



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
WASHINGTON, D.C. 20555-0001

October 19, 1998

MEMORANDUM TO: The Chairman
Commissioner Diaz
Commissioner McGaffigan

FROM: William D. Travers *William Travers*
Executive Director for Operations

SUBJECT: STATUS OF THE DISPOSITION OF THE NEI PETITION FOR
RULEMAKING - LICENSEE CHANGES TO QUALITY ASSURANCE
PROGRAMS, AMENDMENTS TO 10 CFR 50.54 (PRM-50-62)

By letter dated June 8, 1995, the Nuclear Energy Institute (NEI) petitioned the Nuclear Regulatory Commission (NRC) to amend its regulations controlling changes to quality assurance (QA) programs. The petition was docketed 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. Under the petition request, only changes that involve unreviewed safety questions would require NRC review and approval prior to implementation using a process analogous to that used for plant design changes made under 10 CFR 50.59. On September 14, 1995, the NRC published a *Federal Register* notice (60 FR 47716) announcing the receipt of the NEI petition for rulemaking and providing an opportunity for public comment. Public comment consisted of 17 letters, of which 11 were from the industry supporting the petition and 6 were from members of the public who opposed the petition.

The staff has met with NEI on several occasions since receiving the petition and is in general agreement with the NEI proposal to broaden the scope of permitted QA program changes. However, the staff does not believe that using threshold criteria equivalent to those in 10 CFR 50.59 would be effective or appropriate. Nonetheless, in recognition of the fact that licensees should be able to make some unilateral changes to their QA program commitments without requiring NRC advance review, the staff is planning to promulgate a Direct Final Rule change to § 50.54(a) to provide immediate relief in a number of QA control areas that it currently believes to be administrative or routine in nature. Specifically, the regulation is proposed to be modified to allow licensees to unilaterally change their QA programs in the following areas.

1. Adoption of a consensus standard newly endorsed by the NRC,
2. Incorporation of a new QA position previously approved by an NRC safety evaluation at the request of another licensee,
3. Use of generic organizational and position titles rather than specific titles,

4. Use of generic organizational charts to indicate functional relationships and responsibilities,
5. Elimination of descriptive QA program commitments that are duplicative to those contained in QA regulatory guides and associated consensus QA standards, and
6. Implementation of organizational changes that do not affect the independence of the QA function.

On August 27, 1998, the staff met with NEI at a public meeting to discuss this matter and outline NRC's intended response to the petition, which includes a longer term rule change that is discussed later in this memorandum. As a result of the meeting, NEI indicated in general that the NRC proposals would meet the industry needs. Additionally, on September 30, 1998, the staff and NEI discussed the petition with the Advisory Committee on Reactor Safeguards. The staff held a follow-up public meeting on October 15, 1998, in which the preceding relaxations were discussed. During the meeting the NEI, and other industry, participants reacted favorably to the staff's Direct Final Rule concept. They expressed the opinion, however that the actual Direct Final Rule language will have to be carefully written to provide an enabling mechanism to resolve some aspects of the original NEI petition. The staff is preparing a Direct Final Rule package that accounts for comments that have been received on the staff's proposal. The rulemaking will be an acceptance, in part, of NEI's petition. It is expected that the Direct Final Rule package can be forwarded to the Commission for approval by November 30, 1998. It should be noted that this date is later than the target date of October 1998 that was identified in the response to the Chairman's Tasking Memorandum in Topic Area VI, Item H. This is because that in order to partially accept the petition, the acceptance must be accompanied by the rule. The staff thus needs an additional month to prepare the Direct Final Rule. During the intervening time the staff will conduct the meeting with the stakeholders which will provide important feedback on the Direct Final Rule concept. Additionally, the staff will provide a complete rulemaking package for the Direct Final Rule in the Commission paper that will be issued prior to November 30, 1998. Delaying the paper by one month should result in the Direct Final Rule becoming effective four months earlier than originally planned.

The Direct Final Rule discussed above will provide licensees with immediate, but limited, relief for certain specific areas of QA controls. Therefore, for the longer term, the staff believes that the 50.54(a) regulation should be revised further to permit an even broader range of QA program changes to be made by licensees without the necessity of prior NRC review and approval. This approach, to be adopted by licensees on a voluntary basis, would allow unlimited changes provided that the QA regulations [10 CFR Part 50 (Appendix B) and 50.34(b)(6)(ii)] continue to be met, the safety requirements relocated from the technical specifications continue to be implemented, and the licensee makes available for staff review the results of a program to monitor and trend the effectiveness of the QA program and takes appropriate corrective action to maintain its effectiveness. Licensees are already required to review the status and adequacy of their QA programs on a regular basis in accordance with Criterion II of Appendix B. Staff review of the performance monitoring and trending program is intended to ensure that QA programs, one of the foundations of NRC's "defense in depth"

Multiple Addressees

-3-

philosophy for the protection of public health and safety, will not be degraded (as did occur during the early 1980s, resulting in the original promulgation of the 50.54(a) regulation). The staff plans to work with the industry and other interested parties to develop and refine this optional QA program change control process.

cc: SECY
OGC
OCA
OPA
CFO
CIO

philosophy for the protection of public health and safety, will not be degraded (as did occur during the early 1980s, resulting in the original promulgation of the 50.54(a) regulation). The staff plans to work with the industry and other interested parties to develop and refine this optional QA program change control process.

cc: SECY
OGC
OCA
OPA
CFO
CIO

DISTRIBUTION

Central Files
H. Thompson
F. Costanzi

F.Akstulewicz
H.Tovmassian

HQMB Reading File
S.Treby

R.Auluck
G.Tracy

DOCUMENT NAME:A:\TRAM1.FIN

* SEE PREVIOUS CONCURRENCE, LLM.

To receive a copy of this document, indicate in the box: "C" = Copy without enclosures "E" = Copy with enclosures "N" = No copy

OFFICE	HQMB/DRCH*	HQMB/DRCH*	HQMB/DRCH*	DRCH/NRR*	DRPM/NRR*
NAME	WHaass	RGramm	SBlack	LSpessard	JRoe
DATE	10/06/98	10/06/98	10/06/98	10/06/98	10/07/98
OFFICE	AAD:NRR*	D:NRR*	EDO	TECHEDITOR	
NAME	BSheron	SCollins	WDTravers		
DATE	10/07/98	10/08/98	10/19/98	10/02/98*	/ /98

OFFICIAL RECORD COPY

43
1017