

NUCLEAR REGULATORY COMMISSION

COMMISSION MEETING

---

---

In the Matter of:      AFFIRMATION/DISCUSSION SESSION    81-22  
PUBLIC MEETING

---

---

DATE:    June 11, 1981      PAGES:    1 - 7  
AT:      Washington, D. C.

ALDERSON  REPORTING

400 Virginia Ave., S.W. Washington, D. C. 20024

Telephone: (202) 554-2345

8106180389

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

AFFIRMATION/DISCUSSION SESSION 81-22

PUBLIC MEETING

Nuclear Regulatory Commission  
Room 1130  
1717 H Street, N. W.  
Washington, D. C.  
Thursday, June 11, 1981

The Commission met, pursuant to notice, at  
4:05 p.m.

PRESENT:

- JOSEPH M. HENDRIE, Chairman of the Commission
- PETER A. BRADFORD, Commissioner
- JOHN F. AHEARNE, Commissioner

ALSO PRESENT:

- S. CHILK
- L. BICKWIT
- S. TRUBATCH

\* \* \*

DISCLAIMER

This is an unofficial transcript of a meeting of the United States Nuclear Regulatory Commission held on 6-11-81 in the Commission's offices at 1717 H Street, N. W., Washington, D. C. The meeting was open to public attendance and observation. This transcript has not been reviewed, corrected, or edited, and is not suitable for publication.

This transcript is intended solely for general informational purposes. As provided by 10 CFR 9.101, it is not part of the formal or technical record of the Commission or the matters discussed. Expressions of opinion in this transcript do not necessarily reflect final determinations or beliefs. No pleading or other paper may be filed with the Commission in any proceeding in the matter of or addressed to any statement or argument contained herein, except as the Commission may authorize.

POOR ORIGINAL

## 1 PROCEEDINGS

2 CHAIRMAN HENDRIE: That created such a zone of  
3 silence I think we can go ahead.

4 (Laughter.)

5 MR. CHILK: The first affirmation is 81-316,  
6 Reporting of Changes to Quality Assurance Programs in which  
7 the Commission is being asked to approve a notice of  
8 proposed rulemaking which would require licensees to  
9 implement approved quality assurance programs and report  
10 certain changes.

11 The Commission has unanimously approved the  
12 document with the modification suggested by Commissioner  
13 Ahearne.

14 There is an unresolved issue here with regard to  
15 the length of the comment period. The staff has suggested a  
16 60-day comment period. Commissioner Bradford has  
17 recommended a 30-day comment period.

18 COMMISSIONER BRADFORD: The staff originally  
19 suggested it be immediately effective. That was the only  
20 reason I suggested 30 days.

21 MR. CHILK: The paper said 60. There seems to be  
22 diverging views on whether it be 60 or 30.

23 COMMISSIONER AHEARNE: I went with 60.

24 MR. CHILK: Commissioner Gilinsky, who is not  
25 here, went with 30.

1           CHAIRMAN HENDRIE: We are split on the time. I  
2 guess I would prefer to stick with 60 on the basis that that  
3 is where the staff ultimately shook themselves down and I  
4 don't know what 30 means ---

5           COMMISSIONER AHEARNE: My reason really has  
6 nothing to do with the staff proposing. It is just that it  
7 always takes so long to analyze any comments that come  
8 back. When we go to the short comment period it seems to me  
9 that there are more comments that come in right at the end  
10 or after.

11           The 30 days seemed to me more saying well we have  
12 now met the for-comment aspect of it, but I think 60 is  
13 about the shortest that even is reasonable. Otherwise, we  
14 might as well leave it immediately effective.

15           COMMISSIONER BRADFORD: Gee, when I think of all  
16 of the things we have put out for comment that spring on a  
17 15, 20 and 30-day leash ---

18           COMMISSIONER AHEARNE: Let me go back and find  
19 that item.

20           COMMISSIONER BRADFORD: You may have been opposed  
21 to putting it out for comment.

22           (Laughter.)

23           COMMISSIONER AHEARNE: That is right.

24           COMMISSIONER BRADFORD: Well, it is not an end of  
25 the world proposition. I will offer you 45.

(Laughter.)

