

BOB G



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

December 23, 1997

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

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

SUBJECT: NRR COMMENTS ON DENIAL OF PETITION FOR RULEMAKING
LICENSEE CHANGES TO QUALITY ASSURANCE PROGRAMS,
AMENDMENTS TO 10 CFR 50.54(a) (PRM-50-62)

We have reviewed the subject denial of petition for rulemaking and the four associated attachments as requested in your memorandum dated November 12, 1997. NRR is in full agreement with the denial of the petition because the use of the 10 CFR 50.59 criteria as a threshold for determining whether a QA program change requires prior staff approval permits excessive latitude for licensees to make changes that could result in a lack of conformance to 10 CFR 50, Appendix B. In several places in the paper and its attachment, however, the lack of adequate guidance to properly implement the 50.59 criteria is cited as the reason for rejection (See the first full paragraph on page 3 of the Commission Paper; the last sentence on page 11 of Enclosure 2; the last sentence in the top paragraph on page 23 of Enclosure 2). While the lack of guidance is a contributing factor, it is not the primary reason for denying the petition. Our remaining comments are primarily of an editorial nature and are shown in the attached copy.

As suggested in your transmittal letter, we have specifically requested comments from the regional offices. Region I supports the denial and Regions II, III, and IV have no comments.

With proper resolution of our comments, NRR concurs in the issuance of the Commission Paper and its attachments. NRR also notes that OGC will comment that we should offer an advanced notice of proposed rulemaking instead of a meeting with NEI. Due to NRR resource limitations, we have decided to forego staff rulemaking activities unless there is a clear indication that the industry supports the effort.

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

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(301) 415-6231

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argued that 10 CFR 50.54(a)(3) is sometimes interpreted by the staff as requiring NRC approval for any changes in the QA program, ~~regardless that reduce prior commitments, independent~~ 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 or tech spec change 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 the current 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 prior to implementation. 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 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 the possibility of a different and unanalyzed 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, nor is it likely that such guidance can be developed, 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 in 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.~~

The staff has concluded that the excessively broadened threshold for permitting changes, in addition to the absence of adequate guidance, makes the use of 10 CFR 50.59-like criteria for determining the acceptability of QA program changes not appropriate. However, the staff is sympathetic with NEI's concern with the continued use of the 10 CFR 50.54(a) criterion. The staff will continue to consider the types of modifications to 10 CFR 50.54(a) it might find acceptable to ensure that unilateral and unreviewed changes to the QA program continue to assure effective QA program elements while providing relief to the industry from lengthy debate with the Commission concerning changes of no or minimal safety significance. The staff will also continue to work with the industry to identify acceptable

methods to differentiate between QA changes that have minimal safety significance and those that require NRC review and approval prior to implementation. As a minimum, the staff believes that licensees should be permitted to make unilateral changes that are administrative, organizational, incorporate newly endorsed consensus standards, or adopt new QA positions previously approved by the staff provided that these changes result in programs that continue to meet applicable regulations. In addition, the staff plans to continue its interactions with NEI to identify potential alternative criteria to use, such as "maintain the effectiveness" in lieu of the "reduce the commitment" criterion currently used in 50.54(a). Once we have developed criteria that will allow licensees more flexibility to change their QA programs without requiring prior staff review and approval, but assure continued program effectiveness, the staff will consider proposing a revision to 10 CFR 50.54(a). The rulemaking would reflect the changes discussed above. Therefore, subsequent to the denial of this petition, the staff will propose a public meeting in the Spring 1998 time frame to entertain proposals for alternative approaches to 10 CFR 50.54(a) revisions, as discussed above, that will be potentially acceptable to both the NRC and the nuclear industry.

RESOURCES:

Resources to complete the actions associated with the denial of the petition, and interactions with the industry, are included in the FY 1998 budget. Resources for future rulemaking activities are not 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).
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).

- c. That the staff plans to continue interactions with the industry as appropriate to define acceptable criteria to govern future QA program changes.

L. Joseph Callan
Executive Director
for Operations

Enclosures: As Stated (4)

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)

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- b. That the appropriate Congressional committees will be informed of this action (Enclosure 4).

