RULEMAKING ISSUE

(Affirmation)

November 30, 1998 SECY-98-279

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: PARTIAL GRANTING 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 Direct Final Rule which would partially grant the petition for rulemaking submitted by the Nuclear Energy Institute (NEI) that requested amendments to 10 CFR 50.54 and to obtain approval to proceed with an additional rulemaking.

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 the agency's 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 criteria that nuclear power plant licensees are required to use to make changes to QA programs without prior NRC review and approval. The petitioner proposed that only QA

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program changes involving unreviewed safety questions (USQs) or changes to the technical specifications, as defined in 10 CFR 50.59, would require NRC review and approval before implementation.

Under 10 CFR 50.54(a)(3), the licensee may currently change its QA program without NRC approval as long as 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 USQ 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 (60 FR 47716), the NRC published a *Federal Register* Notice that announced receipt of the NEI petition and requested public comments on specific regulatory aspects raised by the 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. All of these letters supported the petitioner's proposed changes. 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. Attachment 2 contains the staff's preliminary analysis of the comment letters. The staff is planning to publish its formal resolution of the comments in the context of a broader rulemaking action for which Commission approval is being sought.

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 that may create a USQ or a change in the technical specifications would require such approval. This would make QA program changes subject 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 in 10 CFR 50.54(a) and would focus the acceptability of changes 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, along with its comments, which it claimed demonstrated how QA and procedural changes could be evaluated using the 10 CFR 50.59 criteria.

In the public comment 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 advantage of this

opportunity to reduce the QA and design requirements for spent fuel dry cask storage equipment. Other reasons cited were the lack of specific guidance for determining 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 staff agrees in principle with the NEI proposal to broaden the range of permitted QA program changes without prior approval, since there are a range of QA program changes which have little or no safety significance which the licensee should be free to implement without prior NRC approval. However, the staff disagrees with NEI's premise that 10 CFR 50.59 criteria should be used as a threshold for determining which changes need prior NRC staff approval. Section 50.59 currently requires that a proposed change to a facility be deemed a USQ 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. To date, the NRC has not developed any guidance, nor is it likely that such guidance can be developed, to make such a determination. Moreover, the staff has concluded that the guidance supplied and referenced by NEI relies too heavily on hardware-oriented considerations and is, therefore, not acceptable for use in evaluating QA program changes. Further, contemplated modifications to the 10 CFR 50.59 regulation are considered to emphasize, even more, its non-applicability to QA program changes.

The staff has concluded that use of 10 CFR 50.59 criteria for determining the acceptability of QA program changes would allow unilateral changes by licensees to their QA programs that may have significant adverse consequences either directly or from a programmatic standpoint (e.g., reductions in independence of QA inspectors). Although the staff believes that 10 CFR 50.59 criteria are not appropriate for evaluating QA program changes, the staff agrees with the NEI objection to the continued use of the present 10 CFR 50.54(a) criterion, in that the staff believes that there are certain additional changes to licensees' QA programs that can be made without prior NRC approval. Therefore, the staff is proposing to proceed with a Direct Final Rule (Attachment 3) to revise 10 CFR 50.54(a) to allow licensees to make additional changes to certain clearly identified aspects of their QA program without prior NRC review or approval. Unilateral QA program changes currently permitted under the existing rule and staff practice include safety upgrades, corrections of typographical errors, and administrative improvements and clarifications. Examples of additional changes that the staff envisions a licensee should be able to 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 the following:

1. Use of a QA standard approved by the NRC which is more recent than the QA standard in the licensee's current QA program at the time of the change,

2. Use of a QA alternative or exception previously approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility,

3. Use of generic organizational position titles that clearly denote the position function, supplemented by descriptive text, rather than specific titles,

4. Use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text,

5. Elimination of QA program information that duplicates other language contained in QA regulatory guides and consensus QA standards to which the licensee is committed, and

6. Organizational revisions that ensure that persons and organizations performing QA functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

The goal of this effort is to provide some immediate relief to licensees by eliminating the need for prior staff approval of changes that are of little or no safety significance.

In addition to promulgating this Direct Final Rule to provide immediate relief, the staff will also pursue an alternative that would further broaden the scope of permitted unilateral QA program changes by establishing a new change threshold to be adopted by licensees as a voluntary option. The staff plans to pursue an initiative with industry and other interested parties to modify the 10 CFR 50.54(a) regulation to permit a more flexible QA program change process. Both the Direct Final Rule and the future voluntary option were discussed with NEI and other interested parties at a meeting on August 22,1998, and full acceptance was indicated. The staff held another meeting with various stakeholders on October 15, 1998, to obtain any additional thoughts on the Direct Final Rule approach. The staff also briefed the Advisory Committee on Reactor Safeguards (ACRS) on September 30, 1998, about the plans to resolve the NEI petition. By letter dated October 20, 1998, the ACRS indicated it was in general agreement with the staff's proposal. The staff also presented its plans for resolving the petition to the Committee to Review Generic Requirements (CRGR) on October 27, 1998, with the conclusion that no backfit is involved. Upon Commission approval, the staff will conduct several public workshops and meetings on this voluntary option and will develop the Proposed Rule one year after receipt of the Staff Requirements Memorandum and a final rule within the following year. These actions will complete the NRC's resolution of the NEI petition.

RESOURCES:

Resources to proceed with a Direct Final Rule are available within the FY 1999 budget. Should significant adverse public comment be received on the Direct Final Rule, the additional resources needed to pursue the rulemaking in the traditional format (estimated to be approximately 1 full-time equivalent (FTE) each year in FY 1999 and FY 2000) will be accommodated within the budget by appropriate reprogramming of currently planned activities. Resources for the pursuit of the long term voluntary option rulemaking activity to accomplish the remaining objectives of the NEI petition are estimated to be approximately 2 FTE each year in FY 1999 and FY 2000 and are not currently budgeted. Once the Commission adopts the staff recommendations, the necessary resources will be reprogrammed.

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 proposed action for resource implications and has no objections. The Office of the Chief Information Officer has reviewed this proposed rulemaking plan for information technology and information management implications and concurs in it.

RECOMMENDATION:

That the Commission

1. Approve

   a. The publication of the enclosed *Federal Register* Notice that promulgates the Direct Final Rule and partially grants the NEI petition (Attachment 3).

   b. The publication of the enclosed *Federal Register* Notice that concurrently publishes a companion Proposed Rule (Attachment 4).

   c. The staff's proposal to proceed with a second rulemaking that would develop a voluntary alternative to 10 CFR 50.54(a) in concert with industry and other interested parties.

2. Note that

   a. In accordance with the provisions of the Administrative Procedures Act of 1946, as amended, the staff will forward a document withdrawing the Direct Final Rule and will resolve the public comments in conjunction with the companion Proposed Rule, in the event that significant adverse public comment is received.

   b. The petitioner will be informed of this action (Attachment 5).

   c. The appropriate Congressional committees will be informed of this action (Attachment 6).

d. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding the economic impact on small entities and the reason for it as required by the Regulatory Flexibility Act.

e. The NRC has determined that this action is not a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and has confirmed this determination with the Office of Management and Budget. This determination is reflected in correspondence to the President of the Senate, the Speaker of the House, and the General Counsel of the General Accounting Office (Attachment 7).

f. A press release will be issued (Attachment 8).

g. The regulatory analysis (Attachment 9) will be available in the Public Document Room.

h. This rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The information collection aspects of this rule have been sent to the Office of Management and Budget for approval.

