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 reactor licensees without adversely impacting public health and safety.

DATES: Comments must be received by March 25, 1999.

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 April 26, 1999. However, if the NRC receives significant adverse comment on the Direct Final Rule by March 25, 1999, 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 this separate part 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 10 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 1995 (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

If a means used to impose 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.

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. 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 § 50.54 (a), paragraph (a)(3) is revised 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 without prior NRC approval, 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 administrative improvements and clarifications, 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, as follows:

(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) The submittal of a change to the Safety Analysis Report quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of appendix B of this part and the Safety Analysis Report quality assurance program description commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(iii) A copy of the forwarding letter identifying the change must be maintained as a facility record for three years.

(iv) Changes to the quality assurance program description included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first

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Dated at Rockville, Maryland, this 17th day of February 1999.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

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