1           CHAIRMAN HENDRIE: I think we have got him moving,  
2 John. Let's see if we can. Why don't you come on up to 60.

3           COMMISSIONER BRADFORD: Sold.

4           MR. CHILK: Will you please affirm your vote.

5           (Chorus of Ayes.)

6           CHAIRMAN HENDRIE: So ordered at 60 days.

7           MR. CHILK: The second is 81-220 which is a

8 Commission Review of ALAB-603, St. Lucie.

9           The latest status at least known in our office is  
10 that the revised memo dated on the 21st was agreed to by the  
11 Chairman and Commissioners Bradford and Ahearne.

12 Commissioner Ahearne provided additional views and  
13 Commissioner Gilinsky provided separate views. Commissioner  
14 Bradford then suggested a changed opinion.

15           CHAIRMAN HENDRIE: We have agreed to go back to  
16 the latest ---

17           MR. BICKWIT: If you are going to discuss it, our  
18 recommendation would be to close the meeting.

19           CHAIRMAN HENDRIE: I hadn't been planning to do  
20 that.

21           COMMISSIONER BRADFORD: I don't think you are  
22 going to discuss it, Joe. I think you are just going to  
23 describe it.

24           CHAIRMAN HENDRIE: I am not going to discuss the  
25 merits of the proposition. I am trying to identify the



1 draft for a certain amount of discussion.

2 MR. BICKWIT: If you are not planning to discuss  
3 it, our recommendation would not be to close it.

4 (Laughter.)

5 CHAIRMAN HENDRIE: It sure is good to have a  
6 counsel talk once more.

7 (Laughter.)

8 That latest draft, I could probably put my hand  
9 on, was your write-up. Peter and I decided to go back and  
10 stand together on that one. John concurs in the  
11 Commission's opinion and has a few line additional comment.  
12 Vic has his own comments.

13 As I see it standing at this meeting then there  
14 are three Commissioners present and able to vote Aye on that  
15 last draft you prepared. We recognize John's additional  
16 remarks. Vic would not vote for that one anyway but would  
17 have his own comments.

18 COMMISSIONER BRADFORD: Has he been asked whether  
19 he has any objection to our voting?

20 MR. CHILK: He has none.

21 COMMISSIONER BRADFORD: He has no objection to our  
22 voting?

23 MR. CHILK: No.

24 CHAIRMAN HENDRIE: I thought that was kind of  
25 where we can to before when you and I were having the last

1 round of discussion.

2 Sam, I think on the basis I have outlined you can  
3 go ahead and ask us.

4 MR. CHILK: Would you please affirm your vote.

5 (Chorus of Ayes.)

6 CHAIRMAN HENDRIE: Good. That is it.

7 249. There was a vote to ---

8 MR. CHILK: That is the fire protection.

9 CHAIRMAN HENDRIE: --- deny the petition on the  
10 stay of a final rule on fire protection. There was a vote  
11 to deny yesterday. Three Commissioners have now agreed on  
12 the text of the order. I have agreed to go with it, so  
13 there is a majority text.

14 COMMISSIONER BRADFORD: Does that need a separate  
15 affirmance?

16 CHAIRMAN HENDRIE: It doesn't need a vote that I  
17 know of.

18 MR. BICKWIT: My understanding was that you voted  
19 to deny and that the order would follow. In that case it  
20 would not need a separate vote.

21 CHAIRMAN HENDRIE: We now have three Commissioners  
22 who have agreed on a text which will be the majority  
23 opinion.

24 Your separate comments say you would deny but for  
25 reasons framed in another way that will accompany it. As



1 soon as we can churn that out why that can be made public.

2 Anything else?

3 MR. CHILK: No, sir.

4 CHAIRMAN HENDRIE: Good. Thank you very much.

5 (Whereupon, at 4:10, the affirmation session  
6 concluded.)

7

8

\* \* \*

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

NUCLEAR REGULATORY COMMISSION

This is to certify that the attached proceedings before the  
COMMISSION MEETING

---

in the matter of: AFFIRMATION/DISCUSSION SESSION

Date of Proceeding: June 11, 1981

Docket Number: \_\_\_\_\_

Place of Proceeding: Washington, D. C.

were held as herein appears, and that this is the original transcript  
thereof for the file of the Commission.

