

# Proposed Rules

Federal Register

Vol. 60, No. 178

Thursday, September 14, 1995

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 50

[Docket No. PRM-50-62]

#### Nuclear Energy Institute; Receipt of a Petition for Rulemaking

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Petition for rulemaking; Notice of receipt.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) has received and requests public comment on a petition for rulemaking filed by the Nuclear Energy Institute (NEI) on behalf of the nuclear power industry. The petition has been docketed by the Commission and assigned Docket No. PRM-50-62. The petitioner requests that the NRC amend its regulations regarding quality assurance programs to permit nuclear power plant licensees to change their quality program described or referenced in a licensee's Safety Analysis Report (SAR) without prior NRC approval under specified conditions. The petitioner believes that this amendment would improve the regulatory process and increase the safety of commercial nuclear power plants through a more efficient use of agency and industry resources.

**DATES:** Submit comments by November 28, 1995. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except to those comments received on or before this date.

**ADDRESSES:** For a copy of the petition, write: Rules Review Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Submit comments to: Secretary, U.S. Nuclear Regulatory Commission,

Washington, DC 20555-0001. Attention: Docketing and Services Branch.

Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:45 am and 4:15 pm on Federal workdays.

Electronic Access, see **SUPPLEMENTARY INFORMATION** section.

#### FOR FURTHER INFORMATION CONTACT:

Michael T. Lesar, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone: 301-415-7163 or Toll Free: 800-368-5642.

#### SUPPLEMENTARY INFORMATION:

##### Electronic Access

Comments may be submitted through the Internet by addressing electronic mail to INTERNET:SECY@NRC.GOV. Comments may also be submitted electronically, in either ASCII text or WordPerfect format (version 5.1 or later), by calling the NRC Electronic Rulemaking Bulletin Board (BBS) on FEDWORLD.

The BBS is an electronic information system operated by the National Technical Information Service of the Department of Commerce. The purpose of this bulletin board BBS is to facilitate public participation in the NRC regulatory process, particularly rulemakings. With publication of this notice, proposed rulemakings and appropriate supporting documents will be available for review and comment on the BBS. These same documents are also available for review and comment at the NRC's Public Document Room, 2120 L Street, N.W. (Lower Level), Washington, DC. The BBS may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or directly via Internet.

The NRC rulemaking bulletin board (rulemaking subsystem) on FEDWORLD can be accessed directly by using a personal computer and modem, dialing the toll free number at 1-800-303-9672. Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using ANSI or VT-100 terminal emulation, the NRC rulemaking subsystem can then be accessed by selecting the "Rules Menu" option from the "NRC Main Menu." For further information about options available for NRC at FEDWORLD consult the "Help/Information Center" from the "NRC Main Menu." Users will find the

"FEDWORLD Online User's Guides" particularly helpful. Many NRC subsystems and databases also have a "Help/Information Center" option that is tailored to the particular subsystem.

The NRC subsystem on FEDWORLD also can be accessed by a direct dial phone number for the main FEDWORLD BBS at 703-321-3339; or by using Telnet via Internet: fedworld.gov. Using the 703 number to contact FEDWORLD, the NRC subsystem will be accessed from the main FEDWORLD menu by selecting the "Regulatory, Government Administration and State Systems," then selecting "Regulatory Information Mall." At that point, a menu will be displayed that has the option "U.S. Nuclear Regulatory Commission" that will take you to the NRC Online main menu. The NRC Online area also can be accessed directly by typing "/go nrc" at a FEDWORLD command line. If you access NRC from FEDWORLD's main menu, then you may return to FEDWORLD by selecting the "Return to FEDWORLD" option from the NRC Online Main Menu. However, if you access NRC at FEDWORLD by using NRC's toll-free number, then you will have full access to all NRC systems, but you will not have access to the main FEDWORLD system.

If you contact FEDWORLD using Telnet, you will see the NRC area and menus, including the "Rules Menu." Although you will be able to download documents and leave messages, you will not be able to write comments or upload files. If you contact FEDWORLD using File Transfer Program (FTP), all files can be accessed and downloaded, but uploads are not allowed, and all you will see is a list of files without descriptions (normal Gopher look). An index file listing all files within a subdirectory, with descriptions, is available. There is a 15-minute time limit for FTP access.

