued that the range for permitted QA program changes, without prior NRC approval, should be broadened providing that no unreviewed safety question is involved. NEI indicated that these industry/staff interactions are costly and served as a disincentive to licensees to make QA program improvements.

On September 14, 1995, the NRC published the NEI petition in a Federal Register notice (60 FR 47716) and requested public comments on specific regulatory aspects of the NEI petition. Seventeen comment letters were received plus one comment letter that supplemented one of the original letters. Eleven of the public comment letters were sent by nuclear power plant licensees and NEI, and ~~all of these letters~~ supported the petitioner's proposed changes in the regulations. The remainder were sent by individual concerned citizens (two are currently employed in the nuclear field), ~~all of whom~~ expressed opposition to the relaxation of regulatory control of changes.

DISCUSSION:

In this petition, NEI proposes that the NRC change the threshold for submittal of QA program changes to the NRC for prior approval. ~~That is, only~~ changes which are deemed to create an unreviewed safety issue or a change in the technical specifications would require such approval. This would subject QA program changes to essentially the same criteria as exists for other plant aspects pursuant to 10 CFR 50.59. NEI believes that this approach will solve industry difficulties encountered with the use of the "reduction in commitment" standard applied to QA program changes in 10 CFR 50.54(a) and would focus more on safety considerations. NEI believes that the use of the "reduction in commitment" standard is often used in instances which have little or no impact on safety. As a result of the proposed regulatory changes, NEI claims that the industry expects considerable cost savings because it believes that the most QA program changes are interpreted by the NRC as reductions in commitment, even if they have little or no safety significance. NEI and other industry commenters reiterated these views in response to NRC's request for public comment. Attached to its comments, NEI provided a draft guidance document which it claimed would demonstrate how QA programmatic and procedural changes could be evaluated using the 10 CFR 50.59 criteria.

In the letters ^{opposing} ~~in opposition to~~ the NEI petition, the primary reasons given for requesting denial of the petition were that licensees should not be given unfettered authority to change QA programs without NRC approval, and that licensees will take this opportunity to reduce the QA and design requirements for spent fuel dry cask storage equipment. Other reasons cited included the lack of specific guidance for the determination of an unreviewed safety question, the need for increased QA controls in the light of component aging problems, the lack of an effective performance indicator program to monitor the effects of the changes, the lack of industry preparation to implement such a program, and the belief that the petition represents an example of a larger industry predilection to eliminate safety-related jobs for the sake of economy.

The staff disagrees with NEI's central premise that 10 CFR 50.59-like criteria should be used to evaluate QA program changes. Section 50.59 requires that a proposed change to

a facility description be deemed an unreviewed safety question if it (1) increases the probability of occurrence or consequences of a previously evaluated accident, (2) creates a possibility of a different type of accident, or (3) reduces the margin of safety. In the case of hardware changes or hardware related procedural changes, the effect of the change on the availability or unavailability of safety related equipment can be determined in order to perform the required evaluation. However, in the case of QA program changes, the determination of the effect of the change on plant safety is very subjective. It is difficult to determine with any degree of certainty how changes such as organizational responsibilities or QA program training will effect the availability of safety related equipment. The NRC has not developed any guidance to provide such a determination. In addition, the staff has concluded that the guidance both supplied and referenced by NEI suffers from a heavy reliance on hardware oriented consideration and is not acceptable for use for evaluating QA program changes.

The staff has concluded that, absent the development of adequate guidance, the use of 10 CFR 50.59-like criteria for QA program changes is not appropriate. The staff is sympathetic with NEI's concern with the continued use of 10 CFR 50.54(a) criterion. The staff will continue to consider the types of modifications to 10 CFR 50.54(a) it might propose to ensure that unreviewed changes to the QA program do not result in unacceptable program elements while providing relief to the industry from lengthy debate with the Commission concerning changes of minimal safety significance. The staff will continue to work with the industry to identify acceptable methods to differentiate between QA changes that have minimal safety significance and those that require prior NRC review and approval. Subsequent to the denial of this petition, the staff will propose a public meeting in the January/February 1998 time frame to entertain proposals for alternative approaches to 10 CFR 50.54(a) revisions which will be acceptable to both the NRC and the industry.

RESOURCES:

Resources to complete the actions associated with the denial of the petition are included in the FY 1998 budget.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer concurs that there will be no resource impacts. The Office of the Chief Information Officer concurs that there will be no information technology or management impacts.

RECOMMENDATION:

That the Commission:

1. Approve: The Federal Register notice that denies the NEI petition (Enclosure 2).

The Commissioners

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2. Note:

- a. That the petitioner will be informed of this action (Enclosure 3), and
- b. That the appropriate Congressional committees will be informed of this action (Enclosure 4).

L. Joseph Callan
Executive Director
for Operations

Enclosures: As Stated (4)

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

PRM-50-62

Changes to Quality Assurance Programs;
Denial of Petition for Rulemaking Submitted by the
Nuclear Energy Institute

AGENCY: Nuclear Regulatory Commission.

