



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

MAY 27 1997

MEMORANDUM TO: Harry S. Tovmassian
Office of Nuclear Regulatory Research

FROM: David L. Meyer, Chief *D-L Meyer*
Rules and Directives Branch
Division of Administrative Services
Office of Administration

SUBJECT: REVIEW OF THE DENIAL OF PETITION FOR
RULEMAKING (PRM-50-62)

The Rules and Directives Branch has reviewed the denial of petition for rulemaking package for PRM-50-62. We have attached a marked copy of the package that presents our comments.

When this notice is forwarded for signature and publication, please have a member of your staff include a 3.5-inch diskette that contains a copy of the notice in WordPerfect 5.0 or 5.1 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 notice.

If you have any questions concerning this matter, please have a member of your staff contact Betty K. Golden, 415-6863, or myself, 415-7162, Rules and Directives Branch, Division of Administrative Services.

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 Part 50 Title 10 of the Code of Federal Regulations.

CATEGORY:

This paper covers a major policy question requiring Commission consideration.

SUMMARY:

By letter dated June 12, 1995, NEI petitioned the Nuclear Regulatory Commission (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. 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 to their QA programs described or referenced in their Safety Analysis Reports (SAR) without prior NRC approval. Changes involving unreviewed safety questions would require NRC review and approval ~~prior to~~ ^{before} implementation under the provisions of ~~10 CFR~~ 50.59.

BACKGROUND:

In its petition, NEI argued that ~~10 CFR~~ 50.54(a)(3), which permits the licensee the flexibility to change commitments in its QA program without NRC approval provided that no prior commitment is reduced, is sometimes interpreted by the staff as requiring NRC approval for any changes in the QA, regardless of the safety significance associated with the change. As a consequence, prolonged and sometimes unnecessary regulatory interactions centered on the correct interpretation of the term "reduction in commitment," often occur. NEI indicated that these industry/staff interactions were costly and served as a disincentive to licensees to make QA program improvements.

^{believes that} In NEI's opinion changes made to a licensee's QA program description without NRC approval should be governed by the effect of the change on safety and not whether the change represents a "reduction in commitment." Thus, NEI proposed that the threshold for submittal of QA program changes should be the same as the regulatory control in effect for changes to other aspects of the nuclear plant as presented in § 50.59 (i.e., whether or not the change involves an unreviewed safety question or results in a change to the technical specifications incorporated in the license). NEI claimed that the proposed approach would still address the concerns that the NRC had when it promulgated § 50.54(a), that some changes might diminish the scope of the QA program, thereby permitting significant deficiencies to arise in various facility activities that could increase the risk to the public health and safety, since QA program changes would continue to be reported periodically (under ~~10 CFR~~ 50.71(e)). The petition goes on to state that the proposed amendment would improve the consistency of the regulatory process by bringing the QA program under the same change control provision as other features of the nuclear facility and would

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result in increased safety of commercial nuclear power plants through more efficient use of agency and industry resources.

DISCUSSION:

On September 14, 1995, the NRC published a Federal Register notice (60 FR 47716) announcing the receipt of the NEI petition for rulemaking and provided an opportunity for public comment. Seventeen comment letters were received plus one comment letter that supplemented one of the original letters. ^(close spaces) Of the 18 letters submitted, 11 were sent by nuclear power plant licensees and NEI, and all supported the proposed change in the regulations. The remaining comments 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.

With a few notable exceptions, in which NEI responded to specific questions posed by the NRC in its Federal Register notice, NEI's comments on the notice were a repetition of the rationale presented for submitting the petition. NEI believes that the proposed regulatory change ~~will~~ ^{would} focus industry and agency attention and resources on the safety significance of QA programmatic changes rather than on reductions in prior commitments, many of which, NEI believes, have little or no impact on safety. ^{this} NEI claims, ^{that this} is consistent with the industry's recognition of the importance of effective and efficient QA programs to public health and safety. NEI further notes that licensees routinely use the § 50.59 criteria for evaluation of non-hardware related changes to procedures and programs described in the SAR. This is consistent with the majority of past QA program changes which have been administrative in nature. As a result of the proposed regulatory changes, NEI claims that the industry expects considerable cost savings.

