ADAMS Template: SECY-067

DOCUMENT DATE:

TITLE: PR-050, 052 AND 072 - 63FR56098 - CHANGES TESTS AND EXPERIMENTS

CASE REFERENCE: PR-050, 052 AND 072
63FR56098

KEY WORD: RULEMAKING COMMENTS

Document Sensitivity: Non-sensitive - SUNSI Review Complete

CHANGES, TESTS, AND EXPERIMENTS

63FR56098

PR-050, 052 AND

MENTNO	DOCDATE	DKTDATE	NAME	REPRESENT	DOCDESC1
	10/14/1998	10/19/1998			
1	11/03/1998	11/09/1998	PAUL SICARD	SELF	
2	11/03/1998	11/09/1998	BRENDAN C. RYA	SELF	
3	11/18/1998	11/27/1998	KURT T SCHAEF	SELF	
	11/23/1998	11/30/1998			LTR FM BRENDAN C. RYA APPLIED TO INCORRECT R 63FR43516)
	12/02/1998	12/02/1998			LTR FM JULIAN TO BREND COMMENT LTR OF 11/03/98 CORRECT DOCKET
4	12/11/1998	12/16/1998	S. K. GAMBHIR	OMAHA PUBLIC PO	
6	12/17/1998	12/18/1998	STEVEN A. TOELL	UNITED STATES EN	

IMENTNO	DOCDATE	DKTDATE	NAME	REPRESENT	DOCDESC1
7	12/17/1998	12/18/1998	MICHAEL L. CRO	LOCKHEED MARTI	
5	12/18/1998	12/18/1998	IAN C. RICKARD	ABB COMBUSTION	
13	12/17/1998	12/21/1998	JAMES P. O'HANL	VIRGINIA POWER	
12	12/18/1998	12/21/1998	RICHARD F. PHA	ILLINOIS POWER C	
11	12/21/1998	12/21/1998	STEVEN P. FRANT	ALLIANT UTILITIES	
10	12/18/1998	12/21/1998	JAMES F. MALLA	SIEMENS POWER C	
14	12/18/1998	12/21/1998	SHERRY BERNHO	FLORIDA POWER C	
9	12/17/1998	12/21/1998	BRIAN GUTHERM	HOLTEC INTERNAT	
8	12/18/1998	12/21/1998	J. BARNIE BEASL	SOUTHERN NUCLE	
15	12/18/1998	12/21/1998	KENNETH E. PEV	ALLIANT UTILITIES	

MENTNO	DOCDATE	DKTDATE	NAME	REPRESENT	DOCDESC1
16	12/21/1998	12/21/1998	DANIEL F. STENG	NUCLEAR UTILITY	
20	12/18/1998	12/22/1998	DONNA B. ALEXA	CAROLINA POWER	
17	12/17/1998	12/22/1998	MICHAEL R. KAN	ENTERGY OPERATI	
23	12/21/1998	12/22/1998	WILLIAM A. HORI	NUCLEAR UTILITY	
19	12/18/1998	12/22/1998	LESTER A. SLABA	SELF	
26	12/21/1998	12/22/1998	NORMAN K. PETE	DETROIT EDISON	
21	12/18/1998	12/22/1998	TED C. FEIGENBA	NORTH ATLANTIC	
22	12/21/1998	12/22/1998	ANTHONY R. PIE	NUCLEAR ENERGY	
25	12/21/1998	12/22/1998	J. F. QUIRK	GENERAL ELECTRI	
24	12/21/1998	12/22/1998	R. M. KRICH, VIC	COMMONWEALTH	

MENTNO	DOCDATE	DKTDATE	NAME	REPRESENT	DOCDESC1
27	12/21/1998	12/22/1998	PAUL A. GAUKLE	SHAW PITTMAN PO	
18	12/18/1998	12/22/1998	LARRY A. GRIME	LARRY A. GRIME A	
31	12/21/1998	12/23/1998	DAVID R. POWEL	PUBLIC SERVICE E	
30	12/21/1998	12/23/1998	GEORGE A. ZINK	MAINE YANKEE AT	
29	12/21/1998	12/23/1998	EDWARD D FULL	BFNL FUEL SOLUTI	
28	12/21/1998	12/24/1998	DUPLICATE OF C	NUCLEAR UTILITY	
32	12/17/1998	12/28/1998	JOHN M. ODDO	YANKEE ATOMIC E	
42	12/17/1998	12/28/1998	RAJIV S. KUNDAL	FLORIDA POWER &	
46	12/21/1998	12/28/1998	MARTIN L BOWL	NORTHEAST NUCL	
45	12/21/1998	12/28/1998	H. A. SEPP	WESTINGHOUSE EL	

MENTNO	DOCDATE	DKTDATE	NAME	REPRESENT	DOCDESC1
44	12/18/1998	12/28/1998	M. S. TUCKMAN,	DUKE ENERGY COR	
43	12/18/1998	12/28/1998	JAMES M. LEVINE	ARIZONA PUBLIC S	
41	12/21/1998	12/28/1998	MATTHEW A .PET	SELF	
39	12/21/1998	12/28/1998	BRADFORD L. HO	NEBRASKA PUBLIC	
38	12/21/1998	12/28/1998	CHARLES H. CRU	BALTIMORE GAS A	
37	12/21/1998	12/28/1998	JOHN C. FORNICO	GPU NUCLEAR, INC.	
36	12/20/1998	12/28/1998	LYNNE GOODMA	SELF	
35	12/18/1998	12/28/1998	ROBERT C. MECR	ROCHESTER GAS A	
34	12/18/1998	12/28/1998	BILL ELLIS	SELF	
33	12/17/1998	12/28/1998	LEW W. MYERS,	THE PERRY NUCLE	

IMENTNO	DOCDATE	DKTDATE	NAME	REPRESENT	DOCDESC1
40	12/21/1998	12/28/1998	ALAN C. PASSWA	AMEREN UE	
51	12/21/1998	12/29/1998	GARY J. TAYLOR,	SOUTH CAROLINA	
48	12/21/1998	12/29/1998	GARRETT D. EDW	PECO ENERGY COM	
47	12/18/1998	12/29/1998	JAMES S. BAUMS	CONSOLIDATED ED	
52	12/21/1998	12/29/1998	MICHAEL D. WAD	NORTHERN STATES	
53	12/21/1998	12/29/1998	C. LANCE TERRY,	TU ELECTRIC	
54	12/21/1998	12/29/1998	M. A. MCBURNET	STP NUCLEAR OPE	
50	12/21/1998	12/29/1998	A. EDWARD SCHE	SOUTHERN CALIFO	
55	12/18/1998	12/29/1998	RICHARD A. MUE	WOLF CREEK NUCL	
49	12/21/1998	12/29/1998	JAMES KNUBEL,	NEW YORK POWER	

MENTNO	DOCDATE	DKTDATE	NAME	REPRESENT	DOCDESC1
56	12/29/1998	12/31/1998	RICHARD C. L. OL	SELF	
57	12/21/1998	01/04/1999	MARK J. BURZYN	TENNESSEE VALLE	
59	12/22/1998	01/11/1999	CARL D. TERRY,	NIAGARA MOHAW	
58	12/22/1998	01/11/1999	NATHAN L. HASK	CONSUMERS ENER	
60	03/16/1999	03/23/1999	ALAN NELSON	SELF	
61	04/16/1999	04/19/1999	JAMES C. KILPAT	SELF	
62	04/30/1999	05/10/1999	ANTHONY R. PIE	NUCLEAR ENERGY	
63	06/14/1999	06/21/1999	FAWN SHILLINGL	SELF	
	06/21/1999	06/24/1999			LTR FM FAWN SHILLINGL CORRECTION TO COMMEN
	06/18/1999	07/02/1999			LTR FM FAWN SHILLINGL WHY SHE HAS NOT BEEN N PRM-72-3 HAD BEEN INCO

MMENTNO	DOCDATE	DKTDATE	NAME	REPRESENT	DOCDESC1
	09/20/1999	09/22/1999			FINAL RULE PUBLISHED O
	12/06/2000	12/27/2000			CONFIRMATION OF EFFEC GUIDANCE FOR FINAL RUL 65FR77773

7590-01-P

Nuclear Regulatory Commission

10 CFR Part 72

RIN 3150-AF94

Changes, Tests, and Experiments; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; correction.

SUMMARY: This document is necessary to correct three erroneous Federal Register citations appearing in a document published on February 26, 2001 (66 FR 11527).

FOR FURTHER INFORMATION CONTACT: Jayne McCausland, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, telephone 301-415-6219, e-mail: jmm@nrc.gov.

SUPPLEMENTARY INFORMATION:

On page 11527, in the first column, in the SUMMARY paragraph, in the third line, "65" is corrected to read "64."

On page 11527, in the first column, in the Background paragraph, in both the first and last lines of the paragraph, "64" is corrected to read "63".

Dated at Rockville, Maryland, this 14th day of June 2001.

For the Nuclear Regulatory Commission.

Alzonia W. Shepard

Alzonia W. Shepard, Acting Chief,
Rules and Directives Branch,
Division of Administrative Services,
Office of Administration.

pub. on 6/20/01
at 66FR 33013

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DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63 FR 56098)

[7590-01-P]

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

RIN 3150-AF94

Changes, Tests, and Experiments; Corrections

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; correcting amendments.

SUMMARY: This document corrects a final rule appearing in the Federal Register on October 4, 1999 (65 FR 53582). This action to correct two editorial errors is necessary for clarity and consistency in the regulations.

DATES: Effective on April 5, 2001.

FOR FURTHER INFORMATION CONTACT: Jayne McCausland [telephone (301) 415-6219, e-mail JMM2@nrc.gov] of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

pub. on 2/26/01
at 66 FR 11527

Background

On October 21, 1998 (64 FR 56098), a proposed rule to revise the "Changes, Tests, and Experiments" regulations was published in the Federal Register, and on October 4, 1999 (65 FR 53582), the NRC published the final rule. The purpose of the rule was to revise §§ 50.59 and 72.48 to reduce regulatory burden and enhance clarity between the regulations in Parts 50 and 72. After the final rule was published, two minor editorial errors were discovered in § 72.48. Industry identified one error in paragraph (c)(2)(iii) and NRC identified the other error in (c)(2)(vii). In paragraph (c)(2)(iii), the term "(as updated)" was omitted. This term had been used in the proposed rule issued on October 21, 1998 (64 FR 56098), and no public comments had been received on its use. In paragraph (c)(2)(vii), the phrase "as described in the FSAR" had been mispositioned in the sentence, resulting in an inconsistency between this section and § 50.59(c)(2)(vii), which issues the same criterion.

Need for Corrections

As published, the final rule entitled "Changes, Tests, and Experiments" (64 FR 53582; October 4, 1999) contains errors which may prove to be misleading and need to be clarified.

List of Subjects in 10 CFR Part 72

Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Reporting and recordkeeping requirements, Security measures, Spent fuel.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendment to 10 CFR Part 72.

PART 72–LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE

1. The authority citation for Part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95 - 601, sec. 10, 92 Stat. 295 as amended by Pub. L. 102-486, sec 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91-190, 83 Stat. (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97-425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100-203, 101 Stat. 1330 - 235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100-203, 101 Stat. 1330 - 232, 1330 - 236 (42 U.S.C. 10162(b), 10168(c), (d). Section 72.46 also issued under sec. 189, 68 Stat. 935 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100-203; 101 Stat. 1330 -235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97-425, 96 Stat. 2202, 2203, 2204, 2222, 2244 (42 U.S.C. 10101, 10137(a), 10161(h). Subparts K and L are also issued under sec. 133, 96 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

2. In § 72.48, paragraphs (c)(2)(iii) and (c)(2)(vii) are revised to read as follows

§ 72.48 Changes, tests, and experiments.

★ ★ ★ ★ ★

(c) ★ ★ ★

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the FSAR (as updated);

★ ★ ★

(vii) Result in a design basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered; or

★ ★ ★ ★ ★

Dated at Rockville, Maryland, this 21st day of February, 2001.

For the Nuclear Regulatory Commission.

Michael T. Lesar

Michael T. Lesar, Acting Chief
Rules and Directives Branch,
Division of Administrative Services,
Office of Administration.

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150-AF94

Changes, Tests, and Experiments: Confirmation of Effective Date and Availability of Guidance

AGENCY: Nuclear Regulatory Commission

ACTION: Final Rule: Confirmation of effective date and availability of guidance.

SUMMARY: The Nuclear Regulatory Commission amended its regulation concerning changes, tests, and experiments for nuclear reactors on October 4, 1999 (64 FR 53582). The effective date of this amendment was deferred until guidance on implementation of the revised provisions of the rule was issued to reactor licensees. This document announces the availability of that guidance (Regulatory Guide 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments") and specifies the effective date for the October 4, 1999, amendment to section 50.59.

EFFECTIVE DATE: [~~INSERT DATE 90 DAYS FROM PUBLICATION~~ March 13, 2001]

ADDRESSES: Regulations, certain regulatory guides, and certain endorsed NEI documents are available for inspection or downloading at the NRC's web site, WWW.NRC.GOV. Single copies of regulatory guides may be obtained free of charge by writing the Reproduction and Distribution Services Section, U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by fax to (301) 415-2289, or by email to DISTRIBUTION@NRC.GOV. Issued guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5285 Port Royal Road, Springfield, VA 22161. Copies of regulations, regulatory guides, and endorsed NEI documents

pub. on 12/13/00
at 65FR 77773

are available for inspection or copying for a fee from the NRC's Public Document Room at 11555 Rockville Pike, Rockville, MD, 20852; the PDR's mailing address is Public Document Room, Washington DC 20555; telephone (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; email PDR@NRC.GOV.

Comments and suggestions in connection with items for inclusion in regulations or regulatory guides are encouraged at any time. Written comments may be submitted to the Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington DC 20555.

FOR FURTHER INFORMATION CONTACT: E. M. McKenna, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555; telephone (301) 415-2189; email EMM@NRC.GOV.

SUPPLEMENTARY INFORMATION:

Background

The Nuclear Regulatory Commission amended its rule, 10 CFR 50.59, "Changes, Tests, and Experiments" on October 4, 1999 (64 FR 53582). This amendment clarified the rule requirements, and also provided licensees greater flexibility to make certain changes without NRC approval that involve only minimal increases in likelihood or consequences of events. The implementation date of this amendment was made dependent upon guidance being issued to nuclear reactor licensees on implementing the revised requirements.

Regulatory Guide 1.187 endorses a document prepared by the Nuclear Energy Institute (NEI), NEI 96-07, Revision 1, dated November 2000. Regulatory Guide 1.187 was published for public comment (65 FR 24231) as DG-1095, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments". The comments submitted by licensees and other commenters were addressed by revisions made by NEI to NEI 96-07, Revision 1, as submitted in November 2000; the NRC staff concurs in these revisions.

Therefore, the effective date of the October 4, 1999, amendment to 10 CFR 50.59 is March 13, 2001 [i~~nsert date 90 days from publication of this notice~~].

Dated at Rockville, Maryland, this 6th day of December 2000

For the Nuclear Regulatory Commission

Annette Vietti-Cook

Annette Vietti-Cook
Secretary of the Commission

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 72

RIN 3150-AF94

Changes, Tests, and Experiments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations concerning the authority for licensees of production or utilization facilities, such as nuclear reactors, and independent spent fuel storage facilities, and for certificate holders for spent fuel storage casks, to make changes to the facility or procedures, or to conduct tests or experiments, without prior NRC approval. The final rule clarifies the specific types of changes, tests, and experiments conducted at a licensed facility or by a certificate holder that require evaluation, and revises the criteria that licensees and certificate holders must use to determine when NRC approval is needed before such changes, tests, or experiments can be implemented. The final rule also adds definitions for terms that have been subject to differing interpretations, and reorganizes the rule language for clarity. Additionally, the final rule grants in part and denies in part, a petition for rulemaking (PRM-72-3) submitted by Ms. Fawn Shillinglaw on December 9, 1995. This notice constitutes final NRC action on this petition.

EFFECTIVE DATE: Sections 72.3, 72.9, 72.24, 72.56, 72.70, 72.80, 72.86, 72.244, 72.246, 72.248 of this rule are effective [I~~NSERT DATE 120 DAYS FROM DATE OF PUBLICATION].~~
February 1, 2000

Pub. on 10/4/99
at 64FR53582

Sections 50.59, 50.66, 50.71(e), and 50.90 become effective 90 days after issuance of applicable regulatory guidance. The NRC will publish a document in the Federal Register that announces the issuance of the regulatory guidance and specifies that the final rule becomes effective in 90 days]. Sections 72.212 and 72.48 are effective [~~INSERT DATE 18 MONTH~~S ~~FROM DATE OF PUBLICATION~~]. April 5, 2001

FOR FURTHER INFORMATION CONTACT: Eileen McKenna, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-2189; e-mail: emm@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

II. Comments and resolution on proposed rule topics

A. Organization of the rule requirements

B.1 Definition of change

B.2 Definition of facility as described in the final safety analysis report

C. Change to the procedures as described in the final safety analysis report

D. Tests and experiments not described in the final safety analysis report

E. Safety analysis report

F. Minimal increase principle

G.1 Frequency of occurrence of an accident

G.2 Likelihood of occurrence of malfunction of structure, system, or component important to safety previously evaluated

G.3 Consequences of an accident or malfunction of structure, system, or component important to safety previously evaluated

H. Possibility of an accident of a different type from any previously evaluated in the final safety analysis report (as updated) is created

I. Possibility of a malfunction of a structure, system, or component with a different result from any previously evaluated in the final safety analysis report (as updated) is created

J. Replacement criteria for "margin of safety as defined in the basis for any technical specification is reduced"

K. Safety evaluation

L. Reporting and recordkeeping requirements

M. No significant hazards consideration determination

N. Part 52 changes

O.1 Part 72 changes

O.2 Petition PRM-72-3

O.3 Part 71 Comments

P. Other topics discussed in the proposed rule notice

Q Enforcement policy

R. Implementation

III. Section by section analysis

IV Finding of no significant environmental impact

V. Paperwork Reduction Act statement

VI Regulatory analysis

VII. Regulatory Flexibility Certification

VIII. Backfit analysis

I. Background

The existing requirements governing the authority of production and utilization facility licensees to make changes to their facilities and procedures, or to conduct tests or experiments, without prior NRC approval are contained in 10 CFR 50.59. Comparable provisions exist in § 72.48 for licensees of facilities for the independent storage of spent nuclear fuel and high-level radioactive waste. These regulations provide that licensees may make changes to the facility or procedures as described in the safety analysis report (SAR), or conduct tests or experiments not described in the safety analysis report, without prior Commission approval, unless the proposed change, test, or experiment involves a change to the Technical Specifications (TS) incorporated in the license or an unreviewed safety question. Section 50.59(a)(2), as codified, states the following:

> A proposed change, test, or experiment shall be deemed to involve an unreviewed safety question (i) if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report may be increased; or (ii) if a possibility for an accident or malfunction of a different type than any evaluated

previously in the safety analysis report may be created; or (iii) if the margin of safety as defined in the basis for any technical specification is reduced.

The rule also specifies recordkeeping and reporting requirements associated with such changes, tests, or experiments.

Section 50.59 was promulgated in 1962 to allow licensees to make certain changes that affect systems, structures, components (SSC), or procedures described in the SAR without prior approval, provided certain conditions were met. In 1968, the rule was revised to modify some of the criteria for determining whether prior NRC approval was required. The intent of the § 50.59 process is to permit licensees to make changes to the facility, provided the changes maintain acceptable levels of safety as documented in the SAR. The process was thus structured around the licensing approach of design basis events (anticipated operational occurrences and accidents), safety-related mitigation systems, and consequence calculations for the design basis accidents.

On October 21, 1998 (63 FR 56098), the NRC published a proposed rule to revise §§ 50.59 and 72.48 to address a number of issues concerning implementation of the current rule, and suitability of the criteria used to determine when an unreviewed safety question exists. Conforming changes were proposed in other portions of the regulations, including §§ 50.66, 50.71(e), and 50.90 for production and utilization facilities licensed under Part 50. Conforming changes were also proposed in § 72.212(b)(4).

The Commission proposed to make similar changes to Appendices A and B of Part 52, the standard design certifications for the ABWR and CE System 80+ designs respectively.

These regulations contain a change control process similar to that in § 50.59. As noted in Section N, "Part 52 changes" below, the Commission has decided to defer consideration of any changes to Part 52 until a later date.

In addition, the Commission proposed to make parallel changes applicable to independent spent fuel storage installations (ISFSIs) licensed in accordance with Part 72. As part of the proposed changes to Part 72, the Commission also proposed to extend the change control authority granted to ISFSI or monitored retrievable storage (MRS) license holders (in § 72.48) to holders of NRC Certificates of Compliance (CoC) for a spent fuel storage cask design.

II. Comments and Resolution on Proposed Rule Topics

The 60-day comment period for the proposed rule closed on December 21, 1998. Comments were received from 60 organizations or individuals. Copies of the comments are available for public inspection and copying for a fee at the Commission's Public Document Room, located at 2120 L Street, N.W., Washington D.C. All comments were considered in formulating the final rule. The comments were submitted by 35 utilities with power reactor facilities; 2 representatives of nonpower reactor licensees; 3 law firms representing several utilities; 2 submittals from the Nuclear Energy Institute (NEI); the U. S. Enrichment Corporation; a nuclear industry group; 6 nuclear utility vendors, service companies or consultants; 4 vendors or service companies for spent fuel storage casks; and 6 individuals. Forty commenters endorsed (sometimes with further comments) the NEI comments. NEI stated in its comment letter that it generally supports the Commission's intent of the proposed rule but had a number of comments or modifications for certain specific provisions of the rule that it wished the Commission to consider in preparing the final rule. Of those commenters who did not endorse the NEI comments, most supported the concept of the proposed rule, and made recommendations to enhance or modify certain elements of the rule. A few commenters stated that the rule revision was unnecessary and presented supporting arguments. These commenters felt that the Commission should endorse NEI 96-07 "Guidelines for 10 CFR 50.59 Safety Evaluations," as being sufficient to satisfy the existing rule requirements. Many of the other comments related to the content of regulatory guidance, suggesting that examples be provided to amplify particular points.

In the following sections, the NRC presents a discussion and resolution of the public comments, and the final rulemaking language in a form that parallels the order of discussion of issues in the proposed rulemaking. The organizational changes are discussed first, followed by discussion of the revised provisions in the rule. Although the discussion of many of the topics specifically focuses upon § 50.59, these matters are equally applicable to § 72.48, except as noted. Topics not related to particular rule sections are at the end of this discussion.

A. Organization of the Rule Requirements

(1) Definitions

In the proposed rule, the Commission added a new paragraph (a) to § 50.59 that contains a number of definitions for terms used in the rule. The Commission sought comment on the need for definitions as well as on the specific definitions offered for the terminology.

Most commenters did not explicitly address whether they thought definitions were needed. One commenter thought that adding definitions only added confusion. Another stated that although the terms in the rule need to be defined, having them in the rule means that any subsequent changes in interpretation would require rulemaking. The Commission believes that having the definitions in the rule adds clarity that improves implementation of the rule, and, in some cases, are necessary for completeness of requirements. Therefore the Commission has retained several definitions in the final rule in §§ 50.59(a) and 72.48(a). The specific definitions are discussed in subsequent sections.

(2) Applicability

The Commission proposed to place all of the provisions concerning applicability of the rule presently contained in several subsections into § 50.59(b), which is clearly labeled "Applicability." The rule applies to: production and utilization facilities (including power and non-power reactors) that are authorized to operate, and reactors (both power and non-power) that have permanently ceased operations. The few commenters who addressed this topic were supportive of this proposal. The final rule is unchanged from the proposed rule in this regard (except that § 72.48 now explicitly has a section with this designation for consistency).

(3) Form of prior Commission approval

In the proposed rule, the Commission combined §§ 50.59 (a) and (c) and revised the regulation to state more clearly that a licensee must apply for *and obtain* a license amendment, pursuant to § 50.90, before implementing changes, tests, or experiments that involve either a change to the TS or that satisfy any of the criteria listed in new section 50.59(c)(2). In addition, the Commission proposed relocating an existing provision that refers to changes to the TS not associated with a change, test, or experiment from § 50.59 to § 50.90. Parallel changes to § 72.48 and § 72.56 were also proposed.

One aspect of the proposed rule that drew comment concerned the requirement to obtain a license amendment before implementing a change that involves a change to TS or meets § 50.59(c)(2) criteria. In particular, for those instances in which a licensee wishes to make a modification to the facility, the use of which would require a TS change (or meet one of the other criteria), the commenters believe that it is acceptable for a licensee to install and test such a modification, as long as such activities themselves do not place the facility in a condition for which NRC review is needed, and as long as the modification is not actually used until the amendment review has been completed. These commenters believe that waiting for NRC approval for use of such modifications before beginning any installation activity is unduly restrictive. Typically this question arises for plant modifications and installations or complex engineering changes which may take months or years to complete.

In the Commission's view, the acceptability of such activities depends upon the meaning of "implementation" and of which aspect of the change requires NRC approval. If installing the modification, or testing it after installation would violate a TS, NRC approval (of both the modification and the revised TS) would be needed before the change is implemented. In addition, the licensee would need to determine whether the test itself meets the criteria in §50.59 so that prior NRC approval of the test is not required. For changes that are not inconsistent with existing TS, but for which the licensee plans to submit an amendment to later revise TS to allow use of the modification (as for instance a modification that may permit less restrictive TS requirements), proceeding with the installation, before the approval is received, is at the licensee's own risk with respect to whether the Commission will approve use of the modification. If the NRC finds the proposed TS or the modification unacceptable, the licensee would need to appropriately revise the modification or may be unable to reap the expected benefits. If the licensee establishes that installation and testing of a modification do not require approval, but its use in facility operations would, NRC approval would be needed before the modification could be put into effect. With these clarifications, the Commission accepts the comments on this aspect. The final rule text is unchanged from that offered in the proposed rule.

(4) Criteria for needing Commission approval of changes, tests, and experiments and unreviewed safety question (USQ) designation

In the proposed rule, the Commission proposed to remove the reference to the term "unreviewed safety question" and instead refer to the need to obtain a license amendment. The Commission concluded that this terminology has sometimes led to confusion about the purpose of the evaluation required by § 50.59. The purpose is to identify possible changes that might affect the basis for licensing the facility so that any changes that might pose a safety concern are reviewed by NRC to confirm their safety before implementation. To avoid confusion between a determination of safety and a determination of the need for NRC approval, the Commission is removing the term "unreviewed safety question." In addition, the Commission proposed to list the criteria (in the new § 50.59(c)(2)) that, if met, would require prior Commission approval for a proposed change, which would be in the form of a license amendment. In the proposed rule, the compound statements contained within the evaluation criteria of the current rule were separated into several individual criteria. The deletion of the term "unreviewed safety question" also required a number of conforming changes to other parts of the regulations.

Commenters generally supported these proposed changes. A few commenters stated that the supplementary information should explain that existing guidance referring to "USQ" (such as Generic Letter 91-18, Revision 1), is still applicable. Further, commenters stated that a simple process should be established by which licensee technical specifications that use the term "USQ" could be revised.

The Commission agrees that the term USQ was used as a convenience to describe those changes that met the rule criteria for prior NRC review and approval, and that any guidance referring to the same category of plant changes is equally valid for describing plant changes that would require prior NRC review and approval under the revised § 50.59(c)(2).

The Commission considered the merits of including specific language in § 50.59 that would address this point, but ultimately did not include such language for a number of reasons. First, the NRC official record copy would not be modified if licensees made changes on their own (in accordance with the rule language). Second, the intent of the specific provision would be to permit such changes; however, the fact that the provision is contained in the rule may make it a requirement to do so. This is clearly an unintended consequence and argues against including such language. Finally, since there is no practical effect of the wording as contained within the TS, there is no compelling reason why licensees would need to promptly conform the wording of their TS. For administrative convenience, the NRC requests that upon such occasion as those sections of the TS require NRC approval for other reasons or a licensee is requesting a license amendment in some other area of the TS, the licensee should include any necessary changes to the existing TS language to bring the plant-specific technical specifications into conformance with the rule language. Such changes could be made at any time if a general formulation of the requirement is used, as for example, replacing "USQ" with "requires NRC approval pursuant to §50.59." Since these are viewed as editorial changes only, effectiveness of the existing TS is not impacted. The implementation period of the rule will give reasonable opportunity to assure that the technical specifications are appropriately modified without the need to file a separate amendment request.

(5) Changes in the scope of the rule

The Commission solicited public comment on the need to revise the scope of the rule in the notice for the proposed rule. Specifically, the Commission asked whether the scope of the rule should be linked to the final safety analysis report (FSAR), as updated, or should the focus of the rule be linked to another set of regulatory requirements.

Only a few commenters indicated interest in a redefinition of the scope of the rule. These commenters suggested that any attempt to redefine the scope of the rule should be considered as part of a longer term revision that might be part of staff efforts to make the rule more risk informed. Therefore, the NRC is not revising the scope of the rule as part of the final rule. The NRC will reconsider the scope of the rule as part of its ongoing initiatives to improve its regulations to make them more risk informed.

B. Change to the Facility as Described in the Final Safety Analysis Report (as updated)

In the proposed rule, the Commission created a new § 50.59(a) to contain definitions for terms such as "change" and "facility as described in the final safety analysis report (as updated)." The definitions in § 50.59 of "change" and of "facility as described in the final safety analysis report (as updated)" were written to more explicitly establish that evaluation is required for changes to the analyses and bases for the facility as well as for physical or hardware changes to the facility. The proposed rule also explicitly stated that additions were changes under the rule.

B.1 Definition of Change

In the proposed rule, the Commission concluded that a "change" is a modification of an existing provision (e.g., structure, system, or component design requirement, analysis method or parameter), an addition or a removal (physical removals or non-reliance on a system to meet a requirement) to the facility (or procedure) as described in the FSAR.

Comment Summary: A number of comments related to the definition of change. The major topic areas of the comments are summarized below. The Commission's resolution of these matters follows.

(a) Screening: most of the commenters were seeking revision of the definition to allow screening of changes that would not affect design functions. For instance, some commenters, while agreeing that additions should be considered changes, also noted that additions, if not limited by qualifiers such as "inconsistent with FSAR or changing operation", could mean that even trivial additions to the facility or to a procedure would require evaluations. A few commenters thought that additions should instead be treated as "tests or experiments," so that evaluations would be needed only if the additions were inconsistent with the FSAR or outside the design basis.

(b) Replacement components or maintenance: Other commenters sought clarification as to whether particular activities, such as the installation of "equivalent" components, or maintenance activities are considered to be changes requiring evaluation against the criteria. For instance, replacement equipment should only require review if the replacement component has characteristics that are different from those described in the FSAR. For maintenance, commenters stated that taking SSC out of service for maintenance is adequately covered by maintenance rule requirements or TS, and that a § 50.59 evaluation should not be required. Other commenters wanted clarification that requirements for environmental qualification of electrical equipment were covered by § 50.49, such that equipment replacements that are qualified per § 50.49 are not "reductions in margin of safety" under § 50.59.

(c) Interdependent changes: A number of comments concerned "interdependent" changes, that is, under what circumstances can more than one change be considered together rather than individually. A few commenters stated that the Commission should adopt a position with respect to interdependent changes that multiple changes to the facility or its procedures may be evaluated collectively if: (1) they are interdependent as in the case where a modification to a system or component necessitates additional changes to other systems or procedures in order for the modified system to perform its function or comply with its design or licensing basis; (2) they are performed collectively to address a design or operational issue; or, (3) they are otherwise planned as elements of a single project undertaken to restore, maintain or improve plant performance or safety. Several commenters also stated that examples would be helpful to illustrate how closely related the changes needed to be in order to be viewed as interdependent.

(d) Removal: One commenter stated that the term "removal" should be clarified to include removal from service, physical removal, retirement in place, discontinued availability, removal from the FSAR text or tables, and removal from FSAR figures.

(e) De Facto Changes: One commenter stated that the NRC should modify the definition or other rule language to explicitly state that the requirements apply only to "proposed" changes and not to so-called "de facto" changes[1]. Another commenter thought the rule language should explicitly codify the resolution process under Generic Letter (GL) 91-18, by including language in the rule such that the respective requirements of Appendix B, criterion 16 and § 50.59 do not interfere.

(f) Changes made in response to NRC communications: Two commenters asked if a proposed change that is the direct result of a response to issues raised in generic communications requires evaluation under § 50.59 to determine the need for NRC approval, or if it is already approved by the NRC. The Commission notes that this subject was also raised by NEI during a meeting on guidance for minimal increases with respect to changes being made to conform with changes to regulations.

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[1]Under the NRC enforcement policy, § 50.59 is sometimes used to form the basis for a violation for circumstances under which the as-built facility differs from the FSAR, in that the existing condition is a "change" from the "as-described FSAR condition", and no evaluation was performed supporting why the change could be made without prior NRC approval. Such situations are referred to as "de facto" changes.

<u>Resolution</u>: The Commission has modified the proposed rule language for "change" to be responsive to the issues raised by these comments. In particular, for comment (a), the Commission has incorporated into the definition of "change" the phrase "that affects design function, method of performing or controlling a function, or an evaluation that demonstrates that intended functions will be accomplished." The Commission concluded that with this revision, other comments about "additions" and "removals" have been addressed (as for instance comment (d)). The definition of change language will allow licensees to eliminate the need to further assess specific changes against the criteria in the rule because the nature of the change would never meet the criteria of the rule and require prior NRC review before implementation (known in the industry as a screening review). The capability to perform such screening reviews for such minor changes will reduce the burden of the review process.

With respect to comment (b) about whether specific types of activities are "changes", the Commission agrees that clarification would be useful and will work with affected stakeholders to address the specific needs for regulatory guidance to successfully implement the final rule. In particular, the Commission finds that guidance would be useful on when "replacement" components must be treated as a change, as for instance because the replacement component has characteristics different from those described in the FSAR, compared to one that is "equivalent" and thus not a change. The Commission also agrees that simply removing a component from service for maintenance does not require a § 50.59 evaluation, but notes that prolonged removal from service appears indistinguishable in its effect from a change that removes the component from the facility. Further, there may be circumstances under which maintenance activities would place the facility in a configuration not previously considered, or require disabling of barriers or movement of heavy loads to accomplish. The Commission further agrees that acceptability of environmental qualification requirements would be determined with respect to § 50.49. However, use of different equipment would also require a § 50.59 review with respect to meeting the evaluation criteria as now defined in the rule (as discussed elsewhere, the criterion on "margin" is being removed). The Commission notes that for certain changes, such as a change that affects post-accident containment conditions, although § 50.49 may be the applicable regulation for equipment qualification, other aspects (containment pressure) would need to be evaluated under § 50.59.

The Commission's previous comments on interdependent changes arises from concern that if multiple changes were considered in a single evaluation, certain aspects of the "combined" change could offset other aspects and lead to a conclusion that the set of changes did not require approval. Certain of the other changes being made to the final rule alleviate much of the Commission's concern about this practice. In particular, the Commission has described in section J how changes to methods, input parameters, and facility changes should be evaluated in determining whether the evaluation criteria are met. Although the Commission agrees with many of the ideas offered by the commenters for interdependent changes, the Commission further believes that providing further discussion and examples in guidance on this point would be useful.

The Commission did not modify the rule language to specifically address comment (e) on "de facto" changes or GL 91-18 guidance, believing that changes were not needed to allow the process under GL 91-18 to be implemented. The Commission did not revise the rule language to specifically state that "changes" resulting from corrective actions under Appendix B do not fall under the "obtain amendment prior to implementing" requirement as suggested by the commenter. The Commission acknowledges that in those instances of "de facto" changes, it is not possible for the licensee to obtain NRC approval prior to implementing a change that has already occurred. In these cases, the "proposed change" that the licensee wishes to make is to its FSAR such that it reflects the "as-found" condition of the plant. The prior approval specified in § 50.59 is the NRC's agreement with the resolution of the nonconformance before the issue is closed. For these instances, the Commission views "implementing the change" as meaning closeout of the corrective action. Further, the Commission does not plan to revise its enforcement policy concerning de facto changes (see also section Q below for more discussion on enforcement for §50.59).

With respect to item (f), the licensee has an obligation to comply with the regulations (including any changes), and to respond appropriately to any generic communication. The licensee must examine the facility changes being made to determine how the facility will function with the change and identify any potential impacts on safety. A rule or generic communication may specify a requirement to be satisfied, or the nature of a change to meet a particular intent, but rarely is the specific issue presented at a level of detail necessary for installation. For some facilities, or some configurations, the "generic" solution intended by the rule or generic communication may not achieve the expected results, or there may be alternative ways that would avoid other problems. These issues can be pursued in the licensee's response to the generic communication or requirement.

The question about the need for NRC approval for the specific means of implementation of an action prompted by NRC initiative (rule, order, or generic communication) is less clear. As an example, NRC has issued a rule requiring the licensee to cope with a station blackout. Suppose that the means a licensee selects to meet the requirement is to cross-connect a new non-safety-related diesel to safety-related buses. Before implementing this modification, the licensee must evaluate the change to determine whether the particular method of satisfying the rule has created other circumstances that would warrant NRC review, such as if the change would increase the likelihood of malfunction of the buses. Given these considerations, the NRC concludes that changes made in response to rules and generic communications must be evaluated in the same way as other changes a licensee may wish to make, with the conduct of § 50.59 evaluations and submittal of license amendment requests as needed. Where there are conflicts in requirements or schedules resulting from these situations, the NRC has an obligation to take timely and appropriate action on the licensee's submittals. To the extent that the impacts of the generic communication or rule are within the range of what the NRC had considered in its deliberations on the rule or communication, the approval of the licensee's submittal will be straightforward.

In summary, the Commission has included a definition of change as meaning a modification or addition to, or removal from the facility or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished. Other points raised by the commenters, such as providing examples, will be handled in the regulatory guidance to be developed.

B.2 Definition of Facility

In the proposed rule, the Commission concluded that changes to information such as performance requirements, methods of operation, the bases upon which the requirements have been established, and the evaluations should be considered to constitute a change to the "facility as described in the FSAR (as updated)". The Commission concludes that changes to methods and other requirements in the FSAR, even if not physical changes to the facility, require evaluation under § 50.59. If changes to methods and performance requirements were not so controlled, a licensee might revise its analyses or other information, update its FSAR, and then subsequently conclude that a later facility change does not require NRC approval because the revised analysis or acceptance requirement can still be satisfied with the facility change (that otherwise would have met the criteria as requiring approval). Thus, the proposed definition specifically itemized these points.

Comment Summary: A few commenters stated that it should be clarified that changes, whether to analysis methods or to the physical facility, are only subject to § 50.59 requirements if they are described in the FSAR. Other commenters stated that if the level of discussion within the FSAR is unaffected by the change, there should be no need for an evaluation.

NEI (as endorsed by other commenters) stated that "methods of operation" should be removed from the definition of facility, as this was better suited to the definition of "procedures."

Some commenters also were concerned that the phrase "required to be included in the FSAR" used in the definition of facility was an attempt to require licensees to look beyond the FSAR, or to undertake actions to add information to its FSAR. These commenters thought such matters were better handled as part of agency actions concerning guidance for updating FSARs (see for instance, Draft Regulatory Guide DG-1083 and NEI 98-03, "Guidelines for Updating Final Safety Analysis Reports").

The Commission had included these words in the rule as an attempt to limit what part of the FSAR needed to be considered for purposes of § 50.59 evaluations. If information was not required to be in the FSAR, then as discussed under NEI 98-03, it could be removed from the

FSAR. On the other hand, a licensee may wish to retain such information in its FSAR for purposes of completeness; then this part of the definition would allow the licensee to screen out changes to the information that does not meet the definition of facility as described. In view of the confusion surrounding this phrase, and in light of other proposed changes to these definitions, the Commission has deleted this phrase from the final rule.

A commenter stated that such administrative changes as organizational information, reporting relationships, and job titles should be excluded from the scope of § 50.59.

Resolution: The Commission considered these comments in selecting the language that allows screening as to whether a change to the facility affects the content of the FSAR. As previously noted in implementation guidance, some SSC or subcomponents may not be explicitly described in the FSAR, but they have the potential to affect the function of an SSC that is described. The approach chosen by the Commission for defining "change" as relating to those additions, modifications, and removals that affect functions, methods of performing or controlling functions and evaluation methods also accomplishes an important purpose for these issues. Some changes a licensee may wish to make to a component or procedure could affect the functions or performance requirements of other SSC. Depending upon the level of detail contained in the FSAR, the particular component being changed may not be explicitly described. If a modification to that (non-described) component could affect any SSC design function or performance requirements that are described, that modification affects the design function, and thus is a change as defined by § 50.59(a) and thus requires evaluation under §50.59. For example, the bearings on a pump may not be specifically mentioned or described in the FSAR. However, the pump function and performance requirement is described. A change being made to the bearings would need to be evaluated to determine if it affects the function or performance requirements of the pump, and if so, whether the criteria in 50.59 (c) are met.

Changes to the definition of "facility" were made in response to the concerns noted above from the commenters, such as deletion of the phrases "required to be included...," and "methods of operation." The Commission has retained "methods of evaluation" as being within the definition of "facility," and as discussed under a later section, added an evaluation criterion specifically designed to provide a standard for evaluation of such changes.

The Commission believes that the definitions provided in the rule for facility and procedures exclude the indicated administrative type of changes from § 50.59, and further notes that many of these details would be part of a licensee's quality assurance plan that is governed by the requirements of § 50.54(a), and therefore excluded from the purview of § 50.59 by virtue of § 50.59(c)(4).

The definition of facility includes performance requirements and evaluations included in the FSAR which demonstrate that functions will be accomplished. In Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants," Section 54.21(d) states that each renewal application must contain an FSAR supplement that contains a summary description of the programs and activities for managing the effects of aging and the evaluation of time-limited aging analyses for the period of extended operation. As discussed in the Statement of Considerations for the final Part 54, inclusion of the program descriptions and analyses in the FSAR provides the appropriate regulatory oversight such that subsequent changes are controlled by § 50.59. The Commission concludes that these summary descriptions fall within the definition of "facility" as demonstrating that functions will be accomplished in light of potential aging effects from the period of extended operation. Therefore changes that affect this information require evaluation under § 50.59. The Commission further finds that supplemental guidance or examples for implementation specific to Part 54 would be beneficial and NRC intends to consider this as part of regulatory guidance.

C. Change to the Procedures as Described in the Safety Analysis Report

The Commission also proposed a definition of "procedures as described in the safety analysis report" in order to have definitions in the rule for all the major terms and criteria. This definition includes the evaluations demonstrating that requirements are met, such as assumed operator actions and response times.

Commenters on the definition primarily expressed concern with the phrase "conduct of operations" because licensees were concerned that this language would inappropriately bring administrative procedures within the scope of the rule. Other commenters suggested wording changes to clarify the definition.

The Commission has decided to remove the phrase "conduct of operations" from the definition. The Commission agrees that administrative procedures are not intended to be within the scope of the rule, and has made other minor wording changes to the final rule for clarity.

Changes governed by other regulatory processes

In the proposed rule, the Commission proposed to exclude from the scope of § 50.59 review, specific types of changes to procedures where other requirements and criteria have been established by regulation for controlling these changes, through a proposed provision in § 50.59(c)(1).

Commenters supported this proposal, and suggested it be clarified to also refer to plant changes in addition to procedure changes. As an example, emergency response facilities are considered as part of the emergency plans that are subject to §50.54(q). If also described in the FSAR, there is a potential for confusion as to whether both a §50.54(q) and §50.59 evaluation would be needed for a change to an emergency response facility.

The Commission revised the rule language to make the requested clarification. Further, this section was relocated to new §50.59(c)(4) in the final rule. This language refers to situations, such as §§ 50.54(a) and 50.54(q), where the regulations explicitly define how changes are to be reviewed, documented, and reported; and thus, where a § 50.59 evaluation would be duplicative. Another example would be § 50.46, which establishes criteria for reporting and for action for changes involving methods for loss-of-coolant analyses. A specific list of regulations was not included in the rule so that if other such rule sections become available, § 50.59 would not need to be revised. The § 50.59 obligation can only be replaced in situations in which other rule requirements specify the governing change process, in order to prevent duplication of reviews, not as a means of avoiding change control requirements.

A few commenters stated that clarification should be included concerning applicability of § 50.59 for certain documents controlled by a variety of processes (e.g., Core Operating Limit Reports contained in TS; Technical Requirements Manual and other matters (e.g., offsite dose calculation manual (ODCM)) that have been relocated from TS to other controlled documents such as the FSAR; and vendor topical reports, etc.).

The Commission notes that in NEI 98-03, which the NRC has proposed to endorse through a regulatory guide, there is discussion about incorporation by reference of other documents (such as ODCM, fire protection plan, etc) into the FSAR. As discussed in Generic Letter 86-10, "Implementation of Fire Protection Requirements," licensees were encouraged to consolidate their fire protection program documents and incorporate them by reference into the FSAR. Then, by the terms of a modified license condition, licensees could make changes to their fire protection program. The vast majority of licensees have made this change so that the program description is incorporated into the FSAR and program changes can be made without NRC approval provided the changes do not adversely affect the ability to achieve and maintain safe shutdown in the event of a fire (or require an exemption). The Commission sees no need to provide additional clarification as the processes for control of most of these documents are already defined.

D. Tests and Experiments not Described in the Safety Analysis Report

The Commission proposed a definition for "tests and experiments not described in the final safety analysis report (as updated)" to be included in § 50.59. The intent of the requirement is that tests that put the facility in a situation that has not previously been evaluated or that could affect the capability of SSC to perform their intended functions should be evaluated before they are conducted. Thus, the definition focused upon the facility being outside its design basis values or inconsistent with the safety analyses in the FSAR.

A few comments were made on this topic, with some indicating that a definition was not needed, and with some noting that certain terms were unclear or stating that the term "activity" should be used instead of condition, to avoid confusion between planned tests and identification of degraded or nonconforming conditions. (Note: because of administrative error, the proposed rule text used the term "condition," although in the proposed rule supplementary information, the term used was "activity.")