ACTION: Denial of petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking (PRM ~~50-62~~) submitted by the Nuclear Energy Institute (NEI) on behalf of the nuclear power industry. The petitioner requested that the NRC amend ^{its regulation} 10 CFR 50.54(a) to change the criteria that nuclear power plant licensees ^{may} are to use to make changes to their to their quality assurance (QA) programs without first receiving NRC approval. These QA programs are described or referenced in the licensees' Safety Analysis Reports (SARs). The petition is denied because the Commission has determined that the criteria recommended by NEI for controlling changes in licensee's quality assurance programs and procedures are not appropriate.

ADDRESSES: Copies of the petition for rulemaking, the public comments received, and the NRC's letter to the petitioner are available for public inspection or copying in the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Harry S. Tovmassian, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6231, email HST@NRC.GOV.

The Petition

By letter dated June 8, 1995, NEI petitioned the NRC to amend its regulations controlling changes to nuclear power plant licensee QA programs. The petition was ^{for rulemaking on QA} docketed ^{as} by the Commission on June 19, 1995, and assigned No. PRM-50-62. The petitioner requested that the NRC modify 10 CFR 50.54(a) to permit nuclear power plant licensees to make a broader range of changes, without NRC approval, to their QA programs. Currently, 10 CFR 50.54(a)(3) allows licensees to "make a change to a previously accepted quality assurance program description included or referenced in the Safety Analysis Report, provided the change does not reduce the commitments in the program description previously accepted by the NRC." NEI requested that the Commission amend this requirement to allow a licensee to "make a change to a previously accepted quality assurance program description included or referenced in its Safety Analysis Report without prior Commission approval unless the proposed change involves a change to the Technical Specifications incorporated in the license or involves an unreviewed safety question." According to NEI's proposal, changes involving unreviewed

safety questions (USQs) would require NRC review and approval prior to implementation under the provisions of 10 CFR 50.59.

Basis for Request

The petitioner argued that 10 CFR 50.54(a) is sometimes interpreted by the NRC as requiring NRC approval for any changes in the QA program, regardless of the safety significance associated with the change. As a consequence, there are often prolonged and sometimes unnecessary regulatory interactions about the correct interpretation of the term "reduction in commitment." NEI provided the following examples of topics that it claimed to be controversial.

1. Changes in the level of approval of administrative, implementation, or policy procedures, regardless of the safety significance, ✓
2. Changes in the company organization as it is described in the licensee's original quality plan, ✓
3. Changes to audit, review, or surveillance frequencies that have minimal, if any, safety significance, ✓
4. Adoption of a more recent national standard, which may or may not have been endorsed by the NRC staff, that results in a different implementation methodology yet fulfills the same function and achieves the same objective as the original standard described in the quality program description through the use of enhanced technology or other developments, ✓ and

5. Adoption of different, more effective and efficient quality processes than those described in a licensee's original quality plan based on the safety significance and past operating performance. ✓

Preliminary estimates provided by the petitioner indicated that the costs to the industry to conduct the resultant industry/NRC interactions were in excess of \$1 million per year. In addition, licensees are occasionally reluctant to pursue quality program improvements because of the resources required, even though the ultimate result, in the petitioner's opinion, would be improvements in efficiency, quality, or safety.

The petitioner opined that the acceptability of changes made to a licensee's QA program without NRC approval should be governed by the effect of the change on safety and not whether the change represents a reduction in commitment. In this way, the attention and resources of the nuclear industry and the NRC would be more appropriately and effectively focused on issues that could have an impact on public health and safety, rather than on administrative details and issues having minimal or no safety impact. ~~To~~ ~~this end,~~ the petitioner proposed that the threshold for submittal of QA program changes should be whether or not the change involves a USQ or results in a change to the technical specifications incorporated in the license. This approach is identical to the regulatory control in effect for changes to other aspects of the nuclear plant, presented in 10 CFR 50.59, including changes in the facility as described in the Safety Analysis Report (SAR), changes in procedures as described in the SAR, and the conduct of tests or experiments not described in the SAR, all of which may be performed without prior NRC approval providing the above described threshold is not exceeded. The petitioner proposed using the same criteria for determining a USQ as are currently used for nuclear plant changes

under 10 CFR 50.59. NEI states that NRC acceptance of the proposed approach would bring QA program changes under the same umbrella as the regulatory change control for many other nuclear plant aspects that have been in effect since 1974.

