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

September 21, 1998

MEMORANDUM TO: R. Lee Spessard, Director
Division of Reactor Controls and Human Factors
Office of Nuclear Reactor Regulation

FROM: Valeria H. Wilson, Director
Division of Administrative Services
Office of Administration

SUBJECT: OFFICE CONCURRENCE ON A DOCUMENT THAT PRESENTS THE ANTICIPATED RESPONSE TO A PETITION FOR RULEMAKING (PRM-50-62)

The Office of Administration (ADM) concurs, subject to the comments provided, on the document that presents the NRC's anticipated response to the petition for rulemaking submitted by the Nuclear Energy Institute that requested amendments to the regulations concerning changes to quality assurance programs by nuclear power reactor licensees (PRM-50-82).

Although this document presents the NRC's intended course of action in responding to the petition, it does not constitute any administrative action that furthers agency progress toward the completion of action on this petition. Therefore, given the visibility and significance of this proceeding, we suggest that this document, with necessary procedural and language adjustments, be modified to serve as the statement of considerations for the direct final rule and that the direct final rule be prepared and presented for Commission approval.

Please note that if this suggestion is not followed care should be taken to ensure that the language used to describe NRC action does not infer that the petition is being granted or denied, in whole or in part, through this document. We have suggested appropriate language in the attached marked copy of the package.

We have provided a rewritten Summary statement that more clearly meets the requirements of the Office of the Federal Register in 1 CFR 18.12.

If you have any questions concerning this matter, please have a member of your staff contact David L. Meyer, Chief, Rules and Directives Branch, at 415-7162 (DLM1) or Michael T. Lesar, ADM, at 415-7163 (MTL).

Attachment: As stated

FOR: The Commissioners

FROM: L. Joseph Callan
Executive Director for Operations

SUBJECT: ~~PARTIAL ACCEPTANCE 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 Partial Acceptance 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 Nuclear Regulatory Commission (NRC) to amend its regulations controlling changes to quality assurance (QA) programs. The petition was docketed by the Commission on June 19,1995, and assigned Docket No. PRM-50-62 (Attachment 1). The petitioner requested that the NRC amend 10 CFR 50.54(a) to change the criterion that nuclear power plant licensees are permitted to use to make changes to QA programs without prior NRC approval. The petitioner proposed that only QA program changes involving unreviewed safety questions (USQ), as defined in 10 CFR 50.59, should require NRC review and approval before implementation.

CONTACT: Harry Tovmassian, NRR
(301) 415-3092

Under the current 10 CFR 50.54(a)(3) regulation, the licensee may change its QA program without NRC approval provided no prior commitment is reduced. If a commitment is to be reduced, a licensee needs NRC approval ~~prior to implementation~~. In its petition, NEI argued that this requirement is sometimes interpreted by the staff as requiring NRC approval for any changes in the QA program, independent of the safety significance associated with the change. As a consequence, NEI argued that prolonged and sometimes unnecessary regulatory interactions occur. NEI further stated that the range for permitted QA program changes without prior NRC approval, should be broadened, provided that no unreviewed safety question or technical specification change is involved. NEI indicated that these industry/staff interactions are costly and serve 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 remaining comments were sent by concerned citizens (two are currently employed in the nuclear field), who ~~expressed~~ opposition to the relaxation of the current regulatory control of changes.

DISCUSSION:

In its petition, NEI proposed that the NRC change the threshold for submittal of QA program changes to the NRC for approval prior to implementation. Only changes which are deemed to create an unreviewed safety question or a change in the technical specifications would require such approval. This would subject QA program changes to essentially the same criteria that exist for other plant aspects ~~pursuant to~~ 10 CFR 50.59. NEI believes that this approach would resolve industry difficulties encountered with the use of the "reduction in commitment" standard applied to QA program changes currently in 10 CFR 50.54(a) and would focus more on safety considerations. NEI believes that the "reduction in commitment" standard is often used in instances that have little or no impact on safety. NEI claims that the industry expects considerable cost savings from the proposed regulatory changes because it believes that 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. NEI provided a draft guidance document, attached to its comments, which it claimed demonstrated how QA and procedural changes could be evaluated using the 10 CFR 50.59 criteria.