The Commission agrees with the commenters and has used "activity" in the final rule. Further, the Commission believes that the phrase "reactor, or any of its structures, systems or components" is sufficiently clear to reflect the intent that the determination as to whether the activity is a test not described in the FSAR, is not affected by whether it is limited to only one component, or involves a wider set, up to and including the entire facility. Therefore, the final rule has been revised to contain a definition of "test or experiment not described in the final safety analysis report (as updated)" which has minor changes from the definition offered in the proposed rule.

E. Safety Analysis Report

The Commission proposed to revise the rule language to add a definition of the "final safety analysis report (as updated)" and to clarify in the evaluation criteria that evaluations need to account for changes made through other processes that have not yet been included in an update to the FSAR. Thus, each of the evaluation criteria contained a phrase referring to evaluations and analyses performed since the last FSAR update was submitted. The rule referred to FSAR (as updated), rather than to updated FSAR to account for both non-power reactors who are not required to submit updates to their FSARs, and to any reactors between the time of initial licensing and the first required update. The definition also refers to Final Hazards Summary Report, because a few facilities were licensed before the rules were revised to require submittal of FSARs.

Commenters generally supported the idea that the FSAR changes since the last update submittal needed to be considered in the § 50.59 evaluations, but sought clarification on a few details. Further, commenters thought the rule language could be simplified by defining in one place that "FSAR (as updated)" includes such information, rather than including in each evaluation criterion the phrase "or in evaluations performed pursuant to this section and safety analyses performed pursuant to section 50.90 after the last final safety analysis report was updated pursuant to section 50.71 of this part."

The Commission has modified the rule text in response to these comments by adding a new paragraph (c)(3) to explicitly state that the "FSAR (as updated)" for purposes of implementing this paragraph, also includes the FSAR update pages resulting from analyses and evaluations performed since the last update was submitted. Accordingly, the statements of the individual evaluation criterion have been simplified.

Two commenters were concerned that the requirement to consider other evaluations since the last update submittal would require a review of all past evaluations to find the most conservative result as the baseline for these evaluations.

The Commission does not believe that the rule requires such action. The Commission's intent in stating that for purposes of implementation of § 50.59, the FSAR (as updated) is considered to include FSAR changes resulting from evaluations of changes made since the FSAR update is to ensure that decisions about particular changes are made with the most complete and accurate information. If other changes did not impact upon the accuracy of the FSAR, they would not need to be examined. If as a result of other changes, the licensee will need to revise the FSAR at the next update because the present information is no longer accurate following that change, that information may be relevant to evaluation of a future change that involves that part of the FSAR. Indeed, for nonpower reactors, this process has already been necessary because these facilities are not required to submit updates to their safety analysis report. Nevertheless, they must ensure that proposed changes are judged with respect to the existing facility, not the facility as originally described in the FSAR at time of licensing. This requirement does not make these evaluations part of the updated FSAR pursuant to § 50.71(e); that rule requires that the FSAR be updated to reflect the effects of the changes and evaluations, not that the evaluations themselves become part of the updated FSAR. Rather, the intent of the requirement is that the changes that were the subject of these evaluations be considered in the process of determining what the "facility as described" now is such that the reference for subsequent evaluations is complete and accurate.

One commenter stated that it should be made clear that the FSAR (as updated) includes the TS and bases because these documents sometimes contain information, such as applicable operating modes, not in the FSAR that is relevant to the evaluation process. A few other commenters thought the definition for "FSAR" should include other documents such as staff safety evaluations, selected commitments and other licensing documents.

The Commission does not agree that these documents fall within the required scope of the rule, or that they are part of the FSAR. However, as noted in existing guidance, licensees are free to refer to other documents to assist in understanding the implications of the change, but the rule language does not require such reviews.

F. Minimal Increase Principle

Strict interpretation of the existing rule language related to the probability of an accident or a malfunction has lead to significant burden to the industry with no clear safety benefits. Therefore, in the proposed rule, the Commission relaxed the standard for which prior NRC review would be required by revising existing paragraph § 50.59(a)(2)(i) of the rule. The specific proposal was to replace the phrase "may be increased" with "would result in more than a minimal increase." As previously discussed, the present § 50.59(a)(2)(i) is being expanded into four separate criteria, two for occurrence of accidents and malfunctions and two for consequences.

The information that can be revised under § 50.59 is limited to that which does not require review under any other sections of the regulations; thus, it is information is of less direct importance to public health and safety. In consideration of the conservatisms in NRC design and analysis requirements and acceptance criteria, "minimal" variations in probability of occurrence or consequences of accidents and malfunctions should not affect the basis for the previous licensing decision. During the plant licensing process, accident probabilities were assessed in relative frequencies (such as likely to occur more than once, likely to occur once during the life of the plant, or limiting fault that is not likely to occur during the life of the plant). System train and equipment failures were generally postulated to gauge the robustness of the design, without estimating their likelihood of occurrence. In this light, minimal increases in probability would not significantly change the licensing basis of the facility and could not impact the conclusions reached about acceptability of the facility design.

Further, the limits for radiological consequences established in the regulations and in the Standard Review Plan are conservatively chosen, so that minimal increases also would not impact the safety determination if demonstrated by a suitably conservative analysis. The Commission therefore concluded that the proposed criteria would provide reasonable assurance that those changes that would affect the NRC's basis for licensing would be identified as requiring NRC approval before implementation. The proposed revisions to the § 50.59 criteria would provide some degree of flexibility for licensees to make changes with smaller impacts without the need to obtain a license amendment.

On the other hand, the Commission intends to limit the amount of increase in probability or consequences of accidents such that it remains substantially less than a "significant increase" as referred to in § 50.92. In accordance with § 50.92, a license amendment involving a significant increase in the probability or consequences of an accident previously evaluated would be categorized as a "significant hazards considerations" and any hearing must be completed prior to issuance of the amendment.

Although the final rule allows minimal increases, licensees still must meet applicable regulatory limits and other acceptance criteria to which they are committed (such as are contained in Regulatory Guides and nationally recognized industry consensus standards, e.g., the ASME B&PV Code and IEEE Standards). Further, departures from the design, fabrication, construction, testing, and performance requirements as outlined in the General Design Criteria (Appendix A to Part 50) are not compatible with a "no more than minimal increase" standard. Because the "no more than minimal" standard allows for there to be some increase compared to the current requirement, which would have required any increase to be submitted for prior staff review, NRC needs to establish a point beyond which one would conclude that the increase is not minimal. Application of the "minimal increase" concept to the specific criteria in the revised final rule is discussed in the next sections.

G. Section 50.59 (c)(2) Criteria on Increases in Probability or Consequences

For each of the four evaluation criteria replacing existing § 50.59(a)(i), the Commission presented language in the proposed rule reflecting the "minimal increase" principle. Resolution of each of these criteria is discussed below, including consideration of the public comments.

For each criterion proposed, the Commission had presented guidance on how the rule could be met, including values as to when the Commission would conclude that each revised criterion is not met. Comments received on this guidance are discussed below. The Commission also notes that regulatory guidance will be provided that is derived from this discussion.

As the rule provides a qualitative standard of "no more than minimal," quantitative calculations are not required except for those instances in which a licensee decides to offer quantitative arguments as part of its evaluation. This is expected to occur for some instances involving increases in consequences, where licensees may perform calculations of the predicted dose from postulated accidents.

<u>(i) More than a minimal increase in the frequency of occurrence of an accident previously evaluated</u>

For criterion (i), the final rule requires prior NRC approval if the change results in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the FSAR (as updated). Several commenters agreed with the premise that "minimal" increases in probability of accidents should not require prior NRC approval. No specific comments were received on the rule language itself. Issues about guidance are discussed below.

The only change made by the Commission in the final rule language from the proposed rule is the substitution of "frequency" for "probability." This was done to provide a better representation of the attribute of concern, that is, occurrence over some period of time, and to emphasize that what is of interest is whether the proposed change has the effect of making the accident occur more often.

Guidance for frequency of accidents

In the proposed rule, the Commission offered guidance concerning "minimal" with respect to increases in probability (now frequency). Several comments were received on certain of these statements, as noted below.

First, the Commission had noted that the current guidance in NEI 96-07 stating: "Where a change in probability is so small or the uncertainties in determining whether a change in probability has occurred are such that it cannot be reasonably concluded that the probability has actually changed (i.e. there is no clear trend towards increasing the probability), the change need not be considered an increase in probability" satisfies the proposed NRC standard for increases in frequency of an accident. Commenters agreed with the characterization that this guidance would satisfy the rule, but also noted that the rule language provides more flexibility than is presently afforded by the NEI guidance.

Second, the Commission had stated that in order to be considered as a minimal increase, the resulting frequency of occurrence (considering the change, test, or experiment) must still satisfy the event frequency classification provided in the licensee's FSAR (as updated). Typically, these would be anticipated operational occurrence (expected once a year) or design basis accidents (not expected during life of plant, but sufficiently credible to require mitigation). The use of frequency classifications will not apply for all facilities subject to §§ 50.59 or 72.48, but is included here because it was a consideration in the licensing of most operating power plants. Some commenters sought clarification as to whether increases that remain within the frequency classification would satisfy the "no more than minimal increase" criterion. Changes that result in a change in classification do not meet the standard; however, remaining within the classification is not sufficient to conclude that no more than a minimal increase has occurred because qualitative judgments are not as rigorous as quantitative assessments and the accident categories and their uncertainties may be large. The Commission agrees that the effect of the change on the frequency of the accident must be discernible and attributable to the change in order to exceed the "more than minimal" increase standard, as compared to uncertainty about the existing frequency value and how it might be quantified.

Some commenters stated that the "minimal increase in probability" standard was too vague and sought more explicit criteria. Others requested quantitative standards for determining minimal increases in probability, and in particular, guidance for using risk insights or probabilistic risk analysis to determine when a more than minimal increase in probability has occurred. For instance, commenters thought that the values for changes in core damage frequency or large early release frequency in Regulatory Guide (RG) 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," might be used. However, this RG was developed for the purpose of guiding changes to the licensing basis where the staff was reviewing and approving the change, not for changes made under § 50.59. The Commission concludes that if use is to be made of PRA in § 50.59, more fundamental changes to the rule would be necessary to provide a coherent set of requirements, in that § 50.59 deals with design basis events, and RG 1.174 deals with risk including that from severe accidents beyond the design basis. In addition, RG 1.174 is specifically dealing with operating power reactors. Applicability to other facilities would need to be examined. The Commission acknowledges that it may be possible to develop more guidance that could be used in a quantitative sense to judge minimal increases. As part of development of the guidance, the NRC will consider using the values developed as part of the revised oversight process (SECY-99-07), so that if the resultant likelihood of occurrence remains well within the acceptable ranges given for initiating events, that the increase is "minimal."

(ii) Minimal increase in likelihood of malfunction of structures, systems or components

In the proposed rule, § 50.59(c)(2)(ii) would require NRC approval for a change that would result in "more than a minimal increase in the probability of malfunction of equipment important to safety previously evaluated in the FSAR (as updated)." Similar changes were proposed in § 72.48(c)(2)(ii), except for use of the term "structures, systems, and components" (SSCs) rather than equipment. These differences in wording reflected differences between existing language in §§ 50.59 and 72.48. Commenters supported the idea that "minimal" increases should not require approval. Commenters also suggested that the terminology in §§ 50.59 and 72.48 should be made more consistent between the two sections.

In the final rule, the Commission has revised the criterion in § 50.59 by referring to SSC rather than to equipment. The Commission concludes that the term "SSC" is commonly used in both Parts 50 and 72 and is well understood, and that "equipment" was an older term that does not have a unique meaning requiring its use. For the final rule, the Commission has also substituted the term "likelihood" for "probability." This change was made to acknowledge that while the criterion refers to "minimal" increases, the Commission is not implying that quantitative assessments are expected. The Commission concludes that the word "likelihood" is more generally understood to represent qualitative judgments.

Guidance for likelihood of occurrence of malfunction

In the proposed rule, the Commission discussed the following positions as guidance for implementing the criterion of a "more than minimal" increase in probability (now likelihood) of a malfunction of equipment (now SSC).

First, the Commission noted that the existing guidance in NEI 96-07 states: "Where a change in probability is so small or the uncertainties in determining whether a change in probability has occurred are such that it cannot be reasonably concluded that the probability has actually changed (i.e. there is no clear trend towards increasing the probability), the change need not be considered an increase in probability." Continued use of this guidance for a determination of whether criterion (i) has been met is satisfactory. Commenters agreed with this guidance, but also believe that this does not represent the outer bound of what would be acceptable to meet the rule. The Commission agrees with this comment.

Second, the Commission concluded that the likelihood of malfunction of SSC important to safety previously evaluated in the FSAR (as updated) would not be more than minimally increased if "design bases" assumptions and requirements are still satisfied (i.e, the seismic or wind loadings, qualification specifications, etc). Thus, for instance, a change that would cause piping stresses to exceed their code allowable values would be more than a minimal increase in likelihood of malfunction. Commenters stated that if design basis requirements are met, there is no increase in probability. The Commission agrees with the essence of this comment, but was attempting to help licensees comply with the rule language by offering ways of demonstrating that the criterion is satisfied. Changes that would invalidate specific commitments made for redundancy, diversity, separation, and other such design characteristics, would be considered as "more than a minimal increase in likelihood of malfunction," and thus would require prior NRC approval.

In the proposed rule, the Commission stated that for purposes of determining whether this criterion has been satisfied, the probability of malfunction would be no more than minimally increased if a new failure mode <u>as likely as</u> existing modes is introduced. Some commenters indicated that the presence of new failure modes should not be a determinant as to whether probability of malfunction has increased; rather, it is whether the effects of the failure modes have previously been considered that would determine the need for NRC review consistent with § 50.59(c)(2)(vi). The Commission finds that the question of likelihood is not addressed if new failure modes are only examined with respect to criterion (vi), since that criterion looks only at whether the effects of the failure are bounded, not how likely it is to occur. However, since likelihood can be increased regardless of whether new failure modes are involved, the Commission has deleted this statement as proposed guidance for assessing increases in likelihood.

Additions of components to a system (cabling, manual valves, protective features) would not generally be viewed as more than a minimal increase in likelihood of malfunction, provided that applicable design and quality standards are followed. For example, adding protective devices to breakers, or installing an additional drain line (with appropriate isolation capability) would not be increases in likelihood of malfunction. However, there could be situations where such additions would impact upon how a system performs its functions that might not satisfy the § 50.59 criteria (for example, a cross-connect between trains that is not suitably isolated).

Substitution of one type of component for another (as for instance, an air-operated valve for a motor-operated valve), would also be viewed as no more than a minimal increase in likelihood of malfunction, provided requirements for redundant motive force, quality, and other requirements are met (and of course that any new failure modes are already bounded by the analysis).

(iii) and (iv) Minimal increases in consequences of accident or malfunction

In the proposed rule, the Commission revised the existing criterion concerning increases in consequences from a standard of "may be increased" to "more than minimally increased," and separated the two statements on consequences within § 50.59(a)(2)(i) into separate criteria. Only a few comments were received concerning the rule language itself. One commenter stated that the two criteria on consequences should not be separate, since consequences would only result from accidents, and having another criterion might force evaluators either to duplicate their documentation, or struggle to explain why consequences were not increased for malfunctions. The Commission concludes that having separate criteria provides greater clarity and is consistent with common practice. Further, the criteria cover different types of changes, that is, some that arise from malfunctions (such as failure of a waste tank or filter systems), and others that might arise from changes in source term or timing of mitigation systems, that are more pertinent to "accidents." Licensees may combine their responses to questions and reference other sections when preparing evaluations.

Commenters requested two areas of clarification. First, they asked if consequences refers only to radiological consequences (dose), and second whether consequences refers only to those associated with accidents and not from normal operations or anticipated operational occurrences. The rule reference to consequences is intended to relate directly to radiological consequences, and not to other outcomes that are covered by the remaining criteria. Secondly, the Commission notes that 10 CFR Part 20 establishes requirements for protection against radiation during normal operations. For anticipated occupational occurrences, NRC requirements are such that there should not be any radiological consequences. However, the Commission also wishes to clarify that "consequences of accidents" includes not only offsite exposure, but also dose to operators in the control room (in accordance with General Design Criterion 19 of Appendix A to 10 CFR Part 50) or other onsite personnel, resulting from accidents and malfunctions previously evaluated in the FSAR.

The language in the rule for criterion (iii) was unchanged from the proposed rule; for criterion (iv), the term "systems, structures, or components" was substituted for "equipment" as it was for criterion (ii), for the reasons already discussed.

Guidance for minimal increase in consequences

In the proposed rule, the Commission had discussed several positions that might be helpful in developing guidance that would successfully implement the revised rule. First, the Commission agreed with the guidance in NEI 96-07 which states: "Where a change in consequences is so small or the uncertainties in determining whether a change in consequences has occurred are such that it cannot be reasonably concluded that the consequences have actually changed (i.e., there is no clear trend towards increasing the consequences), the change need not be considered an increase in consequences." No specific comments were received on this point.

Second, if a licensee has performed an analysis with certain bounding assumptions, and the change would increase a specific parameter from its present value to a different value that is still bounded by the value assumed in the analysis, the NRC concludes that such a change satisfies the criterion of "no more than a minimal increase in consequences." In fact, as noted by some of the comments, this is no increase in consequences, because the bounding analysis is what determines the value from which a change is being judged.

Third, if a licensee would need to change its design basis assumptions or analytical methods, or both, to demonstrate that the change in consequences satisfies this guidance, then the NRC does not view the change as minimal and would expect the licensee to submit a license amendment for such a change. This position is consistent with the logic presented as the basis for implementing new criterion §50.59(c)(2)(viii), which will be discussed in greater detail below. Some commenters thought that adopting methodologies that have been approved by NRC in certain contexts (such as use of International Conference on Radiation Protection

(ICRP) dose conversion factors, or credit for suppression pool scrubbing) should be allowable under § 50.59. New criterion (viii), discussed in section J below, specifies under what conditions changes to evaluation methods can be changed without prior NRC approval.

In the proposed rule, the Commission proposed a graduated approach, consistent with the concept of "minimal" being small enough so as not to impact the basis for the acceptability of the previous licensing decision. The Commission proposed that when the facility is far from the limit, a larger increase could be accommodated without concern about impact on the basis for acceptability. The Commission did not believe that allowing increases up to the regulatory values without approval was consistent with a "minimal" increase standard, and was not consistent with the purpose of the rule, that is, to allow the NRC the opportunity to confirm the adequacy of the licensee's review of the change before it is implemented.

The proposed rule offered three different ways to define what would constitute a minimal increase in consequences. Most commenters favored the third method (10% of the difference between the calculated value and the regulatory guidelines) over the other two. Other commenters thought the limits themselves should be the point at which NRC review would be needed, or offered other suggestions, such as allowing 20 percent of the difference. Comments were also received about the use of Standard Review Plan guideline values[2] as they are not in the regulations and that for some plants, the existing analysis may exceed the guideline such that no changes would be allowed. Some commenters also expressed concern about the criterion for those situations where a previous change may have resulted in a decrease in

[2]In the Standard Review Plan, NUREG-0800, the NRC established acceptance criteria for certain events that are considered of greater likelihood than the limiting accidents as a small fraction of the Part 100 guidelines. Thus, for instance, for a steam generator tube rupture, the SRP guideline is that the dose be 10 percent of the Part 100 value. For the postulated accident with an assumed preaccident iodine spike in the reactor coolant at the time the tube rupture occurs, the full Part 100 value is the acceptance criterion.

consequences, and a subsequent change that increased consequences would exceed the 10 percent difference, but would not have done so if the first change had not occurred.

During the comment period, some commenters were concerned that as the rule is currently planned to be implemented, they would have no flexibility under the rule if their calculated consequence values were already in excess of the current SRP guidelines. In general, the Commission agrees that for cases where a licensee is licensed with calculated consequences in excess of the established SRP guidelines, only limited flexibility under this provision of the revised rule would exist for changes that increased the calculated radiological consequences of accidents. In this regard, the Commission does view differences of about 0.1 rem as being within the error or uncertainty of design basis-type radiological consequences analysis such that NRC review of such changes is not needed.

The Commission has taken these comments into account in revising the "minimal" increases in consequences aspects of the final rule. The Commission will conclude that the requirements of the rule are met if the calculated doses from a change at a facility would be less than 10 percent of the remaining margin between current calculated dose values and acceptance values in the regulations[3] (e.g., GDC 19 or Part 100) for the particular accident. Under this approach, the threshold for what constitutes a minimal change varies as a licensee approaches the regulatory limit. The amount of change allowed would decrease as the limit is approached, and the limit could not be exceeded without prior NRC review. Specifically, it is no

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[3]GDC 19 requires adequate radiation protection to permit access and occupancy of the control room under accident conditions without personnel receiving radiation exposure in excess of 5 rem whole body or its equivalent to any part of the body, for the duration of the accident. Part 100 establishes requirements for exclusion area and low population zones around the reactor so that an individual located at any point on its boundary immediately following onset of the postulated fission product release would not receive a total radiation dose to the whole body in excess of 25 rem or a total radiation dose of 300 rem to the thyroid for iodine exposure. For future applications, as noted in Subpart B to 10 CFR Part 100, the radiological consequences are to meet the criteria stated in 50.34(a)(1), which sets a dose of 25 rem total effective dose equivalent (TEDE).

more than a minimal increase in consequences if the increase is less than or equal to the more limiting of either 10 percent of the difference between the existing calculated value and the regulatory guideline value (10 CFR Part 100 or GDC 19 as applicable), or has reached the SRP guideline value for the particular design basis event.

Examples

The Commission has selected several examples to illustrate the implementation of this criterion. In each example, the Commission assumes that the calculated consequences do not include changes in methodology. As discussed later, changes in methodology used to calculate radiological consequences would fail new criterion (viii) of the revised rule and require prior NRC review regardless of how small the increase would be in the calculated radiological consequences.

Example 1 involves a case in which a licensee has a calculated fuel handling accident (FHA) dose of 50 rem to the thyroid at the exclusion area boundary. Because of some change in the facility, the calculated FHA dose increases to 70 rem. Under the revised final rule, ten percent of the difference between the calculated value and the regulatory limits is 25 rem (10% of 250). The SRP acceptance guideline is 75 rem. Since the calculated increase is less than 25 rem and the total is less than the SRP acceptance guidelines, then the revised § 50.59 consequence criterion would not trigger the need for a prior NRC review and a licensee may make the change to the facility.

Example 2 involves a case in which the calculated consequences for a steam generator tube rupture accident are 25 rem at the exclusion area boundary. Because of a change in the plant, the calculated consequences increase to 29 rem. The implementation of the revised rule language would permit these changes to occur because the new calculated doses do not exceed the established SRP acceptance criteria nor does the incremental change in consequences (4 rem) exceed 10 percent of the difference between the previous calculated value and the regulatory limit of 300 rem. Ten percent of the difference between the acceptance criteria (300 rem) and the calculated value (25) is 27.5 (10% of 275) rem; since 4 is less than 27.5, this change satisfies the criterion.

Example 3 involves a case in which the calculated consequences of a fuel handling accident are 25 rem to the thyroid at the exclusion area boundary. Because of a proposed change in the facility, the calculated consequences increase to 65 rem. For this case, the revised calculated consequences are still less than the SRP acceptance guidelines of 75 rem; however, the incremental increase in consequences (40 rem) exceeds the 10 percent of the difference to the regulatory limit of 300 rem (which would be 27.5 rem). For this example, the change results in more than a minimal increase in consequences and thus requires NRC approval pursuant to § 50.59(c)(2)(iii).

If Example 3 had been an event for which no SRP value was specifically established, so that the Part 100 guideline was the only applicable standard, the rationale would be that an increase up to 52.5 (25 +27.5) rem would meet the "minimal increase" criterion.

Example 4 involves a case where the calculated dose to the control room operators following a loss of coolant accident is 4 rem whole body. A change is made to the control room ventilation system such that the calculated dose increases to 4.5 rem. The regulations dictate that the control room doses are to be controlled to less than 5 rem by General Design Criterion

19. Although the new calculated doses are less than the regulatory limits for the operators, the incremental increase in dose (0.5 rem) exceeds the value of 10 percent of the difference between the previously calculated value and the regulatory value (10% of 1 rem = 0.1 rem). This change would require prior NRC review before the licensee could implement the change.

As an example of the "calculational error" concept, suppose the existing approved analysis for a fuel handling accident at a plant predicts an offsite dose to the thyroid of 77 rem. The SRP acceptance guideline for this event is 75 rem. The change that a licensee wishes to make would predict an increase in the calculated dose from 77 to 77.1 rem. In this case, the proposed change could be made under § 50.59 because the calculated value, even though greater than the SRP value, is satisfied within the level of uncertainty specified above. However, for this example, the Commission notes that increases in consequences that would increase the calculated consequences to 77.2 rem would require prior NRC review before the specific change could be implemented.

H. Possibility of an Accident of a Different Type From Any Previously Evaluated in the Safety Analysis Report May Be Created

The Commission had proposed that the language in existing § 50.59(a)(2)(ii), renumbered to § 50.59(c)(2)(v) in the proposed rule, be revised to read "(would) create the possibility for a design basis accident of a different type from any previously evaluated in the final safety analysis report (as updated)." This change had two parts - the first, changing from may be created to "would create" and the second being the insertion of the phrase "design basis." The purpose of the first change was to provide some flexibility to licensees. Thus, rather than having to prove that an accident had not been created, under this rule language, a licensee would need to request a license amendment only if it could be reasonably concluded that the possibility of an accident of a different type is created by the change, test, or experiment. The intent of the second change was to indicate that in referring to "accidents" in §§ 50.59 and 72.48, the Commission had in mind creation of accidents of the likelihood and significance of those that, had the possibility already existed, would have been a design basis accident in the FSAR. Thus, "accidents" that would require multiple independent failures or other circumstances in order to "be created" would not fall within this criterion.

For an accident to be of a different type, a few commenters thought that the accident must result in a new or greater release path than originally considered, result in a new fission product barrier failure mode, or create a new sequence of events that results in significant cladding failure, "such that the accident would have been included if the FSAR were being written today." The Commission agrees that these are useful considerations for determining whether a change results in an accident of a different type.

One commenter noted that for certain older facilities, the term "design basis accident" was only applied to a very small set of events. Other commenters thought that accidents must be "credible" to be "created." Another commenter was concerned that a slightly different initiator leading to the same design basis accident might be viewed as an accident of a different type.

One commenter stated that "accident of a different type" should be changed to "accident with a different result," for consistency with the criterion on malfunction. However, the Commission also notes the similarity with the criterion in § 50.92 (for no significant hazards consideration determination). Allowing changes that result in an accident of a different type (even if the result has previously been analyzed) appears inconsistent with the criterion in § 50.92.

The Commission has concluded that use of the modifier "design basis" with respect to accidents of a different type in the rule language may be confusing because, by the terms of the rule, accidents of a different type are distinct from those (design basis) accidents evaluated in the FSAR. Therefore, in the final rule, the Commission removed the phrase "design basis." The Commission agrees that the accident must be credible in the sense noted above, of having been created within the range of assumptions previously considered (e.g., random single failure, loss of offsite power, no reliance on non-safety-grade equipment, etc.), and that a new initiator of the same accident is not a "different type" (but may affect the frequency of that accident under § 50.59(c)(2)(i)).

Therefore, the final rule uses the same language as is currently contained in the existing rule, concerning accidents of a different type, except for changing the phrase "possibility ... may be created" to "would create the possibility."

Need for definition of accident

In addition, the Commission had requested comment as to the need for a definition of accident, and offered a specific definition for comment. The term "accident" also appears in other evaluation criteria, specifically, §§ 50.59(c)(2)(i) and 50.59(c)(2)(iii), in the context of accidents previously evaluated in the FSAR.

Several comments were received on the proposed definition of accident. Most commenters felt that a definition in the rule was not necessary, and most also disagreed with the specific definition offered in some respect. Commenters generally agreed that accidents include design basis accidents (typically analyzed in Chapters 6 and 15 of the FSAR), anticipated occupational occurrences, external events that the plant is required to withstand and other special events that are analyzed to demonstrate safety. Included within the set of accidents are those scenarios for which requirements have been established for the facility either to withstand or cope with the event. Notable examples include pressurized thermal shock events (§50.61), anticipated transient without scram (§50.62) and station blackout (§50.63). Commenters also noted that external events, such as earthquakes, high winds, floods, and missiles can be treated as causes of malfunctions of SSC, rather than accidents. Some suggested that examples or a list of accidents could be presented in the implementation guidance.

The Commission concludes that a definition of accident is not necessary in the final rule and that examples of accidents are best discussed in rule implementation guidance.

I. Create the Possibility of a Malfunction of System, Structures or Components Important to Safety With a Different Result from any Previously Evaluated In the Final Safety Analysis Report (as updated)

In the proposed rule, the Commission modified the remaining part of existing § 50.59(a)(2)(ii), concerning malfunctions of a different type by creating a new criterion (vi), that would require approval if a change, test, or experiment would "create a possibility for a malfunction of equipment important to safety with a different result than any evaluated previously in the final safety analysis report (as updated)."

Comments were supportive of the change from "different type" to "different result," and of the change from "may be" to "is" created. Some commenters objected to the insertion of the phrase "important to safety" and suggested other phrases, such as "safety-related" or "FSAR-described." Others suggested that the terminology in §§ 50.59 and 72.48 should be made consistent (the former refers to equipment; the latter to systems, structures or components).

In the final rule, The Commission has revised the existing criterion to read "create a possibility for a malfunction of an SSC important to safety with a different result from any previously evaluated in the final safety analysis report (as updated)." The Commission concludes that the term "SSC" is commonly used in both Parts 50 and 72 and is well-understood, and that equipment was an older term that does not have a unique meaning requiring its use. The modifier "important to safety" was considered as always being part of the criterion in practice, and that its omission from the rule was viewed as editorial and not substantive. Other terms might have the effect of limiting or broadening the scope of SSC to be considered. The Commission notes that since the overall scope of § 50.59 is the facility as described in the FSAR, there is no need to use that phrase in characterizing which SSC need be considered with respect to malfunctions.

Guidance for malfunction with a different result

The proposed rule discussion further stated that this determination should be made either at the component level, or consistent with the failure modes and effects analyses

(FMEA), taking into account single failure assumptions, and the level of the change being made. Several commenters stated that this guidance should be revised to refer only to the failure modes and effects analysis in the FSAR, and not to specify the component level. The Commission agrees that this criterion should be considered with respect to the FMEA, but also notes that certain changes may require a new FMEA, which would then need to be evaluated as to whether the effects of the malfunctions are bounding.

J. Replacement criteria for "Margin of Safety as Defined in the Basis for any Technical Specification is Reduced"

The phrases "margin of safety" and "as defined in the basis for any technical specification" in the third criterion in existing § 50.59(a)(2) have been the subject of differing interpretations for a number of years because section 50.59 does not define what constitutes a margin of safety or a basis for any technical specification in the context of §§ 50.59 and 72.48.

The Commission continues to believe that changes representing a potentially significant decrease in certain margins should require NRC review and approval prior to their implementation. Margins within the plant design and in the established licensing basis exist on many levels. There are margins from the assumptions of initial conditions, conservatisms such as computer modeling and codes to account for uncertainties, allowances for instrument drift and system response time, redundancy and independence of components. Margins are built into the facility to account for routine plant fluctuations and transients and response to accident conditions. Margins also exist in the established regulatory acceptance criteria to be met for response to various accidents and transients. The acceptance criteria are established at a value that accounts for uncertainty about physical properties and other variability. As a result, substantial margins are provided by the regulatory envelope within which a plant has demonstrated its ability to respond to a spectrum of design basis accidents. In sum, not every margin is important to assuring safety such that changes in that margin must be reviewed and approved by the NRC prior to their implementation. However, the Commission recognizes that precisely delineating the margins for which changes would require prior NRC review and approval is a difficult task. A change criterion which does not directly refer to margins, but which nonetheless indirectly assures that important design and licensing basis margins are not changed without prior NRC review and approval, is an acceptable alternative that would meet the Commission's goal of assuring regulatory review of potentially significant changes to certain margins. Such an approach avoids having to describe in the rule the margins of regulatory interest, and the nature of the change in margin for which prior NRC review and approval would be required.

In the proposed rule, the Commission solicited public comment on several options. The Commission also requested the public to provide alternative means for control of margin.

Option 1 in Proposed Rule

The first option in the proposed rule was to control inputs to analyses and the methods and criteria that establish TS. Under this option, the Commission would conclude that the analyses and information in the FSAR establish the basis for the margins of safety for the TS. Thus, the Commission's proposal would have added a definition for "reduction in margin of safety associated with any technical specification" and conformed the criterion for needing a license amendment in new § 50.59(c)(2). Although this option would maintain the safety analyses that underlie the TS, this approach also would have the effect of giving all input values and assumptions within the FSAR the weight of TS (even though they are not included in the TS), which is inconsistent with the philosophy in § 50.36. In many instances, changes to inputs can be accommodated by other available margins so that the licensing envelope is preserved. Several comments expressed strong concern that this option would be too restrictive, for the reasons noted above. The Commission agrees with these concerns and concludes that the approach is not consistent with the intent of the original rule. In this light, this option of requiring prior NRC approval for any change to input parameters associated with TS was rejected as an approach for the final rule.

Option 2 in Proposed Rule

The proposed rule contained a second option that was a proposal to delete the "margin of safety" criterion completely. Instead, the Commission would rely upon the other criteria in § 50.59, as well as the regulatory requirement that all changes to TS be reviewed and approved by the NRC, to assure that there are no significant adverse changes to margins in design and operation. If this option were adopted, the Commission would argue that there is no need for prior review of changes that do not satisfy any of the other evaluation criteria in view of "risk-informed" insights and greater understanding of the margins that exist through meeting the body of regulatory requirements. The Commission also sought comment on whether any of the other evaluation criteria should be revised if this approach were adopted.

A significant number of comments were received in support of the proposal to delete margin of safety as an evaluation criterion. In support of their position, commenters noted that TS and the other six evaluation criteria, in conjunction with other regulatory requirements for design, testing, and operation, make the margin question moot. The Commission did not adopt this proposal because of the variability in existing TS, and uncertainties about how licensees might gauge the other evaluation criteria for specific changes.

Option 3 in Proposed Rule

In the *Federal Register* notice, the NRC also offered a set of options that focused on control of margins associated with results of analyses. Instead of focusing on the inputs to safety analyses, these options would focus on the results of the safety analyses in order to determine whether changes to operational characteristics or other information described in the FSAR (as updated) would reduce the level of protection reflected by the results of safety analyses.

In developing which results would be governed by this evaluation criterion, the Commission considered what aspects of the facility safety are controlled by other requirements and thus what other information might a "margin" criterion be intended to capture. As part of the licensing review for a facility, the NRC established a level of required performance (which will be referred to in this discussion as acceptance criteria) for certain physical parameters, such as those that define the integrity of the fission product barriers (e.g., fuel cladding, reactor coolant system boundary, and containment). Satisfying these acceptance criteria produces a margin of safety to loss of barrier integrity. The safety analyses presented in the FSAR (as updated) demonstrate that the response of the barriers to the postulated accidents, transients, and malfunctions meets the acceptance criteria. Thus, in constructing the options for comment, the Commission suggested a more explicit linkage between when "margin of safety" needed to be preserved to the response of the fission product barriers relied upon to provide protection from uncontrolled release of radioactivity.

In the range of options, the Commission also suggested that certain mitigation system capability, as, for instance engineered safety feature performance parameters (flow rates, efficiencies, etc.) also might be considered with respect to margin, and asked for comment whether there were other parameters that should be explicitly accounted for in any criterion on "margin of safety."

As part of these options, the Commission also offered different approaches to how much flexibility should be allowed, as for instance, minimal reductions, or use of limits as the point at which reductions in margin would be determined. Also, as discussed later, the Commission asked in the proposed rule whether changes to evaluation methods should also be controlled.

Comment Summary for Option 3: The Commission received a large number of comments on the various suboptions under Option 3 concerning results of analyses. With respect to the identification of those parameters to control, many of the commenters who supported a "margin" concept based upon limits for results, believed that the parameters should be limited to those that directly affect fission product barriers and for which there are clearly defined limits. One commenter thought that a criterion on margin is not needed for a reactor that was being decommissioned. Commenters also thought that mitigation system performance was best controlled by other criteria, such as those concerning malfunction of SSC, or consequences of accidents. It was also noted that important characteristics of mitigation systems are governed by TS. With respect to parameters that might be used under Part 72, commenters stated that these should be those with the potential to increase the likelihood or the amount of offsite release, specifically, such things as fuel and cladding temperature, cask temperature and internal pressure, and cask stresses.

For the question as to when NRC approval is needed, comments can be grouped into two main themes: those that are supporting the position currently included in NEI 96-07 related to acceptance limits as being the point of departure for reduction in margin, and those supporting a new proposal from NEI. No commenters supported either a "no reduction in results" or a "minimal" standard, or any type of graduated approach such as that discussed earlier for consequences. As part of its comments on the proposed rule, the NEI proposed to replace the existing margin of safety criterion with one that states that a change requires prior NRC approval if it would result in a design basis limit directly related to integrity of the fuel cladding, the reactor coolant system boundary, or the containment boundary being exceeded or altered. Their proposal is similar in several respects to the guidance offered in NEI 96-07, with respect to using "limits" as the point at which a reduction in margin occurs, and in focusing on parameters for fission product barriers as being the instances where there is margin to protect. The difference is the concept of "design basis limits" as represented in the FSAR instead of acceptance limits that might be found in other documents. Further, NEI suggested that as part of the rule changes to adopt this criterion, the NRC should also delete the third criterion in § 50.92, which states that a determination of "no significant hazards consideration" cannot be made for amendments that would involve a significant reduction in a margin of safety.

Resolution

In SECY-99-054, dated February 22, 1999, the staff presented an alternate proposal for the margin of safety criterion. The staff proposal employed a concept that used the design basis capability for a SSC as the determinant for when prior staff review would be required. As presented in the final safety analysis report, there is a design basis (functions and controlling values of parameters) that determines the minimum performance requirements for SSCs. The controlling value for a parameter is the point at which confidence in the capability of the structure, system or component to perform its intended safety functions begins to decrease. For many parameters, requirements have been established in TS; for others, which are not directly controlled or measured, while certain TS requirements may have been imposed to keep values within required ranges, inclusion of a criterion that verifies that facility changes have not adversely impacted design basis capability provides assurance of completeness beyond the requirements for approval of TS changes.

The staff was supportive of the NEI concept of using the design basis as the determinant of when prior NRC approval was needed. The staff proposal was a modification of the suggested NEI approach that would focus on the effectiveness of systems to protect barriers. The staff thought that the rule language as offered by NEI could be viewed too narrowly, and might not ensure that changes affecting performance of mitigation and support systems were appropriately evaluated with respect to their roles in protecting integrity of the barriers. Therefore, the staff's proposal was more explicit about the design basis capabilities of the SSC being used to determine whether approval of a change was needed. The principal difficulty with this proposal was uniquely identifying the design basis capabilities for all SSCs that would need to be satisfied in order to implement the concept.

Since the time that SECY-99-054 was submitted to the Commission, the NRC has gained a greater understanding of the NEI proposal and how it would be implemented, and, in particular, how it would be used to assess changes to mitigation systems and support systems.

Although the NRC agreed that the process described in the NEI comment letter of December 21, 1998, would be sufficient to ensure that changes to other systems are appropriately examined with respect to impact upon the barriers, it was not apparent that the specific rule language suggested would require licensees to implement such a systematic approach to examination of design basis limits.

Therefore, the approach contained in the final rule is a combination of the NEI proposal contained in its comment letter and the staff proposal contained in SECY-99-054. In the final rule, the Commission is eliminating the existing criterion on reduction of margin of safety. In its place, the Commission is adding a new criterion (vii) that requires prior NRC review of changes that result in a design basis limit related to the integrity of the fission product barriers being exceeded or altered.

The final rule also contains a new criterion (viii) related to the use and control of evaluation methods (see below). These two criteria together in place of a criterion on margin of safety explicitly cover those margins that the Commission believes are important to address in this evaluation process—the first being the margin that exists in the limits that are to be met, and the second being the margin that exists from the conservatisms included in the methods used to demonstrate that requirements are met. Each of these criteria are discussed below.

The Commission concludes that the new criteria (vii) and (viii) together will maintain safety because they will preserve the design basis capabilities that protect the integrity of important fission product barriers, and thus those features that protect against release of radioactive material. The rule will also control the analyses and assessment process through control of the methods and will assure that the required response of the barriers as previously established by NRC review will be maintained.

The Commission does not plan to make any changes to the criterion in §50.92(c)(3), which provides that license amendments involving a significant reduction in a margin of safety do not meet the criteria for a "no significant hazards consideration" determination as discussed in section M below.

Final Rule Language

New Criterion (vii)

New criterion (vii) would require a prior NRC review of any change that would "result in a design basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered." For purposes of implementation of this criterion, the Commission defines *design basis limit for a fission product barrier* as the controlling numerical value for a parameter established during the licensing review as presented in the final safety analysis report for any parameter(s) used to determine the integrity of a barrier. Typically, the controlling value for the parameter is set at a point far enough away from failure that there is confidence in the integrity of the barrier. As a partial substitute for the previous "reduction in margin" criterion in the former Section 50.59(a)(2)(iii), a change which does not exceed or alter a design basis limit for a fission product barrier does not involve any reduction in the margin of safety.

The Commission did not retain the suggested wording from commenters for criterion (vii) which might suggest that the evaluation can be limited to those changes that are directly related to fuel cladding, reactor coolant system boundary, and containment boundary. The Commission believes that a broader initial assessment of parameters is necessary than that which might be suggested by the term "directly related." All changes that might affect the design basis limits, including changes to parameters within mitigation and support systems, must be evaluated for their effects upon the design basis limits for the barriers. Further, the Commission used the term "fission product barrier," rather than listing the specific barriers for operating power reactors as used by NEI, so that the rule language would be appropriate for all Part 50 facilities (including non-power reactors, and reactors undergoing decommissioning). The more general terminology is also appropriate for the Part 72 facilities.

New criterion (vii) narrows the focus for when prior NRC approval is required to those changes which result in the specific limits that relate directly to the performance of fission product barriers being exceeded or altered. For power reactors, these barriers are generally limited to the fuel cladding, the reactor coolant system pressure boundary and containment. For a reactor undergoing decommissioning, where the fuel is stored in the spent fuel pool, the barrier would be the fuel cladding. For non-power reactors, the fission product barriers would include, as applicable to the specific reactor, the fuel cladding, the reactor tank, and the reactor room, building, confinement, or containment.

The proposed criterion (vii) is equally applicable to independent spent fuel storage facilities or spent fuel storage cask designs in Part 72. The particular parameters or barriers would be specified in terms of the barriers against release of radioactivity afforded by fuel storage facilities. For instance, these would include calculated fuel temperature or cladding oxidation, and stresses (or pressures) on the cask structure.

Although the list of fission product barriers includes containment and other features that prevent the release of radiation, the design basis limits for these barriers are for parameters such as pressure. The determination of resultant radiological consequences from leakage through or breech of these barriers is the subject of criteria (iii) and (iv), rather than criterion (vii).

Further, design basis limits for certain fission product barriers may not be applicable to particular facilities or conditions of the facility (such as permanently shutdown facilities). The determination as to the need for evaluation of particular barrier parameters or limits depends upon the safety analyses and information presented in the FSAR (as updated).

The Commission notes that the new criterion (vii) does not incorporate the use of a minimal change concept. The modification of the criterion to reflect design basis limits as a point for evaluating when prior NRC review is necessary would not permit small changes beyond the limits without review.

With respect to changes relating to the design basis capability of SSCs to perform their functions in those circumstances in which the change does not cause any design basis limits to be exceeded or altered, the other evaluation criteria in § 50.59 (as well as other requirements such as TS or ASME code requirements) provide the standards for prior NRC approval of such changes.

The rule language that provides that a design basis limit may not be altered provides important and needed assurance. Changes that involve alteration of the design basis limit for a fission product barrier involve such a fundamental alteration of the facility design that a change, even in the conservative direction, should receive prior NRC review.

Guidance for Implementation

To satisfy new criterion (vii), licensees must determine the parameters that would be affected by the proposed change. The affected parameters are not limited to the specific parameters in the system in which the change is being made or to parameters that are only directly linked to the actual fission product barrier. Rather, the design parameters must include an assessment of all affected parameters, including design parameters of mitigation and support systems. Once the parameters are identified, the licensee must establish whether the parameters have values established in the FSAR, whether the parameters are controlling parameters that are reference bounds for the design, and whether the parameter has the potential to affect the performance of the fission product barrier. If the specific parameter values are already subject to controls established by the TS or other rules or regulation, those requirements shall be followed.

After a licensee assesses the information discussed above, it would need to identify the specific design basis limits that could be affected for each of the identified parameters. After the licensee completes its assessment of the change against each design basis limit, if no design basis limit is altered or exceeded, criterion (vii) is satisfied, and a licensee may make the change without prior NRC review.

Examples

The NRC has selected several examples to illustrate how the new criterion (vii) would be implemented. In these examples, it is assumed that NRC approval is not required because of other reasons, such as need for a TS change, section 50.55a requirements etc.

Example 1: A plant FSAR states that the function of the auxiliary feedwater system (AFW) is to provide feedwater flow to the steam generators following postulated accidents (e.g., main steam line break, feed line break, small break loss-of-coolant accident), or when a reactor trip occurs coincident with a loss-of-offsite power. The FSAR states that 700 gallons per minute (gpm) will be delivered to the steam generators. The licensee's accident analyses used 700 gpm to assess the acceptability of the plant to respond to the accidents and concluded that no safety limits were challenged if 500 gpm were supplied. As a result of recent testing of the AFW system, the licensee determines that the pumps can no longer deliver 700 gpm. The licensee determines that the AFW pumps can deliver only 500 gpm at the required pressure and temperature. The licensee performs the necessary safety analyses and confirms that 500 gpm is sufficient to meet all necessary functions and that no safety limits would be challenged as a result of the flow reduction. The licensee decides to leave the pumps in the plant as is rather than replace the pumps to restore the originally stated capability. The licensee revises the FSAR to state that the AFW system will deliver 500 gpm during postulated accidents or for transients involving a loss-of-offsite power.

