

MEMORANDUM TO: David L. Meyers, Chief
Rules and Directives Branch
Office of Administration
Original signed by: Bruce A. Boger
FROM: Bruce A. Boger, Director
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

June 16, 1999

SUBJECT: FEDERAL REGISTER NOTICE RESPONSE TO COMMENTS ON THE
10 CFR 50.54(a) DIRECT FINAL RULE (TAC NO. M88651)

A direct final and parallel 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 amends the Commission's regulations to permit power reactor licensees to implement certain QA program changes without obtaining prior NRC approval of these changes. In the *Federal Register* notice for the direct final rule, the Commission stated that the direct final rule would become 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 submitted. The Office of the General Counsel (OGC) has reviewed the comments and has no legal objections to the determination that none of the submittals is considered a significant adverse comment. The Generic Issues, Environmental, Financial and Rulemaking Branch is also in agreement with the determination that no significant adverse comments were received.

Consistent with past practice, a *Federal Register* notice has been prepared that summarizes the public comments received, reports the NRC's determination that they are not considered to be "significant adverse" comments, and addresses questions raised in the comments. The comments are summarized and the NRC responses to the comments are stated in the attached *Federal Register* notice.

Attachment: As stated

cc: Sam Collins
William Kane

NRC FILE CENTER COPY

CONTACT: Richard P. McIntyre
(301) 415-3215
rpm1@nrc.gov

99-108

11

DISTRIBUTION:

Central File IQMB R.F. RGEB R.F. Public

* See previous concurrence

L-4-1PT50QA

DFX2

DOCUMENT NAME: G:\IQMB\Draft\bugg\Comments on 54.54(a) Direct Final Rule for Federal Register Notice.wpd
To receive a copy, indicate in the box: "C" = Copy without attachment "E" = Copy with attachment "N" = No copy

OFFICE	IQMB:DIPM:NRR	E	IQMB:DIPM:NRR	E	SC:IQMB:DIPM:NRR	E	BC:IQMB:DIPM:NRR	E	RGEB:DRIP:NRR	E
NAME	MTBugg*		RPMcintyre*		DHDorman*		TRQuay*		HSTovmassian*	
DATE	05/06/99		05/07/99		05/07/99		05/13/99		05/24/99	
OFFICE	OGC	E	DD:DIPM:NRR	E	BC:RGEB:DRIP:NRR	E				
NAME	STreby* No legal objection		BABoger TB		CACarpenter*					
DATE	05/11/99		05/11/99		06/09/99					

OFFICIAL RECORD COPY

9906210170 990616
CF SUBJ
L-4-1PT50QA CF

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN: 3150-AG20

Changes to Quality Assurance Programs: Responses to Comments on Direct Final Rule

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; responses to comments on the direct final rule.

SUMMARY: The Nuclear Regulatory Commission issued a direct final rule that amends the Commission's regulations to permit power reactor licensees to implement certain quality assurance (QA) program changes without obtaining prior NRC approval of these changes. The direct final rule became effective on April 26, 1999, because the NRC did not receive any significant adverse comments in response to an identical proposed rule which was concurrently published in the *Federal Register*. The public comments received, the NRC's reasons for determining that the comments are not significant adverse comments, and responses to questions raised in the comments are discussed in this notice.

FOR FURTHER INFORMATION CONTACT: Harry S. Tovmassian, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001; telephone, 301-415-3092; e-mail, hst@nrc.gov or Richard P. MyIntre, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001; telephone, 301-415-3215; e-mail, rpm1@nrc.gov.

SUPPLEMENTARY INFORMATION: On February 23, 1999 (64 FR 9029), the Nuclear Regulatory Commission published in the *Federal Register* a direct final rule amending its regulations to permit power reactor licensees to implement certain quality assurance (QA) program changes without obtaining prior NRC approval of these changes. The NRC also concurrently published an identical proposed rule on February 23, 1999 (64 FR 9025). The direct final rule became effective on April 26, 1999, since no significant adverse comments were received by March 25, 1999. This direct final rule modifies 10 CFR 50.54(a) to provide six QA programmatic areas within which changes to the QA program will not be considered reductions in commitments and subject to prior NRC approval. 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, D.C.