In response to an issue that NRC sought comment upon, NEI stated that it has considered alternate thresholds for determining the need for prior NRC review of proposed QA program changes, including the "decreased effectiveness" criterion and the previously accepted "Guideline for Managing NRC Commitments" and concluded that use of the ~~10 CFR~~ ^{10 CFR} 50.59 process is the optimum approach ~~since~~ ^{because} it is used to control other hardware and program facility changes. Also The NRC requested comment on the appropriateness of having activities such as safety review committees, independent technical review groups, and audits be controlled so that only licensee changes exceeding the threshold of an unreviewed safety question would require prior NRC approval. NEI commented that no change should be made in the relocation of the QA review and audit functions, previously included in the Technical Specifications, to the QA program, thereby also relegating changes to these functions to the ~~10 CFR~~ ^{10 CFR} 50.59 process.

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 are 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 (4) an assessment of whether the proposed change affects any licensing commitments as a result of a notice of violation within the last 2 years.

Of those letters in opposition to the NEI petition, the primary reasons 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

NEI was the only commenter that responded to the eight issues posed by the NRC in its notice of the petition.

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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 that nuclear plant safety should not be sacrificed to the elimination of jobs, the destruction of families, and the "bottom dollar."

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The staff agrees with the NEI position that the current regulation is too restrictive; however, it also believes that the adoption of the recommended approach, of using the § 50.59 criteria for determining when changes to the QA program require prior NRC approval, is not appropriate. 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. The staff believes that returning to the use of the § 50.59 criteria for QA program changes, as proposed in this petition, would undermine the purpose for which § 50.54 (a) adopted.

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PRM-50-62

RESOURCES:

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The Office of Nuclear Regulatory Research (RES) has budgeted sufficient resources to cover the actions associated with the denial of the petition proposed herein. No additional RES resources will be necessary once these actions have been completed. Similarly, no additional resources from the Offices of Nuclear Reactor Regulation and the General Counsel should be required.

CONCLUSION:

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The staff believes that the NEI petition should be denied. The staff will, however, continue to consider the types of modifications to § 50.54(a) it might promulgate to assure that unreviewed changes to the QA program do not result in unacceptable program elements while providing the relief to the industry from onerous debate with the NRC staff concerning changes of minimal safety significance. The staff will consider the use of the types of questions posed in NEI's draft guidance document for potential inclusion in a future modification to §50.54(a).

COORDINATION:

The Offices of Nuclear Reactor Regulation and Administration concur in this paper. The Office of the General Counsel has reviewed this paper and has no legal objection.

RECOMMENDATION:

That the Commission:

1. Approve:
 - a. The Federal Register notice that denies the NEI petition (Attachment A).
2. Note:
 - a. That the petitioner will be informed of this action (Attachment B).

- b. That the appropriate Congressional committees will be informed of this action (Attachment C), and
- c. That a public announcement announcing this action will be published (Attachment D).

L. Joseph Callan
Executive Director
for Operations

Attachments: As Stated (4)

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150-

[Docket No. PRM-50-62]

Amendments to NRC Regulations Controlling
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 requests that the NRC amend ^{its regulations} 10 CFR 50.54(a) to permit nuclear power plant licensees to make a broader range of changes to their quality assurance programs described or referenced in their Safety Analysis Reports (SAR) without prior NRC approval.

~~This action is taken because the Commission~~ ^{The NRC is denying the petition because it} has determined that the adoption of the criteria recommended by NEI for controlling changes in licensee's quality assurance (QA) 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

20555-0001

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.

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(email —)

The Petition

By letter dated June 8, 1995, NEI petitioned the NRC to amend its regulations controlling 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 modify 10 CFR 50.54(a) to permit nuclear power plant licensees to make a broader range of changes to their quality assurance programs described or referenced in the ~~re~~ their Safety Analysis Reports (SAR) without prior NRC approval. Changes involving ^(USQ) unreviewed safety questions ⁵ would require NRC review and approval prior to implementation ₆ ^{before} under the provisions of 10 CFR 50.59.