Under the new criterion (vii), the licensee would have to assess the impact of the reduced flow rate on the design limits of the fission product barriers. The licensee would have to identify the system parameters that would vary as a result of the changes in AFW system performance, identify the specific design limits that have the potential to affect the fission product barrier performance, and complete the analyses to determine whether the specific design limits for the fission product barriers would be challenged. In this example, it is assumed that the licensee did not change the method of evaluation for the safety analyses. If the licensee had used a different methodology from that used initially in establishing that the limits were met, then, the licensee may have to submit the revised analyses under criterion (viii) of the revised rule.

For this example, the licensee would have to complete the evaluations required by § 50.59 but would not have to submit a license amendment request to lower the expected flow rate of the AFW system, from that stated in the FSAR, to the lower as-found value, nor would a licensee have to request an amendment to remove the old pumps and replace the pumps with new pumps that provide the lower capacity assumed in this example. The basis for this conclusion is that the licensee analyses determined that the design limits of the fission product barriers would not be challenged and, therefore, that the fundamental basis for the staff's initial safety conclusion is maintained.

Example 2: A facility FSAR states that some of the functions of the component cooling water system are to provide cooling water flow to the reactor coolant pump seals and to the shell side of the residual heat removal system (RHR) heat exchangers. The FSAR states that the CCW system provides 400 gallons per minute, 100 gpm for the seals and 300 gpm for the RHR heat exchanger. The licensee has recently obtained a new reactor coolant pump seal which requires an additional 25 gpm of cooling flow. The licensee plans to revise the flow distribution such that 125 gpm is directed to the seals, and 275 gpm to the RHR heat exchangers. The licensee performs analyses to determine that with the reduced CCW flow to the RHR heat exchangers, the RHR system can still perform its required functions with required limits, as for example, removing sufficient decay heat to cool down within required time frames, keeping post-accident temperatures within required limits, etc. The licensee would satisfy criterion (vii) and be able to make this change under §50.59.

Example 3: A licensee discovers an error in the primary system pressure boundary piping fatigue calculation performed to demonstrate compliance with the ASME Code requirements. A corrected calculation shows that the fatigue criterion would be exceeded (for the postulated FSAR events). A change to the licensing basis to accept revised fatigue criteria would require review under criterion (vii) because the design basis limit for one of the fission product barriers (reactor coolant system piping) would be exceeded or altered. (This change would also not satisfy criterion (i), "minimal increase in frequency of occurrence of an accident" because of potential failure of piping due to fatigue cracking, leading to loss of piping system integrity).

NEW CRITERION (viii) - CONTROL OF EVALUATION METHODS

In the proposed rule notice as part of the options presented on margin of safety, the Commission had discussed the issue of controlling methods (also, as noted, the proposed rule had explicitly stated that changes to methods were changes to the facility, and as such, required § 50.59 evaluations). Specifically, the Commission sought comment on whether the rule should include a statement that "all analyses and evaluations for assessing the impact of plant changes must be performed using methodology and analytical techniques which are either reviewed and approved by the NRC or which are shown to meet applicable review guidance and standards for such analyses."

Five commenters stated that methods should not be controlled by § 50.59 because the limits (e.g., acceptance limits) are conservative. These commenters thought that licensees should be allowed to use methods that are accepted by the NRC Standard Review Plan or other processes, without the need for prior NRC approval. A few commenters agreed that methods should either be reviewed and approved by NRC (or meet applicable standards); produce results that are consistent with the licensing basis methods; or that changes to methods should be reviewed as separate changes under § 50.59.

The Commission concludes that control of methods is essential in assuring a consistent application of the change review process, especially in light of the flexibility being provided by changes to the other evaluation criteria, such as having criterion (vii) that uses design basis limits being exceeded as the point at which NRC review is required instead of the "margin of safety" criterion. Although the Commission agreed that changes to methods should be reviewed as separate changes, the other evaluation criteria do not provide a standard that could be used to determine when changes to methods should be reviewed by NRC. While the NEI proposal would have controlled the methodologies through regulatory guidance, the Commission did not judge that process to provide sufficient rigor to assure uniform implementation of the requirement. A statement that the analysis should meet applicable standards was considered, but was ultimately rejected as being too vague. Therefore, the Commission has added criterion (viii) to be specifically used for changes to methods of evaluation.

Final Rule Language

New criterion (viii) will require prior NRC review of any change in a methodology or evaluation method that "results in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses."

Definitions and Guidance

For the purposes of this rule, a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses means (1) changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or (2) changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application. Results from a changed method are conservative relative to results from the previous method, if closer to the limits or values that must be satisfied to meet the design bases.

Results are "essentially the same" if they are within the margin of error needed for the type of analysis being performed, even if tending in the non-conservative direction. Results are essentially the same if the variation in results because of the change to the method is explainable as routine analysis sensitivities, and the differences in the results are not a factor in determining whether any limits or criteria are satisfied. The determination can be made through benchmarking (new vs. old method), or may be apparent from the nature of the changes between the methods. When benchmarking a method to determine how it compares to the previous one, the analyses that are done must be for the same set of plant conditions, otherwise, the results may not be comparable. Approval for intended application includes assuring that the approved method was approved for the type of analysis being conducted, generically approved for the type of facility using it, and that all terms and conditions for use of the method are satisfied.

The rule words were chosen to allow licensees only a small degree of flexibility in methods where the results are tending in the non-conservative direction, without burdening either the licensee or the NRC with the need to review very small changes that are not important with respect to the demonstrations of performance that the analyses are providing. The intent is to limit the need for review to those changes to methods that could impact upon the acceptability of performance were the results to be at the limiting values.

By limiting the methods to those described in the FSAR, and to those used for design bases and safety analyses, the Commission concludes that the burden of requiring review is justified in view of the relaxations in the other evaluation criteria. Unless the methods are used in FSAR safety analyses, as demonstrating that the facility performance continues to meet requirements, or to verify conformance with the design bases, they would not meet the rule requirements for approval. Thus, for example, if a licensee chose to perform sensitivity studies, or to examine alternative approaches for a change being contemplated, or included other analyses in the FSAR for reference purposes, these methods would not be subject to the rule. It is at the point in time that the revised method becomes the means used for purposes of satisfying FSAR safety analysis or design bases requirements that the approval (if the noted conditions are not met) would become necessary.

The Commission has included a definition of "departure" in the definitions section of the rule such that the intended meaning for purposes of § 50.59 is clearly understood.

Design bases as used in criterion (viii) is that information meeting the definition contained in 10 CFR 50.2, and in particular, those controlling values that are restraints derived from generally accepted practices for achieving functional goals, or requirements derived from analysis of the effects of a postulated accident for which a SSC must meet its functional goals. Safety analyses are those evaluations that demonstrate that acceptance criteria for the facility's capability to withstand or to respond to postulated events are met.

Thus, this criterion applies to those methods of evaluation used for demonstrating that design basis limits for fission product barriers are met, for other analyses such as radiological consequences that are part of the safety analyses, and for analyses that demonstrate that functional goals for SSC are met. These would include those analyses that show that SSC will function under limiting conditions such as natural phenomena, environmental conditions, dynamic effects, and so forth. However, as noted in the rule language, only those methods that are used in establishing the design bases or in the safety analyses fall within the criterion. In addition, the Commission notes that changes to time-limited aging analyses and evaluations of aging management programs required by §§ 54.21(d) and 54.37(b), require evaluation with respect to criterion (viii) to the extent that evaluation methods for these analyses are described in the FSAR supplement.

To assure consistent implementation of criterion (viii), the Commission believes that it is important to clearly distinguish between methods of evaluation and input parameters to the methods. *Methods of evaluation* means the calculational framework for evaluating behavior or response of the reactor or any SSC. This includes the following (to the extent that they are described or applicable for a particular method):

- data correlations

- means of data reduction

- physical constants or coefficients

- mathematical models

- specific assumptions in a computer program

- specified factors to account for uncertainty in measurements or data

- statistical treatment of results

- dose conversion factors and assumed source term(s)

Input parameters are defined as those values derived directly from the physical characteristics of structures, systems or components, or processes in the plant. These would include such things as: flow rates, temperatures, pressures, dimensions or measurements (e.g., volume, weight, size), or system response times. Changes to input parameters (that are described in the FSAR) are to be evaluated as facility changes, and criterion (viii) would not be applicable. Additional guidance will be provided in the implementation guidance to describe the specific elements of the evaluation methods or methodology that would require review and to clearly define specific types of input parameters. The NRC intends to work closely with stakeholders to revise the existing guidance related to implementation of § 50.59 to reflect these definitions.

The rule requirements for evaluation methods would allow for use of generic topical reports as not being a "departure," provided that the topical report is applicable to the facility, and is used within the terms and conditions specified in the approved topical report.

The Commission believes that with the guidance concerning "evaluation methods" and the definition of departure, licensees have the capability to perform analyses as needed without being unduly burdened by the need for NRC review, while still preserving those inherent conservatisms in the methods that provide the confidence that safety is maintained when the parameters are calculated to be at their design basis limits and that SSC capability continues to meet design basis requirements.

Examples

Example 1: The FSAR states that a damping value of 0.5 percent is used in the seismic analysis of safety-related piping. The licensee wishes to change this value to 2 percent to reanalyze the seismic loads for the piping. Using a higher damping value to represent the response of the piping to the acceleration from the postulated earthquake in the analysis would result in lower calculated stresses because the increased damping reduces the loads. Since this analysis was used in establishing the seismic design bases for the piping, and since this is a change to an element of the method that is not conservative and is not essentially the same, the NRC concludes that this change would require approval under criterion (viii). On the other hand, had NRC approved an alternate method of seismic analysis that allowed 2 percent damping provided certain other assumptions were made, and the licensee used the complete set of assumptions to perform its analysis, then the use of the 2 percent damping under these circumstances would not be a departure, under the second part of the definition.

Example 2: The licensee wishes to use an inelastic analysis procedure, not previously used in its seismic analyses as described in the FSAR, to demonstrate that the structural acceptance criteria are met for cable trays. NRC concludes that this would be a departure from the methods of evaluation and that it would not be essentially the same because the revised analysis would predict greater capacity than would the previous analysis. Therefore, this change would require NRC approval.

Example 3: The licensee wishes to change a non-LOCA FSAR Chapter 15 transient methodology. The methodology is being changed to a different vendor's NRC approved method. The new vendor's method has been approved generically for the particular reactor type (e.g., 2 loop PWR) and for the particular transient being analyzed. The analysis is being performed in accordance with all the applicable limitations and restrictions. The licensee can make this change without prior NRC approval because using a generically approved method for the purpose it was approved, while meeting all the limitations and restrictions, is not a "departure." Subsequent plant changes can then be evaluated using this new method and the other seven criteria in § 50.59.

Example 4: The licensee wishes to change an analysis described in the FSAR which states that adequate net positive suction head (NPSH) is verified by analysis without crediting containment overpressure. The new analysis will assume that five pounds of overpressure is credited in calculation of available NPSH. The revised analysis predicts more (five additional pounds of) available NPSH for the pumps, a result further from the limit (the required NPSH) for an analysis that establishes part of the design bases for the pumps as being capable of performing their required function under the range of expected conditions. This change can not be made without prior NRC approval because a change in an element of a method described in the FSAR, used to establish the design basis, that is not conservative, or essentially the same, is a "departure."

Example 5: The licensee wishes to change an evaluation method described or incorporated by reference in the FSAR Chapter 15 transient analysis. In an attempt to remove some of the conservatism associated with the analysis, the change the licensee is contemplating is removal from the analysis of consideration of certain instrument uncertainties for a few parameters, by assuming nominal values instead. By not accounting for the greater range of the parameter (including the uncertainties), the analysis predicts response further from the limit to be satisfied. The treatment of uncertainties was an element of the method described in the FSAR, and, therefore, this change can not be made without prior NRC approval because a change in an element of a method described in the FSAR, used in the safety analysis, that is not essentially the same is a "departure."

On the other hand, if an instrument in the plant were replaced with a different one, the assumed uncertainty in the analysis for that instrument could be used in the analysis without prior NRC review, using the other seven § 50.59 criteria rather than criterion (viii), because this is an input change rather than a model change. How the uncertainties are treated in the analysis is part of the method. The range of values of the uncertainties associated with particular instruments is a characteristic of the facility and is thus an input parameter.

K. Safety Evaluation

The Commission proposed to delete the word "safety" in referring to the required evaluation for determining whether the change, test, or experiment requires a license amendment. A similar change was proposed for § 50.71(e), which presently refers to safety evaluations either in support of license amendments or of conclusions that changes did not involve USQs.

The Commission also proposed to change "safety evaluation in support of license amendments" to "safety analysis in support of license amendments." The second part of the existing phrase would be revised to refer to the "evaluation that changes did not require a license amendment in accordance with § 50.59(c)(2) of this part." Conforming changes in Part 72 to revise the language to refer to "evaluation" were also proposed.

Commenters were generally supportive of these proposed changes. A few noted that as with the term "USQ," a simple process should be adopted for revision of TS that use the term safety evaluation (this issue is discussed under Section A(4)). Other clarifying wording changes were included as a result of the comments, as for instance, referring to "approved" license amendments rather than to "requested" license amendments to make clear that the updates, as well as subsequent § 50.59 evaluations, should be based upon what has been approved (and implemented), not on what a licensee may have proposed for approval, but that has not been approved.

The final rule includes these changes offered in the proposed rule for §50.71(e); in addition, the term "approved" was used in reference to license amendments. The final rule language for § 50.71(e) is presented in Section L, which also discusses other aspects of the requirements for FSAR updating.

L. Reporting and Recordkeeping Requirements

Records

Requirements for records for evaluations performed under § 50.59, and for submittal of a summary report are being moved to paragraph (d) as part of this rulemaking. In the final rule, the Commission has simplified the rule text concerning records. Although the text is simpler, there is no change in which records are being required. That is, the Commission views the phrase "made pursuant to paragraph (c)" as referring to those changes, tests, and experiments that require evaluation against the criteria (for example, because they involve the facility as described in the FSAR), but not to those other activities or changes that are determined to not fall within these required evaluations (as for instance, being screened out). As noted in Section K above, the rule now refers to "evaluations" not to "safety evaluations."

In addition, the Commission had proposed a change to the record retention requirements in existing paragraph § 50.59 (b)(3) [renumbered by this rulemaking to (d)(3)]. The change would add to the requirement that the records of changes to the facility be maintained until the termination of the license, the following statement "or until the termination of a license issued pursuant to 10 CFR Part 54, whichever is later." Commenters were supportive of this proposal, and the final rule section is unchanged from the proposed rule in this regard.

Summary Report

Simplified text was also included in § 50.59 (d)(2), concerning submittal of the summary report. The existing text required submittal annually, or along with the FSAR update (which could be up to 24 months between submittals), or at such other frequencies as specified in the license. The Commission sees no need for such variability in submittal dates, and believes that a 24 month interval is acceptable for submittal of the summary report. Licensees may submit reports more often if they wish. If a licensee has a shorter time specified in its license, that licensee may request that the requirement be removed so that the rule frequency would be applicable. The 24 month frequency is also included in the Part 72 sections, as requested by several commenters.

Updates to the Final Safety Analysis Report

In the proposed rule, the Commission proposed to supplement the reporting requirements in § 50.71(e) on "effects" of changes to require that in the FSAR update submittal (with the replacement pages), the licensee shall include a description of each change affecting that part of the SAR that provides sufficient information to document the effect of the change upon the probability or consequences of accidents or malfunctions, or reductions in margin associated with that part of the SAR.

The reason for this proposal was that the Commission was concerned about the potential cumulative effect of minimal increases. Since some increases are allowed in probability and consequences, the Commission thought that these rule changes would place greater importance on: (1) complete and accurate SAR updating; (2) the licensee's evaluation process taking into account other changes made since last update; (3) the licensee's screening process examining plant changes to determine whether they are indeed changes requiring evaluation; and (4) reporting requirements so that staff can assess the ongoing nature of cumulative impact.

The issue discussed in the proposed rule was how the NRC could best oversee the process such that several "minimal" changes do not result in unacceptable results. In the proposed rule, the Commission proposed requiring licensees to report effects of changes in the FSAR update submittal in accordance with § 50.71(e) in a different manner to facilitate evaluation of cumulative effect.

A large number of commenters stated that this proposal was burdensome and unnecessary in view of the minimal standards. Further, commenters thought that this provision would require them to perform additional evaluations of the cumulative effects, or to numerically gauge the result of increases to probability that were judged on a qualititative basis. Others stated that when analyses were performed, such as for consequences or performance of SSC against limits, the existing update requirements would specify that the effects of these analyses be included in the update. The Commission agrees that the burden associated with the proposed rule change is not warranted in view of the specific criteria adopted and the existing update requirements. Therefore, the final rule does not contain such language.

Other wording changes for § 50.71(e) were discussed under section K. Therefore, the following language is in the final rule for this section:

> (e) Each person licensed to operate a nuclear power reactor pursuant to the provisions of § 50.21 or § 50.22 of this part shall update periodically, as provided in paragraphs (e)(3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the operating license, to assure that the information included in the FSAR (as updated) contains the latest information developed. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to

Commission requirement since the last submittal of the original FSAR, or as appropriate the last update to the FSAR under this section. The submittal shall include the effects[1] of: all changes made in the facility or procedures as described in the FSAR; all safety analyses and evaluations performed by the licensee either in support of approved license amendments, or in support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2) of this part; and all analyses of new safety issues performed by or on behalf of the licensee at Commission request. The updated information shall be appropriately located within the update to the FSAR.

[1] *Effects of* changes includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate.

M. No Significant Hazards Consideration Determinations

Under Section 189.a(2)(A), the Commission may issue and make immediately effective an amendment to an operating license if the Commission has made a determination that the amendment involves a "no significant hazards consideration" (NSHC), despite the pendancy of a request for a hearing or the completion of such a hearing. The Commission's criteria for determining whether an amendment involves a NSHC, as set forth in § 50.92(c), are similar to the current USQ criteria in §50.59:

> (c) The Commission may make a final determination...that a proposed amendment to an operating license...involves no

significant hazards consideration, if operation of the facility in accordance with the proposed amendment would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of accident from any accident previously considered; or

(3) Involve a significant reduction in a margin of safety.

The Commission has evaluated whether the NSHC criteria in § 50.92(c) must be modified if the existing criteria in § 50.59 are altered, deleted or supplanted. The AEA does not define NSHC, nor does any provision of the AEA conceptually link the NSHC concept to any particular standard or concept. A review of the legislative history of the "Sholly amendment" which modified Section 189.a did not disclose any reference to § 50.59 or a discussion which links the NSHC concept and the § 50.59 criteria. H.R. Conf. Rep. No. 97-884, 97th Cong., 2d Sess. (1982), Sen. Rep. No. 97-113, 97th Cong, 2d Sess. (1981), H. Rep. No. 97-22, Part 2, 97th Cong., 2d. Sess (1981).

The Commission has also evaluated whether changes to the NSHC criteria to conform more closely to the revised § 50.59 would facilitate implementation of the revisions to § 50.59, even if changes to the NSHC criteria are not required by the AEA. There are three areas where the current NSHC criteria diverge from the revised § 50.59 criteria: (i) the current NSHC criteria do not include the "malfunction of components" criterion in the revised Section §50.59; (ii) the NSHC criteria retains a "significant reduction in margin of safety" criterion, which is no longer part of the revised § 50.59; and (iii) the NSHC criteria do not include the revised § 50.59 criteria (vii) and (viii) concerning changes to fission barrier design basis limits, and changes to and departures from evaluation methods. Although there may be some conceptual tidiness in utilizing the same evaluation factors for changes under § 50.59 and NSHC determinations under § 50.92, nothing in the AEA or the legislative history requires that the criteria be identical. Furthermore, the Commission notes that § 50.59 and NSHC address issues which are fundamentally different in purpose. Section 50.59 is focused upon the NRC's regulatory needs with respect to its review and approval of licensee-initiated changes, tests and experiments. By contrast, the NSHC determination is directed at determining what license amendments will require the Congressionally-mandated 30-day notice in the Federal Register and completion of any hearing granted pursuant to the Congressionally-mandated opportunity for hearing in Section 189.a. In the Commission's view, the existing NSHC criteria have been demonstrated through years of application to provide a workable standard for determining the potential safety significance of a proposed amendment for the purposes of determining whether issuance of a license amendment must await notice in the Federal Register and completion of any requested hearing. On balance, the Commission believes that no changes to the existing NSHC criteria are necessary in order to implement the revised change criteria in the revised § 50.59.

Recognizing the difference between the two sections, the Commission notes that if a change does not require a license amendment by virtue of the new § 50.59(c)(2)((vii) and (viii) criteria, then the change cannot be regarded as involving a "significant reduction in a margin of safety" under § 50.92(c)(3). If a change does require a license amendment by virtue of either §50.59(c)(2)((vii) or (viii), the NRC would be required to determine whether the design basis limit for a fission product barrier being exceeded or altered, or the departure from the method of evaluation used in establishing the design bases or safety analyses, constitutes a significant reduction in a margin of safety. With respect to new § 50.59(c)(2)(ii) and (iv), the Commission regards these criteria as a substitute for and refinement of the "malfunction of equipment" aspect of the existing § 50.59(a)(2)(ii) criterion, for which there is no parallel provision in § 50.92(c)(2). Therefore, the NSHC evaluation for license amendments necessitated by the new § 50.59(c)(2)(ii) and (iv) criteria will be largely the same as the current process for evaluating license amendments necessitated by the "malfunction of equipment" provision in the existing § 50.59(a)(2)(ii).

N. Part 52 Changes

In the proposed rule, the Commission had proposed to revise Appendices A and B to Part 52 to conform with the proposed changes to §50.59 concerning the evaluation criteria for when prior NRC approval is required for changes to certain Tier 2 information in plant-specific design control documents.

Two commenters believe that the changes to Part 52 needed to be expanded to either include certain provisions or definitions, or to refer to § 50.59 to incorporate them. The Commission has decided to defer consideration of the changes in the proposed rule for Part 52. The Commission anticipates other rule changes for Part 52 arising from an ongoing lessons-learned review. Further, the proposed design certification rule for the AP600 design being issued for public comment will emulate the two design certification rules in Appendices A and B. Accordingly, the Commission will consider these proposed changes in an integrated manner later.

O.1. Part 72 Changes

This section first discusses the changes offered in the proposed rule on Part 72, then discusses the comments received and the resolution and final rule language. The comments and rule language are discussed under subheadings relating to the specific requirements, such as for evaluation of changes, FSAR updating, and other conforming changes. A discussion of petition for rulemaking (PRM 72-3), submitted by Ms. Fawn Shillinglaw, and how it relates to the changes to Part 72 is contained in section O.2.

Changes presented in the Proposed Rule

For Part 72, in the proposed rule, the Commission proposed changes to § 72.48 conforming with those made to § 50.59 and proposed to expand the scope of § 72.48 so that holders of a Certificate of Compliance (CoC) approving a spent fuel storage cask design also would be subject to the requirements of this section. The Commission envisioned that a general licensee who wants to adopt a change to the design of a spent fuel storage cask it possesses—which change was previously made to the generic design by the certificate holder under the provisions of § 72.48—would be required to perform a separate evaluation under the provisions of § 72.48 to determine the suitability of the change for itself.

Certificate holders would be required to keep records of such changes as are allowed under § 72.48. New reporting requirements for certificate holders would be added in §§ 72.244 and 72.248, similar to existing requirements imposed on licensees in §§ 72.56 and 72.70, respectively.

In addition to these changes to § 72.48, the Commission proposed making changes in other sections of Part 72 as follows:

In § 72.3 the definition for *independent spent fuel storage installation* (ISFSI) would be revised to remove the tests for evaluation of the acceptability of sharing common utilities and services between the ISFSI and other facilities; and the existing requirement in § 72.24(a) revised to reference shared common utilities and services in the applicant's assessment of potential interactions between the ISFSI and another facility. Proposed changes to § 72.56 would be conforming changes to those made to § 50.90. Changes to §§ 72.9 and 72.86 are conforming changes due to the proposed addition of new §§ 72.244, 72.246, and 72.248. The change to § 72.212(b)(4) would be a conforming change necessitated directly by the change to §50.59, as this section in Part 72 refers to § 50.59 with respect to evaluations for the reactor facility at which site the ISFSI is located.

In the proposed rule, § 72.70 was proposed for revision to conform to § 50.71(e). Requirements would be added on standards for submitting revised Final Safety Analysis Report (FSAR) pages. Requirements would also be established for reporting changes to procedures. New reporting requirements for certificate holders would be added in §§ 72.244 and 72.248, similar to existing requirements imposed on licensees in §§ 72.56 and 72.70, respectively.

New §§ 72.244 and 72.246 would be added to Subpart L, to provide regulations on applying for, and approving, amendments to CoCs. A new § 72.248 would also be added to provide regulations for the certificate holder on submitting and updating the FSAR, which would document the changes it made to procedures or SSC under the provisions of § 72.48. The new § 72.248(c) would also require, in part, that updates to the FSAR use revision numbers, change bars, and a list of current pages.

Resolution of Comments Received: Of the 60 comment letters, 10 raised issues related to Part 72. The following is a summary of those comments and the Commission's responses:

1. Overall Changes to Part 72

All ten of the commenters were generally supportive of the changes to Part 72 and the expansion of scope of § 72.48 to include Part 72 certificate holders. Nevertheless, the commenters indicated that the regulations in Part 72 were more restrictive than similar regulations in Part 50. The commenters pointed to certain Part 72 requirements (i.e., release limits, § 72.48 evaluation criteria on occupational exposure and environmental impact, and update frequency and content for § 72.48 evaluations and FSAR changes) that do not exist in Part 50 or that are more stringent than similar Part 50 regulations. Overall, the commenters believe the risk from spent fuel storage casks and facilities is much less than from reactors. The commenters generally recommended that §§ 72.48 and 72.70 should be more consistent with §§ 50.59 and 50.71(e).

The Commission agrees that where possible the language used in the respective sections in Parts 50 and 72 should be similar. Therefore, except where unique requirements exist (e.g., because § 72.48 involves both licensees and certificate holders, as well as facilities and spent fuel storage cask designs, and § 50.59 only involves licensees and facilities), the final rule has used consistent language in both Parts 50 and 72. The NRC also notes that the comments on revising the release limits for Part 72 are clearly beyond the scope of the proposed rule and no further response is made.

2. § 72.48 (Changes, Tests, and Experiments)

The ten commenters suggested that the tests in § 72.48 should be same as are used in § 50.59; in particular, five commenters said that the significant increase in occupational exposure and significant unreviewed environmental impact tests were unnecessary and therefore should be removed. One commenter indicated the unreviewed environmental impact test should be retained, but only for specific licensees.

The Commission agrees that the occupational exposure test is unnecessary because licensees are currently required by § 20.1101(b) to take actions to maintain occupational exposure as low as is reasonably achievable. The Commission also agrees that the significant unreviewed environmental impact test is unnecessary. As stated in the Finding of No Significant Environmental Impact for this rule, the changes being made in § 72.48 will allow only minimal increases in probability or consequences of accidents (still satisfying regulatory limits) without prior NRC review. Further, changes which result in more than minimal increases in radiological consequences will continue to require prior NRC approval, including NRC consideration of potential impact on the environment. Therefore, consistent with § 50.59, there is no need for this criterion to be included with respect to consideration of a change under § 72.48 and it has been deleted from the final rule.

One commenter suggested that the scope of § 72.48 should be limited to only "important to safety" structures, systems, and components (SSCs), not all SSCs described in the FSAR. One commenter suggested the § 50.59 term "equipment important to safety" should be used rather than "SSC important to safety." One commenter suggested the term "evaluations" should be removed from the definition of the facility in proposed paragraph §72.48 (a)(3)(iii).

The Commission disagrees with these comments. The term SSCs provides a better description than equipment and is consistent with other regulations in both Parts 50 and 72 (as noted earlier, the Commission is revising § 50.59 to refer to SSC instead of to equipment). The scope of these § 72.48 evaluations should include all SSCs described in the FSAR, not just those that are important to safety. The current regulations in § 72.48 require a scope that includes all structures, systems, and components described in the FSAR not just those "important to safety." The Commission continues to believe that this approach is necessary to insure that changes to SSCs considered "not important to safety" do not have a negative impact on SSCs considered important to safety due to interactions and interfaces, and do not cause any adverse impact on public health and safety. The term "evaluations and methods of evaluation" is necessary for the reasons previously discussed for § 50.59 changes, and is retained in final § 72.48(a)(2)(iii).

One commenter stated that the term FSAR should not be used because Part 72 is a one step licensing process and using the term implies a second review step is required by staff. The same commenter added that the discussion of the FSAR [in the rule] could also imply that the § 72.48 process is not required to address changes until the licensee has an FSAR. (The commenter thought the proposed rule language suggested that § 72.48 would not apply until after the FSAR was submitted). Two commenters identified concerns with the current requirement for a specific licensee to update its SAR every 6 months and its role as a hold point [requiring staff review] and the requirement to update the SAR 90 days prior to loading fuel. Two other commenters suggested that the order of paragraphs 72.48 (a)(2) and (a)(3) should be reversed and that the term "required to be included" should be deleted from proposed paragraph (a)(3)(iii).

The Commission has revised §§ 72.48, 72.70 and 72.248 in response to these comments. These changes have clarified the use of the term FSAR to avoid the interpretation that multiple staff reviews of this document will be required. The FSAR being submitted 90 days after license issuance precludes both a hold point and an additional staff review. Further the Commission agrees that providing a periodic FSAR update every 6 months and a final one 90 days prior to fuel load was an unnecessary burden, which does not exist in § 50.71(e), and these requirements have been eliminated. The Commission agrees that language was needed to indicate that the facility or design can be changed using the new process in § 72.48 after a license is issued and prior to issuing the FSAR and that has been reflected in the final rule. Paragraphs 72.48 a(2) and a(3) have been reversed in order and the phrase "required to be included" has been deleted for clarity and for consistency with § 50.59.

Several commenters suggested that a different approach be taken on the margin of safety; that the terms "minimal", "more than minimal" or " significant" required further clarification and should be consistent with § 50.59; suggested reports of § 72.48 changes, tests, and experiments be submitted every 24 months: and that an implementation schedule be provided for the final rule.

The NRC agrees that §§ 50.59 and 72.48 should be as consistent as possible. Therefore §72.48 has used the language adopted in response to comments on §50.59 (see comments on §50.59 on the use of minimal and margin of safety terminology). The NRC agrees that a 24 month reporting frequency is appropriate. The NRC has also provided direction in implementing the final rules.

One commenter suggested that licensees and certificate holders should inform each other of changes implemented under § 72.48 that affect a particular cask design, through the summary reports rather than through the FSAR update, as was stated in the proposed rule. One commenter also suggested that guidance on the timeliness of the review to be performed upon receipt of such changes be provided.

The NRC agrees with both comments and has added § 72.48 (d)(6)(i) - (iii) on providing copies of § 72.48 evaluations to other interested persons who use the particular cask design within 60-days of implementing the change (the proposed language in § § 72.216 and 72.248 on this point has been deleted). Guidance on the timeliness of the reviews will be provided by the NRC along with other guidance information for §§ 50.59 and 72.48.

General licensees who have evaluated a proposed change under § 72.48 and concluded that a CoC amendment is required, must request that the certificate holder submit the application for amendment under § 72.244. Clarifying language was included in § 72.48 on this point.

As a result of other changes made earlier in § 72.48, the section on recordkeeping was reformatted to include subsection numbering. As part of this revision, the text in paragraphs (d)(3)(i) and (d)(3)(ii) was clarified to acknowledge those situations where the facility is no longer being used, but for which the license has not yet been terminated.

3. §§ 72.70, 72.216, and 72.248 (FSAR Updating)

Several commenters suggested that the language in §§ 72.70, 72.216, and 72.248 on updating the FSAR conform to the language in § 50.71(e). Specific changes requested included requiring a 24-month reporting period, adding a 6-month cutoff for reporting changes, clarifying requirements for the initial submittal of the FSAR, and how no changes to the FSAR are to be reported by stating that there are no changes. One commenter felt that requiring a general licensee to maintain its own FSAR (i.e., potentially separate and distinct from the certificate holder) was unnecessary and would cause confusion. One commenter felt that the process for revising the FSAR for a general licensee was confusing.

The NRC agrees that providing a 24-month FSAR update and adding the 6-month cutoff for bringing the FSAR up to date for changes made are consistent with § 50.71(e), are appropriate, and are a reduction in unnecessary regulatory burden. Lastly, the NRC believes that providing a written confirmation when no changes to the FSAR have been made provides a clear and timely record of the status of the FSAR to both the staff and the public and agrees with this comment. The NRC also agrees that having a general licensee keep a separate FSAR from that of a certificate holder is redundant and believes that requiring a separate FSAR is not necessary for the staff to maintain its regulatory oversight over general licensees. Accordingly, proposed paragraph (d) to § 72.216 has been withdrawn. In withdrawing this section, the NRC wishes to clarify that the certificate holder is not expected to incorporate § 72.48 changes made by general licensees into its FSAR; rather the certificate holder is responsible for updating the FSAR for any changes it has made under the provisions of § 72.48. Furthermore, the NRC expects certificate holders to maintain the FSAR current for any version of its cask design, which is being used to store spent fuel.

Two commenters suggested that the proposed rule language in §§ 72.70, and 72.248 that the FSAR update include a "description and analysis of changes in procedures or in [SSC]", was more burdensome than the existing language in §50.71(e) that the update is to "contain all the changes necessary to reflect information and analyses submitted. ..."

The NRC agrees that this language could be read as requiring a separate discussion of the effects of changes beyond the SAR updates themselves, which was not the intent of the proposed rule. The language in §§ 72.70 and 72.248 has been revised to be as consistent with § 50.71(e) as possible and, in particular, refers to "include the effects of" changes, analyses and evaluations, but not stating that the update needs to describe each change.

In the current rule, a licensee must submit to the NRC its FSAR 90 days prior to the receipt of fuel or high level waste and this action serves as a formal notification to the regulator that fuel (or high level waste) is planned to be loaded. A number of comments viewed this requirement as overly restrictive because many changes related to cask loading included in a FSAR will not be identified or analyzed until preoperational testing is performed and, thus, the 90 day FSAR update requirement could be interpreted as another holdpoint before loading. The NRC agrees that the requirement that a FSAR be submitted at least 90 days prior to fuel load was not intended to serve as a holdpoint and in the final rule, this has been changed to require a specific licensee to submit a FSAR 90 days after receiving a license. To maintain the notification aspect of the current regulation, a new requirement was added to § 72.80(g) to notify the NRC of the licensee's readiness to begin operation at least 90 days prior to the first loading of spent fuel or high-level radioactive waste. Specific licensees will update their FSAR every two years. Because the FSAR will be submitted before construction and preoperational testing of the ISFSI would be completed, a requirement was retained in § 72.70 to provide a final analysis and evaluation of the design and performance of SSCs taking into account information since the submittal of the application (i.e., information developed during final design, construction, and preoperational testing), in the next periodic update to the FSAR. This information is not required by the final § 50.71(e); however, it is necessary to require these actions to complete the description of the ISFSI, because of the single-step licensing process in Part 72.

New reporting requirements for certificate holders will be added in §§ 72.244 and 72.248, similar to existing requirements imposed on licensees in §§ 72.56 and 72.70, respectively.

4. §§ 72.3, 72.9, 72.24, 72.56, 72.86, and 72.212 (Miscellaneous Sections of Part 72)

No specific comments were received on §§ 72.3, 72.9, 72.24 and 72.86, and the final rule language is unchanged from the proposed rule language for these sections.

Two commenters believed that § 72.56 was not clear on whether this regulation applied to specific licensees, general licensees, or both.

The NRC agrees and has revised this section to indicate it applies to specific licensees only.

One commenter suggested that § 72.56 be revised to allow licensees to apply for emergency or exigency processing of license amendment requests, similar to that allowed under certain conditions for Part 50 licensees under § 50.91(a)(5) and (6).

The NRC disagrees. The NRC currently has the authority under § 72.46(b)(2) to immediately issue an amendment to a Part 72 license upon a finding that no genuine issue exists that could adversely affect public health and safety. Consequently, the NRC's authority to immediately issue an amendment to a Part 72 license obviates the need for a separate emergency or exigency amendment process.

One commenter recommended that any changes to the written evaluations performed by a general licensee in accordance with § 72.212(b), in determining whether a spent fuel storage cask design can be used at a particular Part 50 reactor site, should be accomplished using the requirements of § 72.48.

The NRC agrees and has revised § 72.212(b)(2)(ii) to require the general licensee evaluate any changes to the written evaluations required by § 72.212 using the requirements of § 72.48(c).

O.2 Petition for Rulemaking (PRM-72-3)

The NRC received a petition for rulemaking submitted by Ms. Fawn Shillinglaw in the form of two letters addressed to Chairman Jackson dated December 9 and December 29, 1995. The Office of General Counsel determined on March 5, 1996, that the issues presented in these letters would be treated as a petition for rulemaking. The petition requested that the NRC amend its regulations in 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Fuel and High-Level Radioactive Waste." The petition was docketed as PRM-72-3 on March 14, 1996. Ms. Shillinglaw supplemented her petition with additional information in a letter dated April 15, 1996. The NRC published in the *Federal Register* on May 14, 1996, a notice of receipt of this petition and stated the issues contained in the petition (61 FR 24249).

Specifically, the petitioner requested that the NRC amend those regulations which govern independent storage of spent nuclear fuel in dry storage casks to require that: (1) the safety analysis report (SAR) for a dry storage cask design fully conforms with the associated NRC safety evaluation report (SER) and Certificate of Compliance (CoC) before NRC certification (i.e., approval) of the dry storage cask design; (2) the revision date and number of an SAR be specified whenever that report is referenced in documents; (3) the NRC clarify the process for modification of an SAR after a cask has been certified; and (4) the NRC make available to the public, the licensees' unloading procedures. In her supplemental letter, the petitioner recommended that to eliminate confusion, the term "CSAR" (i.e., cask safety analysis report) be used when referring to the SAR for any dry storage cask design which has been approved by the NRC and issued a CoC.

The Commission received ten comment letters on PRM-72-3. The commenters included five members of the public, three public interest groups, and the Nuclear Energy Institute (NEI). Copies of the public comments on PRM-72-3 are available for review in the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC 20003-1527. No comments were received objecting to the petition. Eight of the commenters were supportive of all, or some, of the four issues raised in PRM-72-3. One commenter (NEI), neither supported nor opposed the petition and recommended that any rulemaking action based on the petition be delayed until the NRC addressed issues in 10 CFR Part 50 relating to the use of the "FSAR" as a licensing basis document and the application of § 50.59 in 10 CFR Part 50. One commenter objected to NEI's recommendation to delay rulemaking on PRM-72-3.

The Commission has determined that PRM-72-3 issues (1), (2), and (3) should be granted, in part; and issue (4) should be denied. This notice constitutes the Commission's final action on this petition. The basis for the Commission's actions on each issue and responses to public comments received on the petition are described below.

Issue (1):

Part 72 should be amended to require that the safety analysis report (SAR) for a spent fuel dry storage cask design fully conforms with the associated NRC safety evaluation report (SER) and certificate of compliance (CoC) before NRC certification (i.e., approval) of the cask design.

Five comment letters were received supporting Issue (1) of PRM-72-3.

Resolution of Issue (1):

In this final rule the Commission has granted, in part, the petitioner's request on this issue. This rule adds new § 72.248 to Part 72 and this section addresses this issue by requiring a certificate holder to submit a final safety analysis report (FSAR) after issuance of the CoC. This rule also describes the process for periodic updates of the FSAR. Section 72.248, subparagraphs (a)(1) and (a)(2) state, in part:

> Each certificate holder shall submit an original FSAR to the Commission ... within 90 days after the spent fuel storage cask design has been approved pursuant to § 72.238. This original FSAR shall be based on the safety analysis report

submitted with the application and reflect any changes and applicant commitments developed during the cask design review process. The original FSAR shall be updated to reflect any changes to requirements contained in the issued Certificate of Compliance (CoC)....

The Commission agrees with the petitioner that the FSAR should be fully conformed (i.e., consistent) with the operating limits contained in the CoC, because the FSAR contains the design information the staff used to make its safety finding and to approve the dry storage cask design for use. The Commission disagrees with the petitioner's request that the FSAR be conformed to the NRC SER for the dry storage cask design, and that the FSAR be submitted to the NRC before approval of the cask design (i.e., issuance of the CoC). The NRC SER contains staff conclusions on the adequacy of the cask design, not applicant commitments to the NRC on the cask design. Therefore, the Commission believes it is not necessary to conform the FSAR to the issued NRC SER before the CoC can be issued. The NRC SER is available in the NRC Public Document Room for public review.

The Commission disagrees with the petitioner's request that issuance of the CoC (i.e., placement of the CoC in the list at § 72.214 which enables a general licensee to use the cask design) be delayed until after the certificate holder has submitted an FSAR to the NRC (i.e., updated the topical safety analysis report, submitted with its application for approval of a dry storage cask design, to ensure that the SAR is consistent [fully conforms] with the approved CoC). This final rule codifies as a regulation the NRC's current approach which, administratively, requires a certificate holder to update its SAR after issuance of the CoC to ensure it is consistent with the issued CoC. For administrative purposes, the Commission prefers that the original FSAR be submitted to the NRC, within 90 days after the CoC is issued, so that the certificate holder can include [conform] in the FSAR any conditions from the issued CoC. The FSAR does not need to be conformed to the CoC, before the CoC is issued, because this action does not provide any new information the NRC would need to make a determination that the cask design meets the requirements of Part 72, Subpart L, and is acceptable for use.

The Commission also disagrees with the petitioner's supplemental information to use the term "cask safety analysis report (CSAR)" when referring to the SAR submitted after the NRC approves a cask design. Instead, the Commission is using the term "final safety analysis report (FSAR)" to identify the SAR submitted after the NRC approves a cask design. The use of the term "FSAR" is the accepted practice by industry and will not cause confusion. Further, this approach will ensure consistency between Parts 50 and 72, because the term "FSAR" is used by §§ 50.59, 50.71(e), 72.48, and 72.70 in this final rule.

Issue (2):

Part 72 should be amended to require that the revision date and number of an SAR be specified whenever that report is referenced in documents.

Five comment letters were received supporting Issue (2) of PRM-72-3.

Resolution of Issue (2):

In this final rule the Commission has granted, in part, the petitioner's request on this issue. This rule adds new § 72.248 to Part 72 which requires that revision numbers, change bars, and a list of current pages be included in any revisions to the FSAR. Section 72.248, subparagraphs (c)(2) and (c)(3) state:

> The update [of the FSAR] shall include a list that identifies the current pages of the FSAR following page replacement. Each replacement page shall include both a change indicator for the area changed, e.g., a bold line vertically drawn in the margin adjacent to the portion actually changed, and a page change identification (date of change or change number or both).

These features will clearly identify what has been changed, as well as the date of the change, in any revision to a FSAR. While § 72.248 will provide a process for requiring revisions to the FSAR be clearly indicated, the Commission has denied the portion of the petitioner's request to amend Part 72 to require a FSAR revision number and date be specified when the FSAR is referenced in other documents (e.g., an application for a Part 72 license or CoC). Instead, the NRC will revise guidance documents for Part 72 activities (e.g., regulatory guides and standard review plans) to require specification of the FSAR revision date and number whenever a FSAR is referenced in another document. The Commission believes addressing this portion of the petitioner's request in guidance documents rather than in a regulation is more appropriate and meets the intent of the request.

Issue (3):

The NRC must clarify the process for modification of a safety analysis report after a cask [design] has been certified [i.e., approved by the NRC].

Five comment letters were received supporting Issue (3) of PRM-72-3 including a comment from the petitioner clarifying that she believed that "any changes to the SAR [FSAR] should be done by the amendment process of rulemaking." Four commenters also recommended that any changes made to the SAR (including a generic SAR), the cask design, or the CoC should require rulemaking and public comment or a public hearing. One commenter also suggested that the regulations be amended to include more detail on who can make changes to dry storage cask designs and whether vendors (i.e. certificate holders) can make these changes.

Resolution of Issue (3):

The Commission is revising § 72.48 to allow a certificate holder to make certain types of changes to a cask design, or procedures, or to conduct tests and experiments, not described in the FSAR (as updated) without requiring prior NRC approval if the criteria in § 72.48(c) are met. If these criteria are not met, a certificate holder must obtain a CoC amendment pursuant to § 72.244. Following such changes (either resulting from the § 72.48 process or the CoC amendment process), the certificate holder must update the FSAR as required by § 72.248. Section 72.248, paragraphs (b), (b)(2), and (b)(3) state, in part:

> The [FSAR] update shall include the effects of: All safety analyses and evaluations performed by the certificate holder either in support of approved CoC amendments, or in support of conclusions that the changes did not require a CoC amendment in accordance with § 72.48. All analysis of new safety issues performed by or on behalf of the certificate holder at Commission request. The information shall be appropriately located with the updated FSAR.

The Commission is seeking to reduce any unnecessary regulatory burden placed on its licensees and certificate holders without compromising safety. The dry storage cask design review process and the analysis acceptance criteria are defined in the NRC's standard review plans. This final rule allows licensees and certificate holders to make changes to the cask design, without obtaining prior NRC approval, for changes which do not significantly impact the ability of the cask to perform its intended functions. The impact of these changes are then incorporated into an updated FSAR, which is submitted to the NRC. Requiring that all changes to a cask design or changes to a FSAR be reviewed and approved by the NRC through the rulemaking amendment process, including either a public comment period or a public hearing, defeats these efforts with no discernable increase in safety. Further, while rulemaking is currently utilized to amend a CoC, the Commission is presently re-examining the appropriateness of this procedure. Therefore, the Commission has granted petitioner's request to clarify the process for modification of an FSAR after the NRC has approved the cask design and issued the CoC, but has rejected the request to require all changes to a cask design, or the FSAR, be made via a rulemaking amendment process.

Issue (4):

The NRC should make cask unloading procedures publicly available.

Five comment letters were received supporting Issue (4) of PRM-72-3. One commenter also requested that the NRC review, approve, and have tested unloading procedures prior to their being implemented. One commenter suggested suspending all cask loading activities until the NRC reviews procedures [for loading and unloading] and appropriate tests are completed.