In the letters opposing the NEI petition, the primary reasons given for requesting denial of the petition were that licensees should not be given such broad authority to change QA programs without NRC approval, and that licensees would 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 a USQ, 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 "reduction in commitment" standard since its promulgation in 1983 as part of the 10 CFR 50.54(a) regulation, has been an effective means for determining which QAP program changes proposed by licensees require NRC review and approval prior to implementation. The licensee decisions made in conformance to 50.54(a) have been based on a comparison of the proposed QA program changes to the requirements of 10 CFR 50, Appendix B as further defined by the ancillary guidance documents including the QA regulatory guides, the endorsed industry QA standards, and the Standard Review Plan. Appendix B and these guidance documents, used by the staff over the past 25 or more years, served as an identification of the QA elements whose implementation would assure the proper control of design, construction, and operating activities necessary to provide an acceptable level of protection for the public health and safety. The quantitative contribution of the individual QA controls in the licensees' QA programs to the margin of plant safety has not been determined by the staff, and is thus unknown. However, their contribution to plant safety is considered to be positive based on qualitative assessments.

As the nuclear industry has matured and considerable experience has been gained from the implementation of these QA elements, the relative qualitative importance of each of these QA elements to safety has become better understood with the result that the present "reduction in commitment" change control standard is no longer an appropriate criterion for determining the need for prior NRC review and approval of QA program changes. The NEI proposal to utilize the criteria in 10 CFR 50.59 as an alternate standard to provide licensees additional flexibility to make changes without needing prior NRC review appears to be acceptable in principle. Section 50.59 requires that a proposed change to a facility be deemed an unreviewed safety question if it:

1. Increases the probability of occurrence or consequences of a previously evaluated accident or equipment malfunction,

2. Creates the possibility of a different and unanalyzed type of accident or equipment malfunction, or

3. Reduces the margin of safety.

For 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, for QA program changes, it is difficult to determine with any degree of certainty how changes such as organizational responsibilities or QA program training, as examples, will affect the availability of safety-related equipment. The staff has not developed any guidance to provide such a determination, nor is the staff aware of any quantitative correlations between QA elements and equipment performance to provide such a determination. Thus, the staff has concluded that the use of 10 CFR 50.59 criteria for QA program changes, while acceptable in principle, does not appear to be appropriate in practice. Further, contemplated modifications to the 10 CFR 50.59 regulation would emphasize, even more, its non-applicability to QA program changes.

Rather, the staff approach would be to permit licensees to revise their QA program content without prior NRC review provided that the licensees can conclude that the revised program

continues to meet the regulatory requirements of Appendix B, conforms with other pertinent regulations such as 50.34 (b)(6)(ii), and continues to implement the operational safety functions (such as safety review committees) relocated from the Technical Specifications. Therefore, any proposed QA program change that is determined by the licensee to satisfy the ~~above mentioned~~ provisions would be ~~permitted to be~~ implemented without prior NRC review and approval.

~~Since~~ this approach represents a considerable departure from the NRC's present mode of operation, and because the agency is advocating the adoption of performance-based regulations, the staff proposes that the assurance of the continued implementation of effective QA programs can be accomplished by requiring that licensees who, at their discretion, decide to adopt this approach, make available for NRC scrutiny reports that evaluate the adequacy of the performance of their QA programs. The performance of ~~such~~ evaluations is already required by Criterion II of Appendix B; however, with the increased unilateral authority for QA program changes, the NRC may require a slightly more rigorous evaluation. The evaluations should monitor the performance of the QA program and trend pertinent parameters to determine the need for QA programmatic corrective actions. The staff is aware that studies have been initiated by the American Society of Quality to develop metrics that would be useful to assess the effectiveness of QA program implementation. It is also envisioned that the ongoing plant equipment monitoring required by the Maintenance Rule could complement the programmatic monitoring and trending efforts to gauge the effectiveness of the QA program implementation. It is the staff's intent to work with NEI, nuclear industry representatives, and other interested parties to develop the details of this approach.