The petitioner noted that the main purpose of the current regulatory change control requirement (10 CFR 50.54(a)), introduced in 1983, was to preclude licensees from making certain changes to QA programs without informing the NRC. This was necessary ^{because} ~~as~~ some QA programs had been changed ^{and} ~~so~~ that they no longer conformed to NRC regulations. The NRC concern was that some changes might diminish the scope of the QA program, ^{and} ~~thereby~~ permitting significant deficiencies to arise in various facility activities that could increase the risk to public health and safety. Nevertheless, the petitioner claimed that the proposed approach would still address the NRC's concerns because QA program changes would continue to be reported periodically (under 10 CFR 50.71(e)) to the NRC as program updates, ^{and} ~~and~~ changes that raise the potential for a USQ or cause a change to the technical specifications would be formally submitted to the NRC for approval prior to implementation. The petitioner reiterated that this is the same process used for change control for many other aspects of the facility design and operation, ~~and~~ ^{it} should be used for QA programs as well.

The petitioner stated that the proposed amendment would improve the consistency of the regulatory process by bringing the program under the same change control provision as other features of the nuclear facility and would result in increased safety of commercial nuclear power plants through more efficient use of agency and industry resources.

Commission Action on the Petition

On September 14, 1995, the NRC published a Federal Register notice (60 FR 47716) announcing the receipt of the NEI petition for rulemaking and providing an opportunity for public comment. The Federal Register notice requested the public to comment on eight specific questions on critical regulatory aspects of the NEI petition. Seventeen comment letters were received, plus one comment letter that supplemented one of the original letters.

Eleven of the public comment letters were sent by nuclear power plant licensees and NEI, and all supported the proposed change in the regulations. NEI specifically addressed the eight issues raised by the NRC and provided their views on three separate issues. The six non-NEI/non-licensee letters were sent by individual concerned citizens (two are currently employed in the nuclear field), all of whom expressed opposition to the relaxation of regulatory control of changes.

Comments on NRC-Posed Questions

NEI was the only commenter to respond to the eight issues posed by the NRC in its announcement of receipt of the petition. The following are the issues raised by the NRC, the NEI comments on these issues, and the NRC response. Most of the points raised by NEI in response to NRC raised issues are the same as those raised in their other remarks and in the transmittal letter.

Issue 1:

On January 10, 1983, 10 CFR 50.54(a) was issued as a result of instances in which licensees changed their programs without informing the NRC to the extent that some programs were unacceptable. What assurances exist to prevent a similar situation from recurring if the petition and the revised threshold for reporting QA program changes ^{are} adopted? Is it necessary to adopt a regulatory approval system to prevent such situations from occurring?

NEI Comment:

The current 10 CFR 50.54(a) has often resulted in significant and unnecessary discussion on the meaning of "does not reduce the commitments." The proposed use of the 10 CFR 50.59 regulation should result in little or no debate because it has been routinely used by licensees to evaluate equipment and non-hardware changes; ^{and} ~~its use~~ would ~~be expected to~~ provide a greater emphasis and focus on safety. Significant changes that present a potential to degrade safety or affect the technical specifications will require NRC approval prior to implementation. Resource costs associated with changes will be better controlled. NEI claims that the nuclear industry recognizes the importance of effective and efficient QA programs in respect to safety. The only difference between the proposed petition and the existing regulation is that greater emphasis will be placed on safety requirements rather than on a reduction in commitment.

NRC Response:

The NEI comment does not address the question of assurances that the proposed use of 10 CFR 50.59 ^{will not} ~~will not~~ result in changes to the QA program that are unacceptable. Similarly, NEI does not express a view concerning the need for a regulatory approval system to prevent such occurrences. The NRC is sympathetic with NEI's concern that the

use of the "reduction in commitment" standard can cause prolonged discussions with the NRC on non-safety related issues. However, the NRC disagrees with NEI's position that many of these discussions are "unnecessary" because there are fundamental differences between the NRC and industry as to what changes are purely administrative as opposed to those that may ^{only} appear to be administrative ~~but in fact are not~~. Frequently, nuclear reactor licensees propose changes to QA programs that they perceive to have no safety relevance. However, when the NRC reviews these changes they are found to create a safety concern. Changes such as additional duties assigned to the manager of the QA program might, on the surface, appear to be safety neutral but may ~~in fact~~ dilute his or her effectiveness to the point of endangering the proper conduct of the QA program.

NEI provided a draft guidance document with examples as a supplement to their comment letter to assist licensees in implementing programmatic changes. This guidance document cites six QA programmatic changes that are believed to have no safety significance through the use of the proposal in the NEI petition. However, upon reviewing these examples, the NRC has determined that four of the six changes do ~~in fact~~ raise safety concerns and would require prior NRC approval. One proposed administrative change was for the licensee to have the ability to define the qualifications for line or section supervisors based on an assessment by the licensee management. However, the ^{NRC} staff considers that national standards and regulatory guides exist (for example, Regulatory Guide 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," which endorses ANSI N3.1 and ANSI 18.1, and Regulatory Guide 1.28, "Quality Assurance Program Requirements," which endorses ANSI N45.2.6) that delineate personnel qualification criteria associated with various positions in the licensee's organization. A QA program that does not provide adequate provisions (by referencing a suitable standard or

equivalent) would constitute a safety concern to the NRC and, as such, is considered more than an administrative change.