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ENCLOSURE 1



NUCLEAR ENERGY INSTITUTE

PRM-50-62

William H. Rasin
VICE PRESIDENT
TECHNICAL-REGULATORY

June 8, 1995

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington DC 20555

Dear Mr. Hoyle:

The Nuclear Energy Institute (NEI), on behalf of the nuclear energy industry, hereby submits a Petition for Rulemaking pursuant to 10 CFR 2.800 *et seq.* The Petition for Rulemaking requests that the U.S. Nuclear Regulatory Commission amend certain aspects of 10 CFR 50.54(a) that are related to quality programs at commercial nuclear power plants.

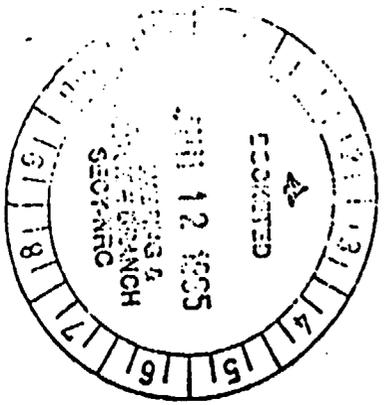
NEI would be pleased to discuss this petition and to respond to any questions NRC personnel may have regarding its content or application.

Sincerely,

A handwritten signature in black ink, appearing to read 'William H. Rasin', is written over a horizontal line.

William H. Rasin

WHR/jes
Enclosures



9

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of a)
Proposed Rulemaking)
Regarding Amendments to)
10 CFR Part 50.54(a))

Docket No. *PRM-50-62*

PETITION FOR RULEMAKING

SUMMARY

This petition for rulemaking is submitted pursuant to 10 CFR 2.802 by the Nuclear Energy Institute (NEI) on behalf of the nuclear energy industry. Petitioners request that the U.S. Nuclear Regulatory Commission ("NRC"), following notice and opportunity for comment, amend certain portions of the regulations contained in 10 CFR 50.54 to improve the effectiveness and efficiency of the regulations pertaining to licensee initiated changes to their quality programs. This petition is the first of several petitions being considered by NEI to improve the consistency of the regulatory change process associated with matters that are described or referenced in a Safety Analysis Report (SAR).

Currently, 10 CFR 50.54(a) allows licensees to make changes to a previously accepted quality assurance program description included or referenced in a SAR without prior NRC approval, provided that the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the quality assurance program description that reduce commitments must receive NRC approval prior to implementation.

This proposed amendment would permit a licensee to change its quality program as described or referenced in the SAR, without prior NRC approval, providing the change does not involve an unreviewed safety question, or result in a change to the Technical Specifications incorporated in its license. This will make the process for changing the quality assurance program consistent with the change process for other matters described in the SAR.

The proposed change is commensurate with the recommendations of the 1993 Report of the National Performance Review conducted by the Vice President of the United States and the 1995 Congressional initiatives currently under consideration to improve the general regulatory regime. The proposed change will significantly

improve the regulatory process and increase the safety of commercial nuclear power plants through a more efficient use of agency and industry resources by improving the focus on matters that have safety significance while reducing unnecessary burdens on licensee and NRC staffs.

In addition to setting forth the information required under 10 CFR 2.802(c) for a petition for rulemaking, NEI has provided supplemental analyses to facilitate the NRC's consideration of the effect of the proposed action on the environment, small business entities, and the paperwork burden on those entities that would be affected by the change. Further, because the NRC must consider whether a regulatory analysis must be performed as well as whether 10 CFR 50.109 (the Backfit rule) applies to this rulemaking, NEI also has included its analysis of those subjects (see the Appendix, *Supplementary Analyses in Support of the Petition for Rulemaking*).

STATEMENT OF PETITIONER'S INTEREST

NEI is responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, nuclear materials licensees, and other organizations and individuals involved in the nuclear energy industry. NEI is an "interested person" within the meaning of 10 CFR 2.802.

STATEMENT IN SUPPORT OF THE PETITION

A. Background

There have been a number of studies and surveys in recent years to identify areas of excessive regulatory burden that have no, or marginal, safety significance. In addition, these studies have recommended areas for further investigation and included proposals for improving the effectiveness of the NRC regulations.