William D. Travers
Executive Director
for Operations

Attachments:
1. NEI Petition
2. Preliminary Analysis of Public Comment
3. *Federal Register* Notice Direct Final Rule
4. *Federal Register* Notice Companion Proposed Rule
5. Letter to NEI
6. Congressional Letters
7. SBREFA Correspondence
8. Press Release
9. Regulatory Analysis

Commissioners' completed vote sheets/comments should be provided directly to the Office of the Secretary by c.o.b. **Friday, December 18, 1998.**

Commission staff office comments, if any, should be submitted to the Commissioners NLT **December 11, 1998,** with an information copy to SECY. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

This paper will be scheduled for affirmation when the voting process nears completion.

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ATTACHMENT 1

NEI PETITION

NUCLEAR ENERGY INSTITUTE

Phillip Bayne

June 8, 1995

The Honorable Ivan Selin
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Chairman Selin:

Enclosed is a copy of a Petition for Rulemaking that the Nuclear Energy Institute filed with the Secretary of the Commission. Our request is that 10 CFR 50.54(a) be amended to permit a more efficient and effective implementation of quality programs at commercial nuclear power plants. The rule revision proposed by this petition will improve the quality assurance program change process.

If approved by the NRC, the 10 CFR 50.54(a) petition will improve the consistency of NRC regulations by evoking the same type of change process for the quality assurance program as for other matters described in a licensee's Safety Analysis Report (i.e., 10 CFR 50.59). Also, it will reduce the administrative burden on nuclear power plant licensees and the NRC staff, and will provide the potential for enhancing public health and safety by improving the focus of industry and NRC resources on more safety-significant issues.

As you know, we believe that further improvements in quality assurance through a performance-based approach will yield even greater benefits. We intend to propose such an approach in the future.

We would be pleased to discuss the petition and respond to any questions NRC personnel may have regarding the purpose or content of the petition.

Sincerely,

Phillip Bayne

Enclosure

c: Mr. James M. Taylor (Executive Director for Operations)
Mr. William T. Russell (Director, NRR)
Karen D. Cyr, Esq. (General Counsel)

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of a	)	
Proposed Rulemaking	)	Docket No. PRM-50-62
Regarding Amendments to	)	
10 CFR Part 50.54(a)	)	

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 heath 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.

ATTACHMENT 2

PRELIMINARY ANALYSIS OF

PUBLIC COMMENT

PRELIMINARY ANALYSIS OF PUBLIC COMMENTS

The following discussion constitutes the staff's preliminary analysis of the public comments received on the Nuclear Energy Institute (NEI) petition. These comments will be formally dealt with and resolved as appropriate as part of the development of the follow-on voluntary option rule to provide a broader range of changes to quality assurance (QA) programs that licensees may make unilaterally.

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 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 issues raised by the NRC are the same as those addressed 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 debate 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 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 (SRP). Appendix B and these guidance documents, used by the staff over the past 25 years or more, served as an identification of the QA elements whose implementation would ensure 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 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 as 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 approval of QA program changes. The NEI proposal that licensees should be given additional flexibility to make changes without needing prior NRC approval 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 proposed by the industry, and it is not clear to the staff that such guidance can be readily developed. Rather, the NRC approach would be to permit licensees, at their discretion, to revise their QA program content without NRC approval 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 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 NRC proposes that the continued implementation of effective QA programs can be ensured by requiring that licensees who adopt this approach develop a formal program that evaluates 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 making QA program changes, the NRC may require a slightly more rigorous evaluation. The evaluations should monitor the performance of the QA program and should 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 for assessing 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 NRC's intent to work with NEI, nuclear industry representatives, and other interested parties to develop the details of this approach.

Issue 2

Traditionally, the NRC staff has used a variety of documents such as the 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 present methods for 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 alternate 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.

[1]"Guideline for Managing NRC Commitments," Revision 2, December 19, 1995, is an NEI document. A copy of this document is an attachment 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.

NRC Response

The NEI comment on the continued use of SRPs, regulatory guides, and industry standards indicated that changes made to commitments in these documents should also be evaluated on the basis of their safety significance and not on "reduction in commitments." NEI suggests that 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. It is noted that the industry has developed NEI 96-07, "Guidelines for 10 CFR 50.59 Safety Evaluations" (September 1997), which supersedes NSAC-125.

Section 50.59 requires that a proposed change to a facility description be deemed a USQ 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.

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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).

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 make such a determination. Moreover, 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 is not appropriate. 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

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 be controlled by different change approval processes. 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 would require proposed changes to these functions to 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 approval 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, 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). The use of a "decreased effectiveness" criterion would be subject to similar problems that the current "reduction in commitment" criterion has faced. To avoid confusion, it would be necessary for the staff to promulgate additional guidance to define what types of changes could be made without triggering a review by the staff. 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 presented 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 Section 50.59 criteria are not appropriate for QA program changes.

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

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, this is not the case for emergency planning and security regulations that contain this criterion. The use of this criterion

for QA programs would ultimately lead to the USQ arena, which is addressed under 10 CFR 50.59. 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, for reasons discussed in response to Issue 4.

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

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 that 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 is aware of the problem that NEI seeks to correct through this petition. As an interim step, the staff has identified a set of programmatic areas to incorporate into 10 CFR 50.54(a) to delineate QA program changes that licensees could make without prior staff approval. These programmatic areas have been discussed with NEI and other stakeholders during public meetings on August 27, 1998, and October 15, 1998. NEI has indicated their acceptance of the alternate staff proposal.

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

Licensees routinely use the 10 CFR 50.59 change process evaluate to 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 continues to believe that QA program changes cannot be reasonably evaluated by the application of criteria used primarily for hardware changes such as those found in NSAC-125.

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 licensees a greater latitude for making QA program changes (See Issue 1). 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.

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 failing to identify 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 would be increased. There would be two different change processes for matters described in the same licensee-controlled document.

NRC Response

In view of NEI's comment regarding the additional complexity and possibility for confusion if two different change criterion are utilized, the NRC agrees that the same change 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

Delete 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, nuclear steam system suppliers, fuel suppliers, and constructors).

NRC Response

The requirements cited by NEI are not duplicative. 10 CFR 50.4(b)(6) pertains only to updates to the final SAR. 10 CFR 50.4(b)(7)(I) pertains to QA program descriptions for both preliminary SARs, and for final SARs, which are submitted by applicants and licensees respectively. Further, there would be no need for 10 copies of the QA program to be submitted as would be required by 10 CFR 50.4(b)(6).

Other Supporting Public Comments

The other 10 comments supporting the petition were from licensees.

NRC Response

The staff's response to the NEI comments addresses the other supporting public comments.

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 prior 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.

NRC Response

The staff agrees with the concern regarding the use of the USQ criteria to determine which QA program changes require prior NRC approval. The staff has developed a set of 6 programmatic areas of potential change that will provide some additional flexibility for licensees to make QA program changes which are of little or no safety significance. As discussed in the NRC response for Issue 1, it is the NRC's intent to work with interested parties to develop optional QA change control provisions subject to an appropriate effectiveness monitoring program.