A second proposed administrative change involved the transfer of receipt inspection activity and oversight from the QA department to the line organization. This is considered a safety concern in that the QA program would need to be revised to reflect how organizational independence would be assured between the receipt inspection staff and the line organization. Further, the QA department interfaces for functions such as training, nonconformance control, and audits would need to be specified in order for the ^{NRC} staff to approve such a proposal. This is not considered an administrative change.

The Commission believes that the NEI comment in response to this issue does not provide adequate support for the petitioner's proposal.

Issue 2:

Traditionally, the NRC staff has used a variety of documents such as the NRC Standard Review Plan ^(SRP), NRC regulatory guides, and associated industry consensus standards to delineate the QA program elements that will comply with Appendix B. Should these standards continue to be used to define acceptable QA programs? Should a change to a licensee QA program that constitutes a departure from a commitment to comply with a specific regulatory position be considered of sufficient importance that the NRC should be notified in advance of implementation? How would such changes be evaluated under the petitioner's proposed criterion?

NEI Comment:

NRC's QA regulations provide reasonable assurance that the pertinent safety functions in the plant will be satisfactorily accomplished. The SRP, regulatory guides, and

associated industry standards provide methods of meeting the regulations. Changes to QA programs should be focused on safety and the regulations, not on a departure from commitments in these documents that in some areas may have minimal safety significance. When assessing any change, the licensee's most important task is to ensure safety. The NRC will be informed of all changes, including those requiring prior approval. ~~Sometimes~~ ^{Because} alternative methods can accomplish the same purpose from a safety perspective, ~~and~~ licensees should be afforded regulatory flexibility to deviate from existing guidance while continuing to meet the regulations. Attempting to reach understanding regarding "departure from commitment" has been a struggle. Recently, ^{the nuclear} industry and the NRC reached a general understanding for managing commitments in ^{the} "Guideline^s for Managing NRC Commitments."¹ This process should also be useful for changes in QA programs.

NRC Response:

NEI did not comment on the continued use of SRPs, regulatory guides, and industry standards but indicates that changes to commitments in these documents should also be governed by their safety significance and not on "departures from commitments." NEI does not provide an opinion on how these changes should be evaluated but alludes to ^{the} "Guidelines for Managing NRC Commitments" that should be "useful" in this regard. The NRC has approved the use of "Guidelines for Managing NRC Commitments" as guidance for licensees to manage and change their commitments to NRC. However, "Guidance for Managing NRC Commitments" relies upon "Guidelines for 10 CFR 50.59 Safety

^s¹"Guideline^s for Managing NRC Commitments" is an internal NEI document. A copy of this document is an enclosure to SECY-95-300 and is available for inspection or copying at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

Evaluations"² (NSAC-125), which is oriented towards performing 10 CFR 50.59 type analyses for proposed changes to plants or procedures. The methodology in NSAC-125 addresses changes to hardware and hardware related-procedures. ~~Section~~ ^{10 CFR} 50.59 requires that a proposed change to a facility description be deemed an unreviewed safety question if it: (1) ^{PP} increases the probability of occurrence or consequences of a previously evaluated accident, (2) ^{PP} creates a possibility of a different type of accident, or (3) ^{PP} reduces the margin of safety. In the case of hardware changes or hardware related procedural changes, the effect of the change on the availability or unavailability of safety related equipment can be determined in order to perform the required evaluation. However, in the case of QA program changes, the determination of the effect of the change on plant safety is very subjective. It is difficult to determine with any degree of certainty how changes such as organizational responsibilities or QA program training will effect the availability of safety related equipment. The NRC has not developed any guidance to provide such a determination. The Commission has concluded that the guidance ~~both~~ ² supplied and referenced by NEI suffers from a heavy reliance on hardware oriented considerations and is not acceptable ~~for use~~ ² for evaluating QA program changes. Absent the development of adequate guidance, the Commission finds that the use of 10 CFR 50.59-like criteria for QA program changes is not appropriate.

²"Guidelines for 10 CFR 50.59 Safety Evaluations," Nuclear Management and Resources Council, NSAC-125, May 1989. Since the receipt of this petition, NEI has revised NSAC-125, but treated it as an internal NEI document. The title is unchanged and the designation is NEI-07 [Draft Revision A]. This document is also available from the NRC Public Document Room (Accession Number 9608190033).

Issue 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 10 CFR 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 a USQ would be reported to the NRC for review before implementation? What kind of changes to a licensee's QA program would constitute a USQ? Assuming that the USQ should or could be applied, does ~~not~~ the use of 10 CFR 50.59 effectively negate the administrative and regulatory advantage of removing this information from technical specifications (because both technical specification changes and USQs are subject to an opportunity for hearing)? 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 to ensure appropriate NRC review of changes prior to implementation?