Resolution of Issue (4):

The NRC does not approve or test a licensee's loading or unloading procedures, rather the licensee is responsible for development, verification, and validation of the loading and unloading procedures. The NRC inspects the licensee's procedures (i.e., reviews the procedures and observes the licensee implementing them) to determine whether the procedures will provide reasonable assurance that public health and safety will be adequately protected.

The Commission does not agree that cask unloading procedures should be required to be public documents. First, in order to make these procedures publicly available, either the NRC must possess the procedures, or the licensee must place the procedures in the public domain. The Commission's position is that only those documents necessary to demonstrate that a dry storage cask is designed to meet the requirements of Part 72, Subpart L, need to be submitted to the NRC on the docket (i.e., to allow the NRC to determine that the cask design is acceptable for use). Cask loading and unloading procedures are implementing documents required by the CoC which are developed and implemented by the licensee.

Although the NRC does not possess the procedures, they are subject to inspection by NRC staff. However, even during inspection activities, NRC generally does not take possession of the procedures. Therefore, the unloading procedures remain the property of the licensees and are not available to the public. The NRC's inspection program for Part 72 licensees requires the inspection of loading and unloading activities, including a review of applicable procedures, before a licensee begins cask loading. NRC inspection personnel perform these activities at the licensee's site and observe the licensee's preoperational testing and dry run activities to assess the adequacy of these procedures and the readiness of the licensee to begin loading spent fuel.

The results of these inspections are documented in reports which are placed in the NRC Public Document Room and are available for public review.

Furthermore, requiring Part 72 licensees to submit their implementing procedures to the NRC (i.e., operating procedures such as loading and unloading procedures, maintenance procedures, surveillance procedures, radiation protection procedures, security procedures, emergency procedures, and administrative procedures), as well as any revisions to these procedures, would impose a huge paperwork burden on both the licensee and on NRC staff without a corresponding safety benefit. Therefore, Issue (4) is denied.

Additional Public Comments on the Petition

In addition to the specific comments that were received on the petition that are discussed above, a number of comments were received on related and unrelated subjects.

Comment: Five comments were received on the VSC-24 cask design being used at the Palisades and Point Beach plants and incidents related to the VSC-24 cask design.

Response: The Commission considers these comments beyond the scope of this petition and this rulemaking.

Comment: Two comments were received suggesting that when a change to an approved dry storage cask design is requested, that the existing CoC be suspended until the changes are approved by the NRC.

Response: The Commission considers these comments would impose an unreasonable burden on Part 72 licensees. Suspending a CoC solely on the basis of receiving a change and not on the basis of a compelling safety need, would imply that any casks manufactured under the CoC, which are in use by Part 72 licensees, should be taken out of service (i.e., unloaded) upon receipt of any request to revise the cask design. Requiring that a cask be unloaded in these circumstances would impose an unreviewed backfit on the Part 72 licensees using that cask design and would also result in unnecessary occupational exposure to licensee workers.

Comment: One comment was received recommending that any rulemaking action based on PRM-72-3 be delayed until the NRC addressed issues in 10 CFR Part 50 relating to the use of the "FSAR" as a licensing basis document and the application of § 50.59 in 10 CFR Part 50.. Another commenter disagreed with this recommendation to delay rulemaking on PRM-72-3.

Response: The Commission believes that issuance of this final rule resolves this comment.

Comment: One commenter requested that the NRC prohibit general licensees from using § 72.48 and only permit cask design changes via rulemaking. One commenter recommended that any identification of an unreviewed safety question submitted to the NRC should require that NRC conduct a hearing on the issue. One commenter suggested that the NRC approve each § 72.48 safety evaluation and place each evaluation in the public document room. One commenter suggested that the NRC "vacate the generic ruling procedure" [Subpart L] and require that public hearings be held prior to NRC cask certification. One commenter suggested a moratorium on additional dry cask storage cask designs.

Response: Petitioner's concerns related to cask certification issues; in particular, the process for modifying a SAR for a dry cask storage design before and after issuance of the CoC. These comments raise broad policy issues that go well beyond the scope of this petition and rulemaking.

O.3 Part 71 (Transportation) Comments

Several commenters stated that a change control process similar to § 72.48 should be established in Part 71 for transportation. These commenters noted that for dual-purpose casks, used for both transportation and storage, the lack of a process in Part 71 would limit the usefulness of the authority provided under § 72.48. Although the Commission agrees that this comment has merit, adding this authority to Part 71 is beyond the scope of the proposed rule. In response to these comments, the Commission will consider adding "§ 71.48-type" change authority as part of a currently planned rulemaking for Part 71 intended to update requirements for compatibility with the most recent International Atomic Energy Agency transportation standards.

P. Other Topics Discussed in the Notice and Comments Not Related to Preceding Topic Areas

The FR notice containing the proposed rule also solicited comments on particular topics that were discussed in the preceding sections. In addition, comments were received on a number of aspects not directly related to the rule language itself, such as guidance, enforcement policy, the regulatory (and backfit) analysis, or on other issues.

Guidance

Many comments were received on the subject of guidance. Many suggested that NEI and NRC work together to develop guidance, and that the guidance be endorsed before the revised rule becomes effective. Commenters also requested examples of such matters as interdependent changes, minimal increases, and screening of changes (as discussed in Sections B and G).

The NRC agrees that guidance is important, and notes that NEI has stated its willingness to revise existing guidance to conform with the final rule such that NRC could endorse it. The NRC will work with interested stakeholders to agree upon guidance that includes consideration of these issues. Further, NRC is delaying the required implementation of the rule for several months to allow time for guidance to be revised.

Fuel Burnup limits

One commenter stated that NRC should clarify the acceptance limits of § 51.55 concerning burnup assumptions for the transportation of spent fuel for BWRs, as well as clarifying if this is subject to § 50.59 evaluations.

The Commission notes that a proposed rule (§ 51.52, not § 51.55 as cited by the commenter) was recently published on February 26, 1999 (64 FR 9884), concerning environmental implications of higher burnup fuel for transportation of spent fuel. Transportation of fuel is not covered by § 50.59 (as noted elsewhere in this notice, the Commission is considering revisions to Part 71 that would add a change control process similar to § 50.59 that could be used for changes to transportation requirements under Part 71). If the commenter was asking whether higher burnup fuel can be used without NRC approval, it is unlikely that such a change would satisfy the criteria of § 50.59, either because TS changes would be involved, other requirements (e.g., § 50.46) would not be met, or the burnup being considered would be outside the range of what was approved in the topical reports for the fuel.

Alternative Criteria

Two commenters proposed the use of alternate criteria for reactors that are being decommissioned. One commenter suggested that a "margin" criterion is not necessary, but that a criterion on environmental impact might be appropriate.

The Commission notes that the new criteria in the final rule that replace the "margin" criterion are appropriate for a reactor being decommissioned. Further, § 50.82(a)(6) specifies that licensees shall not perform any decommissioning activities that result in significant environmental impact not previously reviewed. Section 50.82(a)(4) requires that the post-shutdown decommissioning activities report include a discussion that provides the reasons for concluding that the environmental impacts associated with site-specific decommissioning activities will be bounded by appropriate, previously issued environmental impact statements. For these reasons, the Commission concludes that a criterion on environmental impact is not needed.

The second commenter stated that the scope of § 50.59 should be limited to systems related to spent fuel pool cooling or radiological waste.

The Commission notes that the staff involved in requirements for decommissioning are developing guidance on the scope of information required to be in an updated FSAR for a reactor undergoing decommissioning. This effort is examining what information should be retained in an FSAR for these facilities. The Commission believes that defining the scope of information required to be in the FSAR for a reactor undergoing decommissioning would be the best way to address the apparent concern raised in this comment, rather than by modifying § 50.59 as recommended by the commenter.

Regulatory Analysis

Some comments were received on the regulatory analysis, primarily that NRC underestimated the impacts on NRC and licensees of the number of license amendments that would result, or the burden on Part 72 licensees. These comments would appear to reflect a view that the proposed rule would require more amendments than are currently required, perhaps because of differences between the proposed rule language and existing practice of some licensees using NEI 96-07, or depending upon which formulation of "margin of safety" was ultimately adopted. The Commission has prepared a final regulatory analysis that reflects the final rule language and consideration of the public comments. The Commission does not agree that the final rule language will result in more amendments than presently arise under the existing rule.

Need for Further Notice and Comment

Two commenters stated that the Commission should ensure that the final rule is within the bounds of the proposed rule notice, or should provide opportunity for public comment on substantive changes. The Commission has examined the final rule for consistency with the proposed rule and concludes that the final rule is within the bounds of the proposed rule, taking due consideration of the public comments that sought clarification and revisions in some respects, as well as greater consistency between the Part 50 and Part 72 requirements.

Different Process for non-TS Issues

Several commenters believe that the license amendment process is not well suited to the type of changes that require review under § 50.59(c)(2), but that do not involve changes to the TS or the license directly. They believe that the Commission should establish a different review process for such changes, such as letter approval.

The Commission notes that at one time (until 1974), § 50.59 did contain two approval processes, one for license amendments, and the other for "authorizations." The rule was revised in 1974 to delete the "authorization" process and to handle all the required approvals as license amendments. The Commission notes that the present rulemaking provides some relaxation in the evaluation criteria. Therefore, the NRC has responded to concerns about having to process a license amendment for "minimal" changes. The current process provides opportunity for public participation in the process under the provisions of § 50.90 for changes that exceed the criteria, and for public knowledge, through the summary reports, of those matters that did not require prior approval. Therefore, the Commission does not plan to establish a different process.

Other Definitions

Some commenters felt that NRC should provide better definitions of certain terms that appear in § 50.59 (and elsewhere), specifically, for "design bases" and for "important to safety."

The Commission notes that § 50.2 does define design bases, but also notes that efforts are underway within the agency to enhance understanding of what constitutes design basis information, through possible development of criteria and examples. Concerning "important to safety," the Commission does not believe that a definition is critical to implementation of the rule, since the set of SSCs viewed as important to safety was arrived at during the license review and are described in the FSAR. Thus, lack of an established definition is not an impediment to implementation of the rule (the Commission notes that for Part 72, a definition is provided for SSC important to safety).

Applicability to Part 76

In its development of the proposed rule, as discussed in SECY-98-171, the staff recommended exclusion of Part 76 ("Certification of Gaseous Diffusion Plants") from those regulations for which rule changes were being proposed. The basis for this recommendation was a lack of design detail currently available in the safety analysis reports for these plants. One commenter argued that the flexibility provided by the revised evaluation criteria should also be included in § 76.68 (this section contains requirements very similar to existing §§ 50.59 and 72.48). This commenter stated that the process by which changes are evaluated should not vary based on the detail of the description being changed.

The Commission notes that the gaseous diffusion plants (GDP) have significantly less design basis information than is currently available for reactor facilities. The lack of design detail and lack of understanding of the design basis has been documented in the Compliance Plans for the GDPs, in NRC inspection reports, and is evident in the GDP SARs. The Commission concludes that successful implementation of a change control process is dependent upon the level of knowledge about the design basis of the plant equipment or operation being changed. At the present time, the Commission does not believe that additional flexibility is appropriate for Part 76 facilities.

Q. Enforcement Policy

Some commenters raised issues about how enforcement decisions would be made during the transition period, and following implementation, particularly with respect to evaluations performed in the past.

The Commission recognizes that it will take time to revise existing industry guidance and to revise procedures, and conduct training on the new rule provisions before the rule can be fully implemented. There will still be the possibility of finding previous plant changes performed prior to the implementation of the new rule that would be potential violations of the previous rule. The Commission has concluded that enforcement of potential violations of §§ 50.59 and 72.48 for past evaluations will be handled as described below, and also in accordance with the NRC Enforcement Policy, NUREG-1600, Revision 1.

Following publication of the revised rule, for situations that violate the "old" requirements, but that would not be violations had the evaluation been performed under the revised rule, the NRC will exercise enforcement discretion pursuant to VII.B.6 of the Enforcement Policy and not issue citations against the "old" rule. The staff will document in inspection reports that the issue was identified, but that no enforcement action is being taken because the revised rule requirements are met. However, for those situations identified prior to the effective date of the revised rule that involve a violation of the existing rule requirements but that would not be violations under the revised rule, licensees still need to take the required corrective action within a reasonable time frame commensurate with safety significance to avoid the potential for a willful violation of NRC requirements.

The NRC plans to maintain an enforcement panel made up of NRR (and NMSS as applicable), OE, and OGC representatives for some months after publication to maintain consistency. Additional enforcement policy changes that may be applicable to violations of §§ 50.59 or 72.48 are under consideration. The Commission intends to revise NUREG-1600, Rev. 1, "General Statement of Policy and Procedures for NRC Enforcement Actions," consistent with this enforcement approach prior to the effective date of the rule.

R. Implementation

The Commission recognizes the role that regulatory guidance will play in effective implementation of the revisions to the rule. Existing guidance (e.g., NEI 96-07 and NRC inspection guidance) needs to be revised to conform with the rule changes. To allow time for the guidance to be revised, and for licensees to implement the revised rule provisions using the revised guidance, the Commission has established that the rule changes to Part 50 will become effective 90 days after promulgation of the final regulatory guidance.

For Part 72 facilities, current schedules for guidance would result in availability at a time later than that anticipated for the guidance for Part 50. Accordingly, the effective date for these sections is longer, set at 18 months from publication of the rule in the *Federal Register.* For those sections in Part 72 for which no guidance is needed, as for instance, sections 72.244 and 72.246, the effective date is 120 days from publication.

III. SECTION BY SECTION ANALYSIS

10 CFR Part 50

<u>10 CFR 50.59</u>

As discussed in more detail above, § 50.59 is being restructured and revised to have the following components:

Paragraph (a): This is a new paragraph that contains definitions of terms used in the rule. The terms establish requirements for when evaluations are to be conducted to determine if the proposed changes, tests, or experiments meet the criteria to require prior NRC approval. Accordingly, definitions are given for "change," "facility as described in the final safety analysis report (as updated)..," "procedures as described...," " tests and experiments not described..." etc. The specific definitions were discussed in the preceding sections.

Paragraph (b): Relocation into one paragraph of existing applicability provisions. Section 50.59 applies to facilities licensed under Part 50, including power reactors and non-power reactors, whether operating or being decommissioned.

Paragraph (c)(1): Relocation and clarification of existing provisions establishing which changes, tests, or experiments require evaluation and process for receiving approval when necessary. The provisions now use the terms defined in paragraph (a), and refer to the "final safety analysis report (as updated)," rather than to "safety analysis report." The terminology of "unreviewed safety question" has been replaced by referring to the need to obtain a license amendment.

Paragraph (c)(2): Reformatting of the (existing) evaluation requirements into seven distinct statements of the criteria, addition of an eighth criterion, and revision of the existing criteria for when prior NRC approval of a change, test, or experiment is required. Specifically, language of "more than a minimal increase in frequency (or likelihood)," and of "more than a minimal increase in consequences" was inserted in the criteria concerning accidents and malfunctions, and rule requirements were revised from "may be created" to "would create" concerning creation of accidents of a different type and malfunctions of structures, systems, and components important to safety with a different result (instead of existing language of malfunction of equipment of a different type). In addition, the existing criterion on "margin of safety" was replaced by a criterion focusing upon design basis limits for fission product barriers being exceeded or altered, and a new criterion was added to control evaluation methods. These revisions clarify the criteria for when prior approval is needed and allow some flexibility for licensees to make changes that would not affect the NRC basis for licensing of the facility.

Paragraph (c)(3): This is a new paragraph containing the requirement that evaluations and analyses performed since the last FSAR update was submitted need to be considered in performing evaluations of changes to the facility or procedures, or for conduct of tests and experiments. This paragraph is consistent with the terminology of "final safety analysis report (as updated)."

Paragraph (c)(4): This is a new paragraph that states that § 50.59 requirements do not apply to changes to the facility or procedures when other regulations establish more specific criteria for such changes. Thus, this paragraph clarifies that duplicative reviews in accordance with § 50.59 are not necessary for information that is described in the FSAR, but for which other regulations provide standards for change control.

Paragraph (d)(1): Renumbered paragraph with (existing) recordkeeping requirements. The text was simplified concerning which records are needed, and conforming changes were made for the change in terminology from "safety evaluation" to "evaluation."

Paragraph (d)(2): Renumbered paragraph with (existing) reporting requirements. The text was simplified to state that summary reports must be submitted at least once every 24 months, instead of the existing statement that refers to submitting the summary report along with the FSAR update submittal or annually. This revision will allow all facilities to submit the report on a 24 month frequency.

Paragraph (d)(3): Renumbered paragraph on retention of records. The text was revised to cover retention of records required by §50.59 until the term of any renewed license has expired.

10 CFR 50.66

This section specifies requirements for thermal annealing of a reactor pressure vessel. The changes to § 50.66 are to conform existing language referring to unreviewed safety questions, and to updated final safety analysis report, to the language in revised § 50.59.

10 CFR 50.71(e)

This section discusses requirements for periodic updating of the final safety analysis report, to reflect the effects of changes made either under § 50.59, or through license amendments, or effects of new analyses. The changes to this section are to conform language with respect to unreviewed safety question, safety evaluation, and reference to the final safety analysis report (as updated), with the language in revised § 50.59, as well as other minor wording changes as noted above (e.g., “approved” license amendments).

10 CFR 50.90

A portion of existing § 50.59(c) is being relocated into this section. This change places the requirements for changes to technical specifications themselves (not a result of a change, test or experiment as defined in § 50.59), into the rule section on amendments to licenses rather than retaining the requirement in the section on changes to the facility.

10 CFR PART 72

Most of the revisions in Part 72 mirror those made to § 50.59. As for Part 50, other changes are needed with respect to updating of safety analysis reports, and in other sections for consistent terminology.

10 CFR 72.3

The definition of "independent spent fuel storage installation" is being revised to remove the tests for evaluation of the acceptability of sharing common utilities and services between the ISFSI and other facilities. (Section 72.24 is being revised to include this evaluation.)

10 CFR 72.9

Paragraph (b) is being revised as a conforming change to include in the list of information collection requirements the new requirements in §§ 72.244 and 72.248 for amendments and for updates to the safety analysis reports by CoC holders.

10 CFR 72.24

This section is being revised to reference shared common utilities and services in the applicant's assessment of potential interactions between the ISFSI and another facility (previously covered by § 72.3).

10 CFR 72.48

This section is being totally reformatted and revised, as discussed above for § 50.59. Specifically, it contains the following:

Paragraph (a): This paragraph now specifies definitions for terms such as "change" and "facility as described in the Final Safety Analysis Report (as updated)." Additionally, the term "Final Safety Analysis Report (FSAR) (as updated)" has been defined to provide greater clarity and consistency with § 50.59 and other sections of Part 72.

Paragraph (b): This paragraph specifies that this section is applicable to general and specific licensees for an ISFSI or MRS, and to spent fuel storage cask certificate holders.

Paragraph (c): Paragraph (c)(1) establishes the conditions a licensee or certificate holder must meet in order to (1) make changes to the facility or spent fuel storage cask design as described in the FSAR, or (2) make changes to the procedures as described in the FSAR, or (3) conduct tests or experiments not described in the FSAR, without prior NRC approval. Those conditions are that: (1) a change to the technical specifications is not required; (2) a change in the terms, conditions or specifications incorporated in the CoC is not required; and (3) the change, test, or experiment does not meet any of the criteria in paragraph (c)(2).

Paragraph (c)(2) lists the specific criteria which, if met, permit a licensee or certificate holder to make the changes, or conduct the tests or experiments, described in paragraph (c)(1) without NRC approval. These new criteria revise existing criteria and conform with the criteria adopted in § 50.59(c)(2). Two existing criteria involving a significant increase in occupational exposure or a significant environmental impact have been deleted. Paragraph (c)(3) states that changes made but not yet reflected in the FSAR update also need to be considered in making the determination under paragraph (c)(2). Paragraph (c)(4) states that § 72.48 does not apply to changes to the facility or procedures when the regulations establish other change control processes for such changes.

Paragraph (d): This paragraph contains the recordkeeping requirements and reporting requirements. In the final rule, subsection numbers were included for clarity. For records, the rule is revised to refer to the records of determinations of the need for license or certificate of compliance (CoC) amendments, rather than to records involving unreviewed safety question determinations. The time frame for submitting summary reports in (renumbered) paragraph (d)(2) was revised from 12 months to 24 months. The filing requirements for the summary reports are modified to be consistent with § 72.4 (Communications).

Paragraphs (d)(3), (d)(4) and (d)(5) contain record retention requirements. The retention requirements for changes to procedures and conduct of tests and experiments were revised to be 5 years (instead of until termination). These time frames are more consistent with those in § 50.59, and also reflect that while facility changes need to be maintained until termination, other records are of less importance after a period of time such as 5 years. Paragraph (d)(3)(i) and (d)(3)(ii) are renumbered and clarified with respect to when records no longer need to be maintained.

New paragraph (d)(6) requires licensees who make changes under § 72.48 to provide copies of the records of such changes to the certificate holder for the cask, and for the certificate holders who make changes to provide records to the general and specific licensees using that cask, within 60 days of implementing the changes.

10 CFR 72.56

Existing § 72.48 (c)(2) is being relocated into this section. This is a parallel change to that for §§ 50.59 and 50.90. The Commission is placing the requirements for changes to license conditions in the rule section on amendments to licenses instead of in the section on changes to the facility.

10 CFR 72.70

This section contains requirements for updating of safety analysis reports by licensees. Section 72.70 was reformatted and revised to conform more closely with the update requirements in § 50.71(e), as well as those in (new) § 72.248. The update frequency is being revised from 12 months to 24 months. Paragraphs (a) and (b) are being revised to use the terms "Final Safety Analysis Report," "FSAR," and "as updated." Paragraph (a) is also being revised to indicate the original FSAR for a specific licensee will be submitted within 90 days of issuance of the license. Final analyses associated with completion of construction or preoperational testing will be provided in the next periodic update of the FSAR. The requirement for a licensee to submit a FSAR 90 days before planned receipt of spent fuel has been removed, in lieu of a notification under §72.80(g) by the licensee 90 days before ISFSI operation commences. The section is also being revised to add the requirement that changes to procedures be reflected in the periodic updates of the FSAR. New paragraph (c) is being added to provide requirements on submitting revisions to the FSAR for specific licensees, including provisions for replacement pages, a cut off date for changes, time frame to file, and provisions for updating if no changes were made.

10 CFR 72.80

New paragraph (g) is being added to this section to require a specific licensee to notify the NRC at least 90 days in advance of its readiness to commence ISFSI (or MRS) operations This requirement replaces a requirement in present 72.70(a) that an FSAR be submitted to the Commission at least 90 days prior to the planned receipt of spent fuel or high-level waste. This requirement thus ensures that the NRC is informed in advance of licensee plans to use the facility so that appropriate oversight activities can be conducted.

10 CFR 72.86

Paragraph (b) currently includes those sections under which criminal sanctions are not issued. This paragraph is being revised to add §§ 72.244 and 72.246 as a conforming change to reflect that certificate holders who fail to comply with these new sections would not be subject to the criminal penalty provisions of § 223 of the Atomic Energy Act (AEA). New § 72.248 has not been included in paragraph (b) to reflect that certificate holders who fail to comply with this new section would be subject to the criminal penalty provisions of § 223 of the AEA.

10 CFR 72.212(b)(2)

Paragraph (b)(2)(i) retains the current rule language but has been renumbered and reordered for clarity as a result of the addition of paragraph (b)(2)(ii). Paragraph (b)(2)(ii) was added to require that the general licensee evaluate any changes to the written evaluations required by §72.212 using the requirements of § 72.48(c).

10 CFR 72.212(b)(4)

The change to this section is to conform the reference to § 50.59 provisions, specifically to change from the terminology of unreviewed safety question to referring to the need for a license amendment for the facility (that is, the reactor facility at whose site the independent spent fuel storage installation is located).

10 CFR 72.216

In the proposed rule, a new paragraph (d) would have been added to present requirements for a general licensee to submit annual updates to a final safety analysis report (FSAR) for the cask or casks approved for spent fuel storage that are used by the general licensee. In the final rule, this section was withdrawn because the Commission concluded that it was not necessary for general licensees to submit updates to the safety analysis report for the approved cask design that they are using for storage.

10 CFR 72.244

This new section presents requirements for how a certificate holder is to submit an application to amend the certificate of compliance (CoC). This section is similar to the requirements in § 72.56 for licensees to apply for an amendment to their license.

10 CFR 72.246

This new section presents requirements for approval of an amendment to a CoC. This section is similar to the requirements in § 72.58 for approval of an amendment to a license.

10 CFR 72.248

This new section presents requirements for submittal of periodic updates to an FSAR associated with the design of a spent fuel storage cask which has been issued a CoC. This new section also states that the changes to procedures and SSC associated with the spent fuel storage cask and which are made pursuant to § 72.48 would be included in the update. This section is similar to the requirements in § 72.70 for submission of updates to the FSAR associated with a Part 72 license and to the requirements in §50.71(e) for power reactor FSAR updates.

IV. Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule, as adopted, will not have a significant impact on the environment. The rule changes are of two types: those that relate to the processes for evaluating and approving changes to licensed facilities and those that involve the degree of potential change in safety for which changes can proceed without NRC review. The process changes will make it more likely that planned changes are properly reviewed and approved by NRC when necessary. With respect to the criteria changes, only minimal increases in frequencies of postulated design basis accidents will be allowed without prior NRC review. All changes to the Technical Specifications, which are the operating limits and other parameters of most immediate concern for public health and safety, will continue to require prior NRC review and approval. Changes to the facility that would involve an accident of a different type from any already analyzed require prior approval. Further, changes that result in more than minimal increases in radiological consequences will continue to require prior NRC approval, including NRC consideration as to whether there is a potential impact on the environment. Therefore, the Commission concludes that there will be no significant impact on the environment from this rule. This discussion constitutes the environmental assessment and finding of no significant impact for this rulemaking.

V. Paperwork Reduction Act Statement

This rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The proposed rule was submitted to the Office of Management and Budget for review and approval of the information collection requirements. Existing requirements were approved by the Office of Management and Budget approval numbers 3150-0011 and 3150-0132.

The rule changes affect information collection requirements through the existing reporting requirements in § 50.59 for a summary report of changes, tests and experiments, performed under the authority of § 50.59 as well as recordkeeping requirements. Similar requirements exist in § 72.48 for licensees under Part 72. In addition, revisions are being made to the requirements in § 72.70 and (new) 72.248 for submittal of updates to the safety analysis reports. Further, the final rule establishes recordkeeping and reporting requirements for CoC holders who make changes to an approved storage cask design in accordance with § 72.48.

The public reporting burden for this information collection request was estimated in the proposed rule to average 3100 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The Commission had estimated that there would be only a slight increase in burden associated with these proposed changes over the existing burden. For the final rule, certain of the provisions that might have resulted in an increase in burden have been removed; therefore, the Commission now concludes that the final rule would result in an overall reduction in reporting and recordkeeping burden, other than for the estimated effort required for a one-time revision to procedures and training. Therefore, the present estimate of the public reporting burden for this information collection request under the final rule is 2900 hours per response.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to the information collection.

VI. Regulatory Analysis

The Commission has prepared a regulatory analysis for this rulemaking. The analysis sets forth the objectives of the rulemaking, the alternatives considered, and examines the values and impacts of the alternatives considered by the Commission. The alternatives considered in this analysis include no action, issuance of guidance only, or rulemaking. The analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, D.C.

VII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, (5 U.S.C. 605(b)), the Commission certifies that this rule will not, have a significant economic impact on a substantial number of small entities. This rule affects only the licensing, operation and decommissioning of nuclear power plants, nonpower reactors, and independent spent fuel storage facilities (including cask certificate holders). The companies that own these facilities 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.

VIII. Backfit Analysis

The Commission has evaluated these rule changes under the backfitting requirements in § 50.109 and § 72.62. The Commission does not regard the changes to be backfits as defined in §§ 50.109(a)(1) and 72.62(a), as applicable. Accordingly, a backfit analysis applicable to these changes has not been prepared. However, the Commission has prepared a regulatory analysis which sets forth the objectives of the rulemaking changes, the alternatives that were considered, and the expected benefits and costs associated with the rulemaking changes. The Commission regards this analysis as providing for a disciplined approach for evaluating the impacts of the proposed changes, which satisfies the underlying purposes of the backfitting requirements in § 50.109 and § 72.62.

Changes to Section 50.59

Section 50.59 defines the circumstances under which holders of nuclear power plant operating licenses may make changes to and conduct tests or experiments at their facilities without prior NRC review and approval. In this rulemaking, new definitions are added to § 50.59 (e.g., the definitions for "change," and "facility as described in the final safety analysis report (as updated)"), and the structure and language of the rule were modified (e.g., the addition of a new applicability section, and the removal of the term, "unreviewed safety question"). These changes constitute clarifications of the existing rule, and codification of existing NRC practice and interpretations of terminology which are undefined by the current rule. Clarifications and codification of existing NRC interpretation and practice do not constitute a generic backfit (although the application of the revised rule may constitute a plant-specific backfit). The new criteria in § 50.59(c)(2)(i), (ii), (iii), (iv), (v) and (vi) are being added primarily[4] for the purpose of providing additional flexibility to licensees to make changes and conduct tests without having to

[4]In some cases, these changes coincide with other changes intended to clarify and codify existing practice, and to make the rule easier to understand (e.g., separating the "frequency of occurrence" of an accident from the "consequences" of an accident as a criterion for NRC review and approval.

obtain prior NRC review and approval. Each of these changes constitute permissive relaxations[5] from the superseded Section 50.59(a)(2)(i) and (ii) criteria. Permissive relaxations are not considered to be backfits, inasmuch as a licensee will continue to be in compliance with the final rule even if it uses its existing procedures and the superseded criteria for implementing § 50.59. The new criteria in § 50.59(c)(2)(vii) and (viii) together constitute replacements for the superseded § 50.59(a)(2)(iii) criterion on "margin of safety." As noted in Section J, these two criteria together, in place of a criterion on margin of safety, explicitly cover those margins that the Commission believes are important to address in this evaluation process—the first being the margin that exists in the limits that are to be met, and the second being the margin that exists from the conservatisms included in the methods used to demonstrate that requirements are met. The replacement criteria were thus developed to accomplish two complementary goals: (1) defining with more precision the important safety margins which should be the focus of a § 50.59 determination, rather than the problematic term, "margin of safety as defined in the basis for any technical specification;" and (2) assuring that the relaxations embodied in the § 50.59(c)(2)(i), (ii), (iii), (iv), (v) and (vi) criteria will not result in changes approaching the adequate protection threshold without prior NRC review and approval. As such, the new criteria (vii) and (viii) are fundamentally part of the overall regulatory scheme in the revisions to § 50.59 which relax and clarify the thresholds for licensee-initiated changes and tests requiring prior NRC review and approval before their implementation. In sum, the Commission has determined that the changes to § 50.59 constitute clarifications and codifications of existing practices, or constitute permissive relaxations from the existing § 50.59 criteria, and therefore do not constitute backfits as defined in §50.109(a)(1).

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[5] "Permissive" relaxations are relaxations which licensees may voluntarily choose (but are not compelled) to comply.

Changes to Part 72

Section 72.48 defines the circumstances under which a holder of a ISFSI license may make changes and conduct tests and experiments, analogous to the criteria in § 50.59. The change to §72.48 will conform the criteria for ISFSI and storage cask changes to that in §50.59. Therefore, as with the changes to § 50.59, the changes to § 72.48 constitute a permissive relaxation as compared with the existing criteria in § 72.48. Furthermore, there will be consistency in regulatory approach in changes to nuclear power plants and ISFSIs. Such consistency is appropriate since most ISFSIs are licensed to nuclear power plant licensees; there are resource efficiencies for such licensees using the same criteria for evaluating changes, tests and experiments. The change criteria in § 72.48 are also extended by the final rule to holders of CoCs., which contributes to regulatory stability and predictability since known standards will be utilized in determining whether a change to a CoC may be made without prior NRC review and approval. The existing backfitting provision in § 72.62 only apply to licensees and not to CoC holders. However, even if the backfitting provisions in § 72.62 applied to CoC holders, the changes in § 72.48 would not be regarded as backfits since the extension of § 72.48 to CoC holders represents a permissive relaxation. For similar reasons, the changes in Part 72 applicable to CoC holders, which are necessary to support the extension of the change criteria in § 72.48 to CoC holders, are not considered to be backfits under § 72.62.

The Commission is deferring consideration of conforming changes to the design certifications in Part 52, Appendices A and B, which are the design certifications for the ABWR and System 80+ designs. The Commission will conduct a broader rulemaking to amend Part 52, whose purpose will be to correct typographic errors, clarify language, and reflect lessons learned as a result of the ABWR, System 80+, and AP600 design certification rulemakings. If conforming changes to Appendices A and B are made, in a future rulemaking, the Commission regards this rulemaking amending § 50.59 as satisfying the Commission's obligations under the backfit rule for any conforming changes made to Part 52, inasmuch as the backfitting issues associated with the adoption of the new criteria are being addressed in this rulemaking.

IX. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

X. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995, Pub. L 104-113, requires that Federal agencies use technical standards developed by or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. There are no consensus standards that apply to the change control process requirements established in this rulemaking. Thus the provisions of the Act do not apply to this rulemaking.

XI. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act (AEA), the Commission is issuing this rule to amend 10 CFR Part 50 : 50.59,: 50.66, and : 50.71; and 10 CFR Part 72:

72.48,: 72.70,: 72.212, and : 72.248, under one or more of sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

XII. Compatibility of Agreement State Regulations

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the *Federal Register* (62 FR 46517, September 3, 1997), this rule is classified as compatibility Category "NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of Title 10 of the *Code of Federal Regulations*, and although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws, but that does not confer regulatory authority on the State.

List of Subjects

10 CFR Part 50

Antitrust, Classified Information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and record keeping requirements.

10 CFR Part 72

Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Reporting and recordkeeping requirements, Security measures, Spent fuel.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Parts 50 and 72.

PART 50 - DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

AUTHORITY: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246, (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951, as amended by Pub. L. 102-486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Sections 50.10 also issued under secs. 101, 185, 68 Stat. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L.91- 190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a, and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80, 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 66 Stat. 955 (42 U.S.C. 2237).

2. Section 50.59 is revised to read as follows:

§ 50.59 Changes, tests, and experiments.

(a) Definitions for the purposes of this section:

(1) *Change* means a modification or addition to, or removal from, the facility or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

(2) *Departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses* means (i) changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or (ii) changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

(3) *Facility as described in the final safety analysis report (as updated)* means:

(i) The structures, systems, and components (SSC) that are described in the final safety analysis report (FSAR) (as updated),

(ii) The design and performance requirements for such SSCs described in the FSAR (as updated), and

(iii) The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs which demonstrate that their intended function(s) will be accomplished.

(4) *Final Safety Analysis Report (as updated)* means the Final Safety Analysis Report (or Final Hazards Summary Report) submitted in accordance with § 50.34, as amended and supplemented, and as updated per the requirements of § 50.71(e) or § 50.71(f), as applicable.

(5) *Procedures as described in the final safety analysis report (as updated)* means those procedures that contain information described in the FSAR (as updated) such as how structures, systems, and components are operated and controlled (including assumed operator actions and response times).

(6) *Tests or experiments not described in the final safety analysis report (as updated)* means any activity where any structure, system, or component is utilized or controlled in a manner which is either:

(i) Outside the reference bounds of the design bases as described in the final safety analysis report (as updated) or

(ii) Inconsistent with the analyses or descriptions in the final safety analysis report (as updated).

(b) Applicability. This section applies to each holder of a license authorizing operation of a production or utilization facility, including the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required under § 50.82(a)(1) or a reactor licensee whose license has been amended to allow possession but not operation of the facility.

(c)(1) A licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) without obtaining a license amendment pursuant to § 50.90 only if:

(i) A change to the technical specifications incorporated in the license is not required, and

(ii) The change, test, or experiment does not meet any of the criteria in paragraph (c)(2) of this section.

(2) A licensee shall obtain a license amendment pursuant to § 50.90 prior to implementing a proposed change, test, or experiment if the change, test, or experiment would:

(i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the final safety analysis report (as updated);

(ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the final safety analysis report (as updated);

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the final safety analysis report (as updated);

(iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the final safety analysis report (as updated);

(v) Create a possibility for an accident of a different type than any previously evaluated in the final safety analysis report (as updated);

(vi) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the final safety analysis report (as updated);

(vii)Result in a design basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered; or

(viii) Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses

(3) In implementing this paragraph, the FSAR (as updated) is considered to include FSAR changes resulting from evaluations performed pursuant to this section and analyses performed pursuant to § 50.90 since submittal of the last update of the final safety analysis report pursuant to § 50.71 of this part.

(4) The provisions in this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(d)(1) The licensee shall maintain records of changes in the facility, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test or experiment does not require a license amendment pursuant to paragraph (c)(2) of this section.

(2) The licensee shall submit, as specified in § 50.4, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months.

(3) The records of changes in the facility must be maintained until the termination of a license issued pursuant to this part or the termination of a license issued pursuant to 10 CFR Part 54, whichever is later. Records of changes in procedures and records of tests and experiments must be maintained for a period of 5 years.

3. In § 50.66, paragraph (b),introductory text, paragraphs (b)(4), (c)(2), (c)(2)(i), (c)(2)(ii), and (c)(3)(iii) are revised to read as follows:

§ 50.66 Requirements for thermal annealing of the reactor pressure vessel.

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(b) Thermal Annealing Report. The Thermal Annealing Report must include: a Thermal Annealing Operating Plan; a Requalification Inspection and Test Program; a Fracture Toughness Recovery and Reembrittlement Trend Assurance Program; and an Identification of Changes Requiring a License Amendment

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(4) Identification of Changes Requiring a License Amendment. Any changes to the facility as described in the final safety analysis report (as updated) which requires a license amendment pursuant to § 50.59(c)(2) of this part, and any changes to the Technical Specifications, which are necessary to either conduct the thermal annealing or to operate the nuclear power reactor following the annealing must be identified. The section shall demonstrate that the Commission's requirements continue to be complied with, and that there is reasonable assurance of adequate protection to the public health and safety following the changes.

(c) ★ ★ ★

(2) If the thermal annealing was completed but the annealing was not performed in accordance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program, the licensee shall submit a summary of lack of compliance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program and a justification for subsequent operation to the Director, Office of Nuclear Reactor Regulation. Any changes to the facility as described in the final safety analysis report (as updated) which are attributable to the noncompliances and which require a license amendment pursuant to § 50.59(c)(2) and any changes to the Technical Specifications, shall also be identified.

(i) If no changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to Technical Specifications are identified, the licensee may restart its reactor after the requirements of paragraph (f)(2) of this section have been met.

(ii) If any changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to the Technical Specifications are identified, the licensee may not restart its reactor until approval is obtained from the Director, Office of Nuclear Reactor Regulation and the requirements of paragraph (f)(2) of this section have been met.

(3) ★ ★ ★

(iii) If the partial annealing was not performed in accordance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program, the licensee shall submit a summary of lack of compliance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program and a justification for subsequent operation to the Director, Office of Nuclear Reactor Regulation. Any changes to the facility as described in the final safety analysis report (as updated) which are attributable to the noncompliances and which require a license amendment pursuant to § 50.59(c)(2) and any changes to the technical specifications which are required as a result of the noncompliances, shall also be identified.

(A) If no changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to Technical Specifications are identified, the licensee may restart its reactor after the requirements of paragraph (f)(2) of this section have been met.

(B) If any changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to Technical Specifications are identified, the licensee may not restart its reactor until approval is obtained from the Director, Office of Nuclear Reactor Regulation and the requirements of paragraph (f)(2) of this section have been met.

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4. In § 50.71, paragraph (e) is revised to read as follows:

§50.71 Maintenance of records, making of reports.

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(e) Each person licensed to operate a nuclear power reactor pursuant to the provisions of § 50.21 or § 50.22 of this part shall update periodically, as provided in paragraphs (e)(3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the operating license, to assure that the information included in the report contains the latest information developed. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submittal of the original FSAR, or as appropriate the last update to the FSAR under this section. The submittal shall include the effects[1] of: all changes made in the facility or procedures as described in the FSAR; all safety analyses and evaluations performed by the licensee either in support of approved license amendments, or in support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2) of this part; and all analyses of new safety issues performed by or on behalf of the licensee at Commission request. The updated information shall be appropriately located within the update to the FSAR.

(1) ★ ★ ★

[1] *Effects of changes* includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate.

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5. Section 50.90 is revised to read as follows:

§ 50.90 Application for Amendment of license or construction permit.

Whenever a holder of a license or construction permit desires to amend the license (including the Technical Specifications incorporated into the license) or permit, application for an amendment must be filed with the Commission, as specified in § 50.4, fully describing the changes desired, and following as far as applicable, the form prescribed for original applications.

PART 72 - LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE

6. The authority citation for Part 72 continues to read as follows:

AUTHORITY: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); Secs. 131, 132, 133, 135, 137, 141, Pub. L. 97-425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100-203, 101 Stat. 1330-232, 1330-236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97-425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

7. Section 72.3 is amended by revising the definition for independent spent fuel storage installation or ISFSI to read as follows:

§ 72.3 Definitions.

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Independent spent fuel storage installation or ISFSI means a complex designed and constructed for the interim storage of spent nuclear fuel and other radioactive materials associated with spent fuel storage. An ISFSI which is located on the site of another facility licensed under this part or a facility licensed under Part 50 of this chapter and which shares common utilities and services with such a facility or is physically connected with such other facility may still be considered independent.

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8. In § 72.9, paragraph (b) is revised to read as follows:

§ 72.9 Information collection requirements: OMB approval.

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(b) The approved information collection requirements contained in this part appear in §§ 72.7, 72.11, 72.16, 72.19, 72.22 through 72.34, 72.42, 72.44, 72.48 through 72.56, 72.62, 72.70 through 72.82, 72.90, 72.92, 72.94, 72.98, 72.100, 72.102, 72.104, 72.108, 72.120, 72.126, 72.140 through 72.176, 72.180 through 72.186, 72.192, 72.206, 72.212, 72.216, 72.218, 72.230, 72.232, 72.234, 72.236, 72.240, 72.244, and 72.248.

9. In § 72.24, paragraph (a) is revised as follows:

§ 72.24 Contents of application: Technical information.

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(a) A description and safety assessment of the site on which the ISFSI or MRS is to be located, with appropriate attention to the design bases for external events. Such assessment must contain an analysis and evaluation of the major structures, systems, and components of the ISFSI or MRS that bear on the suitability of the site when the ISFSI or MRS is operated at its design capacity. If the proposed ISFSI or MRS is to be located on the site of a nuclear power plant or other licensed facility, the potential interactions between the ISFSI or MRS and such other facility--including shared common utilities and services--must be evaluated.

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10. Section 72.48 is revised to read as follows:

§ 72.48 Changes, Tests, and Experiments.

(a) Definitions for the purposes of this section:

(1) *Change* means a modification or addition to, or removal from, the facility or spent fuel storage cask design or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

(2) *Departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses* means (i) changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are

conservative or essentially the same; or (ii) changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

(3) *Facility* means either an independent spent fuel storage installation (ISFSI) or a Monitored Retrievable Storage facility(MRS).

(4) The *facility or spent fuel storage cask design as described in the Final Safety Analysis Report (FSAR) (as updated)* means:

(i) The structures, systems, and components (SSC) that are described in the FSAR (as updated),

(ii) The design and performance requirements for such SSCs described in the FSAR (as updated), and

(iii) The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs which demonstrate that their intended function(s) will be accomplished.

(5) *Final Safety Analysis Report (as updated)* means:

(i) For specific licensees, the Safety Analysis Report for a facility submitted and updated in accordance with § 72.70;

(ii) For general licensees, the Safety Analysis Report for a spent fuel storage cask design, as amended and supplemented; and

(iii) For certificate holders, the Safety Analysis Report for a spent fuel storage cask design submitted and updated in accordance with § 72.248.

(6) *Procedures as described in the Final Safety Analysis Report (as updated)* means those procedures that contain information described in the FSAR (as updated) such as how SSCs are operated and controlled (including assumed operator actions and response times).

(7) *Tests or experiments not described in the Final Safety Analysis Report (as updated)* means any activity where any SSC is utilized or controlled in a manner which is either:

(i) Outside the reference bounds of the design bases as described in the FSAR (as updated) or

(ii) Inconsistent with the analyses or descriptions in the FSAR (as updated).

(b) This section applies to:

(1) Each holder of a general or specific license issued under this part, and

(2) Each holder of a Certificate of Compliance (CoC) issued under this part.

(c)(1) A licensee or certificate holder may make changes in the facility or spent fuel storage cask design as described in the FSAR (as updated), make changes in the procedures as described in the FSAR (as updated), and conduct tests or experiments not described in the FSAR (as updated), without obtaining either (i) A license amendment pursuant to § 72.56 (for specific licensees) or (ii) A CoC amendment submitted by the certificate holder pursuant to § 72.244 (for general licensees and certificate holders) if:

(A) A change to the technical specifications incorporated in the specific license is not required; or

(B) A change in the terms, conditions, or specifications incorporated in the CoC is not required; and

(C) The change, test, or experiment does not meet any of the criteria in paragraph (c)(2) of this section.

(2) A specific licensee shall obtain a license amendment pursuant to § 72.56, a certificate holder shall obtain a CoC amendment pursuant to § 72.244, and a general licensee shall request that the certificate holder obtain a CoC amendment pursuant to § 72.244, prior to implementing a proposed change, test, or experiment if the change, test, or experiment would:

(i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the FSAR (as updated);

(ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a system, structure, or component (SSC) important to safety previously evaluated in the FSAR (as updated);

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the FSAR;

(iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the FSAR (as updated);

(v) Create a possibility for an accident of a different type than any previously evaluated in the FSAR (as updated);

(vi) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the FSAR (as updated);

(vii) Result in a design basis limit for a fission product barrier being exceeded or altered as described in the FSAR (as updated); or

(viii) Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.

(3) In implementing this paragraph, the FSAR (as updated) is considered to include FSAR changes resulting from evaluations performed pursuant to this section and analyses performed pursuant to §§ 72.56 or 72.244 since the last update of the FSAR pursuant to §§ 72.70, or 72.248 of this part.

(4) The provisions in this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(d)(1) The licensee and certificate holder shall maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test, or experiment does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section.