Basis for Request

The petitioner argued that 10 CFR 50.54(a)(3), which permits the licensee the flexibility to change commitments in the quality assurance program without NRC approval provided that no prior commitment is reduced, is sometimes interpreted by the NRC as requiring NRC approval for any changes in the quality assurance program, regardless of the safety significance associated with the change. As a consequence, prolonged and sometimes unnecessary regulatory interactions ⁶ centered on the correct interpretation of the term "reduction in commitment," often occur. 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 that 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 cost to the industry to conduct the resultant industry/NRC interactions was in excess of one million dollars per year. In addition, ^{The petitioner believes that} licensees are occasionally reluctant to pursue quality program improvements due to the resources required, even though the ultimate result would be improvements in efficiency, quality, and/or safety. In the petitioners opinion,

The petitioner opined that acceptability of changes made to a licensee's quality assurance program description 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 NRC would be more appropriately and effectively focused on issues that could have an adverse impact on public health and safety, rather than on administrative details and issues having minimal or no safety impact.

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To this end, the petitioner proposed that the threshold for submittal of quality assurance program changes should be whether or not the change involves an unreviewed safety question 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 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 as determined by the licensee. The petitioner proposed the same criteria for the determination of an unreviewed safety question as is currently ^{used} ~~utilized~~ for nuclear plant changes under 10 CFR 50.59. NEI states that NRC acceptance of the proposed approach would bring quality assurance 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 licensee actions to make certain changes to quality assurance programs without informing the NRC. This was necessary as some QA programs had been changed so that they no longer conformed to NRC regulations. The NRC concern was that some changes might diminish the scope of the QA program, thereby permitting significant deficiencies to arise in various facility activities that could increase the risk to the public health and safety. Nevertheless, the petitioner claimed that the proposed approach would still address the NRC's concerns ^{because} ~~since~~ quality assurance 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 an unreviewed safety question or cause a change to the technical specifications would be formally submitted to the NRC for approval ^{before} ~~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 quality assurance programs as well.

The petitioner stated that the proposed amendment would improve the consistency of the regulatory process by bringing the quality assurance 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 provided an opportunity for public comment. The Federal Register notice included eight specific questions directed at eliciting comments by interested members of the public on critical regulatory aspects of the NEI petition. 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 and NEI and all supported the proposed change in the regulations. The remaining comments 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.

Summary of Comments on NRC Posed Questions

NEI was the only commenter that responded 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 and the NEI comments on these issues. Since most of the points raised by NEI in these comments

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are the same as those raised in their other remarks, a paraphrased summary and an NRC response have been prepared and appear at the end of the public comment analysis.

Issue 1: 10 CFR 50.54(a) was issued on January 10, 1983, to correct instances where licensees had changed their programs that resulted in some unacceptable programs without informing the NRC. What assurances exist to prevent a similar situation from recurring if the petition and the revised threshold for reporting QA program changes is adopted? Is it necessary that such situations be prevented from occurring by adoption of a regulatory approval system?

NEI Comment: The current [§] 50.54(a) regulation has often resulted in significant and unnecessary discussion on the meaning of "does not reduce the commitments." Proposed use of ^{the} 50.59 regulation should result in little or no debate since it has been routinely used by licensees to evaluate equipment and non-hardware changes and will 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 ^{before} 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.

Issue 2: Traditionally, the NRC staff has used a variety of documents such as the NRC Standard Review Plan, ^(SRP) NRC Regulatory Guides, ^(RGs) 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 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 ^{would} ~~will~~ be satisfactorily accomplished. The SRP, RGs, and associated industry standards provide an approach to meeting the regulations. Changes to QA programs should be focused on safety and the regulations, not a departure from commitments in these documents which, in some areas, may have minimal safety significance. When assessing any change, the licensee's most important task is to assure safety. NRC ^{would} ~~will~~ be informed of all changes, including those requiring prior approval. However, alternate approaches 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, industry and the NRC have reached a general understanding for managing commitments in "Guideline for Managing NRC Commitments." This process should also be useful for QA program changes.

