PRM-50-62

NUCLEAR ENERGY INSTITUTE

William H. Rasin
VICE PRESIDENT
TECHNICAL/REGULATORY

June 8, 1995

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

Dear Mr. Hoyle:

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

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

Sincerely,

William H. Rasin

WHR/jes
Enclosures

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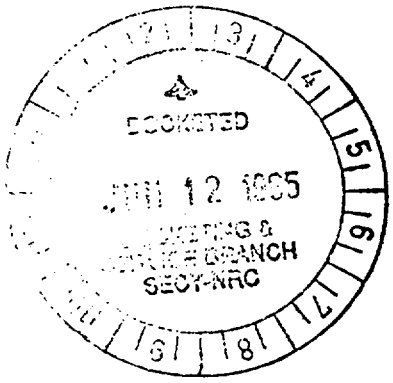
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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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

PETITION FOR RULEMAKING

SUMMARY

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

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

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

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

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

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

STATEMENT OF PETITIONER'S INTEREST

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

STATEMENT IN SUPPORT OF THE PETITION

A. Background

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

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

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

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

- Changes that can be made by a licensee to a facility or procedures without prior NRC approval if the change does not require a change to the Technical Specifications or involve an unreviewed safety question (i.e., 10 CFR 50.59).

- Changes that can only be made to a licensee's quality assurance program described or referenced in the SAR without prior NRC approval if they do not reduce commitments in the program description previously accepted by the NRC, even if the changes do not affect the Technical Specifications, involve unreviewed safety questions, or have any adverse safety significance (i.e., 10 CFR 50.54(a)).

- Varying record retention and reporting frequencies for activities of a similar nature, such as those associated with quality assurance and changes to the SAR.

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

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

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

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

- Changes in the level of approval of administrative, implementation or policy procedures, regardless of the safety significance.

- Changes in the company organization as it is described in the licensee's original quality plan.

- Changes to audit, review or surveillance frequencies that have minimal, if any, safety significance.

- Adoption of a more recent national standard that may, or may not, have been endorsed by the NRC staff that results in a different implementation methodology, yet fulfills the same function and achieves the same objective as the original standard described in the quality program description through the use of enhanced technology or other developments.

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

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

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

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

B. Proposed Change to 10 CFR 50.54 (a)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Other Affected NRC Regulations

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

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

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

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

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

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

D. Conclusion

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