(2) The licensee and certificate holder shall submit, as specified in § 72.4, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. A report shall be submitted at intervals not to exceed 24 months.

(3) The records of changes in the facility or spent fuel storage cask design shall be maintained until:

(i) Spent fuel is no longer stored in the facility or the spent fuel storage cask design is no longer being used, or

(ii) The Commission terminates the license or CoC issued pursuant to this part.

(4) The records of changes in procedures and of tests and experiments shall be maintained for a period of 5 years.

(5) The holder of a spent fuel storage cask design CoC, who permanently ceases operation, shall provide the records of changes to the new certificate holder or to the Commission, as appropriate, in accordance with § 72.234(d)(3).

(6)(i) A general licensee shall provide a copy of the record for any changes to a spent fuel storage cask design to the applicable certificate holder within 60 days of implementing the change.

(ii) A specific licensee using a spent fuel storage cask design, approved pursuant to subpart L of this part, shall provide a copy of the record for any changes to a spent fuel storage cask design to the applicable certificate holder within 60 days of implementing the change.

(iii) A certificate holder shall provide a copy of the record for any changes to a spent fuel storage cask design to any general or specific licensee using the cask design within 60 days of implementing the change.

11. Section 72.56 is revised to read as follows:

§72.56 Application for amendment of license.

Whenever a holder of a specific license desires to amend the license (including a change to the license conditions), an application for an amendment shall be filed with the Commission fully describing the changes desired and the reasons for such changes, and following as far as applicable the form prescribed for original applications.

12. Section 72.70 is revised to read as follows:

§ 72.70 Safety analysis report updating.

(a) Each specific licensee for an ISFSI or MRS shall update periodically, as provided in paragraphs (b) and (c) of this section, the final safety analysis report (FSAR) to assure that the information included in the report contains the latest information developed.

(1) Each licensee shall submit an original FSAR to the Commission, in accordance with § 72.4, within 90 days after issuance of the license.

(2) The original FSAR shall be based on the safety analysis report submitted with the application and reflect any changes and applicant commitments developed during the license approval and/or hearing process.

(b) Each update shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submission of the original FSAR or, as appropriate, the last update to the FSAR under this section. The update shall include the effects[1] of:

(1) All changes made in the ISFSI or MRS or procedures as described in the FSAR;

(2) All safety analyses and evaluations performed by the licensee either in support of approved license amendments, or in support of conclusions that changes did not require a license amendment in accordance with § 72.48;

(3) All final analyses and evaluations of the design and performance of structures, systems, and components that are important to safety taking into account any pertinent information developed during final design, construction, and preoperational testing; and

(4) All analyses of new safety issues performed by or on behalf of the licensee at Commission request. The information shall be appropriately located within the updated FSAR.

(c)(1) The update of the FSAR shall be filed in accordance with § 72.4, on a replacement-page basis;

(2) The update shall include a list that identifies the current pages of the FSAR following page replacement;

(3) Each replacement page shall include both a change indicator for the area changed, e.g., a bold line vertically drawn in the margin adjacent to the portion actually changed, and a page change identification (date of change or change number or both);

(4) The update shall include:

(i) A certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittal, or that no such changes were made; and

(ii) An identification of changes made under the provisions of § 72.48, but not previously submitted to the Commission;

(5) The update shall reflect all changes implemented up to a maximum of 6 months prior to the date of filing; and

(6) Updates shall be filed every 24 months from the date of issuance of the license.

(d) The updated FSAR shall be retained by the licensee until the Commission terminates the license.

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[1] *Effects of changes* includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate.

13. In § 72.80, paragraph (g) is added to read as follows:

§ 72.80 Other records and reports.

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(g) Each specific licensee shall notify the Commission, in accordance with § 72.4, of its readiness to begin operation at least 90 days prior to the first storage of spent fuel or high-level waste in an ISFSI or MRS.

14. In § 72.86, paragraph (b) is revised to read as follows:

§ 72.86 Criminal penalties.

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(b) The regulations in part 72 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 72.1, 72.2, 72.3, 72.4, 72.5, 72.7, 72.8, 72.9, 72.16, 72.18, 72.20, 72.22, 72.24, 72.26, 72.28, 72.32, 72.34, 72.40, 72.46, 72.56, 72.58, 72.60, 72.62, 72.84, 72.86, 72.90, 72.96, 72.108, 72.120, 72.122, 72.124, 72.126, 72.128, 72.130, 72.182, 72.194, 72.200, 72.202, 72.204, 72.206, 72.210, 72.214, 72.220, 72.230, 72.238, 72.240, 72.244, and 72.246.

15. In § 72.212, paragraphs (b)(2) and (b)(4) are revised to read as follows:

§ 72.212 Conditions of general license issued under § 72.210.

★ ★ ★ ★ ★

(b) ★ ★ ★

(2)(i) Perform written evaluations, prior to use, that establish that:

(A) conditions set forth in the Certificate of Compliance have been met;

(B) cask storage pads and areas have been designed to adequately support the static load of the stored casks; and

(C) the requirements of § 72.104 have been met. A copy of this record shall be retained until spent fuel is no longer stored under the general license issued under § 72.210.

(ii) The licensee shall evaluate any changes to the written evaluations required by this paragraph using the requirements of § 72.48(c). A copy of this record shall be retained until spent fuel is no longer stored under the general license issued under § 72.210.

★ ★ ★

(4) Prior to use of this general license, determine whether activities related to storage of spent fuel under this general license involve a change in the facility Technical Specifications or require a license amendment for the facility pursuant to § 50.59(c)(2) of this chapter. Results of this determination must be documented in the evaluation made in paragraph (b)(2) of this section.

16. Section 72.244 is added to read as follows:

§72.244 Application for amendment of a certificate of compliance.

Whenever a certificate holder desires to amend the CoC (including a change to the terms, conditions or specifications of the CoC), an application for an amendment shall be filed with the Commission fully describing the changes desired and the reasons for such changes, and following as far as applicable the form prescribed for original applications.

17. Section 72.246 is added to read as follows:

§72.246 Issuance of amendment to a certificate of compliance.

In determining whether an amendment to a CoC will be issued to the applicant, the Commission will be guided by the considerations that govern the issuance of an initial CoC.

18. Section 72.248 is added to read as follows:

§ 72.248 Safety analysis report updating.

(a) Each certificate holder for a spent fuel storage cask design shall update periodically, as provided in paragraph (b) of this section, the final safety analysis report (FSAR) to assure that the information included in the report contains the latest information developed.

(1) Each certificate holder shall submit an original FSAR to the Commission, in accordance with § 72.4, within 90 days after the spent fuel storage cask design has been approved pursuant to § 72.238.

(2) The original FSAR shall be based on the safety analysis report submitted with the application and reflect any changes and applicant commitments developed during the cask design review process. The original FSAR shall be updated to reflect any changes to requirements contained in the issued Certificate of Compliance (CoC).

(b) Each update shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the certificate holder or prepared by the certificate holder pursuant to Commission requirement since the submission of the original FSAR or, as appropriate, the last update to the FSAR under this section. The update shall include the effects[1] of:

(1) All changes made in the spent fuel storage cask design or procedures as described in the FSAR;

(2) All safety analyses and evaluations performed by the certificate holder either in support of approved CoC amendments, or in support of conclusions that changes did not require a CoC amendment in accordance with § 72.48; and

(3) All analyses of new safety issues performed by or on behalf of the certificate holder at Commission request. The information shall be appropriately located within the updated FSAR.

(c)(1) The update of the FSAR shall be filed in accordance with § 72.4, on a replacement-page basis;

(2) The update shall include a list that identifies the current pages of the FSAR following page replacement;

(3) Each replacement page shall include both a change indicator for the area changed, e.g., a bold line vertically drawn in the margin adjacent to the portion actually changed, and a page change identification (date of change or change number or both);

(4) The update shall include:

(i) A certification by a duly authorized officer of the certificate holder that either the information accurately presents changes made since the previous submittal, or that no such changes were made; and

(ii) An identification of changes made by the certificate holder under the provisions of § 72.48, but not previously submitted to the Commission;

(5) The update shall reflect all changes implemented up to a maximum of 6 months prior to the date of filing;

(6) Updates shall be filed every 24 months from the date of issuance of the CoC; and

(7) The certificate holder shall provide a copy of the updated FSAR to each general and specific licensee using its cask design.

(d) The updated FSAR shall be retained by the certificate holder until the Commission terminates the certificate.

(e) A certificate holder who permanently ceases operation, shall provided the updated FSAR to the new certificate holder or to the Commission, as appropriate, in accordance with § 72.234(d)(3).

★ ★ ★

[1] *Effects of changes* includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate.

Dated at Rockville, Maryland, this 20th day of September, 1999.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook

Annette Vietti-Cook,
Secretary of the Commission.

CC: (Shirley Jackson
(Senator Feingold of WI

DOCKETED USNRC

99 JUL 2 P1:02

OFFICE ... RULEMAKINGS ... ADJUDI...

June 18, 1999
1952 Palisades Dr
Appleton, WI 54915
54915

Dear Tony Di Paulo, US NRC

I understand that my petition (PRM-72-3) was used in the proposed rule on "Changes, tests, and Experiments", Fed. Reg. Oct 21, 1998. My petition was in the Fed Register over 3 years ago - May 14, 1996. In an NRC 3 page description of the petition process I was sent, it says, "During the entire time your petition is being processed by the NRC, you are kept fully informed of the status of the petition. NRC will send you copies of public comments we receive and a copy of any proposed or final rule that addresses the petition, or a notice of denial."

Why didn't I get notified that my petition was finally in a rulemaking proposal? I just found out this week about it when I read a PDR document that referred to it. I think I should be sent a copy of the proposed rule, the final rule, the comments on the rule and the responses. I have now sent in my comments on the rule (June 14, 1999) and would request that they certainly be considered. I understand that NRC has not yet finalized a rule on the proposed one, so I would expect that my comments could still be considered.

I would like to be kept fully informed as to what has happened to my petition in the past since 1996, and what is happening to it now, and in the future, please. I'd like a full explanation as to why I wasn't notified about the Oct 1, 1998 proposed rule. I'd like all the information I'm entitled to on my petition. A letter of comment from the NEI, nuclear industry group wanted my "petition held in abeyance". Seems like it was. Please respond within 5 days of receiving this letter. Thank you, Dawn Shillinglaw

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

DOCKET NUMBER PROPOSED RULE PR 50, 52 & 72
(63FR56098)

June 21, 1999
1952 Palisades Dr.
Appleton, WI 54915

Secretary, US NRC

DOCKETED USNRC

'99 JUN 24 P4:32

OFFICE OF SECRETARY RULEMAKINGS AND ADJUDICATIONS STAFF

I want to correct one word, on page 20, of my June 14 comments I sent to you on "Fed Reg. Vol 63 No. 203 Wed Oct 21, 1998 Proposed Rule 10CFR Part 50, 52, 72 RIN 3150-AF94 Changes, Tests and Experiments (p. 56098).

On Page 20 of my comments already sent in on this proposed rule - about in the middle of the page I say "what happens in an emergency if a cask needs to be unloaded and the temperature is above 30° - "above" should be corrected to the word "below" 30°. (In fact Pt. Beach VSC-24 criteria here has been raised to below 35°. The criteria in the VSC-24 was above 0° for movement of the cask, but it was raised to provide for allowing larger cracks in the structural lid weld found by UT testing, I really think this should not be allowed. The temp. in Michigan and Wis is often below 30° or 35°. If the cracks are a problem at the original 0° for movement set in the C of C, then I suggest you unload the casks. Please correct the word above to below in my June 14 comments on the proposed rule. Thank you, Kaien Shillingford

DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63FR56098)

DOCKETED
USNRC

'99 JUN 21 P4:14

(63)

June 14, 1999.
1952 Palisades Dr.
Appleton, WI 54915

Secretary, U.S. NRC,

Comments on Federal Register/Vol. 63, No. 203/Wed Oct 21, 1998
Proposed Rules — 10CFR Parts 50, 52, and 72
RIN 3150-AF94 Changes, Tests, and Experiments
page 56098

Today I spent an hour on the phone to different people at NRC trying to find out what has happened to my proposed — "Petition for Rulemaking PRM-72-3 10CFR Part 72 — Fed. Reg. Vol 61, No 64 / Tuesday May 14, 1996 / Proposed Rules / page 24249/. I just read the proposed "rulemaking about "changes, tests and Experiments" yesterday and it seems to me it has something to do with my petition, but nobody told me about it. The last I think I heard on my petition was an April 7, 1998 letter from David Meyer NRC in which he told me RM # 438 (Clarifications and addition of Flexibility to Part 72) was not available as public information as it was not yet published. I had previously been told, in a letter from Gail Marcus on Nov 7, 1997, that my petition was included in RM # 438. She said that (in that letter) "you will be provided with proposed or final rules that address your petition". She enclosed a few pages that described "Petitioning for NRC to Initiate, Modify, or Terminate a Rule". It says; "During the entire time your petition is being processed by the NRC, you are kept fully informed of the status of the petition, NRC will send you copies of public comments we receive and a copy of any proposed of final rule that addresses the petition, or a notice of denial."

As I read the proposed rule I am now commenting on, I see a relationship with my petition. *Why wasn't I sent a copy of this proposed rule? By now

JUN 2 4 1999

the alloted comment period has long been over, although you say comments received late "will be considered if it is practical to do so". I was told that there is no final rule on this, so I assume it is still "practical to do so".

My petition really didn't start as a petition. It was several letters I wrote, that the NRC decided, by a determination by the Office of the general counsel, to "treat as a petition". I didn't even see the wording of the petition until after it was put in the Federal Register. Therefore its wording must be interpreted along with comments on it # 2, 3 and 4, which are my own comments on "my" petition to clarify what I really said. You will note that there were, among others, two comments from Nevada on my petition and a very long one from the NEI (comment #8) requesting that a "response to the subject petition should be held in abeyance". I can't help but think that's what has been done. They said "Challenges which are regulatory and technical in nature, could potentially cause significant dry cask storage delays and, in some cases, could impede plant operations." As the Nevada Nuclear Waste Task Force (comment #10 page 3) stated, "It is not NRC's job to keep projects moving, such as Yucca Mt, or to keep plants running as is alluded to in the NEI document you received" (comment #8). I agree. My petition concerned changes to dry cask generic documents — the Safety Analysis Report, The Safety Evaluation Report, The Certificate of Compliance. My comment letter (#4) explains the problems of using 72.48 and not keeping the documents correct to meet reality. I felt that since the VSC-24 was certified by rulemaking as a generic cask, that it should only be changed by the process of amendment with rulemaking. The SAR that the C of C is based on is part of that package and should be changed by amendment with rulemaking also. The public should be able to review and comment on changes to a cask certified by rulemaking. Otherwise their original comments and certification of the cask (with response to these comments) is just a sham. If the vendor and the utility can change the documents at will using 72.48, in secret from public view, then all commitments may be weakened, or broken, <u>without any public input</u>. Conservatism promised in the original proposed design may be weakened also. The public was in on the certification and it should be part of the changes made.

It appears to me that NRC hoped to clarify change in your proposed rule Oct 21, 1998. I think, that you have, instead, muddied the waters even further. First of all I'll tell you how I accidently found out about this proposed rule. I think the details are important here as they relate to the whole history of dry cask storage changes. I was reading a public document letter of April 14, 1999 to NRC from SNC. I was noting how they kept changing from the term "amend", to "revise". In other letters they often use "amend" and "update". It's never clear in a lot of these documents back and forth as to what they really mean at all. It's as if nobody is really sure what process or how they are going to do this. Well this is certainly nothing new (read my May 27, 1996 letter — which is comment #3 on my own petition) There was no change process when the first generic cask was certified. No change process for a generic C of C or SAR was considered. There was no condition in the VSC-24 C of C for change. At that time ANO decided to try and use 72.48, and even made up its own form to do so. It was then that utilities pushed through use of 72.48 (similar to 50.59 for reactors) for dry cask use. This kept change documents out of the PDR, kept it out of public knowledge or comment. We objected. Since then its been a real problem to know who was changing what and who was liable for what change if it created a problem. Vendors made changes, utilities made changes, utilites asked vendors to make changes on their behalf, why I think even subcontractors did "there own thing" too. In the end the VSC-24 SAR was a mess. Utilities and the vendor were using their own changes and nobody seemed to be communicating with each other. This is a key part of what I call the "VSC-24 fiasco", which is still in process.

When I saw in PDR a proposed "amendment" to the VSC-24 C of C with a new "condition #2" in it about a change process, I asked NRC how it got there? No response. NRC has refused for a long time now to answer any of my questions saying I should find the answers in the PDR myself. (It would take Sherlock Holmes to do that a great deal of the time!) I do what I can, so I found that April 14, 1999 letter of SNC to NRC, and on page 1, they comment that Condition #2" is new and not in the current C of C. This condition would require an application for an amendment to address changes in design or procedure as described in the SAR. Proposed revisions to 10 CFR 72.48 would allow certain changes to be made <u>without</u> prior NRC review and approval, contrary to this new condition. To avoid creating a C of C in conflict with the proposed rule, SNC suggests that this condition <u>not</u> be included in the revised C of C". They don't want condition #2 inserted now.

This is so strange, as I think, years ago, SNC would have given anything to have that condition in there. It was put in Nuhoms C of C (#9 I think it was). And today, as BNF takes over SNC, they don't want it anymore. Use of 72.48 allows this to be done away from public scrutiny, and often without NRC scrutiny — at least till the annual report (which is only <u>brief</u> coverage and <u>after</u> it all is a "done deal" months ago.)

Then I see the April 19, 1999 forwarding of a "proposed amendment to the C of C for the VSC-24" from Susan Shankman to Patricia Holahan. This "proposed rule package", it says, is — "to amend 10 CFR 72.214 to <u>add</u> the amended CoC No 1007 for the VSC-24 system <u>to the list</u> of Part 72 approved spent fuel storage designs. Please note that the staff's SER is based on SNC's Fusion Amendment Request 98-01 to Revision 0 of the SAR thus the proposed language to be added to 10 CFR 72.214 should be modified accordingly." What does this really mean I wonder?

Now, a careful reading of what is being proposed here is <u>not</u> amending the <u>Certificate</u> at all. It is amending CFR 72.214 <u>to add</u> the amended certificate. In essence, to <u>add</u> a new certificate — a new cask design — <u>to the list</u> of accepted generic cask designs. You ain't changing the original certificate. You are trying to "replace" it instead. But how do you take the old one out? You are really trying to convert a process of adding acceptable casks to the list, into a process for changing a single certificate. It just doesn't really apply as I see it. It is my understanding that SNC (BNF really) is proposing this "cask addition". How do they intend to remove the old one that the original owners of SNC had certified and added to the list? And actually, isn't ANO, a generic licensee, requesting that SNC do this amendment?

As Joe said since 1993 you need a process for amending certificates, for amending SARs, (and for amending the generic rule probably too). A process including public participation. You can't include them in accepting a cask certificate and then go changing the certificate, and SAR its based on, without them. You can't just promise the public a design (with a certain level of conservatism) and then go and break that promise, bit by bit over the years — change by change —, without public input, until the design + cask system is no longer what was originally certified at all. That's what happened to the VSC-24.

The proposed rule for changes, tests, and experiments in the Fed Reg. Oct 21, 1998 only adds more problems. First of all, if you want to change part 72, then please make a proposed rule for Part 72. The way it was done here was to relate almost every thing to reactor changes in 50.59 and, then here and there, sort of say "and this should work for dry cask too" — never really explaining clearly how. This doesn't work.

As I understand it, after all these years, NRC has decided to clarify use of 72.48 for dry cask. And in doing so, has posed a lot of questions about terms and definitions relating to safety margin, significant increase, etc. It's time to clarify a lot of these terms. "Safety margin" was certainly a problem term in the nuhoms wall and weld thickness mess. Vectra seemed to just go it's own way here as did SNC in the early years. I'm glad to see NRC is finally trying to straighten out the terms.

As I see it, you have a vendor (certificate Holder) that
* is in no way licensed by NRC. His design may have a certificate that adds it to a list of casks generic licensees (utilities) may use — that is all. The utilities are licensed by NRC to build and operate the plants. They can also build and operate cask systems with generic certificates. Question is — shouldn't the vendor be licensed in some way if NRC is going to allow him to change his cask design?. Shouldn't the vendor have to meet some NRC criteria to be able to build casks and oversee subcontractors? Shouldn't the vendor be licensed in some way in order for NRC to cite the vendor with violations and fines (just as the utilities)?
* Question is, who is responsible for a change the vendor is asked to make by the utility??? Question is, if the utility makes a change without consulting the vendor, and the vendor would have cautioned the utility not to make this change (for some reason that the vendor understands, but the utility didn't forsee) then who is responsible? There are a lot of concerns when

you attempt to let both the utility and the vendor make changes to a cask system. It seems to me that is what you are proposing by letting them both use 72.48. You say on p. 56110 under, M part 72 changes, that the commission proposes to "expand the scope of 72.48 so that holders of CofCs are also subject to it" —— without prior NRC approval. It sounds like you are asking for trouble here considering the many problems changes have resulted in already.

You seem to propose that the utilities, as licensees, can change "their" SAR and so can the vendors change "their" SAR. On page 56111 you say "In both of these sections the Commission is adding a requirement that the entity making the change to the cask, either the general licensee (utility) or the certificate holder (vendor) provide a copy of the submittal to the other party for their information." Does this mean just the annual update of each one's SAR, or each 72.48 at the time the change is proposed? This timing could make a big difference. If a licensee can wait for the required annual SAR update to notify the vendor of all the site-specific changes they made to "their" cask design, it would be too late for the vendor to object. Say, for example, that Palisades pool water required that only a certain paint were used on a cask because of the chemical makeup of their pool — so they use 72.48 to change the vendors original paint. They put it in their annual SAR update, a copy of which they send to the vendor long after they made the change. What if the vendor says, "if we would have only known of that site-specific change when the plant made it, we never would have allowed it, as it can create a real problem under certain conditions we know about?" Or what if the vendor used 72.48 to make a generic change in the paint he uses for the cask design, and then doesn't tell the utility of the change till the annual report, long after the vendor has delivered several of these painted casks to the utility? Then the utility says, "hey, why didn't you tell us you changed the paint, we can't use that in our pool?"

You, in essence, are allowing two SAR's for one cask design, the vendor's generic one and the plant's site specific one. How does each keep records of the others changes? And then too, Palisades SAR will be site specific as will Pt. Beach's SAR, and ANO's SAR. How do they know the changes each other have made? If Palisades has made a change to vent the space above the water under the shield lid to avoid a moisture problem in welding, but doesn't tell the vendor, or Pt. Beach how to correct this concern, then Pt. Beach won't realize that Palisades has solved a problem that Pt. Beach should know about. When is a change really generic? When is it really site-specific? How do they relate? This is the crux of the problem I think.

If a vendor is making some changes generically that lower the safety margin or conservatism, and the utility does the same, how do they know when the design is reaching the point of minimal conservatism

as a whole and when the safety margin is very close as a whole? The sum of the total change process of both vendor and utility making changes, and other utilities making changes, means
* you have a lot of different SARs out there. Just how is each to keep the document current to meet reality? This is the basic problem of trying to have a cask design generic. It just doesn't work!

The way it seems best to work it is to have each utility have a site-specific cask (and to have an EIS and public hearing). You know if you look at the history of the 1st generic cask, the VSC-24, you could easily see that a lot of the mistakes were predicted in the public comments. If you did an EIS you would have tested the soil at the Palisades pad before you built it, not after! If you had a public hearing, Palisades would have had an appropriate unloading procedure, before MSB#4 required unloading, not after! Palisades says now a lot of their fuel cannot be put in the VSC-24. That was a concern in the public's mind too — so was the double seal weld. Other vendors questioned a lot of this too. I think an EIS and public hearing might very well have avoided a lot of the VSC-24 mess over the years. In a site specific cask, the utility and the vendor would work out each change
* together specifically for that plants use. There would be one SAR for that cask at that plant. If ANO wanted to put in BPR's then ANO and the

vendor would work out that site specific change for that plant.

Couldn't the vendor then be responsible for a newsletter, sort of a "trouble shooter" kind of material, in which it, say monthly, lists all the changes site-specific casks had made to them by utilities, explain problems at each utility with casks, and how resolved, etc.? Some sort of communication, the vendor is responsible for, to keep his cask users updated in a timely fashion. Would this work?

The licensee in this case could use 72.48 for minor changes — always checking with the vendor. But the vendor could not make any changes by himself — he could advise the licensee and work with him on casks built specifically for that plant. But the vendor should be held accountable in some way by NRC — (licensed?) so that, if they don't build to the plant's criteria, and NRC criteria, they can be cited with violations and fined, or even banned from the dry cask business — some enforcement to keep contractors and subcontractors building to nuclear expectations is needed.

There has got to be some criteria for a vendor, for a contractor, and subcontractor. We aren't building just garbage cans here. This is a project that can do the public great harm. A vendor that is a small new business, with no experience in working with subcontractors, needs to meet very specific criteria and needs to be inspected, without warning, often. And needs to be inspected again to see that corrections have actually been made. We need to use all the lessons we should have learned like this in the history of VSC-24 creation.

Public safety, as conservatism in depth, needs to be carefully defined......

conservatism ← changes allowable → non conservatism
how much? is too much?

If you go too far, you have hardly any conservatism left to account for any uncertainties or assumptions or miscalculations or unknowns. A certain level of conservatism was promised the public when a cask system was given a certificate. How much can this promise be broken? Dry cask systems should not be allowed to function "at the brink" of non conservatism, outside controlling parameters, or inconsistent with analyses. People living near a full cask array, after numerous changes by vendors and utilities, and subcontractors, shouldn't have to worry that the ISFSI is functioning "at the brink" of non conservatism. How close to non conservatism, outside controlling parameters, and inconsistent with controlling analyses can changes be made? How many minimum and insignificant changes add up to the maximum? And who is totaling them up over the years? If you don't keep one site specific SAR for each plants total cask system, you are asking for trouble. How in reality, in the actual paper book of a plant "specific generic" SAR as you really are proposing, is a plant supposed to treat a vendor's generic changes? Does he don't add them to his SAR annually or what? What is the time limit in which he has to add his own changes to his SAR, his site specific changes? Or is he supposed to read both the plants SAR and the vendors SAR in an emergency? The plant should have one, very current, SAR that refers to the plant specific cask system. He should be able to flip to the page he needs in that SAR, in an emergency, and find just what information he needs. (Remember H. Beach during the explosion, trying to figure out the real shield lid weight as they had changed it in a 72.48, but not put it in their SAR — it wasted time they just didn't want to use up for that unnecessary search).

I'll go back here to my original argument at finding, repeatedly in the documents and letters in the PDR, everybody referencing "THE" SAR. There is no "THE" SAR. SNC went from 0 to "0A" to "0AA" to "2" to "revision 1" and then BNF took it back to 0 again and started over. Nobody seemed to know how to record or make changes all these years. I've pointed that out to NRC over and over again ever since Mr. Massey tried to change things right after his VSC-24 design was certified. He did not "update", "revise", (or whatever term you use), his VSC-24 SAR to meet NRC SER required changes in the 90 days. I kept waiting for that to happen, but it didn't — and Palisades had loaded casks the day after the certificate was given. They were built under an exemption ahead. (This caused problems later on). A cask certificate is based on an SAR and I think it should be called a CSAR to keep it clear. (Vectra used that term long ago — good idea I thought) That CSAR is based on an SAR that meets all NRC SER criteria and it should not be allowed for any casks to be loaded until

The CSAR actually does meet SER criteria for that plant. If it takes 90 days, so be it. No cask should be built or loaded until that CSAR meets reality as to what the NRC SER required of it. Then it is "THE" SAR, if you like. I would call it CSAR #0 and then, when it is amended, call it CSAR #1 etc. The vendor and the specific plant change it together and it is site specific to that plant's cask system. That includes the pad, path to the pad, transfer device, crane loads, site specific coatings, unloading procedures etc. etc. The certificate, SAR (CSAR) and CSER are all one package based on each other. The plant and the vendor create them together and change them together and the public gets to comment on amendments to the package as a whole! The Treatment of an MRS needs it's own criteria and should not be lumped together in your attempt to change 50.59 and 72.48 for generic + specific casks and reactors — all in one rulemaking. It is a recipe for disaster I think.

** Reactor changes need their own clear rulemaking. Casks need their own clear rulemaking for whole systems. and an MRS needs its own clear rulemaking also.

An MRS does not have a plant nearby. How is "cask handling" to be done in an emergency? For example, it seems like one proposal at the Goshute Reservation in Utah is to put a problem Holtec canister, which was in a concrete storage shell, back into its original metal storage-transport shell that it was shipped in from the plant (with impact limiters removed I assume). You need different facilities at an MRS than at a plant, using a dry storage "system". Will a pool be there in Utah or a dry transfer facility? who is the responsible party for changes there? all the utilities involved in creating the MRS? using all their different fuel types (from different pool water storage and different original cask storage at the plant etc. etc.) Who makes the SAR changes using 72.48 for an MRS and keeps the utility SAR updated? Who does the vendor send his SAR to in your set up? all the utilities involved in the MRS?

A plant is not a cask system, a generic cask is not a specific cask. An MRS is not a plant ISFSI, yet NRC is trying to make a change process for all of these in one rulemaking. It is very confusing for every body — especially to a vendor just starting out in a "small new business" such as SNC originally called itself. Please sort this all out and do a rulemaking for only cask systems and do a rulemaking for only plant systems. Clearly explain the ramifications of your rulemaking for a full cask array at an ISFSI, and also, how a cask vendor and a plant owner, + rents an array of numerous different cask designs (like 6 VSC-24s, 2 TN casks, 3 Westflex casks etc. etc.) and even a full cask array of casks of one vendor that have changed from one design (SAR?) to another, as each cask was built. For example, two casks with vent holes too small, 3 casks not charpy tested right, one cask with wall welds flawed, 2 casks with a different coating, one cask with a different shield lid structure, etc. etc. — How does all this work when it comes to an emergency? How do you know what that specific cask # 32 (or whatever) is really like in reality? How are records for this to be kept?

It seems to me that the NRC and NEI are bouncing back and forth on all the issues in this rulemaking and the public is left out. Are you trying to accomodate * NEI mandates or protect public safety? I've noted in the PDR documents an attempt to change the actual amount of a change into a percentage. I really object to this. Give the original dose, for example, when you add BPRs to a cask, and then give the actual dose that it's raised to. By saying the dose is raised 6% of the original, nobody knows actually what the new dose to workers or the public is. This seems like a way to minimize a large change by making it into a small percentage number that "looks" a lot better to public acceptance. This is not acceptable. Tell us what it really is and just how much the dose is raised to a final real amount. We need to be able to see the cumulative effect of all these changes using actual amounts. How else will we know when the limit is approached?

I'm looking now at p. 56111 in your proposed ruling in the Fed Reg. It says "The Commission also envisions that a general licensee who wishes to adopt a change to the design it possesses — which was previously made to the generic design by the certificate holder under the provision of 72.48 — would be required to perform a separate evaluation under the provision of 72.48 to determine the suit ability of the change for itself." How does this work for a vendor CoC amendment? Or a vendor SAR amendment? How do the vendor and the plant relate these 2 SAR evaluations in 72.48 if they differ? This just gets more and more confusing. I think if this rulemaking is passed it will be a basis of continuing controversy in the future, as to who is responsible for what, and to who is to blame.

You propose a generic "certificate holder" (vendor) have its own SAR that it changes and sends copies of the changed document to each plant that uses the cask system. What do they do with it then? Do they try to insert the changes into their own SAR for the cask, or do they refer to both in an emergency, or what? Say the vendor changed the paint he used on all the casks he built, so that each plant getting more casks, would get a new batch of casks with a different paint than the old ones. The plant hasn't actually made this change, but the vendor did it generically to the cask so he builds them all like that. The plant didn't make the change, but he is getting a changed generic version anyway. Wouldn't he only find this in an annual update, and if he didn't insert information on this change into the plant specific (generic) SAR they use in loading and unloading, how would he remember it all? And the vendor gets all these site specific changed SARs from plants using his cask every year. What does he do with them? How is he to put this all together? Does he make a "generic (his SAR) / site specific" SAR file to include these yearly updates from the plants or what? One file for each plant containing an SAR for that plant with generic and site specific changes in it? How will this really work in day to day use at the vendor's facility? Plant?

I think that ONE site specific SAR as

it was done originally on a plant-by-plant basis certainly eliminates the confusion. The generic ruling was supposed to create less paperwork and scrutiny, and instead, it just created more — and more problems too. NRC time to research all the concerns of generic casks, inspect them, enforce them, etc. would be a lot less if you'd just eliminate all the confusion, and double paperwork, and go back to one SAR for each ISFSI that the plant maintains as its own. The vendor may work together with the plant to decide on changes needed. But the plant makes them for its own changes for its own facility and is responsible for them in other words — liable for mistakes and blunders.

You know WEPCO forsaw a lot of these problems when SNC divested from its original partner. The partner was a large concern with past nuclear experience. SNC was a small new business with a new design, but little, if any, fabrication experience. It was then that WEPCO had a provision inserted in the SAR that they could build their own casks. By doing this, they did not have to deal with the likes of March Metalfab. Palisades ended up as the "guinea pig" instead. The 1st VSC-24 cask was built and used at Palisades and SNC was in charge of the others built for them. No wonder Palisades is changing to West flex as soon as possible. I don't know, maybe BNF will be able to "fix" everything, but it will take a long long time, I think and all these rulemaking changes will complicate things even more.

I go back to one of the 1st problems brought up when the first generic cask, the VSC-24, was in proposed rulemaking for certification. There was a problem with the use of the term "cask system", "cask", and "ISFSI". A cask is not a cask system. A cask is just the container. A cask system is the cask, pad, path to pad, transfer device, lifting yoke or device, the cables for lifting, crane criteria, pool water criteria, etc. etc. etc. A cask system becomes very site specific to a plant. It just plain is not generic. And a full cask array at a plant is different than one cask at a plant. A full cask array and all its system ramifications needs evaluation before, one cask is put on that plant's pad. You need to evaluate that full cask array system and how it will relate to decommissioning the plant, how it will work in transporting the fuel off-site from the plant, how it will work in transferring the fuel back to the plant pool in an emergency or for general unloading and how it will work in relation to what happens to the spent fuel in that plant's cask system that may affect its final resting in a repository.

When reactors were built, they were basically licensed to operate. Nobody was concerned enough to say, "hey wait, you need to figure out criteria for what happens to the spent fuel when the pool is filled." They just built more hoping the problem would be solved. Aren't we doing the same thing now? You are allowing pads to be built and plants to be licensed to use any cask that gets generic certification, with little thought to that full cask array or even several pads full of different casks at each plant requiring different systems for transfer, unloading, lifting, transporting, etc. etc. How many different "versions" of one cask can a plant be ready to deal with safely in an emergency? How many different site plant specific and vendor generic SAR's should workers be familiar with so that they know what they are doing in an emergency? This can end up in a royal mess when all the fuel from a pool ends up in a full cask array or several pads, I would think. And nobody seems to think an emergency could happen. At the exit meeting for UT testing of loaded casks at Palisades, the question was asked as to "what happens in an emergency if a cask needs to be unloaded and the temperature is above 30° (considering that the cask movement temperature had be raised from 0° to 30° to allow for larger cracks in the structural lid weld)." The response was, as I understand it, "what emergency? We can't think of any". Did NRC, the vendor, or anybody else at the plant think that a paint would cause a hydrogen explosion? There are unknowns, human error and worker mistakes — as well as fabricator blunders etc. You have to expect the unexpected with these new cask designs. This is the first time they have been built and used, the 1st time UT has been used on them, etc. There probably will be more unexpected emergencies and I hate to think of it, but sabotage could be one.

So, for the reasons in all these pages, I oppose this proposed rulemaking and say, go back to site specific cask systems and documents. Generic doesn't work. Sincerely
— Kevin Shillingla(w)

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DOCKET NUMBER
PROPOSED RULE PR 50,52+72
(63FR56098)

Anthony R. Pietrangelo
DIRECTOR, LICENSING
NUCLEAR GENERATION

April 30, 1999

Mr. David Matthews
Director, Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Matthews:

Over the last two months, NEI and NRC staff have participated in several public meetings to discuss the issues concerning the pending revisions to 10 CFR 50.59. We believe these meetings have been constructive and beneficial in gaining a clearer understanding of the intent and implementation impact of a revised rule. The purpose of this letter is to summarize industry views and comments on the principal topics of discussion.

The enclosure provides our comments on the following:

- New criterion (c)(2)(vii) for controlling design basis limits of fission product barriers;
- New criterion (c)(2)(viii) for control of methods of evaluation described in the updated FSAR;
- Guidance for determining when a change involves a minimal increase in the frequency of an accident or likelihood of a malfunction;
- Further guidance on minimal increase in consequences; and
- Enforcement guidance using the "substantial review" criterion.

Our objective throughout this activity has been to achieve stability and clarity in the rule and its implementation. Thus, it is critical that the rule, its statement of considerations, and the implementation guidance be consistent with one another. We urge the NRC staff to be explicit in describing the intent of the rule provisions in the statement of considerations. This is particularly important for the new criterion on evaluation methods. The enclosure provides several recommendations in this regard.

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Acknowledged by card

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We have already begun the process of developing conforming changes to the guidance provided in NEI 96-07. We expect to complete development of the revised guidance this summer and will request NRC endorsement in a regulatory guide. To allow licensees adequate time to effect program changes and train personnel, we recommend that the effective date of the rule be a minimum of six months from the date of issuance of the final regulatory guide.

We look forward to future discussions with the NRC on the final rule and development of conforming changes to the implementation guidance. If you have any questions concerning the enclosure, please contact me at 202-739-8081 or Russ Bell at 202-739-8087.

Sincerely,

Anthony R. Pietrangelo

Anthony R. Pietrangelo

RJB/ARP/ngs
Enclosure

Enclosure

Proposed New Criterion for Controlling Design Basis Limits of Fission Product Barriers

In a public meeting on March 31, the NRC staff proposed the following new 10 CFR 50.59 criterion for controlling design basis limits of fission product barriers:

> (c)(2) Prior NRC approval required if the change, test or experiment would:
>
> (vii) result in a design basis limit for a fission product barrier being exceeded or altered.

- We understand that the phrase "*design basis limit for a fission product barrier*" would be defined in the statements of consideration for the final rule and implementing guidance as:

> a limit established during the licensing review as presented in the final safety analysis report for any parameter(s) used to determine the integrity of a barrier. The limit is the controlling value for the parameter at which confidence in the integrity of the barrier begins to decrease.

- In our planned revision of NEI 96-07, we will identify that the parameters and limits that typically determine fission product barrier integrity are the following:

<u>Fuel Cladding</u>
- DNBR/MCPR
- Fuel temperature
- Fuel enthalpy
- Clad strain
- Clad temperature*
- Clad oxidation*

<u>RCS Pressure Boundary</u>
- Pressure
- Stresses**

<u>Containment</u>
- Pressure

* parameters/limits that are controlled by 10 CFR 50.46

** parameters/limits governed by compliance with the ASME Code and technical specifications

New Criterion for Control of Methods of Evaluation Described in the Updated FSAR

Background

In public meetings on March 31 and April 26, the NRC staff presented a revised proposal for a new criterion (c)(2)(viii) for 10 CFR 50.59 that would provide for control of changes to analysis methods described in the UFSAR. In a similar meeting on March 10, NEI agreed-in-principle that such a criterion was appropriate to include in the revised rule. The rationale for including the new criterion is based on the following:

- Control of analysis methods presented in the UFSAR has been standard practice of licensees based on industry guidance in NSAC-125 and its successor, NEI 96-07[1]. It is reasonable to provide a regulatory basis for this historical licensee practice through a new criterion in 10 CFR 50.59 in light of the importance placed on methodology changes by both the industry and NRC.

- Licensee control of methods has historically been part of evaluations of proposed changes with respect to the existing margin of safety criterion of 10 CFR 50.59. The proposed replacement of this criterion with one focused solely on design basis limits for fission product barriers led the to NRC staff to conclude that an additional criterion methodology was needed.

- Industry and NRC review of several examples identified that certain types of methodology changes, e.g., changing from an NRC-approved code for transient analysis to an unapproved code, would not be explicitly limited by 10 CFR 50.59, absent the additional criterion.

Consistent with the Commission direction to provide flexibility in the revised rule criteria so that licensees can make "minimal" changes to the facility and procedures described in the UFSAR without prior NRC approval, and consistent with the staff's original proposal in SECY-99-054 to permit minimal changes in a methods of analysis, it is important to provide such flexibility with respect to changes in methods of analysis.

---

[1] Per longstanding industry guidance, changes in analytical methodology must be evaluated separately under 10 CFR 50.59 from proposed changes to the physical plant or procedures, be based on sound engineering practice, and meet all pertinent Quality Assurance Program requirements with respect to 10 CFR 50, Appendix B, Criterion III, Design Control; V, Instructions, Procedures, and Drawings; and VI, Document Control. Changes in methods of analysis described in the FSAR (as updated), including their effects on analysis results are reported to NRC under 10 CFR 50 59 and reflected as appropriate in UFSAR updates under 10 CFR 50 71(e)

NRC Proposal

The NRC staff has proposed to incorporate the following new criterion and definition as part of its pending revision of 10 CFR 50.59:

> 10 CFR 50.59(c)(2) Prior NRC approval is required if a change, test or experiment would:
>
> (viii) result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.
>
> *Departure from a method of evaluation* means (i) changing any of the elements of a method described in the FSAR (as updated)* unless the results of the revised method are conservative** or essentially the same for the intended application, or (ii) changing from a method described in the FSAR (as updated) to another method unless that method has been approved by the NRC for the intended application.
>
> Clarifications provided by the NRC staff
>
> * If there is a statement in the UFSAR that a particular method was used to perform an analysis subject to this criterion, that method of evaluation is considered to be a "method described in the FSAR (as updated)" regardless of whether there was further UFSAR discussion of the methodology or whether the referenced methodology was "incorporated by reference" in the UFSAR.
>
> ** As used in Part 1 of this definition, "conservative" means that results using the revised method are closer to the applicable limit than the previous results.

We have the following comments on the scope of the new criterion, definitions, and associated guidance to be incorporated in the Statements of Consideration for the final rule and NEI 96-07.

1. Scope of methods subject to criterion (c)(viii)

In describing its proposal, the staff noted that to be captured by new criterion (c)(viii), a method would have to meet two tests. First, the method must be described in the UFSAR. And second, it must be used to establish design bases or in the safety analyses. As discussed with the staff, many design basis values are either not derived analytically or are themselves inputs to analyses that may be adjusted within the constraints of the other seven criteria of 10 CFR 50.59. Thus to minimize implementation issues, additional guidance is needed to focus the scope of criterion (c)(viii) on the analyses of interest.

Based on the discussion in April 26 public meeting, there appears to be a common understanding on the scope of analyses subject to the new rule criterion. To capture this understanding and clearly focus the scope of criterion (c)(viii), it is important that the following additional guidance be included in the Statements of Consideration and NEI 96-07:.

Methods of evaluation described in the UFSAR subject to criterion (c)(viii) are:

- Methods of evaluation used in analyses that demonstrate that design basis limits of fission product barriers are not exceeded (i.e., for the parameters subject to criterion c(vii))
- Methods of evaluation used in analyses that demonstrate that consequences of accidents do not exceed Part 100 or GDC limits (e.g., Chapter 15 safety analyses)
- Methods of evaluation, including codes and standards, approved by the NRC for use in analyses performed per NRC requirement to establish design basis limits (e.g., analyses of the plant's ability meet its design bases for natural phenomena and other events such as SBO that the plant is required to withstand).

2. Definition of "departure from a method of evaluation"

The phrase "essentially the same," should balance the need to provide licensees some flexibility to refine methods with need to restrict changes to methods of evaluation that move results in the nonconservative direction. To ensure that the phrase "essentially the same" does not become a zero standard for such methodology changes, clear guidance is needed in the Statements of Consideration and NEI 96-07 to provide licensees appropriate flexibility to make minor methodology changes.

We agree with the staff that results that vary due to differences in calculational sensitivities (e.g., rounding errors) between the old and new methods of evaluation would be considered "essentially the same." However, we are concerned that additional guidance is needed to distinguish between "essentially the same" and a zero standard for changes that move analysis results in the nonconservative direction.

We recommend that the Statements of Consideration also reflect that two methods shall be considered "essentially the same" provided that benchmarking demonstrates that a new or revised method of evaluation produces results that are consistent with the old method, and differences between the old and new results are understood by the licensee.

To further clarify the proposed definition of "departure from a method of evaluation," the following additional guidance should also be reflected in the Statements of Consideration:

> The following shall not be considered a departure from a method of evaluation described in the FSAR (as updated):
>
> - Changes in methods of evaluation that (a) are below the level of detail presented in the UFSAR; (b) are consistent with existing SERs, applicable codes, and industry standards; and (c) do not change the fundamental assumptions upon which the methodology is based.
>
> - Use of an updated or new NRC-approved methodology (e.g., computer code) to reduce uncertainty and provide more precise results, or other reason, provided such use is (a) based on sound engineering practice, (b) appropriate for the intended application, and (c) within the limitations of the applicable SER.
>
> - Use of a methodology revision that is documented (benchmarked) as providing results which are consistent with either the previous revision of the same methodology or with another applicable methodology previously accepted by NRC through issuance of an SER.

To supplement the Statements of Consideration concerning the meaning of "departure from a method of evaluation," we intend to work with the staff to provide clear guidance in Revision 1 of NEI 96-07 that will assist licensees (and NRC inspectors) in determining, for several common types of analyses, when a new method of evaluation is "essentially the same" as the existing method described in the UFSAR.