NEI Comment:

NEI's response is ~~basically~~ that the review and audit functions, which were previously located in the technical specifications and are now permitted to be transferred to the QA program description, should remain in the QA program and be subject to change control under 10 CFR 50.59 as is proposed for the QA program itself. Different portions of the QA program should not, in NEI's view, be controlled by different change review processes. NEI also noted that licensees routinely use 10 CFR 50.59 criteria for evaluating non-hardware-related changes to procedures and programs described in the SAR.

NRC Response:

The purpose for NRC's Issue 3 was to determine whether it was acceptable to have an amendment that would allow relocation of administrative functions such as safety review committees, independent technical review groups, and audits of the QA program to be governed by the proposed change process. NEI's response, to leave these functions in the QA program and control all changes via 10 CFR 50.59, is essentially equivalent to accepting the NEI's proposal, which the NRC finds unacceptable (see Issue 1).

Issue 4:

Are there alternative thresholds, in lieu of the USQ threshold, for determining whether licensees must submit their QA program changes for advance review? Provide a technical or policy explanation as to why this or any other threshold would be more appropriate.

NEI Comment:

Alternatives for determining whether QA program changes should be submitted for NRC review prior to implementation include adopting the "decreased effectiveness" standard in 10 CFR 50.54(p) and (q) and replacing 10 CFR 50.54(a) with the process in ^{TRC} "Guideline for Managing NRC Commitments." However, NEI believes that adopting the 10 CFR 50.59 change process is best because it is used routinely for all other matters described in the SAR and because evaluation of QA program changes should not be treated differently.

NRC Response:

The Commission agrees with the NEI position that the "decreased effectiveness" criterion is not a suitable alternative to the existing "reduction in commitments" criterion in

10 CFR 50.54(a). However, NEI's response provides no additional information supporting the adoption of the 10 CFR 50.59 criteria, and NEI provides no rationale supporting its position that QA program changes should be controlled in the same manner as changes in other plant descriptions.

Issue 5:

The NRC Regulatory Review Group (RRG) examined change control mechanisms in 10 CFR 50.54 for controlling 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 ^{NRC} staff review before implementation. Should the ^{NRC} 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 criterion for licensees to report QA program changes to the staff before implementation?

NEI Comment:

NEI states that the use of a "decrease the effectiveness" criterion to judge the acceptability of a proposed QA program change is not appropriate because the QA

However, NEI also states that

program affects the safety function of plant structures, systems, and components, but this is not the case for emergency planning and security regulations that contain this criterion.

NEI
It is believed that the use of this criterion for QA programs would ultimately lead to the USQ arena, which is addressed under 10 CFR 50.59 anyway. The industry's conclusion is that the 10 CFR 50.59 process is the optimum process for changes in QA programs.

NRC Response:

NEI's rationale is not clear in that QA program changes affect safety, unlike security and emergency preparedness programs, and, thus, should not be controlled by the "decrease in effectiveness" criterion. Also unclear is the concern about this criterion leading to the "USQ arena" in light of the fact that NEI's own proposal to use the 10 CFR 50.59 criterion requires a finding that a proposed change does not constitute a USQ in order to proceed without prior NRC approval. However, the Commission agrees with NEI's main point in response to this issue that the "decrease in effectiveness" criterion is not appropriate for use in controlling QA program changes. Thus, the Commission does not intend to modify 10 CFR 50.54(a) to require the use of the "decrease in effectiveness criterion" for controlling QA program changes.

Issue 6:

Should the NRC consider retaining the current language of 10 CFR 50.54(a) and define explicit guidance or identify examples of the types of QA program changes that would be considered to "reduce the commitments in the program"? With 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?

NEI Comment:

~~Since~~^{After} the promulgation of the 10 CFR 50.54(a) change rule, there has been a continuous struggle over the interpretation of the phrase "provided the change does not reduce commitments." The industry believes further guidance and the use of examples will not resolve the problem. The process should be changed to allow licensees to apply the 10 CFR 50.59 rule.

NRC Response:

~~Since~~^{After} the receipt of the petition and NEI's comments on the Federal Register Notice, NEI has modified^{inc} "Guideline for Managing NRC Commitments," to include guidance on interpretation of 10 CFR 50.54(a). Although this guidance has been endorsed by the ^{NRC} staff in SECY-95-300, it has not served as an adequate basis to ameliorate the problem associated with differences in interpretation concerning "reduction in commitment." NEI has not shown that better guidance will ~~not~~^{not} effectively improve the licensee's ability to accurately identify QA program changes that ~~do~~^{do} not have ~~any~~^{any} safety significance. The Commission recognizes the problem that NEI seeks to correct through this petition; however, it is withholding its judgment as to how this problem should be rectified (i.e., improved guidance or modifications to 10 CFR 50.54(a)).

Issue 7:

The petition proposes applying a 10 CFR 50.59 process to evaluate QA program changes to determine the necessity for pre-review by the ^{NRC} staff. Industry guidance for 10 CFR 50.59 exists within NSAC-125. NSAC-125 appears to contain little relevant guidance that would be helpful for determining whether QA programmatic changes would constitute a USQ 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 must be reported to the NRC if the current 10 CFR 50.59 criteria were applied to QA program changes? What are examples of QA program changes that should be considered to meet the USQ threshold?