ATTACHMENT 3

FEDERAL REGISTER NOTICE

DIRECT FINAL RULE

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150-AG20

CHANGES TO QUALITY ASSURANCE PROGRAMS

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct Final Rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to permit power reactor licensees to make certain quality assurance (QA) program changes without obtaining NRC approval of these changes in advance. The final rule allows licensees to make routine or administrative changes that should not have an adverse impact on the effectiveness of their QA programs. This action is intended to reduce the financial and administrative burden on power reactor licensees without adversely impacting public health and safety.

DATES: The Direct Final Rule is effective on [insert the date 60 days after publication in the *Federal Register*], unless significant adverse comment is received by [insert the date 30 days after publication in the *Federal Register*]. If the rule is withdrawn, timely notice will be published in the *Federal Register*.

ADDRESSES: Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff.

Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

Copies of the petition for rulemaking, the public comments received on the *Federal Register* Notice announcing the receipt of the petition, public comments received on this *Federal Register* Notice, and the NRC's response to the petitioner are available for public inspection or copying for a fee in the NRC Public Document Room (PDR), 2120 L Street, NW (Lower Level), Washington, DC.

The public may submit comments via the NRC's interactive rulemaking web site through the NRC home page (http://www.nrc.gov). This site enables commenters to upload comments as files (any format), if their web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, telephone (301) 415-5905, e-mail cag@nrc.gov.

Certain documents related to this rulemaking, including comments received, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These same documents also may be viewed and downloaded electronically via the interactive rulemaking website established by NRC for this rulemaking.

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 Nuclear Regulatory Commission (NRC) is amending its regulations to permit power reactor licensees to make certain changes to their QA programs without obtaining NRC approval in advance. This action is being taken in response to a Nuclear Energy Institute (NEI) petition for rulemaking. The changes that a licensee can make under this rulemaking are administrative or routine in nature and should not adversely impact the effectiveness of the licensee's QA program. There may be other QA program areas for which unilateral changes could be made by licensees without prior NRC approval that would not negatively impact the effectiveness of the licensee's QA program. However, the NRC is in the process of developing suitable criteria for such changes. When such criteria have been developed, an additional rulemaking will be undertaken. This action, the publication of the Direct Final Rule, constitutes the NRC's granting of the petition in part. When the Commission decides to undertake a second rulemaking, it would also be considered a partial granting of the petition.

Because the NRC considers this action noncontroversial, the Direct Final Rule will be published in final form. This action will become effective on [insert the date 60 days after publication in the *Federal Register*]. However, if the NRC receives significant adverse comments by [insert the date 30 days after publication in the *Federal Register*], the NRC will publish a document that withdraws this action. In the Proposed Rules section of this issue of the *Federal Register*, the NRC is publishing a separate document that will serve as the proposal to approve the rule and to constitute the mechanism through which the NRC will consider its final action on this matter, should adverse comment be received. Any significant adverse comment will be addressed in a subsequent final rule. The NRC will not initiate a second comment period on this action.

Background

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 in 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 approval prior to implementation.

The Petition

NEI 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 debates about the correct interpretation of the term "reduction in commitment." NEI presented the following examples of changes that it believed could be made without the need

for prior NRC approval but that have been viewed as "reductions in commitment," requiring prior NRC approval:

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.

NEI estimated that NRC review and approval of these types of changes cost the industry in excess of $1 million per year. In addition, NEI asserted that licensees occasionally were reluctant to pursue QA program improvements because of the resources required for NRC approval, even though the ultimate result would be improvements in efficiency, quality, or safety.

In NEI's opinion, 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 by 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. The NEI 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 10 CFR 50.59, with respect to changes in the facility as described in the SAR, changes in procedures as described in the SAR, and the conduct of tests or experiments not described in the SAR. All these changes may be made without prior NRC approval provided that the relevant thresholds in Section 50.59 are not exceeded. These thresholds restrict the licensee from making unilateral changes if the changes involve (i) a change in the technical specifications incorporated in the license, (ii) an increase in the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report, (iii) the creation of the possibility for an accident or malfunction of a different type than evaluated previously in the safety analysis report, or (iv) a reduction of the margin of safety as defined in the basis for any technical specification[1]. NEI stated that NRC acceptance of the proposed approach would bring QA program changes under the same umbrella as the regulatory change control in Section 50.59 that has been in effect since 1974.

NEI noted that the NRC's main purpose for the current regulatory change control requirement in 10 CFR 50.54(a) (which was adopted in 1983) was to preclude licensees from making certain changes to QA programs without prior NRC approval because, in the past, some QA programs had been changed and no longer conformed to NRC regulations. NEI

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[1] The NRC is currently considering changes to the thresholds in Section 50.59. See 63 FR 56098 (October 21, 1998).

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 NEI further 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 (60 FR 47716), the NRC published a *Federal Register* Notice announcing the receipt of the NEI petition for rulemaking and providing an opportunity for public comment. The *Federal Register* Notice requested that the public comment on the petition and 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; all supported the proposed change in the regulations. The six non-NEI/non-licensee letters were sent by individual concerned citizens (two are currently employed in the nuclear field); all expressed opposition to the relaxation of the current regulatory control of changes. All of the comment letters addressed themselves to issues raised in the petition, particularly to the appropriateness of using the 10 CFR 50.59 criterion for QA program changes.

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. 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 approval of proposed QA program changes. Section 50.59 requires that a proposed change to a facility description be deemed a USQ 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 make such a determination, and 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 10 CFR 50.59 criteria for QA program changes is not appropriate.

The NRC does not believe that NEI's draft guidance document, even in conjunction with the other NEI guidance documents cited, would ensure that acceptable QA programs would result. These documents rely heavily on NSAC-125, which is oriented toward hardware

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

However, the Commission agrees with NEI that the present 10 CFR 50.54(a) criterion for permitting unilateral QA program changes by licensees is too stringent because it prevents licensees from freely making changes to their QA programs of minor safety significance. The Commission believes that new criteria should be adopted that will broaden the scope of such changes that can be made by the licensee without prior NRC approval. Therefore, the Commission, is accepting the petition in part. The first stage of this partial acceptance is the promulgation of this Direct Final Rule to revise 10 CFR 50.54(a) to allow licensees to make additional changes to selected elements of their QA program without having to obtain prior NRC approval. As of the effective date of the Direct Final Rule, licensees would be permitted to make the following types of unilateral changes to their QA programs:

1. The use of a quality assurance standard approved by the NRC which is more recent than the QA standard in the licensee's current QA program at the time of the change,

2. The use of a quality assurance alternative or exception previously approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility,

3. The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles,

4. The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text,

5. The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed, and

6. Organizational revisions that ensure that persons and organizations performing QA functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

Licensees shall continue to conform to the requirements in Appendix B to 10 CFR Part 50 and 10 CFR 50.34(b)(6)(ii) and to notify the NRC of these changes as required by 10 CFR 50.71(e). The Direct Final Rule will provide some immediate relief to licensees by minimizing the need for debate with the NRC on changes that currently would constitute reductions in commitment which need prior NRC approval, but which are of minor safety significance. This action constitutes the first stage of NRC's partial granting of the NEI petition.