Although FEDWORLD also can be accessed through the World Wide Web as well, like FTP, that mode only provides access for downloading files, and does not display the NRC "Rules Menu."

For more information on NRC bulletin boards call Mr. Arthur Davis, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-5780; e-mail AXD3@nrc.gov.

## The Petitioner

The petitioner is the Nuclear Energy Institute (NEI). NEI represents that it is responsible for establishing unified nuclear industry positions 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 power plant designers, major architect/engineering firms, fuel fabrication facilities, nuclear materials licensees, and other organizations and individuals involved in the nuclear energy industry.

## Background

The NRC received an NEI petition for rulemaking on June 12, 1995. The petition is dated June 8, 1995, and was docketed as PRM-50-62 on June 19, 1995. The petitioner requests that the NRC amend its regulations in 10 CFR 50.54(a) to permit licensees to make certain changes to their quality assurance programs without prior approval from the NRC. The petitioner believes that this will change the quality assurance process consistent with the change process for other matters described in the SAR.

## Discussion of the Petition

The petition states that the current § 50.54(a) allows NRC licensees to change their quality assurance programs as long as any prior commitment in that program is not reduced. The petitioner believes that if a commitment is to be reduced, a licensee needs NRC approval prior to implementation. The petitioner believes that 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. The petitioner believes that prolonged and sometimes unnecessary regulatory interactions often occur centered on the correct interpretation of the term "reduction in commitment." The petitioner cites the following examples of topics that have been the subject of concern in the past:

- 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.

The petitioner believes that the current provisions of § 50.54(a) related to the quality assurance program change process are inconsistent with the requirements associated with other changes to the SAR (see § 50.59).

The petitioner believes that a licensee's inability to adjust its quality assurance program descriptions and commitments without prior NRC approval is a significant administrative burden on a licensee and can distract a licensee and the NRC from more significant safety matters. The petitioner also believes that 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 (i.e., a change process similar to the process delineated in § 50.59). The petitioner believes that the proposed amendment ensures that the attention and resources of NRC and industry would be more appropriately and effectively focused on issues that could have an adverse effect on public health and safety.

The petitioner further believes that the proposed amendment is consistent with the overall objectives of the 1993 Report of the National Performance Review, conducted by the Vice President of the United States, and 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 NRC regulations has been performed to identify regulations that are obsolete, unnecessarily burdensome, too prescriptive, or that overlap or duplicate other regulations.

The petitioner states that the NRC's Regulatory Review Group (RRG), in its review of power reactor regulations and related processes, programs, and practices, identified specific examples of inconsistency and incoherence in the current regulations and their associated administrative requirements. The RRG also provided recommendations for improvement. The petitioner states that, in some of the areas reviewed by the

RRG, licensees are responsible for controlling specific activities that are very similar in nature to the quality assurance process; however, these other activities are subject to different regulatory constraints, reporting, and record retention requirements.

The petitioner cites the following examples that the regulatory review group provided in its report of August 1993:

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

The petitioner agrees with the NRC's RRG finding that there is no reason for these inconsistencies in the NRC's regulations. The petitioner believes that 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.

The petitioner states that 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). The petitioner also states that 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 its quality assurance program that do not degrade protection of the public health and safety without the need for administrative and managerial regulatory interactions.

The petitioner states that the proposed amendment does not

introduce a new type of change process. The petitioner believes that the proposed amendment 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 the SAR. Compliance with the regulations to ensure proper control of a facility and the 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 § 50.59 process.

Section 50.59, Changes, tests and experiments, allows the holder of a license authorizing operation of a production or utilization facility to (i) make changes in the facility as described in the SAR, (ii) make changes in the procedures as described in the SAR, and (iii) conduct tests or experiments not described in the SAR, without prior Commission approval, unless the proposed changes, tests, or experiments, involve a change in the technical specifications incorporated into the license or an unreviewed safety question.

The petitioner believes that its proposed amendment would allow the licensee to have the authority to change its quality program if analysis, as described in § 50.59, demonstrates that a proposed change does not involve an unreviewed safety question or change the technical specifications. The petitioner states that the analysis to support this determination would be consistent with that required to support other types of changes to an SAR; therefore, it would be based on the well-proven and established industry guidance.