Mary C. Simons

Official Reporter (Typed)

Mary C Simons

Official Reporter (Signature)



May 19, 1981

SECY-81-316

## RULEMAKING ISSUE (Affirmation)

For: The Commissioners

From: William J. Dircks, Executive Director for Operations

Subject: REPORTING OF CHANGES TO QUALITY ASSURANCE PROGRAMS

Purpose: To obtain Commission approval of a notice of proposed rulemaking which would require licensees to implement the approved quality assurance program and to report certain changes to their quality assurance programs which affect the program description approved by the NRC.

Category: This paper covers a minor policy question.

Issue: Whether licensees, including permit holders for construction of nuclear power plants, should be required to implement the approved quality assurance program and to notify NRC of certain changes to their quality assurance (QA) programs which affect the description of the program included in the Safety Analysis Report as approved by the NRC. These changes would be submitted to the NRC Regional Offices for evaluation; however, policy issues or unusual issues would in turn be referred by IE to NRR for detailed review and evaluation.

Discussion: The QA requirements of 10 CFR Part 50 are one of the cornerstones of the Commission's "defense-in-depth" concept for ensuring safe operation of nuclear power plants. Because of the importance of the QA program as a management tool to attain objectives important to nuclear safety, the NRC staff conducts reviews during the licensing process to ensure that the QA program described in the Safety Analysis Report (SAR) satisfies 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." Following acceptance by the staff, the QA program becomes a principal basis for inspection and applicable enforcement to ensure that the permit holder or licensee complies with all NRC quality assurance requirements for protecting the public health and safety.

Contact:  
S.D. Richardson, RES  
443-5987

J.A. Norberg, RES  
443-5863

*Dup 8106 150020*  
*16pp*

As indicated in paragraph (a)(7) of 10 CFR § 50.34, "Contents of applications; technical information," the Preliminary Safety Analysis Report (PSAR) must include "a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility." Similarly, § 50.34(b)(6)(ii) requires that the Final Safety Analysis Report (FSAR) describe "managerial and administrative controls to be used to assure safe operation" and that it "include a discussion of how the applicable requirements of Appendix B [Quality Assurance Criteria] will be satisfied." It is clear that the QA program described in the SAR report is meant to represent the QA program actually being applied in practice. Consistent with this intent, the staff included a position in Revision 1 of the Standard Review Plan (Enclosure "A," Item 1) which provides that substantive changes to the QA program description in the PSAR be submitted to NRC for review.

The review procedures in effect since issuance of Revision 1 of the Standard Review Plan in early 1980 apply to new applications for construction permits and operating licenses. However, they are not sufficient because all permit holders and all operating plant licensees for which construction permits or operating license applications were reviewed prior to 1980 have not been required to make such commitments, nor is such a commitment, once made, subject to the full range of enforcement options. This lack of enforcement latitude exists because current regulations do not specifically include a requirement that changes to the QA program which affect the description of the QA program in the SAR be submitted to the NRC for review. Additionally, there is no explicit requirement that the approved quality assurance program be implemented as a condition of the construction permit or license.

Past and current problems with some licensees, a number of which have been discussed with individual Commissioners and on occasion with the full Commission in session, have highlighted a need for requiring licensees to report substantive QA program changes to the NRC. A major concern is that an unreported relaxation of the QA program from the program description in the SAR and accepted by the NRC could seriously diminish the effectiveness of the program and permit significant deficiencies to arise in the design, fabrication, construction or operation of the nuclear facility and could result in increased risk to the public health and safety, if these deficiencies remained uncorrected. In some cases, the licensee has revised the QA program without informing NRC of the change and then proceeded to revise affected procedures in accordance with that change. This resulted in use of a "relaxed" QA program without NRC awareness. (See Enclosure "A," Item 2 for examples of such cases currently under review by IE and NRR.)