Comments were received from six respondents, comprising three power reactor licensees, one industry group, and two anonymous sources. Three of the commenters either supported or had no objections to the direct final rule. Two commenters asked for a clarification or interpretation of the direct final rule, and did not explicitly object to 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. The NRC does not consider any of the comments to be a significant adverse comment. Each of the NRC's responses to the questions in the comment, and the NRC's determination that the comment is not a significant adverse comment, are discussed below:

1. *Comment.* We endorse this rulemaking effort and support promulgation of the final rule.

Response. No response necessary.

2. *Comment.* This rule change represents a small step, but certainly in the correct direction. We have reviewed the comments submitted separately by the Nuclear Energy Institute (NEI) on behalf of the nuclear industry and endorse those comments. Therefore, we have no adverse comments on the direct final rule.

Response. No response necessary.

3. *Comment.* It is clear from the section-by-section analysis that 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) standard 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 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. The comment does not directly or indirectly oppose the direct final rule (and therefore does not constitute a significant adverse comment), but rather asks a question. In response, it is the NRC's position that the direct final rule does not distinguish between "programmatic" and "non-programmatic" QA standards included by reference in the QA program described or referenced in the safety analysis report. Therefore, "non-programmatic" QA commitments contained in the approved QA program fall within the purview of 10 CFR 50.54(a)(3)(i) of the direct final rule. Under the direct final rule, 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 QA program at the time of the change, is not considered to be a reduction in commitment.

4. *Comment.* In 10 CFR 50.54(a)(3)(i) of the direct final rule, the Commission 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 to be acceptable by the NRC with respect to the requirements of 10 CFR Part 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 10 CFR 50.54(a)(3)(i)?

Response. The comment does not directly or indirectly oppose the direct final rule (and therefore does not constitute a significant adverse comment), but rather asks a question. In response, it is the NRC's position that 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 consists of: (1) endorsement in a regulatory guide; (2) approval of a plant-specific or topical report by the issuance of a safety evaluation

report (SER), in which case the limitations and conditions stated in the plant-specific or topical report must be followed; and (3) approval by issuance of an SER for a license amendment changing the QA program, in which case the limitations and conditions stated in the SER must be followed.

By contrast, there is no NRC approval if 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 an NRC safety evaluation and approval.

5. *Comment.* The first and only page of a self-described two-page submittal was received from a commenter stating, "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."

Response. The envelope containing the letter, which was addressed to the "Chief, Quality Assurance and Vendor Inspection," did not have a name or a return address, therefore, the NRC is unable to contact the commenter to inquire about the substance of the comments. Based on the information submitted, it is unclear whether the commenter was simply asking if the rule permits the use of older QA standards approved by the NRC. Assuming, however, that the submittal was suggesting that the direct final rule should be modified to prohibit licensees

from using an SER issued in the 1970s when a facility received its original license, the NRC disagrees with the comment. Section 50.54(a)(3)(ii) allows licensees to adopt any QA 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 continuing 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 all cases, it is the licensee's responsibility to ensure that the QA program as revised contains all elements that formed the bases of the NRC approval of alternatives or exceptions so that compliance with Appendix B to 10 CFR Part 50 is maintained. Based on the above, the NRC is not treating this as a significant adverse comment.

6. *Comment.* The NRC should consider clarifying or correcting the direct final rule, 10 CFR 50.54(a)(4)(ii), with respect to the required content of submitted letters requesting NRC review of proposed reductions in QA program descriptions. Although the comment may not be directly related to the specific changes that 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 that are proposed, as recognized by the commenter. Therefore, the NRC does not consider this to be a significant

adverse comment on the direct final rule, and 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 development of the performance-based option, the NRC will carefully consider this issue.

Dated at Rockville, Maryland, this _____ day of June 1999.

For the Nuclear Regulatory Commission,

Annette L. Vietti-Cook,
Secretary of the Commission