In 1992, the NRC reported in the *Federal Register* that it had been assessing NRC regulations that had no significant safety benefit and imposed large burdens on licensees. A summary of the initial NRC conclusions was published for public comment on February 4, 1992 (57 Fed. Reg. 4166). The subsequent public comments were summarized in the announcement of a public workshop to discuss the NRC program for Elimination of Requirements Marginal to Safety (57 Fed. Reg. 55156, November 24, 1992). In that announcement, the NRC stated its commitment to reducing unnecessary regulatory burdens so as to improve the focus and effectiveness of its regulations. This commitment was commensurate with the

intent of the February 1992 request from the President of the United States for federal agencies to conduct a special review of existing federal regulations. The NRC's 1992 study identified performance-based quality assurance as a concept that warranted further study. In addition, the public comments suggested further analysis would be appropriate in the area of the quality assurance criteria contained in 10 CFR Part 50, Appendix B, to assess the potential for burden reduction that would have no impact on safety.

On January 4, 1993, the Executive Director of Operations, NRC, established a Regulatory Review Group to conduct a review of power reactor regulations and related processes, programs, and practices with special attention placed on the feasibility of substituting performance-based requirements and guidance for the existing prescriptive requirements and guidance. Subsequently, the NRC Regulatory Review Group identified specific examples of inconsistency and incoherence in the current regulations and their associated administrative requirements, and provided recommendations for improvement. In some of these areas, licensees are responsible for controlling specific activities that are very similar in nature, but are the subject of different regulatory constraints, reporting, and record retention requirements. Examples provided in the Regulatory Review Group Report, dated August 1993, included:

- Changes that can be made by a licensee to a facility or procedures without prior NRC approval if the change does not require a change to the Technical Specifications or involve an unreviewed safety question (i.e., 10 CFR 50.59).
- Changes that can only be made to a licensee's quality assurance program described or referenced in the SAR without prior NRC approval if they do not reduce commitments in the program description previously accepted by the NRC, even if the changes do not affect the Technical Specifications, involve unreviewed safety questions, or have any adverse safety significance (i.e., 10 CFR 50.54(a)).
- Varying record retention and reporting frequencies for activities of a similar nature, such as those associated with quality assurance and changes to the SAR.

NEI concurs with the NRC Regulatory Review Group Report that there is no reason for such inconsistencies in the NRC regulations. Regulatory effectiveness would be improved, the burden on licensees and the NRC reduced, and regulatory coherence enhanced if there were a consistent change process for changes to the facility, its procedures, tests and experiments, or other matters as described in the SAR.

Further, in the NRC staff briefing of the Commission on January 24, 1994, on the Regulatory Review Group Report Implementation Plan, the need for a consistent approach for dealing with regulatory commitments was acknowledged. As such, the

NRC and industry have been developing a method of addressing the issue of commitments and their associated change process that is based on a determination of safety significance. However, because the quality assurance program change process is specifically addressed in the regulations through Section 50.54(a), it has not been included in that activity.

Currently, under Section 50.54(a) a licensee has the flexibility to change commitments in the quality assurance program as long as any prior commitment in that program is not reduced. If a commitment is to be reduced, a licensee needs NRC approval prior to implementation. This requirement is sometimes interpreted by the NRC as requiring NRC prior approval for any changes in the quality program, no matter the degree of safety significance. Prolonged and sometimes unnecessary regulatory interactions often occur centered on the correct interpretation of the term "reduction in commitment." In this regard, examples of topics that have been the subject of concern in the past include:

- Changes in the level of approval of administrative, implementation or policy procedures, regardless of the safety significance.
- Changes in the company organization as it is described in the licensee's original quality plan.
- Changes to audit, review or surveillance frequencies that have minimal, if any, safety significance.
- 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.
- 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.

Based on preliminary estimates from a cross section of industry representatives on the NEI Appendix B Working Group, the cost to the industry (excluding NRC costs and fees) of these activities is in excess of one million dollars per year. More importantly, on occasions licensees are hesitant to pursue quality program improvements that may be interpreted by the NRC as a reduction in commitment. Such hesitancy is caused by the potential resource burden associated with regulatory interactions on changes to a licensee's quality program where matters might be interpreted as a reduction in commitment, even though the ultimate result would be an improvement in efficiency, quality, and/or safety.

Under Section 50.59, a licensee's ability to make changes in the facility described in its SAR is technically sound and procedurally pragmatic, allowing the licensee the latitude to make a change without prior NRC approval unless the change results in a change to the Technical Specifications, or involves an unreviewed safety question. The method developed for addressing and managing regulatory commitments that is being proven through pilot implementation projects with several licensees is based on the safety significance of the proposed change, not on a reduction in commitment. In the process both for managing commitments and changes to the SAR under Section 50.59, the focus is appropriately on those changes that have safety significance. However, regarding quality assurance programs, the threshold for seeking prior NRC approval is associated with the interpretation of what constitutes a reduction in a licensee's "commitment" rather than its safety significance.