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 § 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 (USQ) be reported to the NRC for pre-review before implementation? What kind of changes to a licensee's QA program would constitute a USQ? Assuming that the USQ should/could be applied, does not the use of § 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 elsewhere 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 as now allowed and be subject to change control under § 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 § 50.59 criteria for evaluation of non-hardware related changes to procedures and programs described in the SAR.

Issue 4: Are there alternative thresholds for determining whether a licensee must submit their QA program changes for advance review in lieu of the USQ threshold? Provide a technical and/or policy explanation as to why this or any other threshold would be more appropriate.

NEI Comment: Alternate thresholds for determining whether QA program changes should be submitted for NRC review ^{before} prior to implementation include: adoption of the "decreased effectiveness" standard in [§] 50.54(p) and (q), and replacement of [§] 50.54(a) with the process in "Guideline for Managing NRC Commitments."

However, NEI believes that adoption of the § 50.59 change process is best ^{because} since it is used routinely for all other matters described in the SAR and evaluation of QA program changes should not be treated differently.

Issue 5. The NRC Regulatory Review Group (RRG) examined change control mechanisms in § 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 § 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 § 50.54(a) provide a sufficiently flexible and technically reasonable criteria for licensees to report QA program changes to the staff before implementation?

NEI Comment: NEI states that use of a "decrease the effectiveness" criterion to judge acceptability of a proposed QA program change is not appropriate ^{because} since the QA program affects the safety function of plant SSCs which is not the case for EP and security regulations that use this criterion. It is

believed that use of this criterion for QA programs would ultimately lead to the USQ arena which is ^{currently} what is addressed under § 50.59, anyway. The industry's conclusion is that the § 50.59 process is the optimum change process for QA program changes.

Issue 6: Should the NRC staff consider retaining the current language of § 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?

NEI Comment: Ever since the ^{issuance} promulgation of the [§] 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 no further guidance and use of examples will resolve the problem. The process should be changed to applying the [§] 50.59 rule.

Issue 7: The petition proposes to apply a § 50.59 process to evaluate QA program changes to determine the necessity for pre-review by the staff. Industry guidance for § 50.59 exists within NSAC-125 "Guidelines for § 50.59 Safety Evaluations." 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 would be necessary to report to the NRC if the current ^{close space} § 50.59 criteria were applied to QA program changes? What are examples of QA program changes that should be considered as meeting the USQ threshold?

NEI Comment: ^o NEI indicated that the § 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 remedies 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 § 50.50 criteria.

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 ^{would} will improve the focus of licensee and NRC resources on safety matters rather than issues associated with a reduction in commitment, many of which have no ^o 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, ^{would} will be considerably reduced in the future. Since ^{Because} the costs involved in pursuing USQ issues are expected to be high, there is a considerable disincentive to propose ^{these} such changes.

Public Comments Other than Those Addressing NRC Identified Issues

Of the 11 letters supporting the NEI petition, 10 were from licensees and were essentially in full agreement. One of these 10 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 (10 CFR 50.54(p) and (q), respectively). One commenter, an NRC licensee, expressed a contrary opinion that the use of the latter criterion could be adapted to QA program changes.

The other supporting letter was received from NEI. In its transmittal letter NEI made several comments in support of its petition.

1. The industry has significant reservations regarding two of the alternatives to the petition which were suggested by the NRC.
 - (a) The industry believes that the adoption of "departure from commitment" standard for requesting NRC approval ^{before} prior to implementation of QA changes a regressive step ^{regarding} 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 quality assurance program description, whether or not there is a nexus to safety. This has the potential of diverting licensee and NRC attention and resources from safety-significant matters, increasing the probability of not identifying a safety-significant issue.
 - (b) The industry believes that establishment of a separate change process and mechanism for review and audit functions as suggested by Issue 3 of the proposed rule 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. The process of implementing the regulations would become more complex, increasing the potential for confusion, misunderstanding and misinterpretation. There would be two different change processes for matters described in the same licensee-controlled document.