~~As noted above,~~ The staff is sympathetic to NEI's objection to the continued use of the present 10 CFR 50.54(a) criterion. To provide immediate relief to licensees, the staff proposes to proceed with a Direct Final Rule, following appropriate interactions with NEI, licensee representatives, and other interested parties, to revise 10 CFR 50.54(a) to allow licensees to make additional changes to selected aspects of their QA program without prior NRC review or approval than is currently permitted. Unilateral QA program changes currently permitted include safety upgrades, corrections of typographical errors, and administrative improvements and clarifications. Examples of additional changes that the staff envisions a licensee could make unilaterally, provided that they continue to meet the requirements in Appendix B to 10 CFR Part 50 and 10 CFR 50.34(b)(6)(ii), would include:

1. Adoption of a consensus standard newly endorsed by the NRC,
2. Incorporation of a new QA position previously approved by an NRC safety evaluation at the request of another licensee,
3. Use of generic organizational and position titles rather than specific titles,
4. Use of generic organizational charts to indicate functional relationships and responsibilities,
5. Elimination of descriptive QA program commitments that are duplicative to those contained in QA regulatory guides and associated consensus QA standards, and

6. organizational changes that do not affect the independence of the QA function.

~~The goal of~~ this effort would ~~be to~~ provide early relief to licensees ~~to~~ eliminate the need for interactions with the staff on changes that currently would constitute reductions in commitment ~~which need~~ prior staff review, but which are of minor safety significance. In parallel with the issuance of a Direct Final Rule as an interim measure, the staff will pursue development of the discretionary alternate approach to provide an even more flexible QA program change process as described previously. These relief efforts are consistent with the staff's recent approval of a graded QA program proposed by the STP Nuclear Operating Company which also permitted more flexible application of QA requirements in accordance with safety significance.

RESOURCES:

Resources to proceed with a Direct Final Rule change associated with partial acceptance of the petition and for exploratory interactions with the industry and other interested parties can be accommodated within the FY 1999 budget by appropriate reprogramming of currently planned activities. Resources for the pursuit of the voluntary option rulemaking activity to accomplish the objective of the NEI petition are currently not in the FY 1999 budget. If the Commission adopts the staff's recommendations, resources within NRC will be reprogrammed under the FY 1999 budget, and FY 1999 Operating Plan changes will be made, as necessary.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

RECOMMENDATION:

That the Commission:

1. Approve:

   a. the Federal Register ~~notice~~ that ~~partially accepts~~ the NEI petition (Attachment 2),

   b. the staff's proposal to issue a Direct Final Rule ~~change~~ to modify 10 CFR 50.54(a),

   c. the staff's proposal to continue interactions with the industry and other interested parties to develop an alternate approach to provide even greater relief to be adopted at the licensee's discretion, and

   d. the staff's proposal to develop a rulemaking plan for items b and c for Commission approval subsequent to issuance of the Commission decision on the petition.

2. Note:

a. that the petitioner will be informed of this action (Attachment 3), and

b. that the appropriate Congressional committees will be informed of this action (Attachment 4).

L. Joseph Callan
Executive Director
for Operations

Attachments: 1. NEI Petition
2. Federal Register Notice
3. Response to NEI
4. Congressional Letters

2. Note:

a. that the petitioner will be informed of this action (Attachment 3), and

b. that the appropriate Congressional committees will be informed of this action (Attachment 4).

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Executive Director
for Operations

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2. Note:

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L. Joseph Callan
Executive Director
for Operations

Attachments: 1. NEI Petition
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NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

PRM-50-62

Changes to Quality Assurance Programs; ~~Partial Acceptance of~~ Response to the Petition for Rulemaking Submitted by the Nuclear Energy Institute

AGENCY: Nuclear Regulatory Commission.

ACTION: ~~Partial acceptance of~~ Petition for rulemaking; Anticipated response.

INSERT A

SUMMARY: The Nuclear Regulatory Commission (NRC) is ~~accepting~~ anticipating that it will grant in part a petition for rulemaking (PRM) submitted by the Nuclear Energy Institute (NEI) on behalf of the nuclear power industry. The petitioner requested that the NRC amend its regulations to change the criterion that nuclear power plant licensees are permitted to use to implement changes to their quality assurance (QA) programs without first receiving NRC approval. These QA programs are described or referenced in the licensees' Safety Analysis Reports (SARs). The petition ~~is~~ would be ~~accepted~~ granted in part because the NRC believes that the scope of possible changes to QA programs without prior NRC approval should and can be broadened, ~~but is~~ however, the petition would also be denied in part because the NRC has determined that the threshold recommended by NEI for permitting the implementation of such changes without prior NRC review is not appropriate. In response to the petition and to provide immediate relief, the NRC staff intends to ~~promulgate~~ develop and issue a Direct Final Rule, following appropriate interactions with NEI, licensee representatives, and other interested parties, to revise 10 CFR 50.54(a) to allow licensees to make additional types of QA program