NEI Comment:

NEI indicated that the 10 CFR 50.59 change process is routinely used by licensees to evaluate non-hardware-related changes to procedures and programs with the exception of QA program changes. The petition would remedy this inconsistency. Additional guidance and examples are presented in NEI's other comments. NEI also submitted a copy of draft guidance for evaluating QA program changes using the 10 CFR 50.59 criteria.

NRC Response:

NEI's response does not adequately address NRC's concern that the guidance provided in NSAC-125 is oriented towards evaluating hardware changes and would not be as useful for determining whether QA changes constitute a USQ. The additional draft guidance that NEI cites in its comments relies heavily on NSAC-125 when it addresses evaluation of safety significance of proposed changes. For example, in response to the question, "Does the proposed activity reduce the margin of safety as defined in the basis for Technical Specifications?" [#]the NEI guidance states ^{that} "No additional clarification is required beyond the guidance given in the NSAC-125." Additionally, as discussed in Issue 2, the NRC does not agree with the content of the NEI guidance, particularly the characterization of administrative changes that would not need NRC approval. Thus, the

Commission finds that existing NEI guidance, as supplemented by NEI's draft guidance provided with their comments, is not sufficient to support the evaluation of QA program changes through use of the criteria in 10 CFR 50.59.

Issue 8:

Would protection of the public health and safety be enhanced if the petition were granted, and if so, in what way? What licensee and NRC costs would be reduced, or increased, if the petition were granted?

NEI Comment:

Implementation of the petition will improve the focus of licensee and NRC resources on safety matters rather than on issues associated with a reduction in commitment, many of which have no or minimal safety significance. The history is that the majority of QA program changes are administrative in nature. The cost incurred in past change activities, both licensee and regulatory, will be considerably reduced in the future. Because the costs involved in pursuing USQ issues are expected to be high, there is a considerable disincentive to propose such changes.

NRC Response:

The Commission disagrees with NEI's opinion that adoption of the ~~petition~~ ^{amendatory language in the PA} will enhance public safety and the implication that administrative program changes do not have any safety significance. NEI has not proposed a viable method of determining whether a QA program change constitutes a USQ and, therefore, such a change made without prior NRC approval may ~~in fact~~ ^{be} deleterious to public health and safety. Further, NEI suggests that resources saved as a result of the proposed rule change would be used in safety

matters. Such^a redirection of licensee resources is a matter of licensee discretion and cannot be mandated by the rule.

Addition Issues Raised by NEI

Issue 9:

NEI Comment:

The industry believes that adopting a "departure from commitment" standard for requesting NRC approval prior to implementation of QA changes is a regressive step in regard to the protection of public health and safety. Licensee and NRC management would be required to address all matters described in a licensee's QA program description, whether or not there is a nexus to safety. This has the potential to divert licensee and NRC attention and resources from safety-significant matters, increasing the probability of not identifying a safety-significant issue.

NRC Response:

The Commission agrees that the use of a "departure from commitment" standard as opposed to a "reduction of commitment" standard will not correct the problem addressed by this petition. The NRC will not pursue the adoption of such a standard for QA program changes. However, in the NRC's ^{belief that} ~~opinion~~, many commitments made by a licensee within a QA program do have a nexus to plant safety. This consideration will have to be accounted for if 10 CFR 50.54(a) is amended.

Issue 10:

NEI Comment:

The industry believes that establishing a separate change process and mechanism for review and audit functions as suggested by Issue 3 of the Federal Register notice would further decrease the coherency and consistency of the regulatory process contrary to a recommendation in the NRC's 1993 Regulatory Review Group Report. Implementing the regulations would become more complex ^{and} increasing ^{the} the potential for confusion, misunderstanding, and misinterpretation. There would be two different change processes for matters described in the same licensee-controlled document.

NRC Response:

The Commission suggested moving the audit and review functions from the QA program and allowing changes in these functions to be controlled by some other appropriate change control mechanism because the Commission was concerned that the type of criteria in 10 CFR 50.59 might not be adequate. The Commission feels that use of the 10 CFR 50.59 criterion is not appropriate for changes in these functions for the same reasons that it disapproves its use for the remainder of the QA program. The NRC also agrees with the industry comment that the same criterion should be used for the entire QA program. ^{Although} ~~While~~ this question does not pertain to the merits of this petition, the Commission will pursue the use of a single criterion for the QA program when it arrives at a final determination as to what ^{is} ~~the~~ criterion will be adopted.