2. NEI recommends the deletion of 10 CFR 50.4(b)(7)(i) from the NRC regulations because there is no need for requiring a separate administrative reporting requirement for changes to the quality assurance program description, from that already provided for updating Safety Analysis Report matters in 10 CFR 50.4(b)(6) (which makes reference to 10 CFR 50.71(e)). Sub-paragraph (ii) of 10 CFR 50.4(b)(7)⁽ⁱⁱ⁾ should not be amended because the requirement is unique to nonlicensees (e.g., architect/engineers, NSSS suppliers, fuel suppliers, constructors).

Of those letters in opposition to the NEI petition, the primary reasons 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 that nuclear plant safety should not be sacrificed to the elimination of jobs, the destruction of families, and the "bottom dollar."

Summary of NEI's comments on the NRC announcement

NEI's rationale for submitting the petition is that the proposed regulatory change ^{would} will focus industry and agency attention and resources on the safety significance of QA programmatic changes rather than on reductions in prior commitments, many of which NEI believes have little or no impact on safety. This NEI claims is consistent with the industry's recognition of the importance of effective and efficient QA programs to public health and safety. NEI has considered alternate thresholds for determining the need for prior NRC review of proposed QA program changes including the "decreased effectiveness" criterion and the previously accepted "Guideline for Managing NRC Commitments" and concluded that use of the 10 CFR 50.59 process is the optimum approach ^{because} since it is used to control other hardware and program facility changes. NEI believes that no change should be made in the relocation of the QA review and audit functions, previously included in the Technical Specifications, to the QA program, thereby also relegating changes to these functions to the 10 CFR 50.59 process. NEI further notes that licensees routinely use the 50.59 criteria for evaluation of non-hardware related changes to procedures and programs described in the SAR. This is consistent with the majority of past QA program changes which have been administrative in nature. As a result of the proposed regulatory changes, NEI claims that the industry expects considerable cost savings.

NEI also 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 are 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 (4) an assessment of whether the proposed change affects any licensing commitments as a result of a notice of violation within the last 2 years.

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 agrees with the NEI position that the current regulation is too restrictive; however, it also finds that the adoption of the recommended approach, of using the § 50.59 criteria for determining when changes to the QA program require prior NRC approval, is not appropriate. ^{Section} ~~The~~ 50.54(a) ~~regulation~~ was originally ^{issued} 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. The Commission believes that returning to the use of the § 50.59 criteria for QA program changes, as proposed in this petition, would undermine the purpose for which § 50.54 (a) was adopted.

NEI's draft guidance document demonstrating how QA programmatic and procedural changes could be evaluated using the § 50.59 criteria appears to consider the appropriate type of questions; however, the NRC believes that 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 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 § 50.54(a). Thus, the Commission is denying the NEI petition. ^T The Commission will, however, continue to consider the types of modifications to § 50.54(a) it might ^{issue} promulgate to assure that unreviewed changes to the QA program do not result in unacceptable program elements while providing the relief to the industry from onerous debate with the Commission concerning changes of minimal safety significance. The Commission will consider the use of the types of questions posed in NEI's draft guidance document for potential inclusion in a future modification to § 50.54(a).

^{note:}
Please include at least two lines of
additional text on the signature page

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

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.

CONGRESSIONAL LETTERS

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). NEI requested that the NRC modify 10 CFR 50.54(a) to permit nuclear power plant licensees to make a broader range of changes to their QA programs described or referenced in their Safety Analysis Reports (SAR) without prior NRC approval. Changes involving unreviewed safety questions would require NRC review and approval prior to implementation under the provisions of 10 CFR 50.59.

