

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 April 26, 1999, unless significant adverse comment is received by March 25, 1999. If the rule is withdrawn, timely notice will be published in the Federal Register.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 April 26, 1999. However, if the NRC receives significant adverse comments by March 25, 1999, the NRC will publish a document that withdraws this action. In this separate part 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 § 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

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

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 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 § 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 § 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 § 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 § 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 § 50.54 specifies that licensees may eliminate QA program information that duplicates language in QA regulatory guides and QA standards to which the licensee is 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 § 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 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 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 1995 (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 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 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 § 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.

* * * * *

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

For the Nuclear Regulatory Commission.
Annette L. Vietti-Cook,
Secretary of the Commission.

[FR Doc. 99-4395 Filed 2-22-99; 8:45 am]

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