The completion of NRC's action on the NEI petition will be accomplished through a second rulemaking action in which criteria will be developed for determining other areas in which unilateral changes could be made by licensees without prior NRC approval that would not negatively impact on the effectiveness of the licensee's QA program.

Section-by-Section Analysis

This Direct Final Rule amends 10 CFR 50.54(a) by specifying six QA programmatic areas in which licensees may make changes without prior NRC approval. Licensees are at liberty to continue the practice of seeking approval for "reductions in commitments" under the provisions of 10 CFR 50.54(a)(3); however, it is expected that most licensees will avail themselves of the relaxations provided by this Direct Final Rule.

1. Paragraph (a)(3)(i) of Section 50.54 specifies that licensees may adopt a QA standard approved by the NRC but only if it is more recent than the QA standard in the licensee's current QA program at the time of the change. The majority of licensee QA programs have committed to implement QA standards endorsed by Regulatory Guide 1.28 (Rev. 2 or earlier) and Regulatory Guide 1.33 (Revision 2 or earlier) that were published in the late 1970s. This provision would allow licensees to adopt a more recent standard (with respect to their previous commitments), provided that the NRC has approved it for use. Under existing regulations, such a change might be considered a reduction in commitment, depending upon the differences between the licensee's QA program and the content of the standard, and could require prior NRC approval. However, if the NRC has evaluated the more recent standard and found it acceptable with respect to the requirements of 10 CFR Part 50, Appendix B, the licensee would be free to implement the provisions of the standard in lieu of the provisions of their current QA program. Such use would have to account for any conditions of the NRC endorsement of the standard or site-specific situations.

2. Paragraph (a)(3)(ii) of Section 50.54 specifies that licensees may use a QA alternative or exception previously approved by the NRC in a safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility. The licensee must demonstrate, however, that the plant conditions under which the previously endorsed alternative or exception was granted apply to its plant as well. That is to say that the NRC

safety evaluation performed to grant the previous alternative or exception is relevant to the licensee's plant and that any QA elements credited by the original licensee or the NRC staff are applied as part of the implementation of the position. Licensee QA programs typically contain an array of alternate positions and exceptions to NRC QA regulatory guides and QA standards. This provision would allow licensees to use other alternatives and exceptions that have an accompanying NRC safety evaluation. In the event that QA alternatives or exceptions have been approved without a safety evaluation (e.g., prior to 1997, the NRC approval letters for QA program changes did not elaborate on the rationale for accepting the change), the NRC is willing to perform the evaluations for the incorporation of these changes by other licensees, if licensees request such actions.

3. Paragraph (a)(3)(iii) of Section 50.54 specifies that licensees may replace specific organizational and position titles with generic titles that clearly denote the position function, supplemented as necessary by descriptive text, without prior NRC approval. This provision permits licensees to revise organizational position titles without the need for prior NRC approval provided that the functional description and organizational relationship of the position remain unchanged, or satisfy the provisions of item 6 below.

4. Paragraph (a)(3)(iv) of Section 50.54 specifies that licensees may make use of generic organization charts to indicate functional relationships, authorities, and responsibilities, or alternatively descriptive text, as opposed to specific ones. QA functional relationships and responsibilities, and lines of authority may be described generically by charts or descriptive text provided that the flow of quality assurance authority and responsibility is clearly presented.

5. Paragraph (a)(3)(v) of Section 50.54 specifies that licensees may eliminate QA program information that duplicates language in QA regulatory guides and QA standards to which the licensee to committed. Typically, QA programs present information in descriptive text

that discusses how each of the 18 criteria of Appendix B are met. In addition, the QA programs describe the level of commitment to QA regulatory guides and QA standards. This permitted change will allow the elimination of information that duplicates the commitments. Licensees should assure that identical provisions exist through their commitments to the NRC regulatory guides or industry standards.

6. Paragraph (a)(3)(vi) of Section 50.54 specifies that licensees may make changes in organization that ensure that persons and organizations performing QA functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations. Changes in organization, however, must continue to assure the proper authority and organizational freedom of the QA functions (i.e., to identify quality problems, to promote solutions, and to verify implementation of activities) from cost and schedule pressures by maintaining independence and an adequate level of management reporting. Of particular importance to an effective QA program is the independence between the performing and verifying activities in the areas of auditing, inspection, and procurement.

Finding of No Significant Environmental Impact

The Commission has determined, in accordance with the National Environmental Policy Act of 1969, as amended and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rulemaking is not a major action significantly affecting the quality of the human environment, and, therefore, an environmental impact statement is not required. This Direct Final Rule amends NRC's regulations pertaining to changes to licensee QA programs that may be made without prior NRC approval. Under the current regulation in 10 CFR 50.54(a),

licensees are permitted to make unilateral changes to their QA programs provided that the change does not reduce the commitments in the program description previously approved by the NRC. The Direct Final Rule amends 10 CFR 50.54(a) to define six types of QA program changes, which the NRC considers to be administrative and routine that, henceforth, will not be considered reductions in commitment. The effect that this rule change will have on NRC licensees is that the prior requests for NRC approval will no longer be necessary in these six program areas. The changes that would be permitted by the rule are those which past NRC experience has shown do not result in any significant reduction in the effectiveness of the QA program as implemented by licensees. For example, correction of typographical errors, use of generic organizational charts as a substitute for more detailed charts, and elimination of duplicative language already contained in standards and guidance to which the licensee has committed cannot have any impact upon the effectiveness of the QA program. The use of a QA alternative previously approved by the staff in circumstances where the licensee has reasonably determined that the basis of the NRC approval is applicable to the licensee's facility, should not significantly reduce the effectiveness of the licensee's QA program to the point where there is an unacceptable level of safety. Since proper implementation of the rule would assure that no significant reductions in the QA program will occur, the rule should have no effect on the probability of occurrence of accidents, result in the occurrence of new accident, or change the consequences of acccidents previously evaluated. For these reasons, the Commission concludes that this rule should have no significant adverse impact on the operation of any licensed facility or the environment surrounding these facilities.

The conclusion of this environmental assessment is that there will be no significant offsite impact to the general public from this action. However, the general public should note that the NRC has also committed to comply with Executive Order (EO) 12898, "Federal Actions

to Address Environmental Justice in Minority Populations and Low-Income Populations," dated February 11,1994, in all its actions. Therefore, the NRC has also determined that there are no disproportionately high adverse impacts on minority and low-income populations. In the letter and spirit of EO 12898, the NRC is requesting public comment on any environmental justice considerations or questions that the public thinks may be related to this Direct Final Rule. The NRC uses the following working definition of "environmental justice": the fair treatment and meaningful involvement of all people, regardless of race, ethnicity, culture, income, or education level with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. Comments on any aspect of the environmental assessment, including environmental justice may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of this Direct Final Rule including the foregoing Environmental Assessment to every State Liaison Officer and requested their comments on this assessment.

Paperwork Reduction Act Statement

The Direct Final Rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1994 (44 U.S.C. 3501 *et seq.*). These requirements were approved by the Office of Management and Budget (OMB), approval number 3150-0011.