In one case involving an operational plant, (see Enclosure "A," Item 2) IE discovered that the licensee used § 50.59, "Changes, tests and experiments," to justify that a QA program change did



not have to be submitted to the NRC since it did not represent an unreviewed safety question. Section 50.71(e), "Maintenance of records, making of reports," promulgated by the Commission (45 FR 30614) on May 9, 1980, which requires periodic updating of the FSARs, will partially alleviate the situation; however, the initial updated FSARs are not due until July 1982. Furthermore, the FSARs only have to be updated annually and construction permit holders are exempt from updating.

The publication of this rule will cause a minor resource impact on the industry which we estimate to be about one person-day per QA program description change. Additionally, we estimate that the impact on the NRC to review each change to be one person-day and that each utility would submit approximately two such changes per year.

Recommendation:

That the Commission:

1. Approve

- a. Publication of the notice of proposed rulemaking (Enclosure B) to amend §§ 50.54 and 50.55.
- b. The staff's conclusions set forth in Enclosure D, which provides the analysis called for by the Periodic and Systematic Review of the Regulations. The criteria used were derived from Executive Order 12044 which was rescinded on February 17, 1981 by Executive Order 12291 (see memorandum from Bickwit to the Commission, February 27, 1981). This approach is proposed as an interim procedure until the staff can make recommendations and the Commission decides what to do in response to Executive Order 12291.

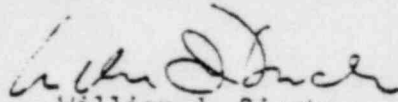
2. In order to satisfy the requirements of the Regulatory Flexibility Act 5 U.S.C. 605(b) certify that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing and operation of nuclear power plants. Publication of a Federal Register Notice on this finding and the basis upon which the finding was made will follow.

3. Note:

- a. That pursuant to Section 51.5(d) of Part 51 of the Commission's regulations neither an environmental impact statement nor a negative declaration need be prepared in connection with the amendment since the amendment is nonsubstantive and insignificant from the standpoint of environmental impact.

- b. That the Subcommittee on Nuclear Regulation of the Senate Committee on Environment and Public Works, the Subcommittee on Energy and the Environment of the House Committee on Interior and Insular Affairs, the Subcommittee on Energy and Power of the House Committee on Interstate and Foreign Commerce, and the Subcommittee on Environment, Energy and Natural Resources of the House Committee on Government Operations will be informed.
- c. That a letter will be sent to each construction permit holder and to each licensee affected by the rule informing them of the requirements of the rule.
- d. The information collection requirements in this proposed rule will be submitted to the Office of Management and Budget as part of the general clearance for 10 CFR 50.

ling: Recommend affirmation at an open meeting.



William J. Dircks  
Executive Director for Operations

- ures:
- Background Information Related to QA Program Changes
  - Federal Register Notice of Proposed Rulemaking
  - Value/Impact Assessment
  - Analysis with Respect to Review of Regulations

Commissioners' comments or consent should be provided directly to the Office of the Secretary by c.o.b. Thursday, June 4, 1981.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT May 28, 1981, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

This paper is tentatively scheduled for affirmation at an open meeting during the week of June 8, 1981. Please refer to the appropriate Weekly Commission Schedule, when published, for a specific date and time.

DISTRIBUTION

- Commissioners
- Commission Staff Offices
- Exec Dir for Operations
- ACRS
- ASLBP
- Secretariat



ENCLOSURE "A"

## BACKGROUND INFORMATION RELATED TO QA PROGRAM CHANGES

1. Since early 1980 the Standard Review Plan (SRP) has contained a provision whereby the applicant (and each holder of an NRC-approved QA Topical Report, is requested to commit to the following staff position:

"(17.1.II)2B2. Provisions are included for notifying NRC of changes (1) for review and acceptance in the accepted description of the QA Program as presented or referenced in the SAR or SSAR prior to implementation, and (2) in organizational elements within 30 days after announcement. (Note: editorial changes or personnel reassignments of a non-substantive nature do not require NRC notification.)"

The above provision of the SRP was not made retroactive to cover existing CP holders and licensees, thus creating a double standard whereby some licensees are committed to report QA Program changes while others are not.