The petitioner believes that if the analysis of a proposed change to the quality assurance program indicates that any unreviewed safety questions 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 § 50.90.

The petitioner states that the proposed amendment would maintain the requirements of § 50.4, requiring licensees to submit a report containing a summary description of the changes to the quality assurance program described or referenced in the SAR. The petitioner states that the report would be submitted annually, or along with the FSAR updates as required by § 50.71(e), or at shorter intervals as determined by each licensee. The petitioner states that

licensees would maintain records of the changes as facility records for 5 years, a period that is consistent with other similar NRC regulations (e.g. § 50.59).

The NEI did not address the impact of removing § 50.4(b)(7)(i) from the Commission's regulations or why NEI believes the deletion is necessary.

The petitioner's suggested amendment would require that only a summary, not a detailed safety evaluation, be submitted to the NRC for changes that do not involve a Technical Specification change or an unreviewed safety question. The petitioner believes that this is consistent with the requirements of similar regulations (§ 50.59). The petitioner also believes that the proposed amendment would require that licensees maintain records of these evaluations until the termination of the license.

The petitioner has provided supplemental analyses to facilitate the NRC's consideration of the effect of the proposed action on the environment and small business entities, as well as the paperwork burden on all entities that would be affected by the change. NEI also included analyses to assist NRC in its consideration of the need for a regulatory analysis or application of the backfit rule to this rulemaking.

The NRC is soliciting public comment on NEI's petition requesting the changes to regulations in 10 CFR Part 50 as discussed below.

**The Petitioner's Proposed Amendment**

The petitioner recommends the following amendments to 10 CFR Part 50.

**§ 50.4 [Amended]**

1. In § 50.4, paragraph (b)(7)(i) and the designation for paragraph (b)(7)(ii) are removed.

2. In § 50.54, paragraph (a) is revised to read as follows:

*§ 50.54 Conditions of licenses.*

(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 before implementation. The licensee shall submit the application to amend the quality assurance 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.

\* \* \* \* \*

**Specific Areas for Public Comment**

In addition to commenting on the petition for rulemaking (petition) presented above, the NRC staff is soliciting specific comments on the issues presented below. Because the NRC staff has not yet developed its positions on the petition, it is soliciting these comments to obtain information that it may consider in developing future rulemakings that provide procedures for licensees to make changes to its quality assurance program.

1. 10 CFR 50.54(a) was issued on January 10, 1983, to correct instances where licensees had changed their programs that resulted in some unacceptable programs without informing the NRC. What assurances exist to prevent a similar situation from recurring if the petition and the revised threshold for reporting QA program changes is adopted? Is it necessary that such situations be prevented from

occurring by adoption of a regulatory approval system?

2. Traditionally, the NRC staff has used a variety of documents such as the NRC Standard Review Plan, NRC Regulatory Guides, and associated industry consensus standards to delineate what QA program elements are necessary to meet Appendix B. Should these standards continue to be used to define acceptable QA programs? Should a licensee QA program change that constitutes a departure from a commitment to comply with a specific regulatory position be considered of sufficient importance that the NRC should be notified in advance of implementation? How would such changes be evaluated under the petitioner's proposed criterion?

3. The NRC has allowed licensees to relocate administrative controls for review and audit functions from the technical specifications. Examples include details on safety review committees, audits, and technical review functions. These have been relocated to the QA program based on the existing change control provisions in § 50.54(a). Would it be appropriate for activities such as safety review committees, independent technical review groups, and audits to be controlled so that only licensee changes exceeding the threshold of an unreviewed safety question (USQ) be reported to the NRC for pre-review before implementation? What kind of changes to a licensee's QA program would constitute a USQ? Assuming that the USQ should/could be applied, does not the use of § 50.59 effectively negate the administrative and regulatory advantage of removing this information from technical specifications (because both technical specification changes and USQs are subject to an opportunity for hearing)? If the revised QA change control mechanism is adopted should aspects of the review and audit functions remain in the QA program or be relocated elsewhere to ensure appropriate NRC review of changes prior to implementation?