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changes unilaterally that have minimal safety significance. Examples of such changes include the following:

1. Adoption of a consensus standard newly endorsed by the NRC,
2. Incorporation of a new QA position previously approved by an NRC safety evaluation at the request of another licensee,
3. Use of generic organizational and position titles rather than specific titles,
4. Use of generic organizational charts to indicate functional relationships and responsibilities,
5. Elimination of descriptive QA program commitments that are duplicative to those contained in QA regulatory guides and associated consensus QA standards, and
6. Organizational changes that do not affect the independence of the QA function.

~~With regard to~~ a revised threshold criterion, the staff will work with the industry and other interested parties to develop an alternate voluntary approach that utilizes the QA criteria of 10 CFR 50, Appendix B, as a threshold, conforms with pertinent QA regulations such as 50.34(b)(6)(ii), and continues to implement safety functions (such as safety review committees) relocated from the Technical Specifications to provide even greater flexibility for licensees to make QA program changes unilaterally. As a part of this approach, licensees that choose to adopt this voluntary option would be required to conduct a performance monitoring, trending, and corrective action process to identify and correct conditions adverse to quality to assure that an effective QA program continues to be implemented.

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.

INSERT

SUMMARY: The Nuclear Regulatory Commission is announcing its anticipated response to a petition for rulemaking submitted by the Nuclear Energy Institute (NEI). NEI requested that NRC amend the regulations concerning the criterion a nuclear power plant licensee may use to make cahnges to its quality assurance program without first receiving NRC approval. The NRC anticipates granting the petition, in part, through the development and publication of a direct final rule and denying the petition, in part.

FOR FURTHER INFORMATION CONTACT: Harry S. Tovmassian, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-3092, e-mail HST@NRC.GOV.

SUPPLEMENTARY INFORMATION:

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 received by the Commission on June 19, 1995, and assigned Docket No. PRM-50-62. The petitioner requested that the NRC modify 10 CFR 50.54(a) to permit nuclear power plant licensees to make a broader range of changes to their QA programs without prior NRC approval. 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," consistent with the criteria of 10 CFR 50.59. According to NEI's proposal, changes involving unreviewed safety questions (USQs) would require NRC review and approval prior to implementation.

Basis for Request

The petitioner stated 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 points of contention:

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 in frequency for audit, review, or surveillance activities 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 QA program description through the use of enhanced technology or other developments; and

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

Preliminary estimates provided by the petitioner indicated that the costs to the industry to conduct the resultant industry/NRC interactions were in excess of $1 million per year. In addition, licensees occasionally are 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.

It is the petitioner's opinion 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 nó safety impact. 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, namely in 10 CFR 50.59, including changes in the facility as described in the Safety Analysis Report (SAR), changes in procedures as described in the SAR, and the conduct of tests or experiments not described in the SAR, all of which may be performed without prior NRC approval provided the above described threshold is not exceeded. NEI stated 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 NRC's 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 prior NRC review and approval. This was necessary because some QA programs had been changed and no longer conformed to NRC regulations. The NRC concern was that some changes might diminish the scope of the QA program and permit significant deficiencies to arise in various facility activities that could increase the risk to public health and safety. 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 involve 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 thereby improve the consistency of the regulatory process 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 the petition and 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 comments on three additional and related matters. The six non-NEI/non-licensee letters were sent by individual concerned citizens (two are currently employed in the nuclear field), all of whom expressed opposition to the relaxation of regulatory control of changes.