Further, the provisions of Section 50.54(a) describing the change process for a licensee's quality program description included or referenced in the SAR are inconsistent with the requirements associated with other changes to the SAR. A licensee's inability to adjust its quality program descriptions and commitments without prior NRC approval is a significant administrative burden on a licensee and can distract licensee and NRC attention from more safety significant matters. The proposed amendment would improve regulatory consistency by instituting the same type of change process for the quality assurance program described or referenced in the SAR as for other matters described in the SAR (i.e., a change process delineated similar to Section 50.59). The result would assure that industry and NRC attention and resources are more appropriately and effectively focused on issues that could have an adverse impact on public health and safety.

B. Proposed Change to 10 CFR 50.54 (a)

The main purpose of the Section 50.54(a) requirement introduced in 1983 was described in the Statements of Consideration for the original rule:

".....some licensees have been changing their quality programs without informing the Commission. In a few cases this has resulted in QA programs which were not acceptable to the NRC staff and which did not conform to all aspects of the NRC regulations. The primary concern with the current situation is that unreported changes to the QA program might diminish the scope of the program permitting significant deficiencies to arise in the design, fabrication, construction, or operation of the facility. This could increase the risk to the public health and safety" (48 Fed. Reg. 1026, January 10, 1983).

The Commission's main concerns were associated with the potential impact on safety and the need to keep the Commission apprised accordingly of changes to the accepted quality assurance program. However, the standard for determining the need for NRC staff prior review and approval, the application of the "reduction in

commitment" standard has, on occasions, presented a significant potential for diverting licensee and NRC staff attention and resources from more safety significant matters.

This petition still addresses the Commission's concerns that prompted the original Section 50.54(a) rule in 1983. Changes will continue to be reported and changes that present the potential for an unreviewed safety question will be formally submitted to the NRC staff for approval prior to implementation. Applying a Section 50.59 type process to quality assurance matters described or referenced in the SAR still meets the Commission's original objective. This would provide enhanced regulatory consistency, improves the emphasis on safety, and maintains the reporting requirement for changes to the accepted quality assurance program.

The NRC Regulatory Review Group Report concluded that the regulatory burden on licensees could be reduced if each licensee was to be held to a consistent set of requirements provided by the NRC's regulations. The Regulatory Review Group Report recommended changes in specific regulations to improve the consistency and effectiveness of the body of NRC regulations and the efficiency of their implementation. The proposed amendment to Section 50.54(a) is consistent with the recommendations of the Regulatory Review Group and the other NRC initiatives to improve the effectiveness of its regulations, in that it will improve regulatory efficiency, consistency, and predictability.

Additionally, the proposed change is consistent with the overall objectives of the 1993 National Performance Review conducted by the Vice President of the United States, and with the 1995 Congressional initiatives on improving federal regulations. In conjunction with phase two of the NRC's National Performance Review Study, a review of current regulations is being performed to identify regulations that are obsolete, unnecessarily burdensome, or too prescriptive, or that overlap or duplicate other regulations. This petition is consistent with the aims of the NRC phased implementation of the National Performance Review. This petition will improve the efficiency of the regulatory quality regime, and enable licensee and NRC staff to improve their focus on safety significant issues which could ultimately result in enhanced public health and safety.

A longstanding goal of the Commission has been to improve regulatory predictability and stability, while protecting public health and safety. The Commission discussions and actions associated with licensing reform and regulation for advanced reactors, predominantly that associated with the adoption and implementation of 10 CFR Part 52, *Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors*, reflect a significant advancement towards such a goal. The proposed amendment continues the progression towards the goal of a more predictable and effective regulatory environment.

Each level of the hierarchical regulatory structure should have a change mechanism that would allow the NRC staff to review licensees' actions at a level consistent with the safety significance of the action. Such an approach is exemplified by the Section 50.59 change process for the SAR and the two tier approach for implementing 10 CFR Part 52. The Section 50.59 change process has proven to be an effective process that has reduced an unwarranted burden on licensees and NRC staff for matters that are not of safety significance. The change process for all elements of the Safety Analysis Report should be consistent, no matter the subject. NRC involvement and prior approval should be consistent, and linked to matters affecting the protection of public health and safety. And just because a change would affect the quality assurance program should not cause its importance to be elevated out of context with its safety significance.