The NRC agrees with the NEI position that the current regulation is too restrictive; however, it also believes that the adoption of the recommended approach, of using the § 50.59 criteria for determining when changes to the QA program require prior NRC approval, is not appropriate. ^{Section} 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. The staff believes that returning to the use of the § 50.59 criteria for QA program changes, as proposed in this petition, would undermine the purpose for which § 50.54 (a) ~~was~~ ^{was} adopted. For this reason, the NRC is denying the NEI petition. The NRC will, however, continue to consider the types of modifications to § 50.54(a) it might promulgate to assure that unreviewed changes to the QA program do not result in unacceptable program elements while providing the relief to the industry from onerous debate with the NRC staff concerning changes of minimal safety significance.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Frank Pallone

The Honorable Chairman Lauch Faircloth
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). NEI requested that the NRC modify 10 CFR 50.54(a) to permit nuclear power plant licensees to make a broader range of changes to their QA programs described or referenced in their Safety Analysis Reports (SAR) without prior NRC approval. Changes involving unreviewed safety questions would require NRC review and approval prior to implementation under the provisions of 10 CFR 50.59.

The NRC agrees with the NEI position that the current regulation is too restrictive; however, it also believes that the adoption of the recommended approach, of using the § 50.59 criteria for determining when changes to the QA program require prior NRC approval, is not appropriate. 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. The staff believes that returning to the use of the § 50.59 criteria for QA program changes, as proposed in this petition, would undermine the purpose for which § 50.54 (a) was adopted. For this reason, the NRC is denying the NEI petition. The NRC will, however, continue to consider the types of modifications to § 50.54(a) it might promulgate to assure that unreviewed changes to the QA program do not result in unacceptable program elements while providing the relief to the industry from onerous debate with the NRC staff concerning changes of minimal safety significance. Section

Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Senator Bob Graham
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Mr William Rasin
Nuclear Energy Institute
1776 I Street, NW
Washington, DC 20006-3708

Dear ~~Sir~~: *Mr. Rasin*

I am responding to the petition for rulemaking that you submitted to the Nuclear Regulatory Commission (NRC) by a letter dated June 8, 1995. Your petition was docketed by the Commission on June 19, 1995 and assigned Docket No. PRM-50-62. You requested that the NRC modify 10 CFR 50.54 (a) to permit nuclear power plant licensees to make a broader range of changes to their quality assurance (QA) programs described or referenced in the their Safety Analysis Reports (SAR) without prior NRC approval. According to your 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. Your public comment letter also provided a draft guidance document to demonstrate how QA programmatic and procedural changes could be evaluated using the § 50.59 criteria. Your proposed procedure appears to consider the appropriate type of questions to be addressed when considering the need for prior NRC approval for QA program changes; however, the NRC believes that more evaluation is required. Your proposed guidance involves subjective analysis of the safety merits of proposed changes versus the continued implementation of pertinent QA elements. 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 your petition and the public comments supporting and opposing your proposal. The Commission agrees with your position that the current regulation is too restrictive; however, it also finds that the adoption of the approach you recommend, of using the § 50.59 criteria for determining when changes to the QA program require prior NRC approval, is not appropriate. 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. The Commission believes that returning to the use of the § 50.59 criteria for QA program changes, as you proposed, would undermine the purpose for which § 50.54 (a) was adopted. For this reason, the Commission has decided to deny your petition. However, the Commission will continue to consider the types of modifications to § 50.54 (a) that it might promulgate to assure that unreviewed changes to the QA program do not result in unacceptable program elements while providing the relief to the industry, which your petition seeks, from onerous debate with the Commission concerning changes of minimal safety significance. The Commission will also consider the use of the types of questions posed in the draft guidance document which supplemented your letter of public comment, for potential inclusion in a future modification

to § 50.54 (a)

Sincerely,

L. Joseph Callan
Executive Director
for Operations

Enclosure:
Federal Register Notice
Denying Petition

deny your petition. However, the Commission will continue to consider the types of modifications to § 50.54 (a) that it might promulgate to assure that unreviewed changes to the QA program do not result in unacceptable program elements while providing the relief to the industry, which your petition seeks, from onerous debate with the Commission concerning changes of minimal safety significance. The Commission will also consider the use of the types of questions posed in the draft guidance document which supplemented your letter of public comment, for potential inclusion in a future modification to § 50.54 (a)

Sincerely,

L. Joseph Callan
Executive Director
for Operations

Enclosure:
Federal Register Notice
Denying Petition

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