3. Methods versus inputs

In the public meeting on March 31, the staff stated that how the plant and its response are modeled is part of the method (controlled by the proposed criterion (c)(viii)). The characteristics of the plant are input parameters or assumptions, changes to which are controlled by the other seven criteria of 10 CFR 50.59 (and in some cases TS), and which may also be subject to limitations specified in applicable SERs. To make clear this important distinction between changes to methods of evaluation subject to criterion (c)(viii) and changes to input assumptions which are not, the NRC staff proposed definitions to be included in the Statements of Consideration and NEI 96-07. The definitions below are the same as proposed by the NRC except we have added examples to the definition of methods of evaluation and included input assumptions in the definition of input parameters:

Methods of evaluation means the calculational framework for evaluating behavior or response, as for the reactor or any system, structure or component. This includes the following:

Methods of Evaluation	Example
• Data correlations	• DNBR correlations
• Means of data reduction	• ASME III and Appendix G methods for evaluating reactor vessel embrittlement specimens
• Physical constants or coefficients	• Heat transfer coefficients
• Mathematical models	• Decay heat models
• Assumptions in the computer program	• No voiding in PWR hot legs for non-LOCA analyses
• Specified factors to account for uncertainty in measurements or data	• 120% of 1971 decay heat model
• Statistical treatment of results	• Westinghouse Revised Thermal Design Procedure
• Dose conversion factors	• ICRP factors

Input parameters and assumptions means values assumed for, or derived directly from, the physical characteristics of structures, systems or components, or processes in the plant. These would include such things as: flows, temperatures, pressures, dimensions (volume, weight, size), response times, etc.

Minimal Increases in Probability

We agree with the shift in terminology to "frequency" of an accident for criterion (c)(2)(i) and "likelihood" of a malfunction for criterion (c)(2)(ii) proposed by the NRC staff in SECY-99-054 for the probability criteria of 10 CFR 50.59.

At a March 2 briefing, the Commission reiterated their intent that the revised rule and guidance provide for licensees to make changes without prior NRC approval that increase frequency of an accident or likelihood of a malfunction by more than a negligible amount. While the proposed rule allowed for "minimal" increases, neither the staff or the industry has provided adequate guidance for making changes that were beyond the negligible threshold.

Restoring the flexibility to make changes that may "negligibly" increase the frequency of an accident or likelihood of a malfunction has been the top priority of licensees in this rulemaking. Nonetheless, the industry supports the Commission's objective to provide the somewhat greater flexibility afforded by the "minimal increase" standard as a means to improve process effectiveness and reduce unnecessary regulatory burden without reducing safety.

Based on discussions in the public meeting with the NRC staff on March 23 and consultations with our industry task force, we have developed proposed criteria and considerations relative to implementing the minimal increase standard for frequency of an accident or likelihood of a malfunction. These are intended as input to supplement the following Statements of Consideration provided in the proposed rule.

> The Commission notes that Sec. 50.59 permits changes that do not otherwise require approval (such as would be the case if the provisions being changed are in TS or license, quality assurance or emergency plans, or inservice inspection and testing programs). Because the information being revised is of less immediate importance to public health and safety, and in consideration of the conservatisms in NRC design and analysis requirements, acceptance criteria, and the precision with which safety analyses are performed, ``minimal'' variations in probability of occurrence or consequences of accidents and malfunctions should not affect the basis for the licensing decision. This conclusion is based upon the qualitative consideration of probability during plant licensing; accident probabilities were assessed in relative frequencies; equipment failures were generally postulated to gauge the robustness of the design, without estimating their likelihood of occurrence. Therefore, minimal increases in probability could not even have been identifiable, and could not impact the conclusions reached about acceptability of the facility design. Radiological consequences for accidents are calculated and reported at a level of precision such that minimal increases also would not impact the safety determination. The Commission therefore

concludes that the proposed criteria would provide reasonable assurance that those changes that would affect the NRC's basis for licensing would be identified as requiring NRC approval before implementation. The revised criteria would also provide some degree of flexibility for licensees to make changes with smaller impacts without the need to obtain a license amendment.

On the other hand, the Commission intends to limit the amount of increase in probability or consequences of accidents such that it remains substantially less than a ``significant increase" as referred to in Sec. 50.92 (in accordance with Sec. 50.92, a license amendment involving a significant increase in the probability or consequences of an accident previously evaluated involves a ``significant hazards considerations;" any hearing for an amendment constituting a "significant hazards consideration" must be completed prior to the grant of the amendment.) The standard in the proposed rule is qualitative (probability or consequences no more than minimally increased). The intent of this proposed rule is to allow changes that are small enough that they would not affect the facility's licensing basis, or adversely affect safety performance. While the proposed rule would allow minimal increases, licensee still must meet applicable regulatory limits and other acceptance criteria to which they are committed (such as contained in Regulatory Guides, etc.) Because the "more than minimal" standard allows for there to be a discernible increase, NRC needs to establish a point beyond which one would conclude that the increase is not minimal. The following guidance is offered, including values as to when the Commission would conclude that the revised criteria are not met. Quantitative calculations are not required except for those instances in which a licensee offers other than qualitative arguments as part of its evaluation.

Supplemental Input for the Final Rule Statements of Consideration

Criteria are provided below that could be used by licensees as basis for evaluating and implementing changes to the facility or procedures under 10 CFR 50.59 that involve a minimal increase in the frequency of an accident or likelihood of a malfunction. The minimal increase criteria would be applied in a manner such that while not all of the criteria will apply to all changes, all that do apply must be true for a change to be considered minimal. For example, the criteria related to new operator actions or increased design stresses will not be relevant to all changes.

Changes that involve a negligible or no increase are not required to be further evaluated against the minimal increase standard because the NRC has stipulated that negligible increases satisfy the proposed minimum standard. Per the guidance in NEI 96-07, an increase is negligible:

> Where a change in probability is so small or the uncertainties in determining whether a change in probability has occurred are such that

it cannot be reasonably concluded that the probability has actually changed (i.e. there is no clear trend towards increasing the probability), the change need not be considered an increase in probability.[2]

Proposed criteria for use where an increase in probability is minimal:[3]

An increase in the frequency of occurrence of an accident is minimal if each of the following is true, as applicable:

1. The change would not cause a change in the relevant event frequency classification.

2. The change would not cause applicable design stresses to exceed their code allowables (e.g., for pipe structural support and internal pressure).

3. The effect of the change on frequency of an accident can be calculated and would not cause more than a 10% increase[4] in the estimated (pre-change) accident frequency. As discussed with the staff, it is recognized that the proposed criterion is conceptual/preliminary in nature. In connection with the planned revision to NEI 96-07, a graded approach to this criterion would be developed to allow larger increases for lower frequency events. In addition, other issues would need to be addressed such as use of conservative versus best-estimate analysis and the availability of baseline accident frequencies to facilitate the evaluation.

An increase in the likelihood of occurrence of a malfunction is minimal if each of the following is true, as applicable[5]:

1. The change would not cause applicable Maintenance Rule performance criteria (e.g., for reliability/availability) to be exceeded. It was noted that while MR performance criteria can change, such changes must have appropriate basis and be made under applicable licensee procedures.

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[2] In response to the point made on March 2 by Commission Diaz, the industry believes, based on this guidance, that if the effects of a change are within the margin of error of the original calculation or analysis, the change is negligible. We intend to clarify NEI 96-07 in this regard

[3] These proposed criteria differ slightly from those discussed with the NRC staff in the public meeting on March 23.

[4] The proposed 10% increase criterion is consistent with the NRC report, Options for Incorporating Risk Insights into 10 CFR 50.59 Process, December 17, 1998, Section 6.4.1

[5] Evaluations of a change for impact on likelihood of a malfunction would be performed at the level of detail of design description contained in the UFSAR

2. The change would not reduce existing design redundancy or diversity provided to meet NRC requirements.

3. The change would not cause applicable design stresses to exceed their code allowables.

4. The effect of the change on likelihood of a malfunction can be calculated would not cause more than factor of two increase[6] in the estimated (pre-change) likelihood of a malfunction that is adverse to safety (i.e., component failure to other than its safe state) .

5. The change is intended to conform the plant or procedures to changes in the regulations where the licensee ensures that the approach used to comply with the regulation does not adversely impact the safety of the plant.

6. Malfunctions considered as part of the evaluation of the change are estimated to be "green" findings within the significance determination process of the new reactor oversight process described in SECY-99-007A.

During the March 23 meeting, the NRC staff put forward the following additional criteria on minimal increase in the likelihood of malfunction, and we recommend they be incorporated into the Statements of Consideration.

7. The change involves installing additional equipment or devices (e.g., cabling, manual valves, protective features) provided all applicable design, functional and quality requirements (including applicable codes, standards, etc.) continue to be met. For example, adding protective devices to breakers or installing an additional drain line (with appropriate isolation capability) would not increase the likelihood of malfunction.

8. The change involves substitution of one type of component for another of similar function (e.g., substituting an air-operated valve for a motor-operated valve), provided all applicable design, functional and quality requirements (including applicable codes, standards, etc.) continue to be met.

9. The change involves a new operator action, including manual action that substitutes for automatic action, provided the action (including required completion time) is reflected in plant procedures and operator training programs, and the licensee has demonstrated that the action can be completed in the time required considering the aggregate affects, such as workload or environmental conditions, expected to exist when the action is required.

[6] The proposed factor of two threshold is consistent with the NRC report, Options for Incorporating Risk Insights into 10 CFR 50.59 Process, December 17, 1998, Section 6.4.1.

Other Comments on SECY-99-054

Minimal Increase in Consequences

In SECY-99-054, the NRC staff accepted, for the most part, the industry proposal for the minimal increase standard on dose consequences. The industry recommendation was that licensees be allowed to make changes without prior NRC approval that increase calculated dose by the lesser of the following:

- 10% of the margin to 10 CFR limits, or
- the applicable SRP acceptance guideline (if any)

The one proviso stipulated by the staff was that SRP acceptance guidelines for dose consequences would be made to apply to all licensees regardless of whether they are currently part of licensing basis for the plant.

While this approach provides uniform criteria for all plants, it has important downsides. First, the staff's approach would effectively establish new regulatory requirements and rigid new restrictions on facility and procedure modifications for licensees that are currently not subject to the SRP acceptance guidelines.

Second, the staff proposal is contrary to the intent to avoid the need for license amendments for changes that increase consequences only minimally. Specifically, for plants licensed to operate with calculated dose consequences above the SRP acceptance guidelines (but below the regulatory limit established in 10 CFR), the staff approach would require a license amendment for all proposed changes that increase consequences by any amount (a zero increase standard).

To avoid the imposition of rigid new requirements and the burden on both licensees and the NRC associated with unnecessary license amendments, we recommend the NRC adopt an alternative approach that would provide a special, more restrictive, minimal increase standard for licensees in the situation described above. Specifically, a licensee that has been approved by the NRC to operate with calculated dose consequences above the SRP acceptance guidelines could make a change without prior NRC approval provided the change does not increase the calculated dose by more than 1% of the margin to the 10 CFR regulatory limit. The 1% increase limit for such licensees is significantly more restrictive than that for licensees that are under the SRP acceptance guidelines. But, by providing appropriately limited flexibility to all licensees, this approach will avoid the need for license amendments that are clearly unwarranted.

NRC Approach for Exercising Enforcement Discretion

We appreciate the staff's intent stated in SECY-99-054 to refrain from enforcement action for non-willful violations of existing §§ 50.59 or 72.48 requirements that would not be violations had the evaluations been performed using the revised rule. We also understand that the staff does not plan to document such matters in inspection reports.

However, as part of its approach to exercise enforcement discretion, the NRC staff also stated that "a failure to submit an amendment as required would be considered a Severity Level III violation *if either a) a substantial review is needed by the NRC before it could conclude that the licensee's actions were acceptable* or b) NRC would not have found the licensee's actions acceptable. [Emphasis added]

We believe it is unduly subjective to base the decision to issue a Level III violation on whether a "substantial review" was needed to determine that the licensee had performed a proper evaluation. Aside from the "substantial review" criterion being inherently subjective, the extent of NRC review needed to verify a licensee's 10 CFR 50.59 evaluation is a function of the complexity of the change and the skill of the NRC reviewer. We strongly recommend that the NRC staff amend its approach for exercising enforcement discretion by eliminating the "substantial review" criterion discussed in SECY-99-054.

DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63FR56098)

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USNRC

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(61)

OFF
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ADJ

From: <JAMES.C.KILPATRICK@bge.com>
To: OWFN_DO.owf2_po(EMM)
Date: Fri, Apr 16, 1999 2:06 PM
Subject: Comments on 50.59 proposed rule

Eileen,

I was at the NRC regulatory conference, in March, and made a number of comments on the 50.59 proposed rule. You were going to look into them, namely:

1) the removal of the word 'proposed' from the current rule, without any apparent justification or reason for removal.

2) the term 'evaluation' used within the context of 'approved UFSAR changes' which have not been submitted to the NRC'. This term is also used to describe the former 'safety evaluations'.

Use of this term in the first context above will confuse it with its use in the second context above.

I don't believe it is the NRC's intent to imply that approved 'evaluations', performed subsequent to an UFSAR submittal to the NRC, are to be considered 'part of the UFSAR'. I believe that it is meant that the corresponding 'UFSAR change',which the 'evaluation' had approved, is to be considered part of the UFSAR (as updated).

3) The definition of 'change' fails to recognize the NRC G/L 91-18, rev 1 guidance on how to treat 'compensatory actions' (Temporary Mods or procedure changes) in response to degraded conditions. The way the 'change' definition is now, it contradicts with the 91-18, rev.1 guidance and since it is the rule, it will have legal precedence over G/L91-18 guidance, thus nullifying the benefit 91-18 gives for these types of 'proposed changes' to minimize the effects of the degraded / non-conforming conditions.

4) The proposed rule definition of change is still vague as compared to the definition / guidance in NRC inspection procedure 37001, on when an evaluation is required.

Can you elaborate on how the above issues were resolved?

Additionally, I've been following the dialog between the NRC and NEI on how to word/phrase the two new criteria (vii and viii). My one comment on the wording is that 'as described/evaluated in the SAR' is conspicuously missing from both of these new criteria. This phrase appears in all of the other six criteria. One can only conclude from this is that criteria vii and viii are broader than the design basis as described in the UFSAR.

APR 19 1999
Acknowledged by card

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RULEMAKINGS & ADJUDICATIONS STAFF
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Document Statistics

Postmark Date 4/16/99 Eileen McKenna E-mailed comment to Sandy Joosten; received on 4/19/99
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From the meeting minutes I have read, it appears that the NRC's intent is to limit these new criteria to that described in the UFSAR, however the proposed wording, so far, goes beyond the UFSAR described design basis and into the plant design basis which, by definition ,is much broader. If this is not the NRC's intent, then the term 'as described in the UFSAR' should be added to criteria vii and viii to make them consistent with the other six criteria.

If it is the NRC's intent to expand criteria vii and viii to beyond the UFSAR described design basis, then this should be clearly communicated to the industry and NEI.

Criteria viii is especially troublesome. as it contains an 'OR' statement which one can only conclude that the question is applicable to both the safety analysis(typically limited to UFSAR Chapter 15 analyses) AND any SSC design basis methodology, whether described in the UFSAR or not.

Could you clarify this for me?

Thank you, in advance, for your time.

James C. Kilpatrick- Baltimore Gas and Electric Co.

From: Eileen McKenna
To: Sandy Joosten
Date: Fri, Apr 16, 1999 4:24 PM
Subject: Fwd: Comments on 50.59 proposed rule

The attached email is related to a rulemaking presently underway on Parts 50, 52, &72. The proposed rule citation was 63 FR 56098. I am forwarding this message to SECY for action to docket these comments as part of the rulemaking record (we did this a few weeks ago for another email that was sent in). I wasn't sure who the right person in SECY was to send this too, so I picked you! Thanks Eileen 2189

(60)

From: "NELSON, Alan" <apn@nei.org>
To: "'Susan Shankman'" <sfs@nrc.gov>
Date: Tue, Mar 16, 1999 10:27 AM
Subject: 72.48 comments

Susan;
Based on our review of SECY 99-054 and follow up discussions at the Workshop on March 2-3, 1999. I would like to provide these additional comments for consideration.
If you have any questions please call.
Alan Nelson

Comments on proposed changes to 10CFR72.48 based on SECY 99-054

1. Proposed 10CFR72.48(d)(6) - This addition proposes that licensees provide copies of all 72.48 evaluations to the certificate holder (or the certificate holder to the licensee) within 30 days of implementation. The party receiving the evaluation then must review the received evaluation for applicability within the next 60 days. This new requirement creates significant additional burden on licensees and vendors that is not present in the current 10CFR72.48. A whole new process (requiring appropriate tracking systems as necessary to prove regulatory compliance with mandated time limits) for transmitting evaluations and another similar process for reviewing received evaluations must be implemented. These tracking systems could require significant personnel resources currently used for other safety significant items. These additional reporting requirements are not discussed in the regulatory analysis. It is not understood why these reporting requirements have such short time limits. The time limits are similar to those for Licensee Event Reports under Part 50. If the NRC does not need notified of a 72.48 evaluation for two years after its completion, why is it mandated to inform a vendor or licensee within 30 days? Similar requirements have not been proposed for 10CFR50.59. If a 50.59 evaluation does not need to be forwarded to vendors of any potentially affected equipment, why should a 72.48 evaluation? Do potential changes to cask components or loading practices have greater significance than changes to reactor components or operating procedures. The proposed rule would suggest such. While the proposed change is something that is desirable from an information exchange viewpoint, no safety reason exists to mandate such short reporting deadlines. Minor items such as these should be relegated to recommendations in a regulatory guide if they are necessary at all.

2. The proposed 10CFR72.48(c)(1) has been revised to state that general licensees may make amendments to a CoC per 10CFR72.244. However, 10CFR72.244 has not been revised to include use by general licensees and remains applicable only to certificate holders.

3. The proposed Part 72 SAR update requirements have been revised to a great extent to reflect wording equivalent to that in 10CFR50.71(e). 10CFR72.248 has been revised to be equivalent to 10CFR50.71(e). However, the 10CFR72.70 wording has not been revised to be equivalent and still includes an additional update requirement, (b)(3), not required for reactor SAR or cask general license SAR updates. It is not clear what special circumstance exists for site specific cask licensees to warrant the additional requirement.

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CC: "HENDRICKS, Lynnette" <lxh@nei.org>

Received: from igate.nrc.gov ([148.184.176.31])
by smtp (GroupWise SMTP/MIME daemon 4.1 v3)
; Tue, 16 Mar 99 10:27:02 EST
Received: from nrc.gov
by smtp-gateway ESMTPœ id KAA11759
for <sfs@nrc.gov>; Tue, 16 Mar 1999 10:27:59 -0500 (EST)
Received: from jetson.nei.org (unverified) by medusa.nei.org
(Content Technologies SMTPRS 2.0.15) with ESMTP id <B0000483455@medusa.nei.org> for
<sfs@nrc.gov>;
Tue, 16 Mar 1999 10:25:06 -0500
Received: by jetson with Internet Mail Service (5.5.2232.9)
id <GVLP6ZD7>; Tue, 16 Mar 1999 10:27:03 -0500
Message-Id: <30DEC91737BED211B57000A0C98959EE9920@jetson>
From: "NELSON, Alan" <apn@nei.org>
To: "'Susan Shankman'" <sfs@nrc.gov>
Cc: "HENDRICKS, Lynnette" <lxh@nei.org>
Subject: 72.48 comments
Date: Tue, 16 Mar 1999 10:27:02 -0500
MIME-Version: 1.0
X-Mailer: Internet Mail Service (5.5.2232.9)
Content-Type: text/plain;
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Subject:	72.48 comments
Creation Date:	Tue, Mar 16, 1999 10:27 AM
From:	"NELSON, Alan" <apn@nei.org>
Created By:	GATED.nrcsmtp:"apn@nei.org"

Recipients

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Priority:	Standard
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59

Niagara Mohawk

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'99 JAN 11 P3:03

Carl D. Terry
Vice President
Nuclear Safety and Assessment and Support

Phone: 315.349.7263
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OFFICE OF THE SECRETARY RULEMAKINGS AND ADJUDICATIONS STAFF

December 22, 1998
NMP1L 1396

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR 56098)

U. S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555

RE:	Nine Mile Point Unit 1	Nine Mile Point Unit 2
	Docket No. 50-220	Docket No. 50-410
	DPR-63	NPF-69

Subject: ***Comments on Proposed Rulemaking, 10 CFR 50.59, "Changes, Tests, and Experiments"***

Gentlemen:

Niagara Mohawk Power Corporation (NMPC) appreciates the opportunity to comment on the proposed rulemaking of 10 CFR 50.59, "Changes, Tests, and Experiments," as published in the Federal Register, October 21, 1998, Volume 63 (63 Fed. Reg. 56098 (1998)).

Overall, NMPC strongly supports the proposed rulemaking, as drafted by the Commission. With regard to the proposed "margin of safety" considerations, NMPC endorses the proposal to delete "margin of safety" as a separate criterion (Option 2) from 10 CFR 50.59. Our specific comments regarding various aspects of the proposed rulemaking are provided in the enclosed attachment.

Very truly yours,

Carl D. Terry
Vice President
Nuclear Safety Assessment and Support

9812300371 981222
PDR ADOCK 05000220
P PDR

CDT/JJL/kap
Attachments

xc: Mr. H. J. Miller, NRC Regional Administrator
Mr. S. S. Bajwa, Director, Project Directorate I-1, NRR
Mr. G. K. Hunegs, Senior Resident Inspector
Mr. D. S. Hood, Senior Project Manager - NRR
Records Management

Acknowledged by card JAN 13 1999

NIAGARA MOHAWK COMMENTS IN RESPONSE TO 56098 FEDERAL REGISTER/VOL. 63, NO. 203/WEDNESDAY, OCTOBER 21, 1998/ PROPOSED RULES

NMPC supports:

- The proposal to split the existing three evaluation criteria in 10 CFR 50.59(a)(2) into individual criteria in new Section (c)(2).

- Replacing the term "safety evaluation" with "evaluation".

- The proposal to clarify that changes controlled by §50.54(a), (p), and (q) need not also be evaluated under §50.59.

- The Commission's proposed definition for "change" to be provided in §50.59.

- The Commission's proposed definition for "facility as described in the final safety analysis report (as updated)" to be provided in §50.59.

- The Commission's proposed definition of "tests and experiments not described in the safety analysis report" to be provided in §50.59.

- The Commission's proposal to allow "minimal" variations in probability of occurrence or consequences of accidents and malfunctions. In regard to this proposal, NMPC recommends the Commission's proposed third option. This option would define "minimal" as being 10% of the remaining margin between current conditions and acceptance guidelines, with the amount of change decreasing as the limit is approached, whereby the acceptance guideline could not be exceeded without first obtaining Commission review and approval. In support of this option, NMPC recommends that the new rule be applied appropriately to the radiological consequences of accidents and not to the radiological consequences associated with normal operations or anticipated operational occurrences. Accordingly, it would apply only to infrequent events and limiting faults (design basis [postulated] accidents) with regard to the "reference values" or "acceptance guidelines" defined in 10 CFR 100. The new rule would not apply to the "dose limits" defined in 10 CFR 20 and General Design Criterion 19, which are regulatory limits not to be exceeded.

NMPC strongly supports:

- The Commission's proposal (Option 2) to delete "margin of safety" as a separate criterion. NMPC believes that a reduction in the "margin of safety" associated with a fission product barrier would be identified and addressed while considering other evaluation criteria.

(58)

Consumers Energy

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USNRC

A CMS Energy Company

'99 JAN 11 P12:58

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Covert, MI 49043

Tel: 616 764 2276
Fax: 616 764 2490

Nathan L. Haskell
Director, Licensing

OFFICE OF SECRETARY
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December 22, 1998

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Attention: Rulemakings and Adjudications Staff
Washington, D.C. 20555-0001

Subject: Consumers Energy Company Comments on Proposed Rulemaking to 10 CFR 50.59, Changes, Tests, and Experiments (63 FR 56098)

Consumers Energy Company is pleased to offer the following comments regarding the Notice of Proposed Rulemaking (NOPR), published on October 21, 1998, to solicit comments on proposed changes to 10 CFR 50.59. In general, the proposed changes remove ambiguity from the existing rule language, while providing needed flexibility for licensees to make beneficial changes. The staff is to be commended for its efforts in this area.

Consumers Energy endorses those comments filed on behalf of the nuclear industry by the Nuclear Energy Institute on December 21, 1998.

We continue to be concerned with the concepts discussed in the NOPR for treatment of margins of safety. We believe the NEI proposal for rule language in this area is reasonable and well focused on the issues of greatest importance, and should be adopted. All of the staff options defined in the NOPR (except deletion) have weaknesses that either excessively expand the applicability of this criterion into areas that are not risk or safety significant, or create new requirements that currently do not exist. Examples of the former weakness are contained within Options 3(A)(1) and 3(A)(2) which remove much of the flexibility for licensees to made cost effective changes without also incurring NRC review costs and delays. These proposals are significantly more restrictive than the standards used by the industry with "de facto" NRC endorsement since NSAC 125 was issued in 1989. An example of the second weakness appears in the discussion provided in part (c) of Option 3. This language can be interpreted as creating a significant new requirement for staff approval of

JAN 13 1999
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methodology where one does not currently exist. We concur that methodology changes must be carefully designed and validated, but formal staff approval is not needed for the great majority of cases. The current controls required by 10 CFR 50, Appendix B, Criterion III, and 10 CFR 50.46 are sufficient to assure technical adequacy of analyses. The discussions of methodology changes already found in NSAC 125 and NEI 96-07 provide sufficient guidance for licensees to identify when NRC review and approval should be obtained. If the staff concludes that this guidance should be strengthened, it should be pursued through a revision of NEI 96-07 rather than rule language.

Nathan L Haskell

Nathan L. Haskell
Director, Licensing

57

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

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'99 JAN -4 A11:35

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TVA

Tennessee Valley Authority, 1101 Market Street, Chattanooga, Tennessee 37402-2801

December 21, 1998

Chief, Rules Review and Directives Branch
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Gentlemen:

NUCLEAR REGULATORY COMMISSION (NRC) - OPPORTUNITY FOR PUBLIC COMMENTS ON PROPOSED RULEMAKING, "CHANGES, TESTS, AND EXPERIMENTS"

On October 21, 1998, NRC published a Notice of Proposed Rulemaking (NOPR) for public comment (63 FR 9581) which was related to licensee evaluations of changes.

TVA finds many of the NRC positions and clarifications to be improvements. However, the proposals outlined for evaluating and tracking increases in consequences and reductions in margin of safety introduce significant regulatory uncertainty that seems unnecessary. TVA's experience with implementation of 10 CFR 50.59 as described in industry guidance, NEI 96-07, shows that the industry guidance leads to results consistent with the goals of the original rule. The rule recognizes that licensees need flexibility to cope with the myriad issues faced daily in the field. The rule also addresses the staff's responsibility to control significant changes and to be able to define which changes are significant. Where the decision of significance has been left to the NRC technical staff, the rule has generally achieved these goals.

The tension that we see today over whether changes do or do not require NRC review is a direct result of imprecise terminology under the current rule and varying interpretations of that terminology. Recent staff overemphasis on literal interpretations of terms and verbatim compliance have left little room for judgment as intended by the original rule. While the lack of specificity in the rule frustrates the desire for precision, it does so to retain the flexibility for NRC to regulate and for licensees to operate plants efficiently.

Acknowledged by card JAN - 6 1999

The current rulemaking attempts to clarify the existing rule by defining new terms and using other terms which have been in existence for several years. TVA is concerned that the introduction of these new terms (e.g., altered in a nonconservative manner, regulatory envelope) and expanded use of terms derived by engineers and technical staff that have been previously used but not universally defined or understood (e.g. design basis, important to safety) will create the very real potential for new areas of regulatory uncertainty and abuse which we currently face under the current rule. A substantial revision of the rule will not eliminate or minimize regulatory uncertainty which has been one of the Commission's longstanding goals.

TVA believes the current rule has been implemented successfully by utilities using the industry guideline, NEI 96-07. Experience shows that the majority of issues identified by the NRC staff have been failures of licensees to perform screens which determine whether full safety evaluations are required. These omissions could have been avoided by proper implementation of NEI 96-07 guidance.

Several years ago, the NRC technical staff had reached agreement with industry and was prepared to endorse industry guidance (NSAC 125). That endorsement stalled due to an internal impasse over the interpretation of "may be created." The current Commission direction to the staff addresses that zero tolerance issue by allowing minimal increases. The Commission direction should allow the staff to endorse the guidance in NEI 96-07. Implementation of such a decision would require minimal changes to industry guidance, could be completed quickly, and would minimize regulatory uncertainty.

Conversely, if the Commission chooses from among several possible options proposed by the staff and industry, a significant amount of time will be needed to develop new implementation guidance. Significant industry and staff interaction will be needed to reach agreement on definitions, and additional Commission involvement is likely to be needed. Licensees will need time to develop lesson plans and implement training for the large population of personnel responsible for implementation. If these more detailed options are chosen, the Commission should allow ample time for implementation and should consider an implementation schedule allowing up to one year.

With respect to allowing minimal increases in consequences, the staff has proposed special requirements for tracking and reporting cumulative effects of minimal changes. The current regulations for UFSAR updates lead to reporting of changes in UFSAR. These provisions should be sufficient to allow the staff to monitor the trend of margins. Additional tracking, justification, and reporting should not be required.

The proposed reporting requirements extend and expand existing reporting requirements. This expansion should be the subject of a careful cost/benefit analysis by the staff. It is not apparent that the existing summary reports are necessary for effective monitoring of the existing programs. Past NRC reviews of 10 CFR 50.59 implementation have been conducted effectively onsite in order to access the more detailed records needed to make a determination of adequacy.

The staff also proposes to require that effects of changes be reflected in the UFSAR including new analysis performed at the Commission's request. This requirement should be explicitly identified in subsequent Commission requests for analysis and factored into future 50.109 determinations.

The NOPR discusses the desire of the Commission to reduce or eliminate redundant change control processes and 10 CFR 50.54(a) and (q) are specifically mentioned. TVA believes the language of the rule itself, accompanying Statements of Consideration, or specific implementation guidance should clarify how 10 CFR 50.59 applies to the following documents. These reports are typically discussed briefly in the UFSAR and have unique revision and reporting requirements.

Core Operating Limits Report (COLR)

Offsite Dose Calculation Manual (ODCM)

Pressure and Temperature Limits Report (PTLR)

Fire Protection Report (FP)

Safeguards Contingency Plan

TVA has reviewed the positions being submitted by NEI, and subject to the comments above, endorses those industry positions.

Sincerely,

Mark J. Burzynski

Mark J. Burzynski
Manager
Nuclear Licensing

cc: U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555-0001

DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63FR56098)

56

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'98 DEC 31 A10:26

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Comments on Proposed Rulemaking re: 10 CFR 50.59

A. The term "removal" in the proposed definition of "change" should be clarified to include the following:

1. Removal from service
2. Physical removal
3. Retirement in place
4. Discontinued availability
5. Removal from the FSAR text or tables
6. Removal from FSAR figures

<u>Reason for comment</u>

The clarification is necessary because "removal" could be interpreted as physical removal only, whereas a proposal might involve retirement in place, but not physical removal, and thus not be interpreted as a "change."

Similarly, a proposal might involve not repairing equipment that has never worked, but neither officially retiring it in place, officially removing it from service, nor physically removing it.

Also, a piece of equipment that no longer functions as intended and that is "described" only on an FSAR Figure might be removed from the Figure by applying the rationale that the equipment, as depicted in the Figure, implies a function that is not performed and, thus, that can be removed without evaluation.

G. It appears that the proposed term "as described in the final safety analysis report (as updated)" may narrow the scope of the regulation, in practice, because some licensees have interpreted "as described in the safety analysis report" to include licensing documents not specifically referenced in the FSAR text.

H. If changes that must be evaluated are <u>limited</u> to those that affect the text (including tables), figures or diagrams (i.e., that cause the text, tables, figures or diagrams to be revised), the effective scope of the regulation will be reduced, based on current practice by some licensees. Specifically, some licensees conservatively interpret the current regulation to mean that, if something <u>appears</u> in the text, tables, figures or diagrams, then it is "described in the safety analysis report," and <u>any</u> change to it, even if the change will not require the text, tables, figures or diagrams to be revised, must be evaluated for a USQ. This point should be considered and clarified in the rule because it can have a significant effect on licensee workload in applying the rule and on the level of detail that is placed and retained in the FSAR.

December 29, 1998

Richard C. L. Olson
1028 Jamieson Road
Lutherville, MD 21093

Acknowledged by card JAN - 6 1999

December 30, 1998

NOTE TO: Emile Julian
Chief, Docketing and Services Branch

FROM: Carol Gallagher
ADM, DAS

Carol Gallagher

SUBJECT: DOCKETING OF COMMENT ON PROPOSED RULE, "CHANGES, TESTS AND EXPERIMENTS (10 CFR PARTS 50, 52, 72)"

Attached for docketing is a comment letter related to the subject proposed rule. This comment was received via the rulemaking website on December 29, 1998. The submitter's name is Richard C. L. Olson, 1028 Jamieson Road, Lutherville, MD 21093. Please send a copy of the docketed comment to Eileen McKenna (mail stop O11F-1) for her records.

Attachment:
As stated

cc w/o attachment:
E. McKenna

DOCKET NUMBER PROPOSED RULE PR 50, 52 & 72 (63FR56098)

(55)

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'98 DEC 29 P4:25

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WOLF CREEK NUCLEAR OPERATING CORPORATION

Richard A. Muench
Vice President Engineering

DEC 18 1998

ET 98-0109

Secretary, U. S. Nuclear Regulatory Commission
Washington, D. C. 20555-0001
ATTN: Rulemaking and Adjudication Staff

Reference: Federal Register Notice, 63 FR 56098, dated October 21, 1998
Subject: Comments on the NRC Proposed Rulemaking to 10 CFR 50.59, Changes, Tests, and Experiments

Gentlemen:

As noted in the referenced Federal Register Notice, the NRC published its proposed rule for Changes, Tests, and Experiments and solicited comments from the public. Wolf Creek Nuclear Operating Corporation (WCNOC) endorses the comments submitted by the Nuclear Energy Institute (NEI) on this issue, and believes that incorporating these comments would provide substantial improvement to both the rule and its implementation.

WCNOC also has some minor comments associated to the proposed definitions. Several definitions continue to introduce uncertainties by the language used or the words chosen. Specifically: in the definition of procedures, terminology such as "assumed operator actions" is used. This is a very vague term. If these actions are not explicit in the Updated Final Safety Analysis Report (UFSAR), or do not affect statements in the UFSAR, then the activity does not constitute a "change in procedure as described in the safety analysis report." In the definition of "change to facility as described in the safety analysis report" the term "analysis method" is too broad. There would be a significant impact and overburden on licensees without commensurate safety benefits. The last definition issue is associated to the use of terms such as "design bases." Since this term does not have consensus in the industry or with the regulator, use of this term can be misleading.

It is our opinion that although the proposed rulemaking makes definite strides toward a rule that can be more efficiently and uniformly implemented, additional changes should be considered such as making the rule more risk-informed. WCNOC, along with the industry, will look forward to these longer term improvements.

If you have any questions concerning this submittal, please contact me at (316) 364-4034, or Mr. Michael J. Angus, at (316) 364-4077.

Very truly yours,

RAMuench

Richard A. Muench

RAM/rlr

cc: W. D. Johnson (NRC)
E. W. Merschoff (NRC)
K. M. Thomas (NRC)
Senior Resident Inspector (NRC)
Document Control Desk (NRC)

JAN -5 1999
Acknowledged by card

54

Nuclear Operating Company

South Texas Project Electric Generating Station P.O. Box 289 Wadsworth, Texas 77483

DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63FR 56098)

December 21, 1998
NOC-AE-000386
STI 30786765
File No.: G03.15
10CFR50.59

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USNRC

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Mr. John C. Hoyle
Secretary of the Commission
Attention: Rulemakings and Adjudications Staff
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Comments on Proposed Rulemaking to 10CFR50.59, Changes, Tests and Experiments (63 Federal Register. 56098 – October 21, 1998)

The STP Nuclear Operating Company (STPNOC) endorses the industry comments on proposed rulemaking to 10CFR50.59 offered by the Nuclear Energy Institute in a letter dated December 21, 1998. In particular, STPNOC supports the new approach to margin of safety that is outlined in the Nuclear Energy Institute's letter.

STPNOC applauds the Nuclear Regulatory Commission's efforts to bring stability to the interpretation and application of 10CFR50.59 by the proposed rulemaking. Discretion from exercising enforcement action is strongly recommended while this rule change is pending for issues,

- where plant change was previously evaluated in good faith consistent with the then accepted industry practice,
- where the safety and risk significance of the change was low, and
- where the change would be acceptable under the proposed rule.

This discretion would prevent the expenditure of licensee and NRC staff resources on issues that have no consequences and distract attention from the overall goals of the NRC and the industry.

M A McBurnett

M. A. McBurnett
Director,
Quality & Licensing

KJT/

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JAN -5 1999
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Ref. # 10CFR50.59

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C. Lance Terry
Senior Vice President
& Principal Nuclear Officer

December 21, 1998

DOCKET NUMBER
PROPOSED RULE PR 50,52+72
(63FR56098)

Mr. John C. Hoyle
Secretary of the Commission
Attention: Rulemaking and Adjudication Staff
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: INDUSTRY COMMENTS ON PROPOSED RULEMAKING TO 10CFR50.59; CHANGES, TESTS AND EXPERIMENTS (53 Fed. Reg. 56098 - October 21, 1998)

REF: Federal Register Notice 53-56098, dated October 21, 1998.

Gentlemen:

Per the above reference, the Nuclear Regulatory Commission solicited public comments on proposed changes to 10CFR50.59 and related changes to other sections of Part 50, Part 52, and Part 72.

TU Electric has reviewed the proposed changes to 10CFR50.59 along with industry and NEI comments. By this letter, TU Electric endorses the NEI comments and provides additional comments as attached.

If you have any questions, please contact Mr. Jimmy D. Seawright at (254) 897-0140.

Sincerely,

C. L. Terry

C. L. Terry

By: Roger D. Walker
Roger D. Walker
Regulatory Affairs Manager

JDS/grj
Attachment

Acknowledged by card JAN - 5 1999

Comments on Proposed Changes to 10CFR50.59

NOPR Section II B, Definitions: "Change"

TU Electric agrees with the NEI comments. It is essential that the final rule preserve the capability to screen out changes for which an evaluation under 50.59 is not necessary and beyond the intent of the regulation. Furthermore, an evaluation should not be required for changes to design details that do not impact design functions or the methods of performing or controlling design functions. As an example, the "Definition of Change" in Section III.A.4 of NUREG 1606 and in Topic III.A of SECY 98-171 states that **non-identical** replacement items are subject to 50.59 review. The proposed rule does not further alter or clarify this position. CPSES believes the current industry practice is to evaluate replacement parts of safety related components for **equivalency** under ANSI N18.7 and 10CFR21. A review for equivalency is most often performed by the vendor. A 50.59 review is only done for non-equivalent replacements for safety related components at the parts level. Requiring 50.59 reviews for all non-identical replacements would add unnecessary burden. The above discussion of "equivalency" verses "identical" at the replacement part level is an example where additional clarification under the definition of "change" is still necessary, either in the rule or its associated guidance.

(52)

NSP

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USNRC

Northern States Power Company

414 Nicollet Mall
Minneapolis, MN 55401
Telephone (612) 330-5500

'98 DEC 29 P4:25

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

December 21, 1998

Comments on Proposed
Rulemaking to 10 CFR 50.59

DOCKET NUMBER
PROPOSED RULE PR 50, 52 & 72
(63FR56098)

The Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attention: Rulemakings and Adjudications Staff

Reference: Federal Register, October 21, 1998, Volume 63, Number 203, Page 56,098, "Requirements Concerning Changes, Tests and Experiments."

Northern States Power Company (NSP) offers the following comments in response to the referenced Federal Register notice on the proposed rulemaking to 10 CFR 50.59, "Requirements Concerning Changes, Tests and Experiments."

NSP considers the following features of the proposed changes to 10CFR 50.59 to be significant improvements:

- Adding definitions to the regulation will provide clarity.
- Elimination of the terms, "safety evaluations" and "USQ" will eliminate confusion.
- Dividing the criteria into seven questions will create consistency.
- Clarification that SAR means FSAR (as updated) will match the regulation to current practice.
- Allowing minimal increases in probability and consequences will provide flexibility for the licensee and regulator to better manage their resources and focus on reactor safety.
- Focusing on the results of malfunctions rather than the failure mode of a piece of equipment injects some practical sense to the rule.

However, NSP is concerned that the proposed rulemaking language would create significant impacts on existing practices. These issues should to be addressed before proceeding.

The industry, through NEI, and the NRC must ultimately agree on the interpretation of the revised rule. The rule changing process will come to naught if the end result does not include NRC-endorsed industry guidance. By separate letter, the Nuclear Energy Institute (NEI) has

Acknowledged by card JAN - 5 1999

provided industry comments on the proposed rulemaking. NSP endorses these comments and provides the following amplification and addition to the industry's comments:

1. *Section II.B* -The proposed definition of "change" and the associated supplementary information unacceptably broaden the scope of the rule because it does not screen out changes that do not affect important design functions. NSP supports the NEI definition of "change" as an alternative and recommends the NRC modify the definition in accordance with industry recommendation.

2. *Section II.B* - The new definition of "facility as described in the FSAR" is blurred by the inclusion of the phrase "required to be included" in two locations. This could expand the scope of the rule to include information which is not included in the USAR, thus exposing licensees to possible violations for not performing 50.59 evaluations in the case of an incomplete USAR. Incomplete USARs should be addressed by the applicable rule, 10CFR50.71(e), not 10CFR50.59. Furthermore, "required to be included" might also be used by licensees to forgo 50.59 evaluations because the USAR content affected by the activity was arguably not considered to be "required." In either case, the wording could permit a subjective disagreement to develop between the regulator and the licensee as to whether specific USAR information is required or not required. Since there are no definitive requirements for specific USAR content, the words "required to be" should be deleted in both locations.

3. *Section II.B* - The background discussion related to the definition of "facility as described in the FSAR" does not include the NRC Staff's previously stated position that trivial facility changes, equivalent changes (i.e., non-identical replacements that meet the same design requirements) and maintenance do not require 10 CFR 50.59 evaluations. Also, the NRC's position that separate changes should be considered separately, unless they are interdependent, is also not addressed in the text of the regulation. This is acceptable, provided these previously agreed to concepts, and others, are spelled out somewhere else (e.g., NRC-endorsed industry guidance document).

4. *Section II.B* - The new definition of "procedures as described in the FSAR" seems reasonable. However, it is unclear what "information on the conduct of operations" includes and does not include. For example, does this include organizational charts? How should the seven questions be applied to administrative procedures or managerial information? Since the proposed rule specifically excludes USAR content controlled by other parts of the federal regulations (e.g., the QA program, Emergency Plans, Training, etc.) what type of information is left in the USAR which would be captured by this part of the definition? The phrase "conduct of operations" should be deleted from the definition as recommended by NEI.

5. *Section II.D* - The new definition of "tests or experiments…" seems reasonable. However, it is unclear what the reactor or any of its systems includes or does not include. This part of the definition needs further refinement in an industry guidance document.

6. *Section II.G* - The proposed rulemaking invites comments on various options for dealing with the concept of "more than a minimal increase in consequences." NSP endorses the

approach which would define "more than minimal increase in consequences" as 10% of the difference between the current USAR value and the 10CFR100 regulatory limit. This approach is simplest to implement. The graduated approach is overly complicated. Cumulative increases will be easy to track between USAR updates.

7. *Section II.G* - The concept of "equipment important to safety" is an important one. However, there is no current definition for this phrase. An important-to-safety test might be useful to better define the scope of the rule and to eliminate instances where prior NRC review would provide no safety benefit. There should be a concise workable definition for "important to safety" that will promote both a clearer understanding of the rule and facilitate more focused 50.59 evaluations.

8. *Section II.J* - NSP agrees with NEI's approach to question 7 (Margin of Safety). NEI's proposed wording of question 7 and the associated five screening criteria preserve the examination of safety significant concepts (i.e., implicit margin), which would be lost if question 7 were eliminated, while refocusing the question onto truly important design features (i.e., fission product barriers). Because the of the completely new approaches being offered by the industry and NRC to handle margin of safety, NSP strongly recommends that the new method be thoroughly benchmarked and that detailed guidance be provided in an NRC-endorsed industry guidance document.

9. *Section II.L* – Reporting and Record Keeping Requirements.
   The changes proposed to 50.71(e) are unnecessary. The new requirement to be added to 10CFER50.71(e) has not been discussed with the industry or any other interested party. Conversely, NEI 98-03, Guidelines for Updating Final Safety Analysis Reports, has been thoroughly discussed between the NRC and the Industry, to the point that it is expected to be endorsed by the NRC in the near future. Any changes to 50.71(e) should be through that forum, and not tacked onto this rule. NSP agrees with the NEI comments on this topic.

10. *General* - With respect to scope, determining when 10CFR50.59 applies (i.e., screening) has often been a more difficult process than the 50.59 evaluation itself. NSP notes that the proposed rule, as published, leaves open the possibility of further changes to the scope of the rule. NSP concedes that the USAR is a "blunt instrument" for the purpose of defining scope and that improvement is desirable. But at least the USAR is a real, definite and reasonably stable collection of licensing information which resides in a searchable document. It may be a blunt instrument, but it is not a comparatively unwieldy one. Any decision to either increase or decrease the scope of the rule should heavily weigh the practicality of implementing and enforcing any new screening criteria. A scope definition which everyone agrees to in principle, may be nearly impossible to implement and enforce in practice.

The comments above highlight the need for an NRC endorsed industry guidance document with sufficient detail to resolve concepts left undefined by the regulation. The proposed regulation introduces new concepts such as "required to be included in the FSAR" and "the reactor or any of it's systems," and new approaches to evaluating margin of safety and increases in consequences which have not been previously defined. NSP wishes to emphasize that the rulemaking process cannot be judged a success until the industry guidance document is endorsed by the NRC.

The revised rule should be subjected to thorough benchmarking using predetermined test cases, hypothetical design changes and an actual USAR. It would be interesting and informative to compare how the regulator and the industry would separately screen and assess the same hypothetical changes given identical facts and circumstances. It would also be interesting to see how much time these screenings and assessment would require each organization to complete. This exercise could be the subject of an Industry/NRC workshop.

We respectively request that our comments be considered in future Commission action on this matter.