The public reporting burden reduction for this information collection is estimated to average 40 hours per response, including reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of this information collection, including

suggestions for reducing the burden, to the Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at bjs1@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs NEOB-10202, (3150-0011), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

If an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The regulatory analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, DC. Single copies of the analysis may be obtained from Harry S. Tovmassian, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, telephone (301) 415-3092 or by e-mail at hst@nrc.gov.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 [5 U.S.C. 605(b)], the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. The Direct Final Rule affects only the licensing and operation of nuclear power plants. The companies that operate these plants do not fall within the scope of the definition of "small entities" as stated in the Regulatory Flexibility Act or the size standards adopted by the NRC (10 CFR 2.810).

Backfit Analysis

The Direct Final Rule permits licensees to make unilateral QA program changes in several program areas but does not require them to do so. Licensees are free to continue to seek NRC approval for changes that reduce the commitments as currently required in 10 CFR 50.54(a)(3), and the NRC would continue to review these requests as it has done in the past. Thus, the NRC has determined that the backfit rule does not apply to the Direct Final Rule; therefore, a backfit analysis is not required for this Direct Final Rule because these amendments do not involve any provision that imposes backfits as defined in 10 CFR 50.109(a)(1).

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of the OMB.

List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plant and reactors, Radiation protection, Reactor siting criteria, Reporting and record keeping requirements.

For the reasons stated in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 50.

PART 50 - DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

AUTHORITY: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246, (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951, as amended by Pub. L. 102-486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Sections 50.10 also issued under secs. 101, 185, 68 Stat. 936, 955, as amended (42 U.S.C. 2131, 2235); sec.102, Pub. L. 910190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a, and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844).

Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80, 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 66 Stat. 955 (42 U.S.C. 2237).

2. In Section 50.54(a), paragraph (a)(3) is modified and a new paragraph (a)(4) is added to read as follows:

§50.54 Conditions of licenses.

(a) * * *

(3) 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 the Safety Analysis Report, provided the change does not reduce the commitments in the program description as accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted to the NRC in accordance with the requirements of §50.71(e). In addition to quality assurance program changes involving spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment:

(i) The use of a QA standard approved by the NRC which is more recent than the QA standard in the licensee's current QA program at the time of the change;

(ii) The use of a quality assurance alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility;

(iii) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(iv) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text;

(v) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed; and

(vi) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(4) Changes to the quality assurance program description that do reduce the commitments must be submitted to the NRC and receive NRC approval prior to implementation.

(i) Changes made to the quality assurance program description as presented in the Safety Analysis Report or in a topical report must be submitted as specified in §50.4.

(ii) * * *

(iii) * * *

(iv) * * *

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

For the Nuclear Regulatory Commission.

_____

John C. Hoyle,
Secretary to the Commission

ATTACHMENT 4

FEDERAL REGISTER NOTICE

COMPANION PROPOSED RULE

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150-AG-20

CHANGES TO QUALITY ASSURANCE PROGRAMS

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed Rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to permit power reactor licensees to make certain quality assurance (QA) changes without obtaining NRC review and approval of these changes in advance. The proposed rule would allow licensees to make routine or administrative changes that should not have an adverse impact on effectiveness of their QA programs. This action is intended to reduce the financial and administrative burden on power rector licensees without adversely impacting public health and safety.

DATES: Comments must be received by [insert the date 30 days after publication in the *Federal Register*].

ADDRESSES: Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff.

Hand-deliver comments to 11555 Rockville Pike, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

Copies of the petition for rulemaking, the public comments received on the *Federal Register* Notice announcing the receipt of the petition, public comments received on this *Federal Register* Notice, and the NRC's response to the petitioner are available for public inspection or copying for a fee in the NRC Public Document Room (PDR), 2120 L Street, NW (Lower Level), Washington, DC.

The public may submit comments via the NRC's interactive rulemaking web site through the NRC home page (http://www.nrc.gov). This site enables commenters to upload comments as files (any format), if their browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, telephone (301) 415-5905, e-mail cag@nrc.gov.

Certain documents related to this proposed rulemaking, including comments received, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These same documents also may be viewed and downloaded electronically via the interactive rulemaking website established by NRC for this rulemaking.

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:

As a partial acceptance of a Nuclear Energy Institute (NEI) petition for rulemaking, the NRC is proposing to amend its regulations related to changes that power reactor licensees may make to their QA programs without obtaining advance NRC approval. This action is necessary because the NRC agrees with NEI's stated position that under the existing regulations many QA program changes that are administrative or routine in nature are burdensome to the industry and NRC because they constitute a "reduction in commitment" and thus require NRC staff approval prior to implementation. This proposed action will provide relief to facility licensees by specifying a number of QA program elements that may be changed unilaterally, without the need for prior NRC approval.

Because the NRC considers this action to be noncontroversial, it is publishing this Proposed Rule concurrently with a Direct Final Rule. The Direct Final Rule will become effective on [insert the date 60 days after publication in the *Federal Register*]. However, if the NRC receives significant adverse comment on the Direct Final Rule by [insert the date 30 days after publication in the *Federal Register*], then the NRC will publish a document that withdraws the Direct Final Rule. If the Direct Final Rule is withdrawn, the NRC will address the comments received in a subsequent final rule. The NRC will not initiate a second comment period on this action.

For additional information, see the Direct Final Rule published in the Rules and Regulation section of this *Federal Register.*

Finding of No Significant Environmental Impact

The Commission has determined, in accordance with the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the Proposed Rule, if adopted would not be a major action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The Direct Final Rule amends NRC's regulations pertaining to changes to licensee QA programs which may be made without prior NRC approval. Under the current regulation in 10 CFR 50.54(a), licensees are permitted to make unilateral changes to their QA programs provided that the change does not reduce the commitments in the program description previously approved by the NRC. The Direct Final Rule amends CFR 50.54(a) to define six types of QA program changes, which the NRC considers to be administrative and routine, and would not be considered reductions in commitment. The effect that this rule change will have on NRC licensees is that the prior requirement for NRC approval will no longer apply to these six programmatic areas. These permitted QA programmatic changes, such as adopting NRC endorsed standards and adoption of generic organizational charts, were specifically selected because the NRC has determined that they would not adversely impact the effectiveness of the QA program. The changes that would be permitted by the rule are those which past NRC experience has shown do not result in any significant reduction in the effectiveness of the QA program as implemented by licensees. For example, correction of typographical errors, use of generic organizational charts as a substitute for more detailed charts, and elimination of duplicative language already contained in standards and guidance to which the licensee has committed cannot have any impact upon the effectiveness of the QA program. The use of a QA alternative previously approved by the staff in circumstances where the licensee has

reasonably determined that the basis of the NRC approval is applicable to the licensee's facility, should not significantly reduce the effectiveness of the licensee's QA program to the point where there is an unacceptable level of safety. Since proper implementation of the rule would assure that no significant reductions in the QA program will occur, the rule should have no effect on the probability of occurrence of accidents, result in the occurrence of a new accident, or change the consequences of accidents previously evaluated. For these reasons, the Commission concludes that this rule should have no significant adverse impact on the operation of any licensed facility or the environment surrounding these facilities.