2. A limited sampling of IE inspection experience reflected in docketed inspection reports shows cases where licensees have made substantive changes to their QA Program without notifying the NRC. Examples are:
  - a. At the Hatch facility, Georgia Power & Light Company unilaterally revised its QA Program commitments to ANSI N45.2.3, "Housekeeping During the Construction Phase of Nuclear Power Plants," and ANSI 45.2.12, "Requirements for Auditing of Quality Assurance

Programs for Nuclear Power Plants." The licensee's basis for not notifying the NRC was that the matter did not comprise an unreviewed safety question per 10 CFR 50.59.

- b. At the Shearon Harris facility, Carolina Power & Light Company changed its QA Program commitments with regard to organization such that the potential existed for quality control inspectors to perform audits of their own, previously completed inspection activities.

Action has been taken or is in process to resolve the above as a result of IE identification of the problems.

3. There have been a number of cases where licensees have been ineffective in implementing their QA Program commitments as presented in the SAR. Some of these have resulted in the issuance of NRC Orders as well as requirements for the licensees to make substantial changes to their QA Programs as part of the required corrective actions. These examples illustrate the importance of changes to the quality assurance program and the importance of NRC awareness and evaluation of such changes. Examples are:

- a. The South Texas Project of Houston Lighting and Power Company. In its response to NRC's Show Cause Order, the licensee included a number of major changes to its quality assurance program which it considered necessary.

- b. The Marble Hill Project of Public Service of Indiana. In response to NRC's Order Confirming Suspension of Construction, the licensee made major changes to its quality assurance program.
  
- c. In an inspection of TVA nuclear activities, NRC inspectors determined that, contrary to SAR commitments, quality assurance personnel did not have sufficient organizational freedom and TVA management was not giving adequate support to quality assurance. In its response to these findings, TVA made substantial changes to its QA Program including elevating the organizational reporting level of quality assurance personnel.

ENCLOSURE "B"

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

Reporting of Changes to the Quality Assurance Program

AGENCY: Nuclear Regulatory Commission

ACTION: Proposed Rule

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations to require holders of nuclear power plant construction permits and holders of operating licenses to implement the approved quality assurance program and to inform the Commission in writing of certain quality assurance program changes which affect the description of the quality assurance program included in their Safety Analysis Report and accepted by the Commission, within 30 days of making any such change. The amendments will provide greater assurance that quality assurance programs approved by the Commission do not have their effectiveness reduced by subsequent changes.

DATES: Comments should be submitted on or before (60 days after publication). Comments received after this date will be considered if it is practical to do so; but assurance of consideration cannot be given except as to comments received on or before that date.

ADDRESSES: Written comments should be submitted to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.  
Attention: Docketing and Service Branch.



FOR FURTHER INFORMATION CONTACT: Steven D. Richardson, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone 301-443-5987.

SUPPLEMENTARY INFORMATION: The quality assurance (QA) requirements of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," are one of the cornerstones of the Commission's "defense-in-depth" concept for ensuring safe operation of nuclear power plants.

Because of the importance of the QA program as a management tool to attain objectives important to nuclear safety, the NRC staff conducts extensive reviews during the licensing process to ensure that the applicant's QA program description satisfies 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." Following acceptance by the NRC staff, the QA program description is then used as a principal inspection and enforcement tool in ensuring that the permit holder or licensee is in compliance with all NRC quality assurance requirements for protecting the public health and safety.

As indicated in paragraph (a)(7) of 10 CFR § 50.34, "Contents of applications, technical information," the Preliminary Safety Analysis Report (PSAR) must include "a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility." Similarly, § 50.34(b)(6)(ii) requires that the Final Safety Analysis Report (FSAR) describe "managerial and administrative controls to be used to assure safe operation" and that it "include a discussion of how the applicable requirements of Appendix B [Quality Assurance Criteria] will be satisfied." The QA programs described in the safety analysis reports are intended to represent the QA programs actually being applied in practice.