Comments on NRC-Posed Questions

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

Issue 1:

On January 10, 1983, 10 CFR 50.54(a) was issued because some licensees had changed their programs, without informing the NRC, to the extent that some programs were unacceptable. What assurances exist to prevent a similar situation from recurring if the petition and the revised threshold for reporting QA program changes 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) regulation 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 used routinely by licensees to evaluate equipment and non-hardware changes and its use would provide a greater emphasis and focus on safety. Significant changes that could 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. 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 "reduction in commitment" standard, since its promulgation in 1983 as part of the 10 CFR 50.54(a) regulation, has been an effective means for determining which QA program changes proposed by licensees require NRC review and approval prior to implementation. The licensee decisions made in conformance to § 50.54(a) have been based on a comparison of the proposed QA program changes to the requirements of 10 CFR 50, Appendix B as further defined by the ancillary guidance documents including the QA regulatory guides, the endorsed industry QA standards, and the Standard Review Plan. Appendix B and these guidance documents, ~~used by the staff~~ the NRC staff has used over the past 25 or more years, ~~served as an~~ to identify ~~identification of~~ the QA elements whose implementation would assure the proper control of design, construction, and operating activities necessary to provide an acceptable level of protection for the public health and safety. The quantitative contribution of the individual QA controls in the licensees' QA programs to the margin of plant safety has not been determined either by the industry or the NRC staff, and is thus unknown. However, their contribution to plant safety is considered to be positive based on qualitative assessments.

As the nuclear industry has matured and considerable experience has been gained from the implementation of these QA elements, the relative qualitative importance of each of these QA elements to safety has become better understood with the result that the present "reduction in commitment" change control standard is no longer an appropriate criterion for determining the need for prior NRC review and approval of QA program changes. The NEI proposal to utilize the criteria in 10 CFR 50.59 as an alternate standard to provide licensees additional flexibility to make changes without needing prior NRC review appears to be acceptable in principle. However, acceptable guidance for assessing whether a specific proposed QA program change constitutes an "unreviewed safety question" has not been developed, ~~or~~ nor has proposed by the industry, and it is not clear to the NRC staff that ~~such~~ this type of guidance can be readily

any such guidance.

developed. Rather, the NRC approach would be to permit licensees, at their discretion, to revise their QA program content without NRC review provided that the licensees can conclude that the revised program continues to meet the regulatory requirements of Appendix B; conforms with other pertinent regulations such as §50.34 (b)(6)(ii); and continues to implement any operational safety functions (such as safety review committees) relocated from the Technical Specifications. Therefore, any proposed QA program change that is determined by the licensee to satisfy the ~~above-mentioned~~ provisions would be permitted to be implemented without prior NRC review and approval.

Because ~~Since~~ this approach represents a considerable departure from the NRC's present mode of operation, and because the agency is advocating the adoption of performance-based regulations, the NRC proposes that the assurance of the continued implementation of effective QA programs can be accomplished by requiring that licensees who adopt this approach develop a formal program that evaluates the adequacy of the performance of their QA programs. Licensees already ~~The performance of such~~ evaluations ~~is already~~ are required by Criterion II of Appendix B. However, with the increased unilateral authority for QA program changes, the NRC may require a slightly more rigorous evaluation. The evaluations should monitor the performance of the QA program and trend pertinent parameters to determine the need for QA programmatic corrective actions. The NRC staff is aware that studies have been initiated by the American Society of Quality to develop metrics that would be useful to assess the effectiveness of QA program implementation. ~~It is also envisioned~~ The NRC believes that the ongoing plant equipment monitoring required by the Maintenance Rule could complement the programmatic monitoring and trending efforts to gauge the effectiveness of the QA program implementation. ~~It is~~ The NRC's intent is to work with NEI, nuclear industry representatives, and other interested parties to develop the details of this approach.

Since the development of the ~~above described~~ approach will require considerable time and effort, NRC is also proposing to ~~promulgate~~ a Direct Final Rule (DFR) to provide immediate relief to licensees. This effort will involve interactions with NEI, licensee representatives, and other interested parties to obtain their views. The DFR will identify specific, limited QA elements that may be subject to licensee change without the need for prior staff review and approval. The QA elements to be included in the DFR are those considered to be of no or minimal safety significance, such as:

1. Adoption of a consensus standard newly endorsed by the NRC;
2. Incorporation of a new QA position previously approved by an NRC safety evaluation at the request of another licensee;
3. Use of generic organizational and position titles rather than specific titles;
4. Use of generic organizational charts to indicate functional relationships and responsibilities;
5. Elimination of descriptive QA program commitments that are duplicative to those contained in QA regulatory guides and associated consensus QA standards; and
6. Organizational changes that do not affect the independence of the QA function.