The conclusion of this environmental assessment is that there will be no significant offsite impact to the public from this action. However, the general public should note that the NRC has also committed to complying with Executive Order (EO) 12898 "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," dated February 11,1994, in all its actions. Therefore, the NRC has also determined that there are no disproportionately high adverse impacts on minority and low-income populations. In the letter and spirit of EO 12898, the NRC is requesting public comment on any environmental justice considerations or questions that the public thinks may be related to this Proposed Rule. The NRC uses the following working definition of "environmental justice": the fair treatment and meaningful involvement of all people, regardless of race, ethnicity, culture, income, or education level with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. Comments on any aspect of the environmental assessment, including environmental justice, may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of this Proposed Rule, including the foregoing Environmental Assessment, to every State Liaison Officer and requested their comments on this assessment.

Paperwork Reduction Act Statement

This Proposed Rule would amend information collection requirements that are subject to the Paperwork Reduction Act of 1994 (44 U.S.C. 3501 *et seq.*). These requirements have been sent to the Office of Management and Budget for approval.

The burden reduction for public reporting of this information collection is estimated to average 40 hours per response, including reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of this information collection, including suggestions for reducing the burden, to the Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail at bjs1@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs NEOB-10202, (3150-0011), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. This draft regulatory analysis is available for inspection in the NRC Public

Document Room, 2120 L Street NW (Lower Level), Washington, DC. Single copies of the analysis may be obtained from Harry S. Tovmassian, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, telephone (301) 415-3092 or by e-mail at hst@nrc.gov.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 [5 U.S.C. 605(b)], the Commission certifies that 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" as stated in the Regulatory Flexibility Act, or the size standards adopted by the NRC (10 CFR 2.810).

Backfit Analysis

The provisions of the Proposed Rule would permit licensees to make unilateral QA program changes in several program areas but would not require them to do so. Licensees would be free to continue to seek NRC approval for QA program changes that are "reductions in commitment," as currently required in 10 CFR 50.54(a)(3), and the NRC would continue to review these requests as it has done in the past. Thus, the NRC has determined that the backfit rule does not apply to the Proposed Rule; therefore, a backfit analysis is not required because these amendments do not involve any provision that would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plant and reactors, Radiation protection, Reactor siting criteria, Reporting and record keeping requirements.

For the reasons stated in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Part 50.

PART 50 - DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

AUTHORITY: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246, (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951, as amended by Pub. L. 102-486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Sections 50.10 also issued under secs. 101, 185, 68 Stat. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. ~~91-190~~ 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a, and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844).

Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80, 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 66 Stat. 955 (42 U.S.C. 2237).

2. In Section 50.54 (a), paragraph (a)(3) is modified and a new paragraph (a)(4) is added to read as follows:

§50.54 Conditions of licenses.

(a) * * *

(3) 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 the Safety Analysis Report, provided the change does not reduce the commitments in the program description as accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted to the NRC in accordance with the requirements of §50.71(e). In addition to quality assurance program changes involving spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment:

(i) The use of a QA standard approved by the NRC which is more recent than the QA standard in the licensee's current QA program at the time of the change;

(ii) The use of a quality assurance alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility;

(iii) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(iv) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text;

(v) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed; and

(vi) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(4) Changes to the quality assurance program description that do reduce the commitments must be submitted to the NRC and receive NRC approval prior to implementation.

(i) Changes made to the quality assurance program description as presented in the Safety Analysis Report or in a topical report must be submitted as specified in §50.4.

(ii) * * *

(iii) * * *

(iv) * * *

* * * * *

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

For the Nuclear Regulatory Commission

_____

John C. Hoyle,
Secretary of the Commission

ATTACHMENT 5

LETTER TO NEI

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 the Nuclear Energy Institute (NEI) submitted to the Nuclear Regulatory Commission (NRC) by a letter from Mr. Phillip Bayne, 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 required to use to permit changes to their quality assurance (QA) programs without prior NRC approval. According to the proposal, changes involving unreviewed safety questions would require NRC approval prior to implementation.

On September 14, 1995 (60 FR 47716), the NRC announced the receipt of your petition in a *Federal Register* Notice 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 and NEI, all supporting the proposed change in the regulations. NEI's letter also transmitted 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 came from 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 it, and has accepted the petition in part, with regard to the need to broaden the scope of unilaterally permitted QA program changes. However, the Commission is not persuaded that 10 CFR 50.59 criteria should be used as a threshold to determine the need for prior approval of QA program changes. Section 50.59 requires that a proposed change to a facility description be deemed an unreviewed safety question if it (1) increases the probability of occurrence or consequences of a previously evaluated accident, (2) creates a possibility of a different type of accident, or (3) reduces the margin of safety. In the case of hardware changes or hardware-related procedural changes, the effect of the change on the availability or unavailability of safety-related equipment can be determined in order to perform the required evaluation. However, for 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 affect the availability of safety-related equipment. The Commission recognizes that NEI's concern with the continued use of the 10 CFR 50.54(a) criterion is valid, and believes that the scope of unilateral QA program changes should be broadened. The NRC has published a Direct Final Rule that amends 10 CFR 50.54(a) to allow licensees to make changes to selected aspects of their QA programs without prior NRC approval, as currently required. 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), include:

1. The use of a QA standard approved by the NRC which is more recent than the QA standard in the licensee's current QA program at the time.

2. The use of a quality assurance alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility;

3. The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

4. The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text;

5. The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed; and

6. Organizational revisions that ensure that persons and organizations performing QA functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

The goal of this rulemaking effort is to provide some relief to licensees by eliminating the need for debates with the staff on changes that currently would constitute reductions in commitment that need prior staff approval, but which are of minor safety significance.

The Commission has also approved the NRC staff's proposal to pursue additional rulemaking to amend the Section 50.54(a)(3) threshold by establishing an alternative change mechanism, to be adopted by licensees, as a voluntary option, to further broaden the scope of permitted unilateral QA program changes. This change mechanism would require licensees to monitor and trend the performance of their QA programs relative to adverse events attributable to QA deficiencies with appropriate corrective action taken to ensure the continued effectiveness of the QA program. The NRC staff plans to pursue this initiative with industry and other interested parties to modify the 10 CFR 50.54(a) regulation.

Sincerely,

William D. Travers
Executive Director
for Operations

Enclosure: *Federal Register* Notice for the Direct Final Rule

ATTACHMENT 6

CONGRESSIONAL LETTERS

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 accepts in part 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 required to use to permit changes to their quality assurance (QA) programs, without prior NRC approval. Only changes involving unreviewed safety questions or the Technical Specifications would require NRC approval prior to implementation, consistent with the provisions of 10 CFR 50.59.