4. Are there alternative thresholds for determining whether a licensee must submit their QA program changes for advance review in lieu of the USQ threshold? Provide a technical and/or policy explanation as to why this or any other threshold would be more appropriate.

5. The NRC Regulatory Review Group (RRG) examined change control mechanisms in § 50.54 for control of licensee plans and programs (quality assurance, security, and emergency preparedness). The RRG recommended that licensees should have greater

flexibility to make changes in their programs without having to receive prior NRC approval. Currently, QA program changes that "reduce the commitments in the program" are submitted for NRC staff review before implementation. Similarly, security plan changes that "decrease the effectiveness" are submitted for staff review before implementation. Should the staff consider a revision to § 50.54(a) to set the threshold for reporting QA program changes for NRC pre-review that constitute a decrease in effectiveness? Would a "decrease in effectiveness" standard in § 50.54(a) provide a sufficiently flexible and technically reasonable criteria for licensees to report QA program changes to the staff before implementation?

6. Should the NRC staff consider retaining the current language of § 50.54(a) and to define explicit guidance or identify examples on what types of QA program changes would be considered to "reduce the commitments in the program"? By developing this guidance could sufficient flexibility be afforded to licensees to make changes in their QA program without having to undergo a pre-review by the staff?

7. The petition proposes to apply a § 50.59 process to evaluate QA program changes to determine the necessity for pre-review by the staff. Industry guidance for § 50.59 exists within NSAC-125 "Guidelines for § 50.59 Safety Evaluations." NSAC-125 appears to contain little relevant guidance that would be helpful for determining whether QA programmatic changes would constitute a USQ that requires NRC pre-review of the change. In particular, Section 4.2 of NSAC-125 deals principally with evaluating changes associated with nuclear plant equipment and not programmatic controls. Is existing guidance for processing 10 CFR 50.59 evaluations sufficient for evaluating QA program changes? What factors or aspects of the existing industry guidance would need to be supplemented? What types of QA program changes would be necessary to report to the NRC if the current § 50.59 criteria were applied to QA program changes? What are examples of QA program changes that should be considered as meeting the USQ threshold?

8. Would protection of the public health and safety be enhanced if the petition were granted, and if so, in what way? What licensee and NRC costs would be reduced, or increased, if the petition were granted?

Dated at Rockville, Maryland, this 7th day of September, 1995.

For the Nuclear Regulatory Commission.

**John C. Hoyle,**

*Secretary of the Commission.*

[FR Doc. 95-22705 Filed 9-13-95; 8:45 am]

BILLING CODE 7590-01-P

## FEDERAL DEPOSIT INSURANCE CORPORATION

### 12 CFR Part 353

RIN 3064-AB63

#### Suspicious Activity Reporting

**AGENCY:** Federal Deposit Insurance Corporation.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Federal Deposit Insurance Corporation (FDIC) is proposing to revise and restructure its regulation on the reporting of suspicious activities by insured state nonmember banks, including the reporting of suspicious financial transactions, such as suspected violations of the Bank Secrecy Act (BSA). This proposal implements a new interagency suspicious activity referral process and updates and clarifies various portions of the underlying reporting regulation. The proposal also reduces substantially the burden on banks in reporting suspicious activities while enhancing access to such information by both the federal law enforcement and the federal financial institutions supervisory agencies, thus meeting the goals of section 303 of the Riegle Community Development and Regulatory Improvement Act of 1994.

**DATES:** Comments must be received by November 13, 1995.

**ADDRESSES:** Written comments shall be addressed to the Office of the Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429. Comments may be hand delivered to Room F-402, 1776 F Street NW., Washington, DC 20429, on business days between 8:30 a.m. and 5:00 p.m. [Fax number: 202/898-3838; (Internet address: [comments@fdic.gov](mailto:comments@fdic.gov))] Comments will be available for inspection at the Corporation's Reading Room, Room 7118, 550 17th Street NW., Washington, DC between 9:00 a.m. and 4:30 p.m. on business days.

**FOR FURTHER INFORMATION CONTACT:** Carol A. Mesheske, Chief, Special Activities Section, (202/898-6750), or Gregory Gore, Counsel, (202) 898-7109.