In the development of a more efficient and effective quality regime, it is important that licensees not be discouraged by an unnecessary administrative burden of seeking prior NRC approval when a change is of no regulatory significance (i.e., does not result in non-compliance with the NRC's regulations, a change to the Technical Specifications, or an unreviewed safety question). Further, in an evolving technological environment, each licensee should be allowed the opportunity to respond to improvements in technology, industry operating experiences, and new operational or technical information by making changes to the quality program that do not degrade public health and safety without the need for administrative and managerial regulatory interactions.

The proposed amendment to Section 50.54(a) does not introduce a new type of change process. The proposed use of a Section 50.59 type change process in this context is based on a well tried and proven process for making changes to a facility, its procedures, tests, or activities that are described or referenced in its SAR. Compliance with the regulations to assure proper control of the facility and quality program associated with the protection of public health and safety is still provided by the adoption of a change process that is similar to the established Section 50.59 process.

Under the proposed rule, a licensee would have the authority to change its quality program if a Section 50.59 type analysis demonstrates that a proposed change does not involve an unreviewed safety question or change the Technical Specifications. The analysis to support such a determination would be consistent with that required to support other types of changes to a SAR. It would be based on the well proven and established industry guidance that has been used to perform Section 50.59 type evaluations.

If the analysis of a proposed change to the quality program indicates that an unreviewed safety question may be involved, a licensee would either decide not to institute the change, or submit the change for NRC approval before

implementation. For changes involving an unreviewed safety question, the complete change, including the safety evaluation, would be submitted in accordance with the requirements of 10 CFR 50.90.

Licensees would still be required to submit, as specified in 10 CFR 50.4, a report containing a summary description of the changes to the quality assurance program described or referenced in the SAR. The report would be submitted annually, or along with the FSAR updates as required by Section 50.71(e), or at shorter intervals as determined by each licensee. Licensees would maintain records of the changes, as facility records for five years, a period that is consistent with other similar NRC regulations (e.g., Section 50.59).

The proposed petition would require that only a summary, not a detailed safety evaluation, be submitted to the NRC for changes that do not involve an unreviewed safety question. This is consistent with the requirements of similar regulations (e.g. Section 50.59). A licensee would maintain records of such evaluations until the termination of the license.

C. Other Affected NRC Regulations

10 CFR 50.4(b)(7), Quality assurance related submittals (i) :

This paragraph has been deleted. There is no reason for requiring a separate administrative reporting requirement for changes to the quality assurance program description included or referenced in the Safety Analysis Report. Administrative reporting requirements for changes to the facility, its programs, procedures, tests or experiments that are described in the Safety Analysis Report should be treated in a consistent manner. The administration of the regulatory process should be as efficient and as consistent as possible through the optimization of the administrative process.

Sub-paragraph (ii) of 10 CFR 50.4(b)(7) is not amended because the requirement is unique to nonlicensees (i.e., architect/engineers, NSSS suppliers, fuel suppliers, constructors, etc.).

10 CFR 50.55(f), Conditions of construction permits:

This petition does not propose any changes to 10 CFR 50.55(f) because of the current regulatory discussions on implementing Subpart C of 10 CFR Part 52, *Combined Licenses* (combined construction permit and operating license). These discussions encompass the new regulatory process associated with licensing and constructing new power plants. It is more appropriate for changes to NRC regulations associated with initial construction activities to be developed as a result of these discussions. More importantly, 10 CFR Part 52 invokes several new



regulatory concepts, and to assure consistency and reduce the potential for unnecessarily impacting the development of the new regulatory regime for licensing new facilities, changes to Section 50.55(f) are not proposed.

D. Conclusion

For the reasons stated herein, 10 CFR 50.54(a) should be amended to permit a licensee to make a change to its quality program description that is included or referenced in its SAR without prior NRC approval, provided that the change does not involve a change in the Technical Specifications incorporated in the license, or pose an unreviewed safety question. Such a change to Section 50.54(a) would represent a significant step towards improving the efficiency, effectiveness, predictability, stability, and consistency of regulations governing nuclear power plants, and would enhance public health and safety by assuring that licensee and NRC resources are better focused on matters that could impact public health and safety.