Issue 2:

Traditionally, the NRC staff has used a variety of documents such as the NRC Standard Review Plan (SRP), NRC regulatory guides, and associated industry consensus standards to delineate QA program elements that 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 may have minimal safety significance in some areas. 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. Because alternative methods can sometimes accomplish the same purpose from a safety perspective, licensees should be afforded regulatory flexibility to deviate from existing guidance while continuing to meet the regulations. Attempting to reach understanding regarding "reduction in commitment" has been a struggle. Recently, the nuclear 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:

The NEI comment on the continued use of SRPs, regulatory guides, and industry standards indicated that changes to commitments in these documents should also be evaluated based on their safety significance and not on "reduction in commitments." NEI suggests that

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[1]"Guideline for Managing NRC Commitments," Revision 2, December 19, 1995, is an NEI document. A copy of this document is an enclosure to SECY-95-300 and is available for inspection or copying for a fee at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

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QA program changes could be evaluated with the "Guidelines for Managing NRC Commitments." 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, this guidance document relies upon "Guidelines for 10 CFR 50.59 Safety Evaluations"[2] (NSAC-125), which is oriented toward performing 10 CFR 50.59 analyses for proposed changes to plant hardware and procedures. The methodology in NSAC-125, as well as 10 CFR 50.59, 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 type of accident; or
3. Reduces the margin of safety.

For 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, for QA program changes, the determination of the effect of the change on plant safety is difficult to quantify. How changes such as organizational responsibilities or QA program training, as examples, will affect the availability of safety-related equipment cannot be determined with any degree of certainty. The NEI petition did not propose, nor has the NRC developed any guidance to provide such a determination. Moreover, the NRC staff is not aware of any quantitative correlations between QA elements and equipment performance to provide such a determination. Thus, the NRC has concluded that use of

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[2]"Guidelines for 10 CFR 50.59 Safety Evaluations," Nuclear Management and Resources Council, NSAC-125, May 1989. This document is also available from the NRC Public Document Room (Accession Number 9608190033).

10 CFR 50.59 criteria for QA program changes, while acceptable in principle, does not appear to be appropriate in practice. ~~Further, it should be noted that~~ currently contemplated modifications to the 10 CFR 50.59 regulation would emphasize, ~~even more~~, its non-applicability to programmatic-type changes. However, the NRC will work with the industry and other interested parties to develop a more flexible approach for QA program changes as discussed in the NRC response to Issue 1.

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 criterion should or could be applied, does 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 that the review and audit functions, which were previously 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 Safety Analysis Report.

NRC Response:

The purpose for NRC's Issue 3 was to determine whether it was acceptable to have QA program changes involving administrative functions relocated from the Technical Specifications such as safety review committees, independent technical review groups, and audits 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 NEI's proposal. NRC ~~response~~ intends that to require proposed changes to these functions be subject to the same controls discussed in the NRC response to 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 NRC agrees with the NEI position that the "decreased effectiveness" criterion is not a suitable alternative to the existing "reduction in commitment" criterion in 10 CFR 50.54(a). As discussed in earlier issues, the NRC believes that there is merit in NEI's position that 10 CFR 50.54(a) needs to be made more flexible to permit certain additional changes to be made to a licensee's QA program without prior NRC review and approval. However, as discussed earlier, NEI provided no definitive guidance that adequately demonstrated how a proposed QA program change could be evaluated against the 10 CFR 50.59 criteria. The NRC finds that the §50.59 criteria, while acceptable in principle, may not be appropriate in practice for QA program changes. As discussed in the NRC response to Issue 1, the NRC staff will develop modifications to 10 CFR 50.54(a) to allow greater flexibility for licensees to modify their QA programs.

Issue 5:

The NRC Regulatory Review Group (RRG) examined change control mechanisms in 10 CFR 50.54 for controlling licensee plans and programs (quality assurance, security, and emergency preparedness). The RRG recommended that licensees should have greater flexibility to make changes in their programs without having to receive prior NRC approval. Currently, QA program changes that "reduce the commitments in the program" are submitted for NRC staff review before implementation. Similarly, security plan changes that "decrease the

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

NEI Comment:

NEI stated 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. However, NEI also states that this is not the case for emergency planning and security regulations that contain this criterion. NEI believes that the use of this criterion for QA programs would ultimately lead to the USQ arena, which is addressed under 10 CFR 50.59. The industry's conclusion is that the 10 CFR 50.59 process is the optimum process for changes in QA programs.

