

April 23, 1999

Prism

MEMORANDUM TO: Bruce A. Boger, Director
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

FROM: Theodore R. Quay, Chief
Quality Assurance, Vendor Inspection,
Maintenance and Allegations Branch
Division of Inspection Program Management

SUBJECT: NO SIGNIFICANT ADVERSE COMMENT DETERMINATION FOR
10 CFR 50.54(a) DIRECT FINAL RULE (TAC NO. M88651)

A direct final and proposed rule for 10 CFR 50.54(a) concerning control of changes to quality assurance (QA) programs was published in the Federal Register (64 FR 9029) on February 23, 1999. The direct final rule will amend the Commission's regulations to permit power reactor licensees to make certain quality assurance (QA) program changes without obtaining NRC approval of these changes in advance. The direct final rule will be effective on April 26, 1999, unless a significant adverse comment was received by March 25, 1999. Based on the nature of the public comments received, the staff has determined that no significant adverse comments were received.

The Office of the General Counsel (OGC) has reviewed the comments received and has no legal objections to the determination that none of the submittals are considered a significant adverse comment. However, OGC advises that a Federal Register Notice should be published which identifies and addresses all comments, consistent with past practices in regards to direct final rules and immediately-effective rules. In an attachment, the staff has prepared a summary of the comments received and drafted responses to the comments. Further discussions with OGC will be necessary to resolve OGC's comments on the staff's proposed responses. The Generic Issues, Environmental, Financial and Rulemaking Branch is also in agreement with the determination that no significant adverse comments were received.

Attachment: As stated

cc: Sam Collins
William Kane

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

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Summary of Comments and NRC's Draft Responses

A direct final and proposed rule for 10 CFR 50.54(a) concerning changes to quality assurance (QA) programs was published in the Federal Register (64 FR 9027) on February 23, 1999. The direct final rule will be effective on April 26, 1999, unless a significant adverse comment was received by March 25, 1999. Copies of the comment letters are available for public inspection and copying for a fee at the NRC Public Document Room at 2120 L Street, NW, Washington, DC.

Comments were received from six respondents, comprising three power reactor licensees, one industry group, and two anonymous sources. Three of the commenters had no adverse comments on the direct final rule. Two commenters asked for a clarification or interpretation of the direct final rule. One commenter's issue pertained to sections of 10 CFR 50.54(a) that were not being changed by the direct final rule. None of the submittals are considered a significant adverse comment. The comments that were considered adverse only required a clarification of the direct final rule.

Six commenters made the following five general comments:

1. *Comment.* This rule change represents a small step, but certainly in the correct direction. Therefore, we have no adverse comments on the direct final rule.

Response. Currently, the NRC is attempting to develop a performance-based voluntary option to 10 CFR 50.54(a).

2. *Comment.* It is clear from the Section-by-Section Analysis that Section 10 CFR 50.54(a)(3)(i) of the direct final rule is intended to apply to programmatic quality assurance standards, such as the American National Standards Institute (ANSI) N45.2 and its daughter standards, endorsed by NRC Regulatory Guides. However, a licensee may have referred to other national codes or standards in its QA program, either as primary references or approved alternatives, that contain specific QA guidance although they are not endorsed by Regulatory Guides. Are non-programmatic QA standards intended to come under the purview of Section 10 CFR 50.54(a)(3)(i) of the direct final rule if earlier editions are presently included by reference in a licensee's approved QA program?

Response. Yes, the direct final rule does not make a distinction between "programmatic" and "non-programmatic" QA standards included by reference in the QA program described or referenced in the Safety Analysis Report. Therefore, the "reduction in commitment" items include "non-programmatic" QA commitments contained in the approved QA program. Pursuant to the direct final rule Section 10 CFR 50.54(a)(3)(i), revising an existing commitment to reference a "non-programmatic" QA standard approved by the NRC which is more recent than the "non-programmatic" QA standard in the licensee's current QA program at the time of the change is not considered to be a reduction in commitment.

