

November 30, 2000

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. 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 previously accepted the petition in part, with regard to the need to broaden the scope of unilaterally permitted QA program changes.

The NRC published a direct final rule that amended 10 CFR 50.54(a) to allow licensees to make changes to selected aspects of their QA programs without prior NRC approval, as previously required. The direct final rule became effective on April 26, 1999. The NRC now permits a licensee to make the following changes 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):

1. The use of a QA standard approved by the NRC that is more recent than the QA standard in a 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 a 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 a 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 considerations, when those concerns are in conflict with safety considerations.

The goal of this rulemaking effort was to provide relief to licensees by eliminating the need for discussions between the industry and the NRC staff on changes that previously would have constituted reductions in commitment that need prior staff approval, but which are of minor safety significance.

On June 7, 2000, the staff conducted a public workshop to solicit feedback on the implementation of the revision to 10 CFR 50.54(a) and to gather information to determine the need for and feasibility of developing a voluntary alternative rule based on the NEI petition. Workshop participants acknowledged the significant burden reduction already achieved through the 1999 revision to 10 CFR 50.54(a). As a result of the discussions at the workshop, NEI concluded, and the NRC agreed, that a separate rulemaking on 10 CFR 50.54(a) is not needed. NEI noted that a separate rulemaking on 10 CFR 50.54(a) is not needed since QA special treatment requirements are being addressed under the NRC's Risk-Informing Part 50, Option 2 initiative. By letter dated August 15, 2000 (Accession No. ML003755305), NEI documented its belief that it is not necessary to pursue further changes to 10 CFR 50.54(a) related to its petition. By letter to NEI dated September 5, 2000, the staff confirmed NEI's intent to withdraw the remainder of the 1995 petition. Consequently, the Commission is completing action on your petition. For a more detailed discussion on the NRC's reasoning in this matter please see the enclosed *Federal Register* Notice.

Sincerely,

/RA/

Annette L. Vietti-Cook

Enclosure: *Federal Register* Notice

NUCLEAR REGULATORY COMMISSION

PRM-50-62

10 CFR Part 50

Changes to Quality Assurance Programs;
Withdrawal of Remaining Issues Concerning a Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking: Withdrawal.

SUMMARY: The Nuclear Regulatory Commission (NRC) is terminating its plans to develop a voluntary option alternative to its regulations to allow licensees to make unilateral changes to their quality assurance (QA) program descriptions. This action is being taken because the petitioner, the Nuclear Energy Institute (NEI), has withdrawn the remaining issues raised in its petition for rulemaking submitted on June 8, 1995 (Docket No. PRM-50-62). NEI's action is related in part to a revision dated February 23, 1999, to the Commission's regulations that was implemented in response to the petition and provided the industry with a reduction of unnecessary regulatory burden. The effect of this action is that further revisions to the Commission's quality assurance regulations are not being developed.

ADDRESSES: Copies of the petition for rulemaking, the public comments received on the notice of receipt of the petition (60 FR 47716; September 14, 1995), NRC's response to the petitioner, public comments received on the direct final rule (64 FR 9029; February 23, 1999), NRC's response to comments received on the direct final rule partially granting the petition (64 FR 42823; August 6, 1999), the Petitioner's letter (Accession No. ML003755305), stating that it is not necessary to pursue further changes, and NRC's confirmation letter (Accession No.

ML003747685), pertaining to the withdrawal of the petition are available for public inspection or copying for a fee in the NRC Public Document Room (PDR), One White Flint North, Room O-1F21, 11555 Rockville Pike, Rockville, Maryland 20852. These documents are also available for perusal at the NRC's rulemaking website <http://ruleforum.llnl.gov>. Questions or comments regarding this website should be directed to Carol A. Gallagher at 301-415-5905 or CAG@NRC.GOV.

FOR FURTHER INFORMATION CONTACT: Michael T. Bugg, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone 301-415-3221, e-mail mtb@nrc.gov.