Because existing regulations do not specifically include a requirement that changes to the accepted QA program be reported to the Commission, some licensees have been changing the QA program without informing the Commission. In several cases, this has resulted in QA programs which were not acceptable to the NRC staff and which did not conform to all aspects of the NRC regulations. The primary concern with the current situation is that unreported changes to the QA program which could affect the QA program description finally approved by the NRC might diminish the effectiveness of the program permitting significant deficiencies to arise in the design, fabrication, construction or operation of the facility. This could result in increased risk to the public health and safety.

The proposed amendments would require that construction permit holders and licensees implement the approved quality assurance program, provide a current description of the program, evaluate all changes to the approved program and, for certain changes that meet the criteria in the rule submit the evaluation to the NRC for review.

#### REGULATORY FLEXIBILITY ACT CERTIFICATION

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121.

Accordingly, notice is hereby given that, pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendment to 10 CFR Part 50 is contemplated.

PART 50 - DOMESTIC LICENSING OF  
PRODUCTION AND UTILIZATION FACILITIES

1. Section 50.54 of 10 CFR Part 50 is revised by adding a new paragraph (a) to read as follows:

§ 50.54 Conditions of licenses.

\* \* \* \* \*

(a)(1) Each licensee shall implement the quality assurance program described or referenced in the Safety Analysis Report and modified by changes thereto.

(2) Each licensee shall submit to the appropriate NRC Regional Office within 90 days of the effective date of this regulation the current description of the quality assurance program unless the description previously approved has not been changed.

(3) After the effective date of this rule, the licensee may make changes to a previously submitted quality assurance program description, provided the change does not decrease the effectiveness of the program such that the revised program no longer meets the criteria of Appendix B of 10 CFR Part 50. Prior to making any change to a previously submitted QA program description, the licensee shall prepare a written evaluation identifying the change, the reason for the change, and the basis for concluding that the change satisfies the criteria of Appendix B of 10 CFR

Part 50. A copy of this evaluation shall be maintained at the facility for three years.

(4) For changes made to the quality assurance program affecting the program description included in the Safety Analysis Report which (i) change or affect the authority, independence, or management reporting levels previously established for organizations or persons performing quality assurance functions; or (ii) change or affect the controls previously established over activities affecting the quality of the nuclear power plant structures, systems, and components, the evaluation described in paragraph (3) shall be submitted within 30 days of making any such change to the appropriate NRC Regional office shown in Appendix D of Part 20 of this chapter, with one copy sent to the Resident Inspector and one copy sent to the Chief of the Document Management Branch, TIDC, ADM, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

\* \* \* \* \*

2. Section 50.55 of 10 CFR Part 50 is revised by adding a new paragraph (f) to read as follows:

§ 50.55 Conditions of construction permits.

\* \* \* \* \*

(f)(1) Each construction permit holder shall implement the quality assurance program described or referenced in the Safety Analysis Report and modified by changes thereto.

(2) Each permit holder shall submit to the appropriate NRC Regional office within 90 days of the effective date of this regulation the current description of the quality assurance program unless the description previously approved has not been changed.

(3) After the effective date of this rule, the permit holder may make changes to a previously submitted quality assurance program description,



provided the change does not decrease the effectiveness of the program such that the revised program no longer meets the criteria of Appendix B of 10 CFR Part 50. Prior to making any change to a previously submitted QA program description, the permit holder shall prepare a written evaluation identifying the change, the reason for the change, and the basis for concluding that the change satisfies the criteria of Appendix B of 10 CFR Part 50. A copy of this evaluation shall be maintained at the facility for three years.

(4) For changes made to the quality assurance program affecting the program description included in the Safety Analysis Report which (i) change or affect the authority, independence, or management reporting levels previously established for organizations or persons performing quality assurance functions; or (ii) change or affect the controls previously established over activities affecting the quality of the nuclear power plant structures, systems, and components, the evaluation described in paragraph (3) shall be submitted within 30 days of making any such change to the appropriate NRC Regional office shown in Appendix D of Part 20 of this chapter, with one copy sent to the Resident Inspector and one copy sent to the Chief of the Document Management Branch, TIDC, ADM, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

\* \* \* \* \*

(Secs. 103, 104, 161o., Pub. L. 83-703, 68 Stat. 936, 937, 948; Sec. 201, as amended, Pub. L. 93-438, 88 Stat. 1242 (42 U.S.C. 2133, 2134, 2201(o), 5841)).