PROPOSED CHANGES TO 10 CFR Part 50.54(a)

10 CFR 50.54(a) is revised in its entirety to read as follows:

(a)(1) Each nuclear power plant or fuel reprocessing plant licensee shall implement a quality assurance program pursuant to § 50.34(b)(6)(ii) of this part, as described or referenced in its Safety Analysis Report.

(2) Each licensee described in paragraph (a)(1) of this section may 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.

(i) A change shall be deemed to involve an unreviewed safety question (A) if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in a licensee's Safety Analysis Report may be increased; or (B) if a possibility for an accident or malfunction of a different type than any previously evaluated in a licensee's Safety Analysis Report may be created; or (C) if the margin of safety as defined in the basis for any technical specification is reduced.

(ii) When changes are made to a previously accepted quality assurance program description, a licensee shall submit, as specified in § 50.4, a report containing a brief description of the change, including a summary of the safety evaluation of each change. The report may be submitted annually, or along with FSAR updates as required by § 50.71(e), or at shorter intervals as determined by each licensee.

(iii) Records of changes to the quality assurance program shall be maintained as facility records for five years.



(3) For changes to the quality assurance program description that involve an unreviewed safety question, licensees shall submit the proposed change to the NRC for approval prior to implementation. The licensee shall submit the application to amend the quality program pursuant to the requirements of § 50.90.

(4) For changes that involve a change to the Technical Specifications, a licensee shall submit an application for a license amendment pursuant to § 50.90.

PROPOSED CHANGES TO OTHER REGULATIONS

10 CFR 50.4(b)(7)(i) is deleted.

APPENDIX

SUPPLEMENTARY ANALYSES IN SUPPORT OF THE PETITION FOR RULEMAKING

INTRODUCTION

Pursuant to 10 CFR 2.802, a petition for rulemaking must set out the problem for which petitioners seek redress, the proposed solution, and the substantive basis for the proposed solution. In turn, the NRC must evaluate the procedural and substantive merit of the proposed action against the dictates of the Atomic Energy Act and evaluate the ramifications of the proposed action against several statutes in addition to the Atomic Energy Act. Specifically, the other statutes that must be addressed are the National Environmental Policy Act, the Paperwork Reduction Act, and the Regulatory Flexibility Act. Also, the NRC must draft a Regulatory Analysis if certain criteria are met, and it must determine whether 10 CFR 50.109 is applicable, and if so, an additional evaluation must be conducted.

Petitioner submits the following information to assist the NRC in conducting those analyses.

THE NATIONAL ENVIRONMENTAL POLICY ACT

These proposed regulations are the type of action described in categorical exclusion 10 CFR 51.22(c)(3). Therefore, neither an environmental assessment nor an environmental impact statement is necessary for these proposed amendments.

THE PAPERWORK REDUCTION ACT

The objective of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is to ensure that the Office of Management and Budget has the opportunity to review and approve regulatory actions that create an increased burden on the public due to additional information collection requirements imposed by the federal government. This statute does not apply to the instant rulemaking.

The proposed rule amends the change process and the reporting requirements for changes to a licensee's quality program description that is included or referenced in a licensee's Safety Analysis Report.

The amendment makes the reporting requirements consistent with the procedures for other SAR changes. This amendment will reduce the administrative burden on the NRC as well as on licensees, which are the only entities affected by the proposed amendment.

REGULATORY ANALYSIS

Under certain circumstances, the NRC is required to perform a Regulatory Analysis. The purpose of the analysis is to assure that the NRC obtains adequate information regarding the need for, and consequences of, a proposed regulatory action and that the NRC appropriately considers costs and benefits of alternative regulatory actions. A Regulatory Analysis must be prepared if it is determined that the proposed action contemplated by the rule will likely result in any of the following: (1) an annual effect on the economy of \$100,000,000 or more in direct or indirect costs; (2) a significant impact on health, safety, or the environment; or (3) a substantial increase in the cost to NRC licensees, permit holders or applicants, to federal, state or local governments, and geographic regions. Also, preparation of an analysis may be required by the Commission or the Executive Director of Operations. Analyzing each of the criteria in turn, the following discussion supports a conclusion that the NRC is not required to perform a Regulatory Analysis of the proposed amendment to 10 CFR 50.54(a).