3. *Comment.* Section 10 CFR 50.54(a)(3)(i) of the direct final rule allows later editions of QA standards currently referenced in a licensee's QA program to be adopted by that licensee if they have been found acceptable by the NRC with respect to the requirements of 10 CFR 50 Appendix B. Does inclusion of a later edition by reference in a licensee's approved licensing bases constitute acceptance by the NRC for adoption by another licensee under the direct final rule Section 10 CFR 50.54(a)(3)(i)?

Response. It is unclear what the commenter means by "inclusion of a later edition [of a QA standard] by reference in a licensee's approved licensing basis." Under Section 50.54(a)(3)(i), a licensee may use later editions of QA standards pursuant to Section 50.54(a)(3)(i) only if the NRC explicitly approved the later edition of the QA standard. NRC approval includes: (i) endorsement in a regulatory guide, (ii) approval by the issuance of a Safety Evaluation Report (SER) for a topical report (in which case, the limitations and conditions set forth in the topical report must be followed); for the use of a QA standard for another facility and (iii) approval by issuance of a SER for a QA program (in which case, the limitations and conditions set forth in the QA program must be followed); for the use of a QA standard for another facility.

By contrast, there is no NRC approval where a licensee unilaterally changes its QA program to use a later standard under Section 50.54(a)(3) on the basis that the change did not constitute a "reduction in commitment." Accordingly, a second licensee could not use the later edition of a QA standard pursuant to Section 50.54(a)(3)(i). Nor could that licensee use the later standard under Section 50.54(a)(3)(ii) since the first licensee's change did not involve a NRC safety evaluation report and approval.

4. *Comment.* The first and only page of a self-described two page submittal was received from an anonymous source that stated, "My main issues deal with not having the rule to address the use of old safety evaluations that may be general in nature as some were written in the 1970s and 1980s, and 2) the other public comments provided in early March at the information conference [Regulatory Information Conference in March 1999] addresses my other issues." The envelope containing the letter that was addressed to the "Chief, Quality Assurance and Vendor Inspection" did not have a return address, therefore, the NRC is unable to contact the anonymous source to inquire about the substance of the comments.

Response. Based on the information submitted, the NRC does not regard this as a significant adverse comment. However, if the submittal was suggesting that the direct final rule should be modified to prohibit licensees from using a safety evaluation report (SER) issued in the 1970's when the facility received its original license, the NRC disagrees with the comment. The direct final rule Section 10 CFR 50.54(a)(3)(ii) allows licensees to adopt any 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. Licensees may use alternatives or exceptions approved for a facility during issuance of the operating licenses, provided that the bases of the NRC approval are applicable. Alternatives and exceptions approved in SERs were approved in the context of the entire QA program. In many cases, it may not be clear in the SER which specific program elements provided the bases for acceptability of an alternative or exception. In such cases, the NRC is willing to perform the evaluation for adoption of an alternative or exception if requested. In all cases, it is the licensee's responsibility to ensure that the QA program as revised includes all elements that formed the bases of the NRC approval of alternatives or exceptions such that compliance with Appendix B to 10 CFR Part 50 is maintained.

Attachment

5. *Comment.* The NRC should consider clarifying or correcting the direct final rule Section 10 CFR 50.54(a)(4)(ii) with respect to the required content of submittal letters requesting NRC review of proposed reductions in quality assurance program descriptions. While the comment may not be directly related to the specific changes which are proposed, it is directly related to the correct functioning of the rule being changed.

Response. The comment is not directly related to the specific changes which are proposed, as recognized by the commenter. Therefore, the NRC will not take any action at this time to address this issue. However, the NRC is attempting to develop a performance-based option to 10 CFR 50.54(a). During the performance-based option development period, the NRC will carefully consider this issue in the direct final rule Section 10 CFR 50.54(a)(4)(ii).