Yours very truly,

Michael D Wadley

Michael D. Wadley
President, NSP Nuclear Generation

c: Roger Anderson

(51)

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SCE&G
A SCANA COMPANY

December 21, 1998
RC-98-0230

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

G[illegible]Taylor
V[illegible]ent
Nuclear Operations

Attention: Rulemakings and Adjudications Staff

Dear Sir:

Subject: VIRGIL C. SUMMER NUCLEAR STATION
DOCKET NO. 50/395
OPERATING LICENSE NO. NPF-12
Proposed Rulemaking to Amend 10 CFR Parts 50, 52, and 72, Changes, Tests and Experiments
63 Federal Register 56098, dated October 21, 1998

South Carolina Electric & Gas Co
Virgil C. Summer Nuclear Station
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Jenk[illegible]ille, South Carolina
29[illegible]

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803.345.5209
www.scana.com

South Carolina Electric and Gas (SCE&G) has reviewed the Federal Register Notice of October 21, 1998 that provides details of the NRC proposed rulemaking to amend 10 CFR Parts 50, 52, and 72, Changes, Tests and Experiments. SCE&G has also reviewed the comments submitted to you by the Nuclear Energy Institute (NEI) dated December 21, 1998.

SCE&G fully endorses the comments submitted by NEI.

Additionally, SCE&G would like to note the following specific objections to the proposed rulemaking for Reporting and Recordkeeping Requirements:

> <u>No expansion of 10 CFR 50.71(e) is necessary to address increases in the consequences of an accident or malfunction.</u>
>
> SCE&G recommends that the Commission define minimal increases so as to allow a given change to consume up to 10% of the remaining margin to the applicable regulatory (10 CFR)

Acknowledged by card JAN - 5 1999

limit. Limiting increases to a small fraction of the available margin ensures that any approach toward an applicable regulatory limit would be, at most, a slow one. As described in the industry comment, licensees would be further limited by any applicable acceptance guidelines.

As noted in the NOPR, this approach ensures that applicable regulatory limits cannot be exceeded. Based on this self-limiting feature, and the small fractional steps (a maximum of 10% of available margin) permitted under this approach, we feel it is unnecessary to add new NRC requirements for tracking the cumulative effects of such changes. (NOTE: Tracking of cumulative effects is already performed per Engineering procedures as part of maintaining design bases.)

In addition to the potential to substantially increase burden associated with updating FSARs, the specific proposal in the NOPR is presented with virtually no discussion about how the new requirement would be implemented. In particular, SCE&G is deeply concerned about what is meant by *"the net effect of all changes made since the last update on the safety analyses, including probabilities* [which are not found in the VCSNS FSAR], *consequences, calculated values, system or component performance..."* and how the updated information is to be *"...appropriately located in the FSAR."* Prior to the NOPR, there had been no discussion with the Nuclear Power Industry about a potential need for new reporting requirements or possible alternatives.

We understand that the proposal to track cumulative effects via expanded reporting requirements was included because it might be appropriate for implementing the minimal increase standard. Because of the way the minimal increase standard is to be structured in the rule and supporting implementation guidance, it is unnecessary to expand the existing 10 CFR 50.71(e) reporting requirements for the purpose of tracking cumulative effects.

In summary, SCE&G opposes the proposed changes to 10 CFR 50.71(e). However, if the Commission elects to establish new reporting requirements in connection with this rulemaking, we request that the industry be given appropriate opportunity to continue the cooperative effort with NEI and the Nuclear Power Industry to work with the NRC staff to address the significant associated implementation concerns.

Should you have any questions, please contact Mr. Michael J. Zaccone at (803) 345-4328.

Very truly yours,

D. Lavigne for

Gary J. Taylor

MJZ/GJT/dr

c: J. L. Skolds
W. F. Conway
R. R. Mahan
R. J. White
L. M. Padovan
NSRC
RTS (PR 980007)
File (811.02)
DMS (RC-98-0230)

SOUTHERN CALIFORNIA
EDISON
An EDISON INTERNATIONAL℠ Company

DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63FR 56098)

50

A. Edward Scherer
Manager of
Nuclear Regulatory Affairs

December 21, 1998

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Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
Attention: Rulemaking and Adjudications Staff

Gentlemen:

Subject: Southern California Edison Comments on Proposed Rulemaking to 10 CFR 50.59, "Changes, Tests, and Experiments" (63 Fed. Reg. 56098 - October 21, 1998)

This letter provides the Southern California Edison Company (SCE) comments on the subject proposed rulemaking. **SCE has participated in, and supports, the Nuclear Energy Institute (NEI) comments on these proposed revisions to the Rule.**

SCE understands that the proposed rulemaking seeks to:

1. Clarify which changes, tests, and experiments require evaluation and prior Commission approval.

2. Reorganize the Rule requirements for clarity and establish definitions for terms that have been subject to differing interpretations.

3. Clarify evaluation criteria for determining when a proposed changes, test, or experiment requires prior Commission approval.

SCE supports the intent of the proposed changes to 10 CFR 50.59 and its applicability to Part 72. These proposed changes are essential to overcome NRC's recent restrictive interpretation of 10 CFR 50.59 and to restore the original purpose of the Rule. SCE believes that the NEI proposal improves upon the options discussed in the proposed rulemaking and produces a step towards a more workable approach to evaluating plant changes. As a result, and as noted above, SCE endorses the NEI proposal.

If the Commission should conclude that it can not, or will not, adopt the NEI proposal, SCE would take this opportunity to endorse the option included in the proposed rulemaking to remove the "margin of safety" criteria from 10 CFR 50.59. SCE believes that the remaining six screening criteria could be modified to provide adequate assurance of identifying changes which require prior NRC approval.

P. O. Box 128
San Clemente, CA 92674-0128
949-368-7501
Fax 949-368-7575

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Further, should the Commission conclude that neither the NEI proposal nor the proposal to delete the "margin of safety" criteria can be found to be acceptable, SCE would then recommend that the definition of "minimal" for increase in consequences and/or reductions in margins of safety be explicitly defined as reductions of twenty percent (20%) of the remaining difference between the current values and the acceptance guidelines. (This would serve as a modification of the "third options" as discussed in the proposed rulemaking.)

Finally, Southern California Edison encourages the Commission to now move as expeditiously as possible to complete its revision to 10 CFR 50.59 by addressing the question of the scope of the Rule. We believe that the current interpretation in use by the Staff is one that is overly broad and results in the dilution of the ability of Licensees, and the Staff, to focus on issues important to safety.

If you have additional questions regarding our comments, please feel free to contact me.

Sincerely,

cc: Document Control Desk
Eileen McKenna, NRR
Naiem Tanious, NMSS

123 Main Street
White Plains, New York 10601
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914 287.3309 (Fax)

49

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New York Power Authority

James Knubel
Senior Vice President and
Chief Nuclear Officer

December 21, 1998
JPN-98-052
IPN-98-142

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

Mr. John C. Hoyle
Secretary of the Commission
Attention: Rulemakings and Adjudications Staff
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555-0001

SUBJECT: Indian Point 3 Nuclear Power Plant
Docket No. 50-286
James A. FitzPatrick Nuclear Power Plant
Docket No. 50-333
Comments on Proposed Rulemaking Concerning
10 CFR 50.59 – "Changes, Tests and Experiments"
<u>63 Fed. Reg. 56098 - October 21, 1998</u>

REFERENCES:

1. Comments on Proposed Rulemaking Concerning 10 CFR 50.59, Changes, Tests and Experiments, 63 Fed. Reg. 56098 October 21, 1998

2. Nuclear Energy Institute (NEI) letter to USNRC dated December 21, 1998 regarding the same subject.

Dear Sir:

The Authority has reviewed the notice soliciting comments on the subject proposed rule change (Reference 1). The Authority has also reviewed the comments being submitted on behalf of the nuclear power industry by the Nuclear Energy Institute (NEI) (Reference 2). The Authority endorses and supports the position presented in NEI's letter.

Together with NEI, we commend the Commission for its initiative to address disconnects between the rule and accepted industry practice, to restore intended flexibility to licensees for making changes that have little or no impact on plant design or operation without prior NRC approval, and to expedite rule changes to restore regulatory stability in this important area.

As indicated in NEI's comments, the industry supports many of the proposed changes to 10 CFR 50.59. In other areas, NEI has provided important comments and recommendations for

JAN -5 1999
Acknowledged by card

Commission consideration. Most significantly, NEI has recommended a new approach to margin of safety that complements the other 10 CFR 50.59 evaluation criteria by focusing on design parameters associated with the integrity of fission product barriers (fuel cladding, RCS pressure boundary and containment).

The Authority looks forward to working with the Commission, NRC staff and NEI on the resolution of rulemaking issues, revision and endorsement of NEI 96-07 and a smooth transition to the new rule requirements. In addition, the Authority encourages the Commission to pursue longer-term improvements to 10 CFR 50.59, including better focusing its scope of applicability, making the rule more risk-informed and other improvements identified in Section V of the industry comments.

This letter does not contain any new commitments. If you have any questions, please contact the Director – Nuclear Licensing, Ms. C. Faison.

Very truly yours,

J. Knubel
Senior Vice President and
Chief Nuclear Officer

cc: Next page

cc:

Regional Administrator
U.S. Nuclear Regulatory Commission
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King of Prussia, PA 19406

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Station Support Department

(48)

PECO NUCLEAR
A Unit of PECO Energy

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PECO Energy Company
965 Chesterbrook Boulevard
Wayne, PA 19087-5691

December 21, 1998

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Attn: Rulemakings and Adjudications Staff
Washington, DC 20555-0001

Subject: Comments Concerning Proposed Rule 10 CFR 50, 52, and 72, *"Changes, Tests, and Experiments"* (63FR56098, dated October 21, 1998)

Dear Mr. Hoyle:

This letter is being submitted in response to the NRC's request for comments concerning Proposed Rule 10 CFR 50, 52, and 72, *"Changes, Tests, and Experiments,"* which was published in the Federal Register (i.e., 63FR56098, dated October 21, 1998). The NRC is proposing to amend its regulations concerning the authority for licensees of production and utilization facilities, such as nuclear reactors, and independent spent fuel storage facilities, to make changes to the facility or procedures, or to conduct tests or experiments, without prior NRC approval. This proposed rule would clarify which changes, tests and experiments conducted at a licensed facility require evaluation, and the criteria that determine when NRC approval is needed prior to the changes being implemented at the facility.

PECO Energy appreciates the opportunity to comment on this proposed rule. We believe that the proposed rule provides only a short-term fix with regard to clarifying the requirements associated with 10CFR50.59. We strongly encourage the pursuit of a more risk-informed approach in resolving issues surrounding 50.59 requirements. We recommend that the NRC continue its efforts in establishing a more risk-informed regulation. The upcoming January, 1999, public meeting to discuss various options on incorporating risk insights into 10CFR50.59 regulations is indicative of such efforts.

PECO Energy offers the attached comments concerning the proposed rule for consideration by the NRC. In addition, we fully support the Nuclear Energy Institute's (NEI's) position and comments pertaining to this proposed rule.

If you have any questions, please do not hesitate to contact us.

Very truly yours,

Garrett D. Edwards

Garrett D. Edwards
Director - Licensing

Attachment

JAN - 5 1999
Acknowledged by card

bcc:	G. R. Rainey - 63C-3	w/ attachment
	J. D. von Suskil - LGS, SMB1-1	"
	J. Doering - PBAPS, SMB4-9	"
	J. J. Hagan - 62C-3	"
	M. P. Gallagher - LGS, GML5-1	"
	M. E. Warner - PBAPS, A4-1S	"
	E. F. Sproat - 63B-1	"
	R. W. Boyce - 63C-3	"
	G. L. Johnston - PBAPS, SMB3-2A	"
	J. P. Grimes - LGS, SSB3-1	"
	G. J. Beck - 63A-3	"
	J. A. Basilio - 63A-3	"
	T. A. Moore - LGS, SSB2-4	"
	M. J. Taylor - PBAPS, A4-5S	"
	G. H. Stewart - LGS, SMB2-4	"
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	D. J. Foss - PBAPS, PS2-2	"
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Attachment

PECO Energy
Specific Comments Concerning Proposed Rule
10 CFR 50, 52 and 72,
"Changes, Tests, and Experiments"

PECO Energy
Specific Comments Concerning Proposed Rule
10 CFR 50, 52 and 72,
"Changes, Tests, and Experiments"

PECO Energy offers the following comments regarding Proposed Rule 10 CFR 50, 52 and 72, *"Changes, Tests, and Experiments,"* published in the Federal Register (i.e., 63FR56098, dated October 21, 1998).

<u>Comments Regarding Proposed Changes to Part 50 (50.59)</u>

PECO Energy is opposed to increasing reporting requirements associated with the Updated Final Safety Analysis Report (UFSAR) as stipulated in 10CFR50.71(e). The proposed rule would add a reporting requirement to 10CFR50.71(e) to: *"describe the effects of...the net effect of all changes made since the last update on the safety analyses, including probabilities, consequences, calculated values, system or component performance, that are in the FSAR (as updated)."* Despite the potential to substantially increase the burden associated with updating FSARs, the specific proposal in the proposed rule is presented with virtually no discussion about how the new requirement would be implemented. We are concerned about what is meant by this proposed requirement, and how the updated information is to be appropriately located in the FSAR (as updated). If the NRC elects to establish this new reporting requirement in connection with this rulemaking, the industry should be given the opportunity to work with the NRC staff to address the significant associated implementation concerns.

PECO Energy suggests that when defining what constitutes "changes to the facility," it should specifically address and exclude from the 50.59 process administrative changes to organizational, reporting relationships, and job titles.

PECO Energy suggests that when defining what constitutes "changes to procedures," additional clarification is needed in explaining "information on conduct of operations." We recommend that any additional clarification explicitly discuss and exclude procedures of an administrative nature.

Furthermore, PECO Energy fully endorses the Nuclear Energy Institutes (NEI's) position and comments regarding this proposed rule.

<u>Comments Regarding Proposed Changes to Part 72</u>

PECO Energy offers the following specific comments on the Part 72 changes of the proposed rule.

1. 72.48(a)(2)(ii)

Delete "an ISFSI or MRS" from the definition of FSAR for general licensees. In accordance with the proposed 72.216 requirements, the FSAR only includes the cask SAR. The ISFSI/MRS is currently documented to be in compliance with regulatory requirements in 72.212. Therefore, the definition in 72.48 is in conflict with 72.212 and 72.216. The ISFSI description and analyses for general licensees is included in the 212 report under discussions of the haul path and the storage pad.

2. 72.48(a)(2)(iii)

To increase clarity that some changes require prior NRC approval, we suggest the following wording for this requirement: "For certificate holders, the Safety Analysis Report for an approved cask, modified either in support of approved license amendments, or in support of conclusions that changes did not require a license amendment in accordance with Section 72.48(b)(1) of this Section."

3. 72.48(b)(2)(viii) - Significant Increase in Occupational Exposure

Consider deleting this requirement be deleted for the following reasons: 1) a similar requirement does not exist in 10CFR 50.59 although more significant dose related activities exist in Part 50 activities, 2) the limiting factor for dose issues is normally offsite dose rates and not occupational dose rates, and 3) occupational dose limits are already controlled under Part 20 and by using the ALARA principle. At a minimum, "significant" should be defined.

4. 72.48(b)(2)(ix) - Environmental Statement Review

While this is an appropriate requirement for site-specific license holders, we recommend that it be deleted for general licensees and certificate holders for the following reasons: 1) certificate holders do not have a Final Environmental Statement, so this requirement is meaningless; 2) for general licensees, the review for environmental impact is done under 50.59 since cask changes that are performed under 72.48 drive the need to re-review the 72.212 evaluations which includes performing a 50.59 review for the Part 50 license including environmental technical specifications; and 3) the Final Environmental Statement for general licensees is contained in the Part 50 license.

5. 72.48(a)(5) and (b)(2)(vii) - Eliminate Margin of Safety Discussion

As discussed in the Federal Register notice, PECO Energy concurs with other commentators that the margin of safety requirement in 72.48 and 50.59 is not beneficial since similar evaluations are performed when evaluating probabilities and consequences of accidents and malfunctions to equipment important to safety.

6. 72.70 - SAR Updating

It should be noted in the code that this section only applies to site specific licensees since 72.216 applies to general licensees and 72.248 applies to certificate holders. This has been a point of confusion in the past.

7. 72.216 (d)(1) and (d)(2) and 72.248 (b)(1) and (b)(2) - Content of yearly FSAR submittal

The requirements for summary analyses in addition to the page changes goes beyond the corresponding requirements in 50.71(e). These summaries are already provided in the annual 72.48 report. Therefore, there are duplicative analyses that adds unnecessary licensee and certificate holder burden.

8. 72.216 (d)(3) - Submittal of replacement pages

The provision of replacement pages should be noted in the rule to apply to generic FSAR changes only. There may exist cask specific changes during cask fabrication that only affect one cask and are not intended for other casks. These changes will be submitted to the NRC as part of the 72.48 report. Therefore, developing replacement pages for the FSAR is not necessary since the change is not generic and does not affect other casks. Additionally, the cask specific changes are administratively tracked through the licensees' engineering processes such that licensing and engineering configuration control is maintained.

9. 72.216 (d)(3) and 72.248 (c) - Copies of FSAR pages

The requirement for copies of FSAR page changes to be transmitted between the general licensee and certificate holder is not timely enough. It would be more appropriate to add this requirement to 72.48 such that 72.48 evaluations are sent to each other within 30 days of approval rather than waiting for up to a year to receive FSAR pages. Therefore, consider deleting the FSAR page change copy submittal and adding a submittal requirement to 72.48.

10. 72.216(d)(3) - Notation of certificate holder's FSAR revision number

Consider revising the wording to reference the C of C revision number instead of the FSAR revision number. The FSAR revision number implies that all changes made by the certificate holder have been incorporated into the licensee's SAR. This is not an appropriate regulatory requirement. Some changes made by the certificate holder may only need to apply to a particular site or may only be an enhancement or option. The FSARs at this time are separate documents. Referencing the certificate holder's FSAR revision number will lead to significant confusion.

47

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December 21, 1998

Re: Indian Point Unit No. 2
Docket No. 50-247

Secretary
US Nuclear Regulatory Commission
Washington, DC 20555

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

Attention: Rulemakings and Adjudications Staff

Subject: Proposed Rule Amending 10 CFR 50.59
Changes, Tests, and Experiments (63 Fed. Reg. 56098 10/21/98)

The Nuclear Regulatory Commission (NRC) in 63 Federal Register 56098 dated October 21, 1998 promulgated a proposed rule reflecting amendments to the subject regulation.

We have reviewed the proposed changes and fully support the comments and recommendations provided in the Nuclear Energy Institute's (NEI) letter on this matter, dated December 21, 1998. We believe that the comments contained therein will foster a better understanding and consistent application of the Rule, and thus would significantly benefit the continued safe operation of our facility. Consequently, we urge the NRC's endorsement of these changes in the final issuance of the Rule.

Should you or your staff have any questions, please contact Mr. Charles W. Jackson, Manager, Nuclear Safety and Licensing.

Very truly yours,

A. Alan Blind

cc: Mr. Hubert J. Miller
Regional Administrator - Region I
US Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1498

JAN - 5 1999
Acknowledged by card

Senior Resident Inspector
US Nuclear Regulatory Commission
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(46)

Northeast Nuclear Energy

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Millstone Nuclear Power Station
Northeast Nuclear Energy Company
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The Northeast Utilities System

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DEC 21 1998

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DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR 56098)

Mr. John C. Hoyle
Secretary of the Commission
Attention: Rulemakings and Adjudications Staff
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Northeast Nuclear Energy Company
Millstone Nuclear Power Station
Comments on Proposed Rulemaking to
10 CFR 50.59, "Changes, Tests, and Experiments"

The purpose of this letter is to provide the NRC with the Northeast Nuclear Energy Company (NNECO) response to the request for public comment on the proposed changes to 10 CFR 50.59 published in the Federal Register on October 21, 1998 (63 FR 56098). We appreciate the opportunity to comment on this issue and commend the NRC's initiative to help clarify this key regulation.

In general, NNECO endorses the comments provided by the Nuclear Energy Institute (NEI) on behalf of the nuclear industry. Among the NEI comments, NNECO considers that the adoption of a definition for "change" in 50.59 with an appropriate threshold is particularly important. We strongly believe that defining "change" as proposed by NEI will help assure that the 50.59 process is applied to substantive changes, avoiding the application of licensee and NRC resources to perform evaluations for changes that are inconsequential or that experience has shown would not result in the need for NRC review and approval.

NNECO notes that in the Notice of Proposed Rulemaking, the NRC asked for comments regarding deletion of the "margin of safety" as a criterion in 50.59. Although this option was not recommended by NEI, NNECO considers that the third criterion in 50.59 related to "margin of safety" should be eliminated.

OS3422-5 REV. 12-95

JAN - 4 1999
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U.S. NUCLEAR REGULATORY COMMISSION
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NNECO believes that the margin associated with a narrow interpretation of the phrase "margin of safety as defined in the basis for any technical specification" is directly maintained through compliance with the technical specifications. That is, the safety margin defined in the bases of technical specifications is preserved by demonstrating continual adherence to the Limiting Conditions for Operations (LCO) or entering the appropriate Action Statements when the LCO is not satisfied. Thus, any proposed change to the facility that would obviate either meeting the LCO or satisfying the Action Statement could not be implemented because it would result in a violation of the technical specifications. Hence, the third criterion is not needed in 50.59 to maintain the margin of safety related to a technical specification.

Moreover, we consider that a broader interpretation of the term "margin of safety" is encompassed by the first two criteria in 50.59. NNECO believes that if a proposed change to the facility does not increase the consequence or increase the probability of a currently evaluated malfunction or accident, or does not create the possibility of a new type malfunction or accident, then there is no increased risk to the public health and safety. Thus, the third criterion is not needed to demonstrate adequate protection of the public health and safety.

Finally, as stated by the NRC in Section II.J of the Notice of Proposed Rulemaking, the phrases "margin of safety" and "as defined in the basis for any technical specification" have been the subject of differing interpretations regarding what limit or value to use in assessing whether a reduction in margin would occur. Varying interpretations that may have been historically accepted by the NRC in past licensing actions may involve margin evaluations based on limits or values found in one or more of the following:

- 10 CFR 50
- NUREG-800, "Standard Review Plan"
- Regulatory Guides
- NRC Safety Evaluation Report
- Final Safety Analysis Report
- Individual Plant Examination (Probabilistic Risk Analysis)
- Outputs from Design Basis Calculations or Analysis
- Inputs to Design Basis Calculation or Analysis
- Docketed Correspondence

Since past evaluations of margin reductions were the basis for licensing actions currently in force, redefining how the margin is calculated in a revised third criterion to 50.59 could result in altering the existing licensing basis for a facility. This licensing change may require individual backfit analyses to be performed in accordance with 10 CFR 50.109. Since the margin of safety is preserved by compliance with the plant's technical specifications and the first two criteria of 50.59, the resources associated with performing case-specific backfit analyses is not warranted and retaining a revised third criterion in 50.59 is considered problematic.

Finally, NNECO strongly encourages the NRC to consider providing alternate definitions or criteria in 50.59 for plants that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel in accordance with 10 CFR 50.82(a)(i) and (ii). For example, the NRC may consider limiting the scope of the rule for non-operating, defueled plants to changes that affect structure, systems, or components related to spent fuel cooling and radiological waste. NNECO believes that applying the same criteria for operating plants to those that have permanently ceased operations would not result in a prudent use of licensee or NRC resources.

If you have any questions regarding these comments, please contact Mr. Mario Robles at (860) 447-1791, Ext. 0279.

NORTHEAST NUCLEAR ENERGY COMPANY

ML Bowling

Martin L. Bowling, Jr.
Recovery Officer - Technical Services

cc: H. J. Miller, Region I Administrator
L. L. Wheeler, NRC Project Manager, Millstone Unit No. 1
D. P. Beaulieu, Senior Resident Inspector, Millstone Unit No. 2
S. Dembek, NRC Project Manager, Millstone Unit No. 2
A. C. Cerne, Senior Resident Inspector, Millstone Unit No. 3
J. W. Andersen, NRC Project Manager, Millstone Unit No. 3
W. M. Dean, Director, Millstone Project Directorate
D. L. Meyer, Chief, Rules and Directives Branch
A. R. Pietrangelo, Director, Licensing, Nuclear Energy Institute

(45)

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Westinghouse Electric Company,
a division of CBS Corporation

Box 355
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NSD-NRC-98-5818

December 21, 1998

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

Mr. John C. Hoyle
Secretary of the Commission
Attention: Rulemakings and Adjudications Staff
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555-0001

SUBJECT: Industry Comments on Proposed Rulemaking to 10 CFR 50.59, Changes, Tests, and Experiments (63 Fed. Reg. 56098 – October 21, 1998)

Westinghouse Electric Company offers the following comments in response to the subject *Federal Register* notice which solicited public comments on proposed changes to 10 CFR 50.59 and related changes to other sections of Part 50, Part 52 and Part 72. The proposed rulemaking seeks to:

1. Clarify which changes tests and experiments require evaluation and prior Commission approval via license amendment
2. Reorganize the rule requirements for clarity and establish definitions for terms that have been subject to differing interpretations
3. Clarify evaluation criteria for determining when a proposed change, test or and experiment requires prior Commission approval

In general, Westinghouse Electric Company endorses the NEI comments and recommendations transmitted to the NRC in the NEI letter on this subject dated December 21, 1998 and signed by Anthony R. Pietrangelo.

Additionally, Westinghouse Electric Company has the following comment to the referenced Federal Register notice. Section B, titled "Change to Facility as Described in the Safety Analysis Report", the statement in the middle of the paragraph as follows, "*The Commission concludes that modification of any existing provision (e.g., SSC, design requirement, analysis method or parameter)...*", the word "parameter" is to broad and should be clarified to read , "*changes to parameters that affect regulatory limits", or "effects of the parameter change*."

The following editorial comment is also being provided for your incorporation. In Section J., Option 3, the statement at the end of the second paragraph currently states "*cannot be modified with NRC review.*" should read " *cannot be modified without NRC review.*"

0120S

JAN - 4 1999
Acknowledged by card

We look forward to working with the NRC staff and Commission on the resolution of rulemaking issues, and in making further, long term improvements to 10 CFR 50.59.

If you have any questions concerning these comments, please contact me.

Sincerely,

H. A. Sepp, Manager
Regulatory & Licensing Engineering

cc: Mr. Anthony P. Pietrangelo/NEI

0120S

(44)

Duke Energy

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December 18, 1998

Mr. John C. Hoyle
Secretary of the Commission
Attention: Rulemakings and Adjudications Staff
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555-0001

SUBJECT: Comments on Proposed Rulemaking to 10 CFR 50.59, Changes, Tests, and Experiments (63 Federal Register 56098 - October 21, 1998)

Duke Energy Corporation (Duke) offers the following comments on the proposed rule change to the 10 CFR 50.59 regulation. We have reviewed and support many of the comments submitted by the Nuclear Energy Institute (NEI). We also support many of the NRC's proposed changes to the regulation. In other areas, we provide comments and recommendations for Commission consideration. Some of these comments provide additional information or emphasis to those submitted by NEI. Duke offers the following comments:

1. <u>Definition of "As Described in the SAR" (Section II-B):</u> Second tier programs such as procurement specifications, evaluative methods, and other sub-tier design information documents, are controlled under Appendix B. Therefore, control of that information is under the Appendix B programs, which should ensure that the licensing basis is not challenged. We therefore recommend that the rule, or NRC endorsed guidance, clarify that there is no need for 10CFR50.59 evaluations for changes in these areas.

2. <u>Safety Analysis Report (Section II-E):</u> Duke prefers the following definition of Safety Analysis Report - "The set of licensing basis documents used to support issuance of a plant operating license. These documents include, but

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are not limited to, the Facility Operating License, the NRC Safety Evaluation Report, the UFSAR, Selected Licensee Commitments, the Technical Specifications, and other licensing documents. "

3. <u>Accident Frequency (Section II-G):</u> The frequency classification of accidents or events is not specified for older plants. Thus, the frequency would have to be inferred for these plants, which raises questions with regards to changes in categories. Also, post-licensing documents that address accidents/events do not have specified frequencies. A method for determining "more than a minimal increase" needs to be available for these cases.

4. <u>Dose Consequences (Section II-G):</u> Duke prefers the definition in NEI 96-07. In section I of the proposed rule, the following information is provided:

   "When a plant is licensed, the NRC states in its Safety Evaluation Report (SER) why it found each FSAR analysis acceptable. An FSAR analysis may be accepted because it was considered to be adequately conservative and because the NRC's acceptance criteria for that analysis are met. Frequently, the SER states specific conditions the NRC relied upon for concluding that the analysis was conservative."

These statements appear to indicate information in SERs specify the acceptance limits, as currently described in NEI 96-07.

However, of the proposed definitions in the draft regulation, Option 3 is Duke's preference. For Option 3, current conditions needs to be more explicitly defined to indicate that this is referring to the dose consequences as determined by the licensee. Duke also suggests a higher allowed percentage increase, such as 20 %, for determining minimal change. Some licensees may also have already exceeded the specified percentage increase since they used NSAC-125/NEI 96-07 guidance. NRC guidance would be needed concerning what actions to take in those cases.

5. Cumulative Effect of Dose Increases (Section II-G): The proposed change in 50.71 reporting will be burdensome for the industry, because the industry will have to implement procedures to track cumulative dose changes.

6. Possibility of an Accident of a Different Type (Section II-H: Add "credible" to the definition of accident.

7. Definitions of Accidents (Section II-H): Delete "required to be analyzed and/or accounted for by the Commission". The term "design basis accidents" should not be used. For example, the only design basis accident for some older plants is LOCA/LOOP, and that does not appear to be the intent of the proposed regulation. For whichever approach is used, the definition of event should be "a combination of postulated challenges and failure events against which plants are designed to ensure adequate and safe plant response."

8. Margin of Safety (Section II-J):

   Duke supports NEI's proposed alternative rule, with the following additional comments: The NEI proposed alternative rule focuses only on "design basis limits" for the fuel cladding, RCS pressure boundary, and containment boundary. There is no distinction as to whether these design basis limits are based on values included in the licensee's submittals or the NRC's acceptance limits usually included in a Safety Evaluation Report. Duke's view is that the design basis limits need to be based on NRC acceptance limits for the fission product barriers (see discussion on acceptance limits in item 4). Although the proposed alternative rule helps eliminate current subjectivity associated with the term "margin of safety", it may not capture all prescribed NRC acceptance and design code limits. Therefore, Duke suggests the rule be written in the following manner:

   "A license amendment request is required for a proposed change, test, or experiment that results in exceeding or altering a prescribed NRC acceptance or design code limit related to the fuel cladding, RCS pressure boundary, or containment boundary, as determined by NRC approved methodology and/or analytical techniques."

9. Technical Specification Approval (no section): In topic III.J of NUREG 1606, the staff concluded "that, where technical specifications are involved with a planned modification, such that staff review of the associated TS will be required, staff approval of the proposed modification (and TS) must occur before the ongoing modification is implemented."

Duke's view is that the rule should allow a modification that requires a license amendment to be installed or tested prior to approval of the TS if the 10 CFR 50.59 evaluation concluded that the installation and testing did not require a licensing amendment.

If there are any questions, please call Lee Keller at (704)382-5826.

Sincerely,

M. S. Tuckman

M. S. Tuckman

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Anthony R. Pietrangelo, NEI

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DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

102-04228-JML/SAB
December 18, 1998

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Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
ATTN: Rulemaking and Adjudications Staff
Washington, DC 20555-0001

Dear Sir:

Subject: Comments on Proposed Rulemaking to 10 CFR 50.59, Changes, Tests, and Experiments (63 Federal Register 56098 dated October 21, 1998)

The subject Federal Register notice solicited public comments regarding proposed changes to 10 CFR 50.59 and related changes to other regulations. Arizona Public Service Company (APS) is pleased to provide the enclosed comments. APS believes the proposed rule is a significant step forward in resolving the differences that have existed between the industry and the NRC in the interpretation and application of 10 CFR 50.59. The proposed rule addresses many of those differences with an aim toward a process that is both reasonable and prudent.

APS has been heavily involved in the development of the industry comments being submitted by the Nuclear Energy Institute (NEI) and, therefore, fully endorses their comments. A number of the comments have greater significance to the efficiency and effectiveness of the process and, therefore, we reiterate those comments as follows:

Definition of Change

The definition of change is important to the determination of which activities require an evaluation to the c (2) criteria of 10 CFR 50.59. This definition is part of the "screening" step that is used to eliminate trivial activities from requiring an evaluation to each of the c (2) criteria. As such, the proposed definition contained in the NEI comment letter is essential to retain this screening capability while maintaining the integrity of the process such that non-trivial activities are evaluated appropriately.

JAN - 4 1999
Acknowledged by card

Provision for Minimal Increases in Probability and Consequences

The provision for allowing minimal increases in probability and/or consequences is a significant improvement in the regulation. In practical terms, defining and applying the minimal provision to consequences is much more straightforward than applying it to probability because consequences are more likely to be determined quantitatively while probability is normally determined qualitatively. APS agrees with the NRC that the current industry guidance in NEI 96-07 meets the minimal standard for probability. It is recognized that the choice of minimal was intended to grant greater flexibility than the NEI 96-07 standard of "so small or negligible." For the purposes of defining when a change exceeds the minimal standard, the staff should establish limits based on appropriate regulatory guidance such as Regulatory Guide 1.174, An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Current Licensing Basis.

With regard to consequences, APS supports the NEI position that consequences refer to radiological dose and, likewise, requests the NRC to state this in the supplementary information for the final rule. APS also supports the NEI recommendation for defining minimal with respect to consequences. The NEI proposal, a refinement of NRC option 3, accounts for different standards used during initial licensing with respect to the NRC's use of acceptance limits and regulatory limits. The NEI proposal provides for a small increase in consequences while retaining adequate margin to the regulatory limit.

Margin of Safety

The Notice of Proposed Rulemaking provided several options for addressing margin of safety. The industry evaluated each of the options and found strengths in each. The industry's proposal, as described in detail in the NEI comments, was built from an analysis of each of the NRC's proposed options and the underlying premises of the original "margin of safety" rulemaking. APS endorses the NEI proposal and suggests the NRC carefully consider its merits. It eliminates the ambiguity in the existing rule language while satisfying the original intent of the margin of safety determination.

Cumulative Effects

In concert with the provision to allow minimal changes in probability and consequences, the NRC included a companion requirement in the proposed rule to track and report the cumulative effects of minimal changes. APS does not believe this is warranted for the following two reasons:

1) The provision for increasing consequences by a minimal amount is self-limiting. That is, consequences can only be increased by a fraction of the remaining margin to the regulatory limit. As such, the regulatory limit or acceptance limit, as applicable, can be approached but not exceeded without prior NRC approval. For minimal increases in probability the appropriate ceiling should also be established using applicable regulatory guidance.

2) If the parameters in question (i.e., probabilities of occurrence, and radiological dose consequences) were sufficiently important they would be required to be in the FSAR. Typically, dose consequences are provided in the FSAR. Therefore, any changes to these parameters would require corresponding changes to the FSAR, which would be "reported" in required FSAR updates.

APS appreciates the opportunity to comment on this proposed rule and looks forward to working with the NRC to resolve the few remaining issues. Achieving regulatory stability in this important area is important to our industry.

If you have any questions or comments, please contact Scott Bauer at 602-393-5978. APS is making no commitments in this letter.

Sincerely,

James M. Levine

JML/SAB/mah

cc: E. W. Merschoff
M. B. Fields
J. H. Moorman

(42)

Florida Power & Light Company, P. O. Box 14000, Juno Beach, FL 33408-0420

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FPL

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DOCKET NUMBER
PROPOSED RULE PR 50,52+72
(63FR56098)

John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555
Attn: Rulemakings and Adjudications Staff

Re: Florida Power & Light Company Comments on Proposed Rulemaking to 10 CFR 50.59 Changes, Tests, and Experiments (63 Fed. Reg. 56098 (Oct. 21, 1998))

Dear Mr. Hoyle:

Florida Power & Light Company (FPL), the licensed operator of the St. Lucie Nuclear Plant, Units 1 and 2, and the Turkey Point Nuclear Plant, Units 3 and 4, offers the following comment in response to the subject notice which solicited public comments on proposed changes to 10 CFR 50.59 and related changes to other sections of Part 50, Part 52 and Part 72. FPL endorses the comments of the Nuclear Energy Institute on the proposed rulemaking in the letter to John C. Hoyle from Anthony Pietrangelo, dated December 21, 1998.

We appreciate the opportunity to comment on this important issue.

Sincerely yours,

Rajiv S. Kundalkar

Rajiv S. Kundalkar
Vice President
Nuclear Engineering

cc: Anthony Pietrangelo, Nuclear Energy Institute

Acknowledged by card JAN -4 1999

41

Matthew A. Petitclair, P.E.
9111 Muirfield Cir. NW
Ramsey, MN 55303

December 21, 1998

The Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attention: Rulemakings and Adjudications Staff

Subj: Comments on Federal Register, October 21, 1998, Volume 63, Number 203, Page 56,098, "Requirements Concerning Changes, Tests and Experiments."

As an engineer who writes 10CFR 50.59 evaluations and teaches others to do so, I offer the following:

A Plea for Simplicity

10 CFR 50.59 is unlike other regulations in Part 50 in that it is used, not by a handful of highly trained specialists, but by large numbers of ordinary workers at the nuclear plants who develop changes, tests and experiments. Considering the many engineers, technical personnel, procedure writers and NRC Staff involved in implementing and enforcing of this regulation, it is very important that it be kept as simple and unambiguous as practicable.

However, in an attempt to focus parts of 10CFR50.59 more narrowly on specific concerns, some aspects of the proposed regulation have become unbelievably complex. For example, the Chairman in her comments on the proposed regulation suggested that the definition of Margin of Safety include the following in a footnote:

> *The "margin of safety as defined in any technical specification" (margin of safety) is the amount (quantitative or qualitative) of margin between the operation of the facility as described in the technical specifications and the exceedance (sic) of safety limits listed in the technical specifications or regulatory limits. In relation to accident analysis, the margin of safety is typically the difference between the calculated parameters (e.g., peak fuel clad temperature, maximum RCS pressure, etc.) and the associated regulatory or safety limit. The margin of safety is a product of specific values and limits contained in the technical specifications (which cannot be changed without NRC approval) and other values, such as assumed accident or transient initial conditions or assumed safety system response times, which are not specifically contained in the technical specifications. Any change to the values not specifically contained in the technical specifications must be evaluated for impact on the margin between the calculated result of an accident or transient and the safety or regulatory limit. Changes, or the net effect of multiple changes, which result in a reduction in the margin of safety require prior NRC approval.*

Changes, or the net effect of multiple changes, which do not cause a reduction in margin of safety do not require prior NRC approval. All evaluatory (sic) work in assessing the impact of proposed changes must be performed using methodology and analytical techniques which are either reviewed and approved by the NRC or which are reviewed and vetted in a manner approved by the NRC.

The regulations are difficult enough now, without hiding statements like these in the fine print. (It is noted that the words "evaluatory" and "exceedance" do not even appear in the dictionary.)

I implore the Commission to remember that this regulation will be implemented directly by thousands of engineers and technical staff across the industry who screen and write tens of thousands of 50.59 evaluations each year, not to mention a large part of its own Staff. If the regulation can only be understood by someone with degrees in law, engineering and linguistics, there is no chance that the regulation will ever be implemented successfully.

To quote the Father of Nuclear Power,

> Those of us who are compelled to work with ordinary people and real technical problems do not have time to become familiar with rarefied and abstruse words such as you have used... Therefore, it would be most helpful if, in future, you write... in ordinary English.[1]

Please keep it simple.

Sincerely,

M A Petitclair

M. A. Petitclair

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[1] Hyman G. Rickover memo to CAPT E. E. Henifin, dtd 10 Nov 77

Union Electric

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(40)

December 21, 1998

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
Attn: Rulemaking and Adjudications Staff

Gentleman:

ULNRC-3943

AmerenUE

COMMENTS ON NRC PROPOSED
RULEMAKING TO AMEND 10 CFR 50.59

AmerenUE hereby submits comments in response to the NRC's request for public comments on NRC's proposed rulemaking to amend its regulations concerning the authority for licensees of production or utilization facilities to make changes to the facility or procedures, or to conduct tests or experiments, without prior NRC approval, (Federal Register vol. 63, Number 203; October 21, 1998).

AmerenUE has actively participated in the review and generation of comments on the proposed rulemaking to amend 10 CFR 50.59, coordinated by Nuclear Energy Institute (NEI). Therefore, we fully endorse the comments submitted on December 21, 1998 by Mr. Anthony R. Pietrangelo of NEI on behalf of the nuclear energy industry.

If you have any questions on our endorsement of these comments, please contact us.

Very truly yours,

Alan C. Passwater

Alan C. Passwater
Manager, Corporate Nuclear Services

BFH\jdg

U.S. NUCLEAR REGULATORY COMMISSION
RULEMAKINGS & ADJUDICATIONS STAFF
OFFICE OF THE SECRETARY
OF THE COMMISSION

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39

Nebraska Public Power District
Nebraska's Energy Leader

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NLS980202
December 21, 1998

DOCKET NUMBER PROPOSED RULE PR 50, 52 & 72
(63FR56098)

Secretary of the Commission
U. S. Nuclear Regulatory Commission
Washington, DC 20055-0001

ATTN: Rulemakings and Adjudications Staff

Gentlemen:

Subject: Comments on Proposed Rulemaking for 10 CFR 50.59, Changes, Tests, and Experiments
Cooper Nuclear Station, NRC Docket 50-298, DPR-46

Reference:
1. 63 Federal Register 56098, dated October 21, 1998, Proposed Rulemaking to 10 CFR 50.59, "Changes, Tests, and Experiments"
2. SECY-98-171, dated July 10, 1998, "Proposed Rulemaking on 10 CFR Parts 50, 52, and 72 Requirements Concerning Changes, Tests, and Experiments and Staff Recommendations on Changes to Other Regulations and Enforcement Policy."

The Nebraska Public Power District (District) hereby submits comments on the proposed rulemaking in Reference 1 for Nuclear Regulatory Commission (NRC) consideration.

The District supports many of the proposed changes to 10 CFR 50.59, and believes that the initiative to improve the language and application of the rule will be of direct benefit to the industry and the NRC. The attachment to this letter tabulates the District's comments and recommendations on the proposed rule organized in the following manner:

1. Rulemaking Package Section Number
2. Proposed Rule Language and/or Rulemaking Discussion
3. District Comments/Recommendations.

Cooper Nuclear Station
P.O. Box 98 / Brownville, NE 68321-0098
Telephone: *(402) 825-3811 /* ***Fax:*** *(402) 825-5211*
http://www.nppd.com

JAN -4 1999
Acknowledged by card

The District also wishes to express support and endorsement of forthcoming comments on the proposed rulemaking submitted by the Nuclear Energy Institute (NEI) on behalf of the nuclear industry. Concurrent with rule implementation, the District would expect that the industry work with the NRC to agree on a revision to NEI 96-07 consistent with the final rule such that the NRC may endorse this guidance document for use in applying the revised Section 50.59.

Detailed comments and recommendations are included in the attachment. The District agrees with the following proposals:

- Adding a new Section (a) on Definitions.

- Consolidating the rule applicability statements.

- Expanding the existing three evaluation criteria in 10 CFR 50.59(a)(2) into additional criteria in new Section (c)(2).

- Relocating the existing requirement in 10 CFR 50.59(c)(3) on control of technical specifications to 10 CFR 50.90.

- Changing the language from "safety evaluation" and "unreviewed safety question" to "evaluation" and "need to obtain a license amendment."

- Clarifying that changes controlled by 10 CFR 50.54 (a or q) need not also be evaluated under 10 CFR 50.59.

- Allowing an increase in consequences of an accident or malfunction of equipment important to safety, provided that increase is within a percentage of remaining margin (between existing analyses and the regulatory limits). The District is endorsing an industry position that this limit be 20% of remaining margin, as opposed to the 10% stated in the proposed rule.

With regard to Margin of Safety, the District does not agree that deletion of this criterion is appropriate. However, the District also does not agree that the margin of safety should be those input assumptions, analytical methods, acceptance criteria and limits of the safety analysis (Option 1 of the proposed rule), as this approach has the effect of giving input values and assumptions the weight of Technical Specifications. A focus on the original intent of Margin of Safety, in terms of protecting the principal fission product barriers such as fuel clad and containment, is a more appropriate approach. NEI is submitting, on behalf of the industry, an alternative to the options offered in Reference 1 for NRC consideration. The District agrees that an approach based on preservation of the fission product barriers, not already contained within the Technical Specifications, is appropriate. However, the District also believes that the regulation or guidance should be specific enough in terms of the affected parameters subject to review but broad enough to allow for the varied plant designs and analyses that exist.

Reporting of cumulative effects, as indicated in the proposed language for 50.71(e), poses a significant concern for the District. The District is strongly opposed to this new requirement and disagrees that it would not be burdensome on licensees. The rationale behind this position is described further in the attachment.

Enforcement discretion is a necessary component of implementing the proposed rule. While not specifically addressed in the rulemaking package of Reference 1, it is discussed in SECY 98-171 (Reference 2) under Item 4. The District proposes that the NRC make an enforcement discretion policy consistent with that contained in Enforcement Guidance Memorandum (EGM) 96-005 and 98-007 with respect to FSAR enforcement discretion. The District agrees with NEI's request that the NRC consider refraining issuance of notices of violations or minor violations in cases where violations of the existing rule would not constitute a violation of the proposed rule. This would prevent the unnecessary diversion of industry and NRC resources on issues that are non-safety significant. In addition, it would afford a better appropriation of those resources to ensure a smooth transition to the new rule. The District also respectfully requests that the NRC consider a "grandfather clause" in enforcement policy as part of the transition from the existing rule to the final revised Section 50.59. The purpose of this clause would be to alleviate concerns of enforcement action being taken prior to issuance of the new regulation based on previous interpretations of the rule then in effect (an exception to this would be in cases of willful noncompliance).

In closing, the District is pleased to participate in this landmark rulemaking event. Should you have any questions concerning this matter, please contact me.