First, the proposed change to Section 50.54(a) will not have an annual effect on the economy of \$100,000,000 or more in direct or indirect costs. To the contrary, the proposal will reduce industry and NRC costs of administering and implementing the NRC regulations. Provisional industry estimates from a cross section of the industry indicate savings in excess of one million dollars per year.

Second, there will be no adverse impact on health, safety or the environment. As noted *infra*, the proposed amendment to 10 CFR 50.54(a) has four objectives: (1) to improve the consistency in the body of regulations by having a consistent change process for items described or referenced in the SAR; (2) to better focus industry and NRC attention and resources on matters that have safety significance such that the protection of public health and safety would be enhanced; (3) to improve the effectiveness and efficiency of NRC regulations; and (4) to reduce unnecessary effort and burden on licensees in implementing NRC regulations.

The achievement of these objectives does not reduce the margin of safety or otherwise degrade public health and safety. Compliance with the regulations to assure proper control of facility and program changes is still provided by basing the change process on the well established and proven process described in 10 CFR 50.59. In addition, licensee and NRC administrative tasks will be reduced, enabling NRC and industry to focus on ~~more~~ safety-significant matters that have a potential impact on public health and safety. The proposed change process will enable licensees to more efficiently assess the impact of new information and circumstances, and implement appropriate changes while ensuring that public health and safety are not adversely affected.

Third, the proposed changes will not lead to any, much less a substantial, increase in the cost to NRC licensees, permit holders, or applicants; state or local governments; or geographic regions. To the contrary, the current restraints and controls impose an unnecessary burden, often resulting in the consumption of significant licensee and NRC resources to address matters that have minimal safety significance and that present no challenge to public health and safety. Recent industry surveys conclude that approximately 30 percent of industry management time is associated with regulatory interactions, as opposed to plant or personnel management matters. Improvements in efficiency, effectiveness and productivity are being encouraged and pursued through several industry and government (Presidential, Congressional, and agency) initiatives. Through these initiatives, unnecessary activities are being identified and eliminated. The current change process for quality assurance programs, as described by Section 50.54(a), meets the criteria for inclusion in these initiatives to improve the effectiveness and efficiency of the regulatory process. This petition is consistent with these initiatives for improving the federal regulatory process and with the NRC's phased approach for implementing such activities initiated on March 9, 1995.

The NRC Regulatory Review Group and the industry independently have determined that Section 50.54(a) should be amended to improve the consistency in the body of NRC regulations and to improve the effectiveness and efficiency in the implementation of those regulations. Also, such a change would enable licensee and NRC staff to better focus their attention on matters of safety significance that could impact public health and safety rather than specific administrative issues.

THE BACKFIT RULE

The proposed rule amends the process that licensees would use to implement changes to the quality assurance program described or referenced in a licensee's Safety Analysis Report. The proposed amendment would bring consistency to the change process for matters described or referenced in a licensee's Safety Analysis Report. The proposed amendment would not impose additional, more stringent requirements on 10 CFR Part 50 licensees. Rather, it will allow licensees to reduce costs through the deletion of submittals for NRC approval of changes to the quality assurance program description that have no safety significance. Accordingly, the proposed rule would not constitute a backfit as defined in 10 CFR 50.109 and the Commission is not required to prepare a backfit analysis.

REGULATORY FLEXIBILITY ACT

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory



Flexibility Act, or the Small Business Size Standards set out in the regulations issued by the Small Business Administration at 13 CFR Part 121.

ENCLOSURE 2

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 10 CFR 50.54(a) to change the criteria that nuclear power plant licensees are to use to make changes to their to their quality assurance (QA) programs without ~~the~~ receiving NRC approval. These QA programs are described or referenced in the licensees' ^{Final} Safety Analysis Reports (SARs). ^F

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.

Prior to implementation



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 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, 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 ~~will~~^{are} 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 ^{Final} Safety Analysis Report ^F(SAR), changes in procedures as described in the ^FSAR, and the conduct of tests or experiments not described in the ^FSAR, 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

For QA program 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} some QA programs had been changed ^{to the extent} 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 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 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.

the current

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 ^{presented} ~~raised~~ by NEI in response to NRC ^{the} ~~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 ^{QA} deemed unacceptable. 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 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; 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 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

Shifting of QA responsibilities from the QA organization to the line organizations, while ~~seem~~ neutral with regard to function performance, can be contrary to Appendix B requirements (Criterion I) due to the potential influence of cost and schedule pressures on QA activities.