Issue 11:

NEI Comment:

NEI recommends deleting 10 CFR 50.4(b)(7)(i) from the NRC regulations because there is no need to require a separate administrative reporting requirement for changes to the QA program description. [#] 10 CFR 50.4(b)(6) (which refers to 10 CFR 50.71(e)) already provides for updating SAR matters. ~~Sub-paragraph (iii) of~~ 10 CFR 50.4(b)(7) ⁽ⁱⁱ⁾ should not be amended because the requirement is unique to nonlicensees (such as architect/engineers, NSSS suppliers, fuel suppliers, constructors).

NRC Response:

The requirements cited by NEI are not duplicative. ^{10 CFR} Paragraph 50.4(b)(6) pertains to updates to the Final Safety Evaluation Report. ^{10 CFR} Paragraph 50.4(b)(7)(i) pertains only to QA submittals and makes the distinction between applicants and licensees to avoid confusion.

Other Supporting Public Comments

The other 10 comments supporting the petition were from licensees ~~and were essentially in full agreement.~~ One of these 10 comments stated that no relief from the current "reduce the commitments" criterion in 10 CFR 50.54(a) would be realized by the adoption of a "decrease the effectiveness" criterion as is used for safeguards contingency plan and emergency plan changes (see Issue 5 above). One commenter, an NRC licensee, expressed a contrary opinion that the use of the latter criterion could be adapted to QA program changes.

Non-industry Commenters

The non-industry commenters ^{believe} had one position: that the NRC should deny this petition, but they gave various reasons for their position. One commenter stated that licensees should not be given unfettered authority to change QA programs without NRC approval. Other commenters believed that licensees will take ^{advantage of the amended rule} ~~this opportunity (the~~ ~~proposed rule change)~~ to reduce the QA and design requirements for spent fuel dry cask storage equipment. Other reasons cited included a need for increased QA controls in the light of component aging problems, lack of an effective performance-indicator program to monitor the effects of the changes, lack of industry preparation to implement such a program, and that nuclear plant safety should not be sacrificed to the elimination of jobs, the destruction of families, and the "bottom dollar."

One commenter stated that the petition should be denied because there is a lack of specific guidance for the determination of a USQ.

Commission Decision

The Commission has given careful consideration to the merits of this petition as well as the public comments received in response to the Federal Register notice announcing the receipt of the petition. The Commission disagrees with NEI's central premise that 10 CFR 50.59-like criteria should be used to evaluate QA program changes. Section 50.59 requires that a proposed change to a facility description be deemed an unreviewed safety question if it (1) increases the probability of occurrence or consequences of a previously evaluated accident, (2) creates a possibility of a different

type of accident, or (3) reduces the margin of safety. In the case of hardware changes or hardware related procedural changes, the effect of the change on the availability or unavailability of safety related equipment can be determined in order to perform the required evaluation. However, in the case of QA program changes, the determination of the effect of the change on plant safety is very subjective. It is difficult to determine with any degree of certainty how changes such as organizational responsibilities or QA program training will effect the availability of safety related equipment. The NRC has not developed any guidance to provide such a determination nor has NEI provided an acceptable methodology to do so. Thus, the Commission has concluded that, absent the development of such guidance, use of 10 CFR 50.59-like criteria for QA program changes is not appropriate.

The NRC does not believe that NEI's draft guidance document, even in conjunction with the other NEI guidance documents cited, would ensure that acceptable QA programs would result. These documents rely heavily on the NEI document NSAC-125, which is oriented towards hardware changes and does not provide acceptable guidance on determining whether a QA program change constitutes a USQ or a change in the technical specifications. In addition, the NRC disagrees with the NEI's characterization in their guidance document that certain QA program changes are only administrative in nature. Furthermore, as part of the probabilistic risk assessment implementation plan, the NRC is considering the impact of QA on plant performance. The results of that program may be useful in formulating a revision to 10 CFR 50.54(a).

The Commission finds that the proposal in NEI's petition to use a standard equivalent to the standard specified in 10 CFR 50.59 for determining whether QA program changes require prior NRC approval is unacceptable. The 10 CFR 50.59 standard and the

guidance related to it are oriented towards hardware and hardware-related changes and are not appropriate for programmatic changes such as those in the QA program. The Commission finds that the guidance documents cited in the petition do not provide an adequate mechanism for licensees to discriminate between QA program changes of minimal safety significance and those that require prior NRC approval. Thus, the Commission is denying the NEI petition. The Commission will, however, continue to consider the types of modifications to 10 CFR 50.54(a) that might ensure that unreviewed changes to the QA program do not result in unacceptable program elements while providing relief to the ^{nuclear} industry from ^a lengthy debate with the Commission concerning changes of minimal safety significance. The Commission will continue to work with the industry, through public meetings and workshops, to identify acceptable methods to be used to accurately discriminate between QA changes that have minimal safety significance and those that require prior NRC review and approval.

Dated at Rockville, Maryland, this ____ day of _____ 1997.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.