Dated at Washington, D.C. the \_\_\_\_\_ day of \_\_\_\_\_, 1981.

For the Nuclear Regulatory Commission.

\_\_\_\_\_  
Samuel J. Chilk  
Secretary of the Commission

ENCLOSURE "C"



## VALUE/IMPACT ASSESSMENT

### Revision to 10 CFR Part 50 Regarding Reporting of Changes to Quality Assurance Programs

#### 1. PROPOSED ACTION

##### 1.1 Description

The proposed action is to initiate rulemaking to revise 10 CFR Part 50, Section 50.54, "Conditions of licenses" and Section 50.55, "Condition of construction permits" to require licensees and construction permit holders, respectively, to implement the approved quality assurance program and to identify to the Commission certain changes made to their quality assurance programs which affect the quality assurance program descriptions included in their Safety Analysis Report (SAR).

##### 1.2 Need for Proposed Action

The quality assurance requirements of 10 CFR Part 50 are one of the cornerstones of the NRC defense-in-depth concept for quality construction and safe operation of nuclear power plants.

Due to the importance of the quality assurance program as a management tool to attain objectives important to nuclear safety, the NRC staff conducts extensive reviews during the licensing process to assure that the applicant's QA Program satisfies 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." With staff acceptance, the applicant's QA Program is then used as a principal inspection and enforcement tool in ensuring that the applicant/licensee is in compliance with all NRC requirements important to assuring public health and safety.

Current rules are not specific on whether or not a licensee is required to notify the NRC of changes to the QA Program previously accepted by the staff. Additionally, current regulations do not explicitly require licensees or permit holders to implement the approved program. However, as discussed under 10 CFR 50.34, it is intended that the QA Program described in the SAR, and not unreviewed changes thereto, be applied to the design, fabrication, construction and testing

of structures, systems, and components of the facility. Consistent with this intent, the staff included criteria in the 1979 revision of the Standard Review Plan (Enclosure A, Item 1) that changes to the accepted QA Program description referenced or presented in the SAR be submitted to NRC for review and approval prior to implementation.

The review procedures in effect since 1979 apply to new license applications and the annual review of topical reports. However, they are not sufficient in that those utilities licensed prior to 1979 have not been required to make such commitments, nor is such a commitment, once made, subject to the full range of enforcement options.

This lack of a commitment exists because current regulations do not specifically include a requirement that changes to the QA Program described in the SAR be submitted to the NRC for review and approval prior to implementation.

A major concern is that an unreviewed relaxation of the QA Program described in the SAR could diminish the effectiveness of the QA program and permit significant deficiencies to arise in the design, fabrication, construction or operation of the nuclear facility.

### 1.3 Value/Impact of Proposed Action

#### 1.3.1 NRC

Value - The proposed action will provide a positive regulatory basis from which the NRC can be kept aware of and evaluate changes to licensees' quality assurance programs. Current regulations are unclear in this regard.

Impact - The proposed action will represent on a case-by-case basis an increase in the review of and follow up action with respect to changes to licensees' quality assurance programs. It is estimated that staff resources of approximately one person-day per change report will be required and that each utility will submit approximately two such changes per year.

#### 1.3.2 Other Government Agencies

Not applicable unless the government agency is an applicant or a licensee, such as TVA.

### 1.3.3 Industry

Value - The proposed action will clarify the NRC staff position regarding the types of changes to licensees' and applicants' quality assurance programs that can be made without informing the NRC.

Impact - It is estimated that approximately one person-day per quality assurance program change will be required. It is also estimated that each utility will submit to the NRC reports of two changes per year.

### 1.3.4 Public

Value - Unreported changes to licensees' and applicants' quality assurance programs that could diminish the effectiveness of the quality assurance program would be minimized thus increasing plant safety and reliability.

Impact - No impact on the public is foreseen.

### 1.3.5 Workers (Relative to ALARA)

Not applicable.

## 1.4 Decision on Proposed Action

Requirements should be provided in 10 CFR Part 50 to require that applicants and licensees implement the approved quality assurance program and inform the NRC of changes to their quality assurance programs.