SUPPLEMENTARY INFORMATION:

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 a nuclear power plant licensee to make a broader range of changes to its QA programs without prior NRC approval. At the time of the petition submittal, 10 CFR 50.54(a)(3) allowed a licensee 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 before 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 a 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 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 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 hesitant 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.

NEI also noted that the NRC's main purpose for the current 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 claimed that its proposed approach in PRM-50-62 would still address the NRC's concerns because QA program changes would continue to be reported periodically to the NRC as required by 10 CFR 50.71(e) as program updates, and changes that involve a USQ or cause a change to the technical specifications would be submitted to the NRC for approval before they are implemented. The petitioner reiterated that this is the same process used for change control for many other aspects of the facility design and operation, and should be used for QA programs as well. NEI further stated that the proposed amendment would improve the consistency of the regulatory process and would result in increased safety of commercial nuclear power plants through more efficient use of NRC and industry resources.

COMMENTS RECEIVED ON THE PETITION

On September 14, 1995 (60 FR 47716), the NRC published a notice of receipt of the NEI petition for rulemaking and provided an opportunity for public comment. The document requested that public comment on eight specific questions on critical regulatory aspects of the NEI petition. Seventeen comment letters were received, plus one comment letter that supplemented one of the original letters.

Eleven of the public comment letters were sent by nuclear power plant licensees and NEI; 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 current requirements that address changes in QA programs. All of the comment letters addressed issues raised in the petition, particularly the appropriateness of using the 10 CFR 50.59 criteria for QA program changes.

COMMISSION DECISION

The Commission agreed with NEI that the 10 CFR 50.54(a) criteria under which a licensee was allowed to make unilateral QA program changes was too stringent because it prevented a licensee from making QA program changes of minor safety significance without first obtaining NRC approval. The Commission decided that new criteria should be adopted to broaden the scope of changes that could be made by a licensee without prior NRC approval. Therefore, the Commission accepted the petition in part and issued a direct final rule (64 FR 9029; February 23, 1999) that revised 10 CFR 50.54(a) to allow a licensee to make additional changes to selected elements of its QA program without having to obtain prior NRC approval. As of April 26, 1999, a licensee is permitted to make the following types of unilateral changes to its QA programs:

1. The use of a quality assurance standard approved by the NRC that is more recent than the QA standard in a 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 a 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 a 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 considerations, when these concerns are in conflict with safety considerations.

Licenses 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 provided immediate relief to licensees by clearly defining six categories of QA program changes that do not require NRC approval prior to implementation. On June 7, 2000, the NRC staff conducted a public workshop to solicit feedback on the implementation of the revision to 10 CFR 50.54(a) and to gather information to determine the need for and feasibility of developing a voluntary alternative rule based on the NEI petition. Workshop participants acknowledged the significant burden reduction already

achieved through the 1999 revision to 10 CFR 50.54(a). As a result of the discussions at the workshop, NEI concluded, and the NRC agreed, that a separate rulemaking on 10 CFR 50.54(a) is not needed at this time. By letter dated August 15, 2000 (Accession No. ML003755305), NEI documented its belief that "it is not necessary to pursue" further changes to 10 CFR 50.54(a) related to its petition. By letter to NEI dated September 5, 2000, the NRC staff confirmed NEI's intent to withdraw the remainder of the 1995 petition.

In the direct final rule published on February 23, 1999 (64 FR 9029), the NRC noted that completion of the NEI petition should be accomplished in two stages. The first stage was the immediate burden relief of partially granting the NEI petition through the direct final rule. The second stage proposed was a follow-on rulemaking action in which criteria would have been 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. However, given the petitioner's belief that it is not necessary to pursue further changes and based upon feedback from a public workshop on the implementation of the direct final rule, the NRC has decided not to pursue the previously planned second rulemaking.

For these reasons, the NRC finds that all outstanding issues relating to PRM-50-62 are resolved. This completes NRC action on PRM-50-62.

Dated at Rockville, Maryland, this 30th day of November, 2000.

For the Nuclear Regulatory Commission.

/RA/

Annette L. Vietti-Cook,
Secretary of the Commission.