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

The Honorable Dan Schaefer, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The Nuclear Regulatory Commission (NRC) has sent to the Office of the Federal Register the enclosed Federal Register notice in which it denies a petition for rulemaking submitted by the Nuclear Energy Institute (NEI). The petitioner requested that the NRC amend 10 CFR 50.54(a) to change the criteria that nuclear power plant licensees are to use to make changes to their quality assurance (QA) programs, without prior NRC approval. Only changes involving unreviewed safety questions would require NRC review and approval prior to implementation, consistent with the provisions of 10 CFR 50.59.

The Commission disagrees with NEI's central premise that Section 50.59-like criteria should be used to evaluate QA program changes. Section 50.59 requires that a proposed change to a facility description be analyzed to determine whether it constitute an unreviewed safety question. This determination is based on questions related to the availability of safety related equipment and is thus hardware oriented. For QA program changes, the determination of the effect of the change on plant safety is very subjective because it is difficult to establish the relationship between QA program changes and the availability of safety related equipment with any degree of certainty. Therefore, the Commission has concluded that the use of Section 50.59-like criteria for QA program changes is not appropriate. The Commission is sympathetic with the industry's concerns in this matter and intends to pursue appropriate alternatives to the Section 50.54(a) criterion.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Ralph Hall



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

The Honorable James M. Inhofe, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The Nuclear Regulatory Commission (NRC) has sent to the Office of the Federal Register the enclosed Federal Register notice in which it denies a petition for rulemaking submitted by the Nuclear Energy Institute (NEI). The petitioner requested that the NRC amend 10 CFR 50.54(a) to change the criteria that nuclear power plant licensees are to use to make changes to their quality assurance (QA) programs, without prior NRC approval. Changes involving unreviewed safety questions would require NRC review and approval prior to implementation.

The Commission disagrees with NEI's central premise that Section 50.59-like criteria should be used to evaluate QA program changes. Section 50.59 requires that a proposed change to a facility description be analyzed to determine whether it constitute an unreviewed safety question. This determination is based on questions related to the availability of safety related equipment and is thus hardware oriented. For QA program changes, the determination of the effect of the change on plant safety is very subjective because it is difficult to establish the relationship between QA program changes and the availability of safety related equipment to any degree of certainty. Therefore, the Commission has concluded that the use of Section 50.59-like criteria for QA program changes is not appropriate. The Commission is sympathetic with the industry's concerns in this matter and intends to pursue appropriate alternatives to the Section 50.54(a) criterion.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Senator Bob Graham



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

Mr. Ralph Beedle
Nuclear Energy Institute
1776 I Street, NW
Washington, DC 20006-3708

Dear Mr. Beedle:

I am responding to the petition for rulemaking that was submitted by the Nuclear Energy Institute (NEI) to the Nuclear Regulatory Commission (NRC) by a letter from Mr. William Rasin, dated June 8, 1995. The petition was docketed by the Commission on June 19, 1995, and assigned Docket No. PRM-50-62. The petition requested that the NRC amend 10 CFR 50.54(a) to change the criteria that nuclear power plant licensees are to use to make changes to their quality assurance (QA) programs, without prior NRC approval. According to the proposal, changes involving unreviewed safety questions would require NRC review and approval prior to implementation under the provisions of 10 CFR 50.59.

On September 14, 1995, the NRC announced the receipt of your petition in a Federal Register notice (60 FR 47716) and provided an opportunity for public comment. Seventeen comment letters were received plus one comment letter that supplemented one of the original letters. Of the 18 letters submitted, 11 were sent by nuclear power plant licensees or the Nuclear Energy Institute and all supported the proposed change in the regulations. NEI's public comment letter also provided a draft guidance document to demonstrate how QA programmatic and procedural changes could be evaluated using the 10 CFR 50.59 criteria. The remainder of the public comments were sent by individual concerned citizens, all of whom expressed opposition to the relaxation of regulatory control of changes.

The Commission has considered the merits of NEI's petition and the public comments supporting and opposing your proposal. The Commission agrees with NEI's position that the current regulation is too restrictive; however, it also finds that the adoption of the approach you recommend, of using the 10 CFR 50.59 criteria for determining when changes to the QA program require prior NRC approval, is not appropriate. The 10 CFR 50.54(a) regulation was originally promulgated in January 1983, because QA programs were being unilaterally changed by licensees to the extent that they were no longer acceptable. The Commission believes that the use of the 10 CFR 50.59 criteria for QA program changes, as NEI proposed, is not appropriate. Thus, the Commission has denied the petition. The Commission will, however, continue to consider the types of modifications to 10 CFR 50.54(a) that might ensure that unreviewed changes to the QA program do not result in unacceptable program elements while providing relief to the industry from lengthy debate with the Commission concerning changes of minimal safety significance. The Commission will continue to work with the industry, through public

ENCLOSURE 3

R. Beedle

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meetings and workshops, to identify acceptable methods to be used to accurately discriminate between QA changes that have minimal safety significance and those that require prior NRC review and approval.

Sincerely,

L. Joseph Callan
Executive Director
for Operations

Enclosure:
Federal Register Notice
Denying Petition

ENCLOSURE 3