significant

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 appear to be administrative but in fact are ~~not~~ ^{related to safety}. 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, ^{and on occasion are contrary to the requirements of 10 CFR 50, Appendix B.} 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 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 ^{and now NQA-1-1989} 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

Safety Significant

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 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, 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 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, industry and the NRC reached a general understanding for managing commitments in "Guideline 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 "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

¹"Guideline 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 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 ^{or unanalyzed} 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 ^{as examples,} will _{1, 2} affect 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 supplied and referenced by NEI suffers from a heavy reliance on hardware oriented considerations and is not acceptable for use ⁱⁿ 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.

and to develop such guidance would be difficult, if not impossible.

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 "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.

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Thank you

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 staff review before implementation. Should the staff consider a revision to 10 CFR 50.54(a) to set the threshold for reporting QA program changes for NRC pre-review that constitute a decrease in effectiveness? Would a "decrease in effectiveness" standard in 10 CFR 50.54(a) provide a sufficiently flexible and technically reasonable 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

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. 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 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 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 the receipt of the petition and NEI's comments on the Federal Register Notice, NEI has modified "Guideline for Managing NRC Commitments," to include guidance on interpretation of 10 CFR 50.54(a). Although this guidance has been endorsed by the 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~~ effectively improve the licensee's ability to accurately identify QA program changes that do not have any safety significance. The Commission recognizes the problem that NEI seeks to correct through this petition; however, it is ^{at the present time} ~~withholding its judgment as to~~ ^{not clear} how this problem should be rectified (i.e., improved guidance or modifications to 10 CFR 50.54(a)).

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

Addition Issues Raised by NEI

Issue ^A:

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 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.

B
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, increasing 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~~ ^{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. 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 criterion will be adopted.

Issue ^C 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 (ii) of 10 CFR 50.4(b)(7) should not be amended because the requirement is unique to nonlicensees (such as architect/engineers, NSSS suppliers, fuel suppliers, constructors).

NRC Response:

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

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 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 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~~ ^{important to safety} 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 ^a affect the availability of ~~safety related~~ ^{important to safety} equipment. ~~The NRC has not developed any guidance to provide such a determination nor has NEI provided an acceptable methodology to do so.~~ X

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. X

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

23 provides too broad a threshold for QA program changes without NRC review, ENCLOSURE 2

guidance related to it ^{is} oriented towards hardware and hardware-related changes and ~~are~~ ^{is} not appropriate for programmatic changes such as those in the QA program. ^{In addition,} ~~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. ^{For these reasons,} ~~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 industry from 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.

ENCLOSURE 3



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

will result in changed QA programs that no longer meet 10 CFR 50, Appendix B.

ENCLOSURE 3



R. Beedle

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



R. Beedle

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

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R. Beedle

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Sincerely,

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ENCLOSURE 4



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 ~~any~~ 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

prior to implementation



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

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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:
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cc: Representative Ralph Hall

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 Subcommittee on Energy and Power
 Committee on Commerce
 United States House of Representatives
 Washington, DC 20515

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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 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 staff believes that the use of the 10 CFR 50.59 criteria for QA program changes, as proposed in this petition, is not appropriate. For this reason, the NRC is denying the NEI petition. The NRC 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 NRC concerning changes of minimal safety significance.

Sincerely,

Dennis K. Rathbun, Director
 Office of Congressional Affairs

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cc: Representative Ralph Hall

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 Subcommittee on Energy and Power
 Committee on Commerce
 United States House of Representatives
 Washington, DC 20515

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Enclosure:
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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

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

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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:
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cc: Senator Bob Graham

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cc:	HTovmassian*	SBahadur*	JMurray	MKnapp	DRathbun
Date:	08/08/97	1/197	1/197	1/197	1/197
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Property and Nuclear Safety
Committee on Environment and Public Works
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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 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 staff believes that the use of the 10 CFR 50.59 criteria for QA program changes, as proposed in this petition, is not appropriate. For this reason, the NRC is denying the NEI petition. The NRC 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 NRC concerning changes of minimal safety significance.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

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Name: HTovmassian* *for SBahadur*

D 08/08/97 *9/2/97*

C Yes/No Yes/No

D:DRA:RES

JMurphy

1/97

Yes/No

D:RES

MKnapp

1/97

Yes/No

D:OCA

DRathbun

1/97

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 Committee on Environment and Public Works
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