## 2. ALTERNATIVE APPROACHES

Although alternative methods for obtaining information on changes to licensee or construction permit holder quality assurance programs are available (such as by means of a Regulatory Guide), rulemaking has been adopted in order to impose a specific, enforceable requirement for reporting such information.

## 3. STATUTORY CONSIDERATION

This rulemaking would fall under the Commission's authority under the Atomic Energy Act to impose requisite safety requirements on licensees and permit holders under sections 103 and 104 of the Act, and require appropriate reports under section 161o.

4. NEED FOR NEPA ASSESSMENT

The proposed action is not a major action, as defined by 10 CFR Part 51.5(a)(10), and does not require an environmental impact assessment.

5. RELATIONSHIP TO OTHER EXISTING OR PROPOSED REGULATIONS OR POLICIES

No conflicts or overlaps with requirements promulgated by other agencies are foreseen.

6. SUMMARY AND CONCLUSIONS

A revision to 10 CFR Part 50 should be prepared to require that construction permit holders and licensees implement the approved quality assurance program and inform the NRC of changes to their quality assurance programs.

ENCLOSURE "D"



ANALYSIS WITH RESPECT TO PERIODIC SYSTEMATIC REVIEW OF REGULATIONS  
(TMI ACTION PLAN TASK IV.G.2)

SUBJECT: Reporting of Changes to Quality Assurance Programs

Criteria for Periodic and Systematic Review  
of Regulations

NRC Compliance

- |   |  |
|---|--|
| 1. The proposed regulations are needed.   | The need for the proposed regulation are discussed in the Value/Impact Assessment prepared in connection with the rulemaking (Enclosure C).  |
| 2. The direct and indirect effects of the regulations have been adequately considered.                                  | The direct and indirect effects of this rulemaking were considered in the Value/Impact Analysis prepared in connection with the proposed rule. (See Enclosures C).   |
| 3. Alternative approaches have been considered and the least burdensome of the acceptable alternatives has been chosen. | Although alternative methods for obtaining information on changes to licensee and construction permit holder quality assurance programs are available (such as by means of a Regulatory Guide), rulemaking has been adopted in order to impose a specific, enforceable requirement for reporting such information. |
| 4. Public comments have been considered and an adequate response has been prepared.                                     | The proposed revisions are being issued for public comment.  |
| 5. The regulation is written in plain English and is understandable to those who must comply with it.                   | The proposed amendments have been reviewed and edited for the specific purpose of ensuring that the regulation is clear and can be understood by persons who are required to comply with it.   |



SUBJECT: Reporting of Changes to Quality Assurance Programs

Criteria for Periodic and Systematic Review  
of Regulations

NRC Compliance

6. An estimate has been made of the new reporting burdens or recordkeeping requirements necessary for compliance with the regulation.
7. The name, address, and telephone number of a knowledgeable agency official is included in the publication.
8. A plan for evaluating the regulation after its issuance has been developed.

Such an estimate has been included in the Value/Impact Assessment prepared in connection with the rulemaking (Enclosure C).

The Federal Register notice promulgating the rule contains the name, address, and telephone number of a knowledgeable agency official.

This regulation will be reviewed in the second cycle of NRC's periodic and systematic review process (1986-1991).

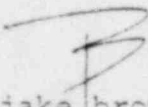
TRANSMITTAL TO:  Document Control Desk,  
016 Phillips

ADVANCED COPY TO:  The Public Document Room

DATE: June 12, 1981

Attached are the PDR copies of a Commission meeting transcript/s/ and related meeting document/s/. They are being forwarded for entry on the Daily Accession List and placement in the Public Document Room. No other distribution is requested or required. Existing DCS identification numbers are listed on the individual documents wherever possible.

1. Transcript of: Affirmation/Discussion Session 81-22, June 11, 1981. (1 copy)
  - a. SECY Paper - Rulemaking Issue. SECY-81-316 dated May 19, 1981 from W. Dircks to the Commissioners, Subj: Reporting of Changes to Quality Assurance Programs. (1 copy)

  
jake brown  
Office of the Secretary