NRC Response:

NEI's rationale is not clear in stating that QA program changes affect safety, unlike security and emergency preparedness programs, and thus should not be controlled by the "decrease in effectiveness" criterion. The concern about this criterion leading to the "USQ arena" is also unclear because NEI's 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 NRC agrees that the "decrease in effectiveness" criterion is not appropriate for controlling QA program changes. Thus, the NRC does not intend to modify 10 CFR 50.54(a) to require the "decrease in effectiveness criterion" for controlling QA program

changes. As discussed in the NRC response to Issue 1, the staff will develop modifications to 10 CFR 50.54(a) to allow greater flexibility for licensees to modify their QA programs.

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 NRC staff?

NEI Comment:

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

NRC Response:

The NRC recognizes the problem that NEI seeks to correct through this petition and is ~~proposing that a~~ considering the development and issuance of a Direct Final Rule ~~change be promulgated~~, following appropriate interactions, with NEI, licensee representatives, and other interested parties, to permit additional types of QA program changes to be made by licensees unilaterally. Further, the NRC is ~~proposing that an~~ considering an alternate approach that would be made available, for adoption at a licensee's discretion, ~~whereby~~ under this option licensees could make changes to the QA program ~~could be made providing~~ if regulatory QA requirements continue to be met, safety functions relocated from the Technical Specifications will continue to be implemented,

and the licensee periodically evaluates the effectiveness of the QA program and makes reports available for NRC scrutiny as determined by a program of performance monitoring, trending, and corrective action to ensure that adverse quality conditions are not permitted to persist (See Issue 1).

Issue 7:

The petition proposed applying a 10 CFR 50.59 process to evaluate QA program changes to determine the necessity for pre-review by the NRC staff. Industry guidance for 10 CFR 50.59 exists within NSAC-125. NSAC-125 appears to contain little relevant guidance that would be helpful for determining whether QA programmatic changes would constitute a USQ that requires NRC pre-review of the change. In particular, Section 4.2 of NSAC-125 deals principally with evaluating changes associated with nuclear plant equipment and not programmatic controls. Is existing guidance for processing 10 CFR 50.59 evaluations sufficient for evaluating QA program changes? What factors or aspects of the existing industry guidance would need to be supplemented? What types of QA program changes must be reported to the NRC if the current 10 CFR 50.59 criteria were applied to QA program changes? What are examples of QA program changes that should be considered to meet the USQ threshold?

NEI Comment:

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

NRC Response:

NRC's concern is that the guidance provided in NSAC-125 is primarily oriented toward evaluating hardware changes and, by itself, may not be sufficient for determining whether QA program changes constitute a USQ. The additional draft guidance that NEI cites in its comments relies heavily on NSAC-125 for evaluation of the safety significance of proposed changes. NRC believes that an alternate to the present change control regulation can be developed to permit a greater scope of QA program changes to be implemented without prior NRC review and approval (See NRC response to Issue 1).

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 NRC agrees with the NEI opinion that the present 10 CFR 50.54(a) regulation should be modified to permit a greater latitude for unilateral QA program changes by licensees (see Issue 1). NEI suggests that resources saved as a result of the proposed rule change would be used in safety matters. ~~Such~~ Any redirection of licensee resources is a matter of licensee discretion and cannot be mandated by the rule.

Additional Comments Made by NEI

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 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 NRC 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, the NRC believes that many commitments made by a licensee within a QA program do have a nexus to plant safety. Therefore, the identification of an expanded set of QA program changes that could be made unilaterally by licensees in the Direct Final Rule, and voluntary option to 10 CFR 50.54(a) discussed in the NRC response to Issue 1, will consider the safety implications of the change rather than just the reduction in commitment.

NEI Comment:

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

NRC Response:

The NRC also agrees with the industry's comment that the same criterion should be used for the entire QA program. An approach to modify the QA program change control process, including the review and audit functions, is described in the NRC response to Issue 1.

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

NRC Response:

The requirements cited by NEI are not duplicative. 10 CFR 50.4(b)(6) pertains to

updates to the Final Safety Analysis Report. 10 CFR 50.4(b)(7)(i) pertains only to QA submittals and makes the distinction between applicants and licensees to avoid confusion.