While the Commission agrees with the need to broaden the scope of unilateral QA program changes that licensees are permitted to make, it disagrees with NEI's premise that Section 50.59 criteria should be used to evaluate the need for prior NRC approval of QA program changes. Section 50.59 requires that a proposed change to a facility description be analyzed to determine whether it constitutes 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 criteria for QA program changes is not appropriate. The Commission is sympathetic to the industry's concerns in this matter and is promulgating a Direct Final Rule, for immediate relief, that would allow licensees greater flexibility to unilaterally amend their QA programs. The Direct Final Rule is included in the *Federal Register* Notice mentioned above. To provide even greater flexibility, the NRC will initiate additional rulemaking, including staff interactions with the industry and other interested parties, to permit further unilateral QA program changes, at a licensee's discretion, provided that the licensee monitors and trends the performance of its QA program relative to adverse events attributable to QA deficiencies with appropriate corrective action taken to ensure the continued effectiveness of the QA program.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: *Federal Register* Notice

cc: Representative Ralph Hall

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

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

Dear Mr. Chairman:

The Nuclear Regulatory Commission (NRC) has sent to the Office of the *Federal Register* the enclosed *Federal Register* Notice in which it accepts in part 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 required to use to permit changes to their quality assurance (QA) programs, without prior NRC approval. Only changes involving unreviewed safety questions or the Technical Specifications would require NRC approval prior to implementation, consistent with the provisions of 10 CFR 50.59.

While the Commission agrees with the need to broaden the scope of unilateral QA program changes that licensees are permitted to make, it disagrees with NEI's premise that Section 50.59 criteria should be used to evaluate the need for prior NRC approval of QA program changes. Section 50.59 requires that a proposed change to a facility description be analyzed to determine whether it constitutes 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 criteria for QA program changes is not appropriate. The Commission is sympathetic to the industry's concerns in this matter and is promulgating a Direct Final Rule, for immediate relief, that would allow licensees greater flexibility to unilaterally amend their QA programs. The Direct Final Rule is included in the *Federal Register* Notice mentioned above. To provide even greater flexibility, the NRC will initiate additional rulemaking, including staff interactions with the industry and other interested parties, to permit further unilateral QA program changes, at a licensee's discretion, provided that the licensee monitors and trends the performance of its QA program relative to adverse events attributable to QA deficiencies with appropriate corrective action taken to ensure the continued effectiveness of the QA program.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: *Federal Register* Notice

cc: Senator Bob Graham

ATTACHMENT 7

SBREFA CORRESPONDENCE

Mr. Robert P. Murphy
General Counsel
General Accounting Office
Room 7175
441 "G" Street, N.W.
Washington, DC 20548

Dear Mr. Murphy:

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801, the Nuclear Regulatory Commission (NRC) is submitting final amendments to the Commission's rules in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

The NRC is revising its regulations pertaining to quality assurance program changes that power reactor licensees may make without first obtaining NRC approval. Specifically, the Direct Final Rule being published cites six types of quality assurance changes that licensees may make unilaterally, without the need to seek prior NRC approval.

The NRC has determined that the Direct Final Rule is not a "major rule" as defined in 5 U.S.C. 804(2). This finding has been confirmed with the Office of Management and Budget.

Enclosed is a copy of the direct final rule that is being transmitted to the Office of the *Federal Register* for publication. This direct final rule will become effective 60 days after it is published in the *Federal Register* unless significant adverse public comment is received within 30 days after publication.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: Final Rule
Regulatory Analysis

cc: SECY
OGC
OCA
OPA
CFO
CIO

The Honorable Al Gore
President of the United
States Senate
Washington, DC 20510

Dear Mr. President:

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801, the Nuclear Regulatory Commission (NRC) is submitting final amendments to the Commission's rules in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

The NRC is revising its regulations pertaining to quality assurance program changes that power reactor licensees may make without first obtaining NRC approval. Specifically, the Direct Final Rule being published cites six types of quality assurance changes that licensees may make unilaterally, without the need to seek prior NRC approval.

The NRC has determined that the Direct Final Rule is not a "major rule" as defined in 5 U.S.C. 804(2). This finding has been confirmed with the Office of Management and Budget.

Enclosed is a copy of the direct final rule that is being transmitted to the Office of the *Federal Register* for publication. This direct final rule will become effective 60 days after it is published in the *Federal Register* unless significant adverse public comment is received within 30 days after publication.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: Final Rule
Regulatory Analysis

cc: SECY
OGC
OCA
OPA
CFO
CIO

The Honorable Newt Gingrich
Speaker of the United States
House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801, the Nuclear Regulatory Commission (NRC) is submitting final amendments to the Commission's rules in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

The NRC is revising its regulations pertaining to quality assurance program changes that power reactor licensees may make without first obtaining NRC approval. Specifically, the Direct Final Rule being published cites six types of quality assurance changes that licensees may make unilaterally, without the need to seek prior NRC approval.

The NRC has determined that the Direct Final Rule is not a "major rule" as defined in 5 U.S.C. 804(2). This finding has been confirmed with the Office of Management and Budget.

Enclosed is a copy of the direct final rule that is being transmitted to the Office of the *Federal Register* for publication. This direct final rule will become effective 60 days after it is published in the *Federal Register* unless significant adverse public comment is received within 30 days after publication.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: Final Rule
Regulatory Analysis

cc: SECY
OGC
OCA
OPA
CFO
CIO

ATTACHMENT 8

PRESS RELEASE

NRC AMENDS QUALITY ASSURANCE REGULATIONS FOR NUCLEAR POWER PLANT LICENSEES

The Nuclear Regulatory Commission is amending its regulations to allow nuclear power plant licensees to make certain changes to their quality assurance (QA) programs without the need to obtain advance NRC approval.

This action grants in part a petition from the Nuclear Energy Institute (NEI).

The revisions to the regulations will be effective 60 days after publication of a *Federal Register* Notice on this subject, unless significant adverse comments are received within 30 days of the *Federal Register* Notice. If significant adverse comments are received, the revised regulations will be withdrawn, and the proposal will be reviewed further.

The changes that a nuclear power plant licensee will be able to make under the revised regulations are considered administrative or routine in nature and should not adversely impact the effectiveness of the licensee's QA program.

"Quality assurance" refers to actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service.

The current regulations permit a licensee to make changes to its NRC-accepted QA program description without prior NRC approval only if the change does not reduce the commitments made in the program description.

NEI stated in its petition that this criterion is sometimes interpreted by the NRC as requiring agency approval for <u>any</u> change in the QA program, regardless of its safety significance. As a result, NEI said, there are often prolonged and sometimes unnecessary regulatory debates about the correct interpretation of the term "reduce the commitments."

NEI contends that the acceptability of changes to a licensee's QA program through NRC approval should be governed by the effect of the change on safety, and not by whether the change represents a reduction in commitment. NEI suggested a change control approach similar to that used in NRC's regulations for determining when changes to other aspects of a nuclear power plant may be made without prior NRC approval.

NRC published a *Federal Register* Notice on September 14, 1995, announcing receipt of the NEI petition and providing an opportunity for public comment.

NRC agrees with the NEI proposal to broaden the scope of permitted QA program changes and is sympathetic to NEI's objection to the continued use of the current criterion. However, it does not believe that the change control approach involving the use of 10 CFR 50.59 criteria suggested by NEI would ensure acceptable QA programs.

In lieu of NEI's suggested approach, the revised regulations will permit a licensee to make the following types of changes to its QA program without prior NRC approval:

(1) The use of a QA standard approved by the NRC which is more recent than the QA standard in the licensee's current QA program at the time of the change,

(2) The use of a quality assurance alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility,

(3) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles,

(4) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text,

(5) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed, and

(6) Organizational revisions that ensure that persons and organizations performing QA functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

Persons who wish to submit comments should direct them to the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, Attention: Rulemaking and Adjudications Staff, within 30 days after publication of the *Federal Register* Notice. Comments may also be submitted electronically via the NRC's interactive rulemaking web site at http://www.nrc.gov.

This action constitutes the first stage of NRC's partial granting of the NEI petition. The second stage will be consideration of an additional change to the regulations that would permit further changes to QA programs without prior NRC approval, provided that applicable regulations are met and licensees take steps to demonstrate the continued effectiveness of their QA programs.

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Attachment 9

Regulatory Analysis

REGULATORY ANALYSIS FOR THE DIRECT FINAL RULE:
CHANGES TO QUALITY ASSURANCE PROGRAMS

1. Statement of Problem and Objective

Since the promulgation of 10 CFR 50.54(a) in 1983, nuclear power plant licensees have been permitted to make changes to their quality assurance (QA) programs included or referenced in their safety analysis reports, provided that the changes did not constitute a "reduction in commitment" in the program description previously accepted by the NRC. This requirement was imposed because the NRC learned that previously licensees were making unilateral changes to their QA program elements, which, in some cases, resulted in unacceptable program elements. However, the implementation of this requirement has led to considerable debate between the nuclear industry and the NRC over the definition of "reduction in commitment." The Nuclear Energy Institute (NEI) has petitioned the NRC to amend its regulations to allow unilateral changes to QA programs through a change process equivalent to that in 10 CFR 50.59. While the NRC agrees that there should be a broadening of the range of changes that licensees could make to their QA programs without prior NRC approval, it is not convinced that the NEI proposed criterion is workable or appropriate. The Direct Final Rule identifies six program areas in which unilateral program changes by licensees can be permitted. The Direct Final Rule would provide immediate relief to the industry in these areas and constitutes NRC's partial response to the NEI petition. A follow-on rulemaking involving NRC/stakeholder cooperation is also planned in which further relief will be granted in combination with licensees taking steps to demonstrate the continued effectiveness of their QA programs.

2. Background

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 QA 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 QA 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 approval prior to implementation.

The Commission has considered the NEI proposal and has validated the NEI contention that the current regulatory process is burdensome. However, it is not convinced that NEI's proposal to use the criteria in 10 CFR 50.59 is workable or appropriate. Thus, the NRC has developed this Direct Final Rule to provide immediate relief to licensees in

areas that it believes are administrative and non-controversial. The Direct Final Rule will be followed by development of an alternate process whereby QA program changes may be made without prior NRC approval, but accompanied by a process where licensees take steps to demonstrate the continued effectiveness of the QA program.

3. Identification and Analysis of the Alternative Approaches

3.1 Alternative 1 - Take No Action

If Alternative 1 is selected, nuclear power reactor licensees will continue to request their proposed QA program changes in the six programmatic areas identified by the NRC as before, through the process defined in 10 CFR 50.54(a)(3). There would be no relief for purely administrative and non-controversial changes which currently fall under the "reduction in commitment" umbrella.

3.2 Alternative 2 - Proceed with the Direct Final Rule

If Alternative 2 is selected, nuclear power reactor licensees would be able to make unilateral changes to their QA programs in the six programmatic areas identified by the NRC without seeking prior NRC approval. These changes will still need to be documented and ultimately reported to the NRC pursuant to 10 CFR 50.71(e) and be available for NRC examination. However, detailed justifications and licensee/staff debates will be eliminated for changes in the specified categories.

4. Regulatory Impact - Qualitative Costs and Benefits

Facility Licensees

Alternative 2 is clearly a burden reduction on the licensees as opposed to Alternative 1. Several categories of savings can be postulated. One area of reduced burden will be information collection requirements. Licensees will no longer need to prepare detailed descriptions of the QA program changes and accompanying justifications for submittal to the NRC. Also, there will be no need for responding to requests for further information from the NRC while the staff is evaluating the changes proposed. However, the description of the QA program change must still be reported periodically in accordance with 10 CFR 50.71(e). Burden will be reduced further through the elimination of administrative activities involved in seeking NRC approval. These would include activities such as internal meetings, obtaining appropriate management approvals, and telephone calls and or meetings with the NRC staff.

Based on NEI's estimates, if NRC granted the petition as presented, the burden reduction to the industry would be approximately $1 million per year. Elsewhere in the comment letter, NEI stated that they did a survey of licensee costs for Section 50.54(a) compliance costs for a 5 year time frame and found that those costs range from $3 thousand to $45 thousand per year per unit. The wide variability in these estimates was due in part to the inability to accurately separate costs for Section 50.54(a) compliance from other costs. NEI stated that these costs savings could be extrapolated to a

$330 thousand to $4.9 million per year savings for the industry. The Direct Final Rule will produce a burden reduction only for the six categories of changes specified. The NRC estimates that only 10 to 25 percent of QA program changes would fall in these six categories. Thus the burden reduction could be as low as $33 thousand per year or as high as $1.25 million per year across the industry. This would equate to a range of approximately 330 to 12500 man hours per year. As mentioned above, only a portion of this burden reduction would be due to lessened information collections; the staff estimates that this amounts to about 40 percent (or 132 to 5400 man hours) of this burden reduction. A recent NRC analysis indicated that over a one year period, 45 requests for reviews of proposed reductions in commitment were received. If 18 percent (8) of these were in the six categories identified in this rule, then the information collection requirements would range between 17 and 771 man hours per response. However as noted above, the high side of this range is most likely overstated. Also, the categories of changes permitted under the Direct Final Rule are considered administrative and routine. Thus, the NRC staff has estimated that the average information collection burden per response would be more on the order of 40 man hours per response.

In its comment letter NEI also identified several qualitative values associated with the reduced emphasis on reductions in commitment. First, it would focus licensee resources on issues that directly affect safety. While the NRC cannot mandate how licensees apportion their resources, there is the possibility that licensees will increase their emphasis on safety significant problems. Also, NEI indicated that many licensees were reluctant to introduce improved QA measures because of the perceived lengthy debates with the NRC to resolve "reduction in commitment" differences. The Proposed Rule should influence licensees positively in these directions.

NRC Staff

Necessary NRC staff resources would also decrease somewhat. Resources required for each staff review of a QA program change vary broadly. In many cases, the review is routine and no further licensee contact is required for NRC approval of the change. On the other hand, some reviews are complicated and require frequent discussions with the licensee and several months of staff time to resolve. Since the six program areas identified are considered administrative and routine in nature, it is surmised that they would be at the low end of the spectrum of staff time required to obtain NRC approval. Thus, the burden reduction in this area would appear to be modest.

5. Decision Rationale

As noted in Section 4 of this analysis, this rulemaking should provide a reduction in burden on the licensees, although there is considerable variability in the magnitude of these cost reductions. The Direct Final Rule is not expected to have any significant positive or negative effect on the public health and safety.

6. Implementation Schedule

The Direct Final Rule will become effective 60 days after the date it is published in the *Federal Register*, unless significant adverse public comment is received within 30 days of its publication. In that case, the Direct Final Rule will be withdrawn and the companion Proposed Rule will be processed as a final rule.