Other Supporting Public Comments

The other 10 comments supporting the petition were from licensees. 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 believed that the NRC should deny this petition, and gave various reasons for their position. One commenter stated that licensees should not be given such broad authority to change QA programs without NRC approval. Other commenters believed that licensees will take advantage of the amended rule 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~~ document announcing the receipt of the petition. While the Commission agrees with the NEI proposal to broaden the scope of permitted QA program changes, it does not agree with NEI's central premise that 10 CFR 50.59 criteria, by themselves, can be used to determine the need for prior NRC review of propsoed QA program changes. ~~The~~ 50.59 ~~regulation~~ Section 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. For 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, for QA program changes, the determination of the effect of the change on plant safety is difficult to quantify. How changes such as organizational responsibilities or QA program training, as examples, will affect the availability of safety-related equipment cannot be determined with any degree of certainty. The NEI petition did not propose any guidance, NRC has not developed an analytical technique to provide such a determination, and the staff is not aware of any quantitative correlations between QA elements and equipment performance to provide such a determination. Thus, the NRC has concluded that use of 10 CFR 50.59 criteria for QA program changes, while acceptable in principle, does not appear to be appropriate in practice.

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 NSAC-125, which is oriented toward hardware

changes and does not provide acceptable guidance for determining whether a QA program change constitutes a USQ. In addition, the NRC is concerned with NEI's characterization in their guidance document of certain QA program changes as being administrative in nature and having no relation to safety.

The Commission, however, is sympathetic to NEI's objection to the continued use of the present 10 CFR 50.54(a) criterion for permitting unilateral QA program changes by licensees and is willing to consider new criteria that will broaden the scope of such changes. The Commission, therefore, ~~is accepting~~ intends to grant the petition in part. The NRC ~~proposes~~ intends to proceed with a Direct Final Rule ~~change to~~ that would revise 10 CFR 50.54(a) to allow licensees to make additional changes to a limited set of selected elements of their QA program without having to obtain prior NRC review and approval as is currently required. Examples of the additional changes that the NRC envisions a licensee could make unilaterally, provided that they continue to meet the requirements in Appendix B to 10 CFR Part 50 and 10 CFR 50.34(b)(6)(ii), would include:

1. Adoption of a consensus standard newly endorsed by the NRC;
2. Incorporation of a new QA position previously approved by an NRC safety evaluation at the request of another licensee;
3. Use of generic organizational and position titles rather than specific titles;
4. Use of generic organizational charts to indicate functional relationships and responsibilities;
5. Elimination of descriptive QA program commitments that are duplicative to those contained in QA regulatory guides and associated consensus QA standards; and
6. Organizational changes that do not affect the independence of the QA function.

The goal of this effort would be to provide some immediate relief to licensees to minimize the need for interactions with the NRC on changes that currently would constitute

reductions in commitment which need prior NRC review, but which are of minor safety significance.

In addition to the Direct Final Rule ~~change~~, the NRC will also consider another alternative, to be adopted at a licensee's discretion, to further broaden the scope of permitted unilateral QA program changes. This can be achieved by establishing a change threshold of 10 CFR Part 50, Appendix B, while also assuring that other pertinent QA regulations continue to be met such as § 50.34(b)(6)(ii), and by continuing to implement the operational safety functions (such as safety review committees) relocated from the Technical Specifications. An added requirement would be that the performance of the QA program be monitored and trended to assure that appropriate corrective action would be taken in response to adverse events attributable to QA program deficiencies to maintain the effectiveness of the QA program. A licensee adopting such a discretionary approach would be required to make available for NRC scrutiny reports regarding the results of such performance monitoring and the changes made to their QA programs. Therefore, subsequent to the issuance of this decision, the NRC will pursue an initiative with industry and other interested parties to improve the flexibility of 10 CFR 50.54(a). This is consistent with the staff's recent approval of a graded QA program proposed by the STP Nuclear Operating Company, which also permitted more flexible applicability of QA requirements in accordance with safety significance.

Dated at Rockville, Maryland, this _____ day of _____1998.

For the Nuclear Regulatory Commission.

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John C. Hoyle,
Secretary of the Commission