Sincerely,

JH Swailes for

Bradford L. Houston
Nuclear Licensing and Safety Manager

/lrd
Attachment

Cc: J. H. Swailes

NEBRASKA PUBLIC POWER DISTRICT
COMMENTS ON PROPOSED RULEMAKING
10 CFR 50.59 and 50.71(e)

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
(a) Definitions (Rulemaking Package Sections B, C, D, and E)		
Comment #1 (1) Change (Rulemaking Section B)	Modification, addition, or removal	This is true only in cases where the modification, addition, or removal renders the Final Safety Analysis Report (FSAR), as updated, incomplete or inaccurate in any way. There are cases where changes to structures, systems, or components (SSCs) may be made and in no way deviates from the FSAR (as updated) description. The new rule should not preclude a screening process. The District recommends adoption of a an alternative definition of change, which will be reflected in comments forwarded by Nuclear Energy Institute (NEI): *"Change means a modification or addition to, or removal from, the facility or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished."* The screening process should allow for the fact that not all additions or changes should be under the purview of 50.59, even in cases where FSAR descriptions exist. NEI 96-07 Rev. 0 refers to this type of change as "inconsequential." An inconsequential change is one that has no discernible effect on the design, performance, and methods of operation, evaluations, or methods of evaluations of SSCs that are important to safety. For example, a support building air conditioning system may be described in the SAR. Addition of a second air conditioning unit may be desired, but should not required to be evaluated as a change in the facility as described in the FSAR (as updated) when it <u>can be demonstrated</u> to have no impact on the operation of the facility. An

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
		FSAR update may be warranted, however. "Commercial" changes and even minor changes to SSCs that do not affect the design, function, or method of performing the function should be excluded from the "change" definition. Another example would be an equivalency change. These changes would be appropriately analyzed in accordance with station approved procedures, but by definition would not impact the design function or method of performing its function and thus should be excluded from 50.59 (though may still be required in FSAR updates pursuant to 50.71(e)). What we desire to achieve is a better focus on safety. This would be appropriate to contain in guidance, however the language of the rule could be modified to include applicability to those SSCs that are important to safety.
Comment #2 Analyses, bases, methods, assumptions	Evaluation is required for changes to the analyses and bases for the facility. 50.59 does apply to the requirements for design, construction and operation and the safety analyses that are documented in the FSAR. Changes to information such as performance requirements, methods of operation, the bases upon which the requirements have been established, and the evaluations, are changes to the facility as described in the SAR and thus must be subject to the 50.59 criteria to determine if prior Commission approval is required. This includes changes to methods and assumptions.	As above, this should only apply if the FSAR (as updated) is rendered incomplete or inaccurate in any way as a result of the change.
Comment #3 Interdependent Changes	Interdependent changes (i.e., where a second change is caused by the fist, with respect to function or performance) can be treated as a single change. Treating as one change the combination of changes to offset one that would otherwise require prior approval is not an appropriate application of 50.59.	Agree. This is reflected in and consistent with NEI 96-07 and the District concurs that it is more appropriately handled in guidance rather than the rule.
Comment #4 (2) Facility as described in the final safety	(i) Structures, systems, and components (SSCs) that are described in the final safety analysis report (as updated) (ii) Design or performance requirements or methods of operation for such SSC required to be included or described in the final safety analysis report (as updated),	As discussed above for the definition of change, care must be taken in the final rule language to ensure it is not implying that any change to an SSC would require an evaluation to determine if a license amendment is required simply by the fact that the SSC is described in the FSAR (as updated). Specifically, evaluation against the seven criteria of proposed

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
analysis report (as updated) (Section B)	and (iii) Evaluations or methods of evaluation required to be included in the FSAR (as updated) for such SSC that demonstrate that their intended function(s) will be accomplished	Section (c)(2) should not be required for changes to design details that do not impact design functions. The District contends that a reiteration of the requirements for the contents FSAR (as updated), that are codified elsewhere in the regulation should not be repeated in 50.59. Thus the phrase, "required to be included" should be deleted from subparagraphs (ii) and (iii).
Comment #5 (3) Final Safety Analysis Report (as updated) (Section E)	Submitted in accordance with 50.34, as amended and supplemented, and as modified as a result of changes made pursuant to 50.59, 50.90, and, as applicable, 50.71(e) and (f).	The phrase, "…as modified as a result of changes…." should be replaced with the phrase: *"…as modified as a result of changes made in accordance with 10 CFR 50.71(e)."* The District recommends deleting the cumbersome language in proposed Section (c)(2)(i – vi): *"…or evaluations performed pursuant to this section and analyses performed pursuant to Section 50.980 after the last final safety analysis report was updated pursuant to Section 50.71 of this part."* This language represents a new requirement for evaluating whether a proposed change requires a license amendment. NEI suggests that the FSAR definition be expanded similar to the below, to compensate for deleting the language described above: *"'Final safety analysis (as updated)' means the current revision of the FSAR as updated pe the requirements of 10 CFR 50.71(e).* *For purposes of implementing Section 50.59, the FSAR (as updated) is considered to include evaluations pursuant to this section and analyses performed pursuant to Section 50.90 after the last update of the final safety analysis report pursuant to Section 50.71 of this part."*

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
		The District believes that review of pending FSAR changes or license amendments, which have been approved according to licensee's policies and procedures, should be reviewed under 50.59; however review of other 50.59 evaluations appears to be a new requirement and redundant. Guidance would be required for implementing this new requirement. For example, if a facility performs internal, interim updates to the FSAR (as updated) at a frequency greater than required by 50.71, (for example, bi-monthly), would it be acceptable to only review those safety evaluations performed since the last internal update? The District recommends deleting the following phrase: *"...evaluations pursuant to this section and..."*
Comment #6 (4) Procedures as described in the final safety analysis report (as updated) (Section C)	Information in the FSAR (as updated) regarding how SSCs are operated and controlled (including assumed operator actions and response times), and information describing the conduct of operations.	No comments. NEI will be forwarding comments regarding this definition which which the District agrees.
Comment #7 (5) Tests or experiments not described in the final safety analysis report (as updated)	Any condition where the Reactor or any of its SSCs are utilized or controlled in a manner which is either: (i) Outside the controlling parameters of the design bases as described in the FSAR (as updated), or (ii) inconsistent with the analyses in the FSAR (as updated).	Language "Reactor or any of its SSCs" could be misleading. The point is that any SSCs (including the Reactor) which are described in the SAR but are operated/tested in a manner that was not previously intended or enveloped by the SAR should be evaluated to ensure prior commission approval (via a license amendment) is not required. The term, "Design bases" has been used here. It may be appropriate to reference the 50.2 definition for Design Bases in a guidance document.

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
(Section D)		
(b) Applicability (Rulemaking Package Section A)		
Comment #8 50.59 applicability	Applies to each holder of a license authorizing operation of a production or utilization facility, including those submitting certification of permanent cessation, or license authorizing possession but not operation	Agree.
(c) Make changes without obtaining a license amendment (Rulemaking Package Section A)		
Comment #9 (1) Criteria	A licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) without obtaining a license amendment pursuant to 50.90 only if: (i) A change to the Technical Specifications (TS) is not required (ii) Change, test, or experiment does not meet any of the criteria in (c)(2) of 50.59. The provisions in this section do not apply to changes in procedures when the applicable regulations establish more specific criteria for accomplishing such changes.	Agree.
Comment #10 (2) Amendment required per 50.90	A licensee shall obtain an amendment to the license pursuant to 50.90 prior to implementing a change, test or experiment if it would…	Additional guidance should be published concurrent with the rule for consistency in the format and content of requested license amendments when the criteria of 50.59(c)(2) are not met. For example, is it expected that proposed changes to the FSAR (as updated) be included? The District believes that changes to the FSAR (as updated), which may occur pending approval of the license amendment, should not be subject to NRC approval. The change should be described in as much detail as needed for NRC approval of the change, however FSAR changes should be conducted in accordance with 50.71(e) pending NRC approval of the license amendment.
Comment #11	Removal of the terminology: Unreviewed Safety Question (USQ).	The removal of the term "USQ" is consistent with the philosophy and application of 50.59. Since the NRC acknowledges that TS should be revised in accordance with the final wording of 50.59 in cases where "USQ" is mentioned, the NRC should NOT require facilities to submit license amendments for this change. This also applies to other licensing documents (e.g., Quality Assurance plans). Otherwise it would result in

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
		an unnecessary burden on both licensees and NRC.
PROBABILITY—Accident (Rulemaking Package Section G)		
Comment #12 (i) Probability of Occurrence of an Accident	Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in either the final safety analysis report (as amended) or in evaluations performed pursuant to this section and safety analyses performed pursuant to 50.90 after the last final safety analysis report was updated pursuant to 50.71 of this part	The District agrees with the elimination of the phraseology "may result" or "may be created," which has proven problematic with no real safety benefit. The District believes that the existing NEI 96-07 guidance for evaluating the Probability of Occurrence of an Accident (specifically determining if no clear trend towards increasing the probability exists) guidance applies. A minimal increase may mean that the resulting probability of the proposed activity still satisfies the event frequency classification provided in the FSAR (as updated). The definition and application of "minimal" is what is key here. What is unclear is how sites will be expected to deal with potential cumulative probabilities. Are we expected to review all changes annually, or at some other predetermined frequency, to ensure that any minimal increases in probability do not, when taken cumulatively, produce more than a minimal increase in probability? The District disagrees with this approach, which is discussed in greater detail later in this attachment in the comments on proposed changes to 50.71(e) (Rulemaking Package Section L).
PROBABILITY—Malfunction (Rulemaking Package Section G)		
Comment #13 (ii) Probability of Occurrence of Malfunction	Result in more than a minimal increase in the probability of occurrence of a malfunction of equipment important to safety previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to 50.90 after the last final safety analysis report was updated pursuant to 50.71 of this part.	One of the statements in the rulemaking package is that if "design bases" assumptions and requirements are still satisfied, the probability of malfunction of equipment important to safety is no more than minimally increased. The District maintains that the probability of malfunction is simply NOT increased. The District also disagrees that the probability of malfunction is more than minimally increased if a new failure mode as likely as existing failure modes is introduced. It is not axiomatic that the introduction of a new failure mode results in an increase in probability of malfunction of equipment. I t is incumbent on the licensees to arrive at this determination through engineering judgment and quantitative analysis

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
		when appropriate. As discussed above for probability of accidents, The District is concerned with the apparent emphasis on quantitative evaluations. The accepted practice is to rely on reasonable engineering practices, engineering judgement, or other qualitative assessments. The NRC should recognize that qualitative assessments are an acceptable means and that quantitative may be used if desired, but is not required. A requirement to have quantitative assessments, especially for the discussion on reporting cumulative effects (discussed later in the attachment) would pose a significant resource burden on the District with little safety benefit.
Comment #14	External hazard design requirements—NRC concludes that licensees can treat changes in external hazard design requirements as potentially affecting equipment probability rather than as accident probability.	This should be reflected in guidance.
CONSEQUENCES (Rulemaking Package Section G)		
Comment #15 (iii) Increase in consequences of an accident	Result in more than a minimal increase in the consequences of an accident previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to 50.90 after the last final safety analysis report was updated pursuant to 50.71 of this part	Recommend that the NRC clearly indicate that the term "consequences" refers to radiological dose. As with probability, the NRC is interested in the cumulative effects of such changes. The rulemaking package indicates that this will not significantly increase the burden on licensees. The District disagrees. This will force licensees to analyze all changes at some regular frequency to determine the net impact of minimal increases in consequences. This goes beyond what is currently expected in annual updates. Again, this is discussed in greater detail in the section on proposed changes to 50.71(e).
Comment #16 (iv) Increase in consequences of malfunction	Result in more than a minimal increase in the consequences of a malfunction of equipment important to safety previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to 50.90 after the last final safety analysis report was updated pursuant to 50.71 of this part	Agree. See **Comment #19**. The District agrees with a modified Option 3, which allows for minimal changes up to a certain percentage of remaining margin. Guidance should expand upon the application to General Design Criteria (GDC) 19 considerations, and whether it should be included in the scope.

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
Comment #17 OPTION 1	Consequences OPTION 1: Consequences—0.5 rem increase in calculated dose would require prior commission approval. If the licensee would need to change design basis assumptions or analytical methods or both to demonstrate change in consequences s less than 0.5 rem, then the change would not be minimal and NRC would expect a license amendment request.	Disagree. This is too absolute and for licensees who are currently licensed to "well within" the regulatory limits does not allow enough flexibility.
Comment #18 OPTION 2	Consequences OPTION 2: Graduated approach ≤ 50% limit, a minimal change would be ≤ 10% increase ≤ 80% limit, a minimal change would be ≤ 5% increase More than 80%, a minimal change would be ≤ 1%, NOT TO EXCEED LIMIT.	Although a degree of flexibility exists with this option, it would be negated by the administrative controls that would be required to track implementation of this option. For example, besides controlling the use of the graduated approach, the burden would also fall on licensees to ensure that changes in progress do not "move each other" into the next category (i.e., from the ≤ 50% to the ≤ 80%).
Comment #19 OPTION 3	Consequences OPTION 3: Limit the fraction of remaining margin that can be consumed by a particular change. Minimal changes would be 10% of the remaining margin between current conditions and acceptance guidelines	Limiting a fraction of remaining margin provides the greatest amount of flexibility while still minimizing impact on plant design or operation. By virtue of its self-limiting nature, this option eliminates the need for reporting of cumulative effects. The District endorses the NEI proposal to change the percentage of remaining margin that would be considered "minimal" from 10% to **20%.** Finally, to support the above, consequences of accidents in the Cooper Nuclear Station (CNS) Updated Safety Analysis Report (USAR) are well within (less than 10% of) the 10 CFR Part 100 limits.
ACCIDENT OF DIFFERENT TYPE (Rulemaking Package Section H)		
Comment #20 (v) Possibility for design basis accident of different type	Create a possibility for a design basis accident of a different type than any previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to 50.90 with respect to design basis accidents after the last final safety analysis report was updated pursuant to 50.71 of this part	If we refer to "design basis accident," then that is what needs to be defined. For example, the CNS USAR only has four Design Basis Accidents (DBAs): Control Rod Drop, Main Steam Line Break, Refueling Accident, and Loss of Coolant Accident (LOCA). A new DBA would have to be in the same category of the above. New transients would not apply, because in the CNS USAR they are not considered DBAs.
Comment #21	Accidents evaluated in the SAR—those events that a plant must	Currently CNS applies "accident" in its broadest sense—it includes the

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
Definition of Accident	show that it can withstand Transients—these are defined as more likely, low consequence events. In the context of PRA, transients are typically viewed as initiating events Accidents—more serious; in the context of PRA, accidents are typically viewed as sequences that result from various combinations of plant and safety system response.	DBAs (evaluated in the CNS USAR Chapter XIV), transients, and other events for which the plant was designed to cope (fire, flood, Anticipated Transient Without Scram, or ATWS). The District concurs with NEI in proposing a definition for "Accident" similar to the below: *The term "accidents" refers to the anticipated operational transients and postulated design basis accidents, and special events that are analyzed to demonstrate that the plant can be operated without undue risk to the health and safety of the public.* This definition would encompass events from fast closure of a turbine bypass valve to ATWS to LOCA. It would NOT encompass the "beyond design basis" type of events which are typically the subject of Severe Accident Management. Consideration should also be given to application of this philosophy for older plants, such as CNS, whose FSARs do not conform (nor were required to conform) to the Standard Review Plan in NUREG-0800. For example, Standard Review Plan plants, accidents are described in Chapter XVI (15) of their FSARs. At CNS, accidents and transients are discussed in Chapter XIV (14) and Appendix G, respectively.
Comment #22 OPTION 1	Definition of Accident PROPOSAL 1: an initiating event or combination of events and/or conditions that could occur from equipment failure, human error, natural or manmade hazards which challenges the integrity of one or more fission product barriers (fuel, RCS, release of radionuclides (confinement/containment)), required to be analyzed and/or accounted for by the Commission and addressed in the licensee's safety analysis report. In other words, the Design Basis Accidents addressed in the SAR.	See **Comment #21.**

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
Comment #23 OPTION 2	Definition of Accident PROPOSAL 2: Add "design basis accident" into the existing criteria, either for the three criteria or just the one on accident of a different type (preferred NRC choice)	Would need to explain how to get to DBA. The District would interpret this as meaning that if existing DBA analyses bound the change, it would NOT constitute an accident of a different type. Again, see above discussion.
MALFUNCTION WITH DIFFERENT RESULT (Rulemaking Package Section I)		
Comment #24 (vi) Possibility for malfunction with different result	Create a possibility for a malfunction of equipment important to safety with a different result than any previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to 50.90 with respect to design basis accidents after the last final safety analysis report was updated pursuant to 50.71 of this part Prior approval is required "if a possibility for a malfunction of *equipment important to safety* ***with a different result*** than any evaluated previously in the final safety analysis report (as updated) ***is*** created." Equipment malfunctions are generally postulated as potential single failures to evaluate plant performance. Unless the equipment would fail in a way not already evaluated in the safety analysis, there is no need for NRC review of the change. Review must be done at the level at which equipment is being replaced. It is not sufficient for a licensee to state that since failure of a system or train was postulated in the SAR, any other equipment failure is bounded by this assumption, unless there is some assurance that the mode of failure can be detected and that there are no consequential effects such that it can be reasonably concluded that the SAR analysis was truly bounding and applicable.	Agree. This is consistent with NEI 96-07 guidance on this topic.

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
MARGIN OF SAFETY (Rulemaking Package Section J)		
Comment #25 (vii) Reduction in margin of safety	Result in a reduction in the margin of safety associated with any TS	This language is dependent upon the definitions for "reduction" and "margin of safety associated with any TS." The District believes that a change in focus from "margin of safety associated with TS" to language similar to the below, consistent with recommendations from NEI, is more appropriate: *"A licensee shall obtain an amendment to the license pursuant to 10 CFR 50.90 prior to implementing a change if it would result in a calculated design basis limit associated with the integrity of the fuel cladding, RCS pressure boundary, or containment boundary being exceeded or altered."*
Comment #26 Licensing Envelope concept	Margin of Safety—concept of the "licensing envelope" There are many margins that exist in facility design. Margins are also built into the plant to establish the regulatory envelope within which a plant has demonstrated its ability to respond to a spectrum of design basis accidents. It is in this category termed the "regulatory envelope," that the NRC believes that regulatory oversight of changes in margin may be needed from the standpoint of 50.59.	The licensing envelope varies from plant to plant and by vintage. It could be very difficult to create a consistent standard of what constitutes the licensing envelope.
Comment #27 OPTION 1	Input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the final safety analysis report (as updated), that established any TS requirement, are altered in a non-conservative manner (OPTION 1)	The District agrees that this approach has the effect of giving input values and assumptions the weight of TS, which is inconsistent with the philosophy in 50.36 of establishing TS only on those values of most immediate safety importance. The District STRONGLY recommends NOT adopting this option.
Comment #28 OPTION 2	Delete margin of safety criterion—in this option, it is argued that the other criteria and regulatory requirement for prior approval for TS changes assure that there are no significant adverse changes to margins in design and operation.	Although the District agrees that the other six criteria cover a broad scope to preserve the safety analysis of a facility, they do not automatically provide for direct changes to fission product barriers which, even if probabilities or consequences would not be changed (or would be changed minimally), may be of interest to the NRC.
Comment #29 OPTION 3	Examine the RESULTS of the safety analyses, and determine whether changes to operational characteristics or other information described in the FSAR (as updated) would reduce the	This option appears to be redundant to the other six criteria (consequences, probabilities, new or different accidents/malfunctions).

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
	level of protection afforded by the TS (i.e., by the limiting safety system settings and limiting conditions of operation), as reflected in the results of safety analyses. NRC established a level of required performance (acceptance criteria or regulatory limits) for certain physical parameters, such as those that define the integrity of the fission product barriers. Satisfying them produces a margin of safety to loss of barrier integrity.	
Comment #30 Option 3(A)(1)—Safety and Regulatory Limits	Margin of Safety Option 3(A)(1): Margin as reflected in approved safety and accident analyses, between the LSSS and LCOs of TS and the associated regulatory limits. Licensees could make desired changes to operational characteristics without prior NRC approval, provided that the change does not result in accident analysis results that are nearer the regulatory, or safety, limits than the corresponding results that the NRC used in evaluating the acceptability of the TS during licensing.	Again, appears to be redundant to the other criteria.
Comment #31 Option 3(A)(2)—Fission product barriers—definition	Margin would be defined as that margin associated with preserving integrity of three barriers (fission product (FP) barrier response): fuel, reactor coolant system, and containment. The margin is the difference between the calculated value and its associated acceptance criteria. FP barrier response means those parameters that must be satisfied in the even to f postulated Design Basis Events to demonstrate integrity of the fuel, Reactor Coolant System (RCS) and containment system barriers. Specifically: Fuel and cladding performance (PCT, or energy deposition, DNBR or MCPR, oxidation) RCS performance (pressure, flows, stress) Containment performance (peak pressure, containment leakage)	NEI has drafted a proposal for implementing a similar option, and is submitting it with their comments on the proposed rulemaking for consideration. The District is concerned that the regulation or guidance would have to be specific in terms of the affected parameters subject to review but broad enough to allow for the varied plant designs and analyses that exist.
Comment #32 Option 3(A)(3)—	Actually list the parameters of interest. Criterion could read:	See **Comment #31** above.

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
Specified Parameters	"...result in a change to the FSAR (as updated) calculated value of RCS peak pressure, containment peak pressure, or fuel performance (DNBR/MCPR, others), etc.	
Comment #33 Option 3(A)(4)—Include Mitigation Capability	In addition to the specific parameters related to fission product barrier performance, this option would also add mitigation capabilities, such as ECCS performance (pressures, flows, actuation values) and engineered safety feature performance (flows, pressures, spray effectiveness, system efficiencies) For example, spent fuel pool, periods when reactor is shut down, there may be other analysis results (water level, pool temp)	See **Comment #31** above.
Comment #34 Option 3(B)(1)—No Reduction	Changes, or the net effect of multiple changes, which result in a reduction in the margin of safety require prior NRC approval. Changes, or the net effect of multiple changes, which do not cause a reduction in the margin of safety do not require prior NRC approval.	"Nonconservative" is essentially the same as "no reduction." See **Comment #31** above regarding the scope of this criterion.
Comment #35 Option 3(B)(2)—Minimal Reduction	Modeled upon the options offered for minimal increases in consequences	How would this be applied consistently? The District believes that this would not be consistent with the intent of this final criterion in maintaining the fission product barriers intact. See **Comment #31** above.
Comment #36 Option 3(B)(3)—Available margin	This option allows minimal reductions with respect to the acceptance criteria (available margin). For example, a license amendment would be required if "...there is more than a 10% reduction in the difference between the calculated value and the acceptance criteria for fission product barrier response to accidents evaluated in the SAR."	This would require definition of acceptance criteria: those values, established by NRC regulation or review guidance, to which the licensee is committed through its FSAR (as updated), as the basis for acceptability of response to the postulated accident, transient, or malfunction. It would also require specific identification of what is to be included in this definition.
Comment #37 Evaluation of effect of the change upon analysis results	All analyses and evaluations for assessing the impacts of proposed changes must be performed using methodology and analytical techniques which are either reviewed and approved by the NRC or which are shown to meet applicable review guidance and standards for such analyses. Alternative: rely on licensee's design control process to provide assurance that any evaluative work has been conducted with	To control the analysis methodologies is too restrictive. This means that in order to apply state of the art technology, licensees would almost always have to apply for a license amendment. This could prove to deter licensees from pursuing improvements that benefit safety.

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
	methods and techniques commensurate with the safety significance of the analyses being performed.	
Safety Evaluation (Rulemaking Package Section K)		
Comment #38 Safety evaluation	50.59(b)(1)—proposes deleting term "safety" from describing the required evaluation for determining whether a change, test, or experiment requires a license amendment.	Agree. Again, the District would like to reiterate that any changes, which may be required to TS to simply incorporate this terminology change, should not require submittal of a license amendment.
Comment #39 Safety Evaluation—50.71(e)	Proposes to change "safety evaluation in support of license amendments" to "safety analysis in support of license amendments" to reduce confusion between the information prepared by the licensee for the amendment (safety analysis) and the NRC reviewed (safety evaluation) Instead of referring to "changes did not involve USQs" it would read "evaluation that changes did not require a license amendment in accordance with 50.59(c)(2)..."	Agree.
(d) Records & Reporting Requirements (Rulemaking Package Section L)		
Comment #40 (1) Written records	Licensee shall maintain records of changes in the facility and of change in procedures made pursuant to this section, the extent that these changes constitute changes in the facility as described in the final safety analysis report (as updated) or to the extend that they constitute changes in procedures as described in the final safety analysis report (as updated). The licensee shall also maintain records of tests and experiments carried out pursuant to paragraph (c) of this section. Records must include a written evaluation which provides the bases for the determination that the change, test, or experiment does not require a license amendment.	No comments.
Comment #41 (2) Reporting	Submit as specified in 50.4, a report containing a brief description of any changes, tests, or experiments, including a summary of the evaluation of each. The report may be submitted annually or along with the FSAR updates as specified by 50.71(e), or at such shorter intervals as may be specified by the licensee.	No comments.
Comment #42	Records of changes in the facility must be maintained until	This only applies to the written records specified in (d)(1).

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
(3) Record retention	termination of the license. Records of changes in procedures and records of tests and experiments must be maintained for a period of five years.	
50.71(e) changes (Rulemaking Package Section L)		
Comment #43 Effects of changes	Proposed language, 50.71(e): The submittal must describe the effects of: (1) all changes made in the facility or procedures as described in the FSAR; (2) all safety analyses and evaluations performed by the licensee either in support of requested license amendments, or in support of conclusions that changes did not require a license amendment in accordance with 50.59(c)(2) (3) all analyses of new safety issues performed by or on behalf of the licensee at the Commission request; (4) the net effect of all changes made since the last update on the safety analyses, including probabilities, consequences, calculated values, system or component performance, that are in the FSAR (as updated)…	The District disagrees that this would not result in a significantly increased burden. Describing the "effects of the changes" implies that a 50.59 summary as currently required would not be of any value, because the "effects" of the changes are discussed in the 50.59 evaluation (e.g., how the consequences/probabilities/etc. are affected). We would be summarizing the 50.59 along with USAR update. It seems that Item (4) would also require a significant amount of effort each updating period to determine the net effects. What are the guidelines for determining cumulative impacts? For probabilities, this implies that all 50.59 evaluations would require PRA in order to determine cumulative effects at the end of the reporting period. However, it should be acceptable to apply reasonable engineering practices and judgment to determining increase in probabilities. As such, it would not be practical to report a net effect. In addition, the District (in Comment # 19 above) proposes allowing an increase in consequences up to 20% of the remaining margin; by its self-limiting nature, reporting cumulative effects of minimal increases is unnecessary. The District is STRONGLY opposed to requiring a reporting of net effects with the FSAR update pursuant to 50.71(e). I
Comment #44	Reporting requirements for the FSAR update should be enhanced to enable the NRC to better understand the potential cumulative impact of changes that might have been made since the last update.	See **Comment #43** above.
Comment #45	NRC is proposing a requirement that the FSAR update submittal (with the replacement pages), the licensee shall include a description of each change affecting that part of the SAR that provides sufficient information to document the effect of the	See **Comment #43** above. Note that all of this would have to be revised depending upon the final decisions on how to treat consequences, probability, and margin of safety.

Section Number	Proposed Rule Language and/or Rulemaking Discussion	District Comments/Recommendations
	change upon the probability or consequences of accidents or malfunctions, or reductions in margin associated with that part of the SAR.	
QA Plan and Emergency Plan with respect to 50.54 and 50.59		
Comment #46 Excluding QA/E-Plan	Proposing that language be added to specifically exclude from scope of 50.59 changes to QA or Emergency Plans/programs, as they are governed by 50.54 requirements, unless other information described in the FSAR is also being changed.	Consistent with current programs.

(38)

Charles H. Cruse
Vice President
Nuclear Energy

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USNRC

'98 DEC 28 P1:36

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Baltimore Gas and Electric Company
Calvert Cliffs Nuclear Power Plant
1650 Calvert Cliffs Parkway
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DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63 FR 56098)

BGE

December 21, 1998

Secretary
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTENTION: Rulemakings and Adjudications Staff

SUBJECT: Calvert Cliffs Nuclear Power Plant
Unit Nos. 1 & 2; Docket Nos. 50-317 & 50-318
Comments on NRC Proposed Changes to 10 CFR 50.59, Changes, Tests, and Experiments

REFERENCES:

(a) Letter from Mr. A. R. Pietrangelo (NEI) to Mr. J. C. Hoyle (NRC), dated December 21, 1998, Industry Comments on Proposed Rulemaking to 10 CFR 50.59, Changes, Tests, and Experiments (63 Federal Register 56098, dated October 21, 1998)

(b) Federal Register Notice 63FR56098, dated October 21, 1998, Changes, Tests, and Experiments

The Baltimore Gas and Electric Company (BGE) welcomes the opportunity to provide comments on the subject proposed changes. Baltimore Gas and Electric Company has reviewed the comments submitted by the Nuclear Energy Institute (NEI) (Reference a). Baltimore Gas and Electric Company endorses, in general, NEI's comments to the proposed rule, for the areas NEI chose to comment on. However, there are areas where additional comments are warranted by BGE. In our opinion, even with the proposed rule language and NEI comments, these areas continue to remain vague and require further clarification. Our detailed section-by-section comments are provided in Attachment (1) to this letter.

As a general comment, we would like to stress the importance of developing an implementation guidance document concurrently with the rulemaking. We agree with Commissioner Diaz's comment, on page 56116 of Reference (b), regarding the need for the NRC staff to continue its interactions with NEI to resolve differences between the NRC's position on 50.59 implementation guidance and that contained in NEI 96-07. In the past, lack of a definitive position on NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations," by the staff was a major source of confusion in implementing 50.59. We urge the Commission to avoid a repeat of this condition. We also urge the Commission to clearly establish the

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jurisdiction of 10 CFR 50.59/10CFR72.48 to preclude any contradictory overlap with maintenance activities (10 CFR 50.65) and degraded and non-conforming conditions (10 CFR Part 50, Appendix B, Criterion 16 and NRC Generic Letter 91-18, Revision1).

Should you have questions regarding this matter, we will be pleased to discuss them with you.

Very truly yours,

CHC/GT/dlm

Attachment (1) Baltimore Gas and Electric Company's Comments on NRC Proposed Changes to 10 CFR 50.59, Changes, Tests, and Experiments

cc: R. S. Fleishman, Esquire
J. E. Silberg, Esquire
S. S. Bajwa, NRC
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ATTACHMENT (1)

BALTIMORE GAS AND ELECTRIC COMPANY'S COMMENTS ON NRC PROPOSED CHANGES TO 10 CFR 50.59, CHANGES, TESTS, AND EXPERIMENTS

Section II, B, Changes to the Facility as Described in the Safety Analysis Report

1) The discussion in this section involves a list of design considerations, analysis methods, etc., that are supposedly changes requiring a safety evaluation. Intermingled within this list, on occasion, the phrase "as described in the SAR *[Safety Analysis Report]*" has been used. We believe when changing/affecting this list of design considerations, the main focus must be the FSAR *[Final Safety Analysis Report]* described facility. Therefore, the phrase "FSAR described" should be consistently used in this discussion before each element listed requiring a safety evaluation. Hence, we recommend adding the phrase "FSAR described" in the following places:

   Page 56101, column 3, last sentence: . . . **FSAR described** provision . . .

   Page 56102, column 1, third line: . . . **FSAR described** requirement . . .

   Page 56102, column 1, 2nd page, line 11: . . . **FSAR described** evaluative methods . . .

   Page 56102, column 1, 2nd page, line 16: . . . **FSAR described** requirements . . .

   Page 56102, column 1, line 11 from the bottom: . . . **FSAR described** information . . .

   Page 56102, column 2, first page, line 14: . . . **FSAR described** analyses . . .

   Page 56102, column 2, first page, line 15: . . . **FSAR described** bases . . .

2) Additions to the Facility as described in the FSAR should be evaluated within the context of the existing SAR description as outlined in NRC Inspection Procedure 37001. In this document, the NRC correctly addresses this issue as follows:

   "If an SSC *[structure, system, or component]* to be added to the facility would affect the FSAR description of another SSC, then a section 50.59 safety evaluation of the indirect change to the FSAR-described SSC must be done. A description of the new SSC must be included in the next FSAR update".

   This is the correct prospective on additions to the physical facility and how they relate to the FSAR described facility. Otherwise, any addition, no matter how minimal or small would require a safety evaluation. An example would be the installation of a pressure transmitter control loop in place of a simple pressure switch. Both the pressure switch and the pressure control loop perform the same function, and the FSAR described SSC in which this control loop will be installed is described at a system level. The addition of the control loop in place of the switch does not change the system's FSAR described design, function or method of performing the function. Thus, no subsequent FSAR change is required.

3) Although with the above recommended changes the discussion in this section of the proposed rule may provide adequate guidance on the subject, we recommend the following clearer guidance, provided in NRC Inspection Procedure 37001, be used.

   NRC Inspection Procedure 37001 states:

   ". . . a change in a structure, system or component (SSC) or a procedure requires a Section 50.59 safety evaluation only if the following statements are both true·

   i) The SSC (or procedure) being changed is described in the most recently updated FSAR submitted to the NRC in accordance with Section 50.71(e).

ii) The FSAR description of the SSC (or procedure) being changed would be affected by the change."

Recently the NRC Staff issued SECY-98-171, dated 7/10/98, providing their latest positions along with their proposed rulemaking on 10 CFR 50.59. In this document, the staff provides their definition of 'As Described' as follows:

Definition of "As Described"

Staff Position: Considering the intended function of 10 CFR 50.59, the staff now concludes that if the change affects any SSC as described in the SAR (not just the SSC that is being directly changed) such that the FSAR description is no longer accurate, then a 10 CFR 50.59 evaluation is required.

This current NRC Staff position is consistent with their previously issued (1992) Inspection Procedure 37001 guidance. This NRC guidance is the clearest and most precise definition on the subject of screening issued by the NRC to date, and the most appropriate.

There has been significant disagreements over the years regarding screening criteria. In our opinion, this disagreement is being driven by the fact that there are two distinct but separate concepts associated with "as described in the SAR." These two concepts are interrelated but have very different meanings. The two concepts are: a) Changes in the facility as described in the SAR; and b) Implicit and explicit SAR descriptions.

a) Changes in the facility as described in the SAR

This rule language ("Changes in the facility as described in the SAR") could be conservatively interpreted to mean that changes proposed to any SAR described SSC requires a safety evaluation, even though a SAR change is not required because the change is at a level below that which is explicitly described in the SAR. This conservative rule language interpretation was, however, somewhat dispelled in 1984 with the issuance of NRC I&E Manual; Part 9900, which provided guidance on what constitutes a change in the facility as described in the SAR. In this NRC document, the NRC specified that a change in the facility as described in the SAR pertains to **changes which alter the design, function or method of performing the function of a component, system or structure described in the SAR**.

Although not crystal clear in meaning, this guidance did provide insight into the meaning of the rule language. In fact, this NRC guidance became the basis for similar NSAC-125/NEI-96-07 wording which still exists today. Basically, if the SSC's SAR described design, function or method of performing the function is altered, then a safety evaluation is required.

In 1992, the NRC further clarified this concept with the issuance of NRC Inspection Procedure 37001. As can be seen from the 37001 excerpt provided above, this NRC guidance provided crystal clear direction on the subject. What becomes clear, from this NRC guidance, is that a safety evaluation is required only if an accompanying FSAR change is being proposed. This makes sense, as in order to adequately address the seven unreviewed safety questions (USQ) criteria, there has to be a proposed FSAR change, against which the answers can be formulated. The USQ questions deal with evaluating the differences between the FSAR-described plant and proposed FSAR-described plant. When there is no FSAR description change, answering the questions is a meaningless exercise.

b) Implicit and explicit SAR descriptions

While explicit SAR descriptions (text, figures, drawings, etc.) are well understood, the concept of implicit FSAR descriptions can cause confusion. This concept was initially introduced in NSAC-125 in the 1989. The NSAC-125 example of this concept is the "replacement of a relay in the overspeed trip circuit of an emergency diesel generator with a non-equivalent relay." The replacement of the relay **might** change the performance or the design of the overspeed trip circuit as described in the FSAR. **If so**, a safety evaluation would be required.

As presented in this example, the relay function and operation **may be** implicitly described in the FSAR as part of the explicit FSAR description of the overspeed trip circuit. During the design review process of this 'change,' the effects, this non-equivalent relay has on the trip circuit, would be determined. As part of this same design review process, these identified effects would be evaluated to determine their acceptability in the circuit and conclusions reached that the change meets acceptable engineering standards.

Once this technical evaluation process is complete, sufficient information is available to determine the change's impact on the FSAR. A safety evaluation screen is then performed. Based on the technical information available to the screener, a positive determination as to the impact this change has on the FSAR description, of the trip circuit, can be determined. Either the FSAR description is affected or it's not.

At this point in the design control process, there should be no '**mays**' or '**potentials**' as the effects of this change have been evaluated and determined to be acceptable and the resultant affect, if any, on the SAR description is known.

4) Separate definitions for "change" and "facility as described in the SAR" is a departure from the historical perspective of the intent of these terms. Nuclear Regulatory Commission Inspection and Enforcement Manual, Part 9800, dated January 1, 1984, discusses applicability and provides a relatively clear picture of the term 'change to the facility as described in the SAR'. This NRC guidance stipulates that in order for a change to the facility as described in the SAR to be a change, there must be a change in the design, function, or method of the function of an SSC described in the SAR. It became the original basis for determining applicability (screening). In June 1989, NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations," expanded on this concept to create the screening process that is widely used in the industry today.

Inspection Procedure 37001 provided a clearer definition of change to the facility as described in the SAR. Specifically, the change that was referred to was a change in the SAR description (text or drawings) itself. It eliminated a minor clarification point that had existed in the industry since 1984. There were two differing positions concerning the 50.59 applicability (screening). The first position was based on the wording in the 1984 NRC guidance and NSAC-125. According to this position, any change to a SAR-described SSC, no matter how detailed the SAR description of the SSC was, would require a safety evaluation, even if the change was minor and did not require a corresponding SAR change. The second position was also based on the wording of these same two documents, but limits the changes requiring safety evaluations to only those changes to the SAR-described facility (i.e., design, function, method, etc.) resulting in an SAR change. At stake here, were a considerable number of safety evaluations that would not have been required to be written.

Typically, many changes are performed on SSCs described in the SAR that are minor in scope and do not affect the design, function, or method of performing the function of the FSAR-described SSC. However, because the SSC was described in the FSAR, a safety evaluation was performed. These types of safety evaluations rarely, if ever, actually addressed the USQ criteria due to the fact that the USQ criteria themselves involve evaluation of the changed facility to that described in the SAR.

5) The proposed definition of change fails to recognize that there are two separate changes that need to be defined. The first is the actual change to the plant, which must be evaluated to determine if 50.59 is applicable. The second is the text or drawing change to the FSAR description of the facility, which requires a 50.59 safety evaluation. As mentioned in the above comments, a 50.59 safety evaluation should only be applicable to the FSAR-described facility and any text/drawing changes. All other actual changes to the plant would screen out because 50.59 would not be applicable.

6) The proposed definition of change fails to take into consideration temporary changes in response to degraded and non-conforming conditions (i.e., NRC Generic Letter 91-18, Revision 1). A clarification is needed to preclude any potential for violation of 10 CFR 50.59. Without recognizing this caveat, the rule takes legal precedence over the Generic Letter, and licensees could be subjected to violations with the language of the proposed rule, regardless of the content of a Generic Letter. This apparent legal conflict exists today, with the current version of 10 CFR 50.59 and Generic Letter 91-18, Revision 1. The Generic Letter is, in essence, allowing licensees to purposely not comply with the requirements of 10 CFR 50.59. This requires resolution, within 10 CFR 50.59 itself, in order to prevent future legal conflicts.

7) The definition should recognize that the changes to be evaluated are **proposed** changes only. Without this recognition, as found conditions where the physical plant is different from the FSAR-described plant could cause the immediate application of 50.59 even though the licensee has determined that the plant/SSC is operable and has decided to restore the physical plant to FSAR-described configuration. It is important to note that based on the language of the existing rule, in 1992, the NRC had imposed the logic of "De Facto design change" in their Inspection Procedure 37001.

8) The proposed definition of change fails to take into consideration equipment taken out-of-service for maintenance. Without the definition of change recognizing the allowance for taking equipment out-of-service as detailed in NRC Inspection and Enforcement Manual Part 9800, NRC Inspection Procedure 37001, dated December 29, 1992, clarifications provided by the Staff in SECY 98-171and the proposed rulemaking on 10 CFR 50.65, a potential exists for unintentional violation of 10 CFR 50.59. A licensee could be subject to violations based on the language of the proposed rule, as the licensee is 'changing' the facility by taking equipment out of service for maintenance. This situation also exists today, with the current rule. The Inspection Procedures are, in essence, allowing licensees to purposely not comply with the requirements of 10 CFR 50.59. This requires resolution, within 10 CFR 50.59 itself, in order to prevent future legal conflicts.

9) We believe Chairman Jackson's logic, on the definition of procedures (discussed below under Section II, C comments), needs to be applied to 'the definition of "Facility as described in the FSAR." To further Chairman Jackson's philosophy, the staff should seek to indicate that all changes to the facility which are described as being required in the SAR are subject to a 50.59 screening. The screening would identify the need for a safety evaluation only if a proposed change would create a

change to the information in the FSAR regarding the SSC's design, function or method of performing the function. This definition requires changing to reflect this philosophy.

We recommend the following definition:

> Facility as described in the final safety analysis report (as updated) means (i) The FSAR description of the design, function or method of performing the function of any system, structure or component (SSC).

Section II, C. Change to the Procedures as Described in the Safety Analysis Report

1) We share Chairman Jackson's concern on page 56115 that the proposed rulemaking definition of procedures as described in the FSAR is flawed in that it "may cloud the distinction between: (1) Those procedures which must be screened, or evaluated, under Sec. 50.59, and (2) the criteria which necessitates a full safety evaluation." The proposed definition does cloud the issue. We agree with Chairman Jackson ". . . that staff seeks to indicate that all procedures which are described as being required in the FSAR are subject to a Sec. 50.59 screening. The screening would identify the need for a full safety evaluation only if a proposed procedure change created a change to the information in the FSAR regarding how structures, systems, and components are operated and controlled . . ." We recommend the following definition:

   > Procedures as described in the final safety analysis report (as updated) means the FSAR description of the operation and control (including assumed operator actions and response times), of any system, structure, or component (SSC) and information on conduct of operations.

   (NOTE: The proposed definition on page 56102 has the phrase "including assumed operator actions and response times" repeated twice within the same definition.)

Section II, D. Tests and experiments not described in the SAR

1) All 'tests and experiments performed at licensee's facilities are performed in accordance with procedures. This is an overall quality assurance requirement to ensure that adequate controls are placed on the performance of these tests and experiments so as not to create an unsafe situation. When 50.59 was first promulgated, there may have been times when true' tests and experiment's were run on Vallecitos, which required this question to be asked. This phrase 'Tests and Experiments' should be revised to reflect the way evolutions are conducted at Nuclear facilities today. These 'Tests and Experiments' are procedures and the proposed rule should define test and experiment and address how their control as procedures, separate from 'procedures as described in the FSAR' should be controlled.

Section II, E. Safety Analysis Report

1) As discussed in the 'Overview of Licensing Process' section, the FSAR formed the basis for the creation of the Technical Specifications. It is discussed that the FSAR contained, in part, the Technical Specifications that became part of the license, however, in the proposed rule; Section E; 'Safety Evaluation Report,' the Technical Specifications, that are part of the license, are not identified as part of the FSAR definition. In some cases the Technical Specifications include additional detail, such as applicable operating mode requirements, which are not described separately in the FSAR. This mode applicability is part of the facility as described in the FSAR and should be utilized in situations when the Technical Specifications provide a more definitive description than the FSAR text.

Similarly, the Technical Specification Bases should also be part of the FSAR described facility. We recommend that the definition of the FSAR be expanded to include both the Technical Specifications and the Technical Specification Bases.

We recognize, however, that the Technical Specifications, as part of the license, can only be changed by a license amendment process (10 CFR 50.90). This should also be made clear in the definition.

2) As part of this FSAR definition, the concept of incorporated by reference should be defined to ensure consistency in the use of this term.

3) The definition of the FSAR should recognize its required update frequency so that each time the term "FSAR" is stated, it would not be necessary to add the term "as updated." This is cumbersome and adds little to no value in understanding the definitions in which the term FSAR is used.

Section II, F. Probability of Occurrence or Consequences of an Accident or Malfunction of Equipment Important to Safety Previously Evaluated in the Safety Analysis Report May Be Increased

1) While this discussion provides the NRC's perspective on this set of questions, it fails to clearly define "consequences" as relating to radiological dose. It is commonly understood that 'consequences' relates to dose, presumably accident derived, this is not defined in the regulations.

This is an important definition that needs to be added to the rulemaking to ensure that future misinterpretations do not arise.

(Note: This issue was raised by the NRC staff during their review of Nuclear Energy Institute (NEI) 96-07, which caused doubt by implying that consequences entail more than dose. The NRC comments are documented in their letter to NEI, dated January 8,1998.)

2) The discussion of industry's enhanced ability to calculate probabilities, such that the effect of even minor changes can be evaluated, implies that PRA type analysis will be required for changes which require answering these questions. In SECY 98-171, the Staff is clear (Topic III.M) that presently, PRA is not suitable as a decision making tool for 50.59 evaluations. Discussions alluding to using PRA should be avoided until genuine 'risk based' regulation is proposed.

Section II, G. More than a Minimal Increase in Probability or Consequences

Probability of Occurrence of an Accident

1) The "accident" definition should recognize the accident frequency classification used by many licensees, which classifies accidents as moderate frequency, infrequent incidents, or limiting faults.

2) The second paragraph in this section is confusing. A reference is made to the frequency classification provided in the FSAR as the sole basis for determining whether a minimal increase of probability of occurrence of an accident has occurred. It is inferred from this that as long as the event (accident) being analyzed remains the same frequency classification as prior to the proposed change, then it is a minimal increase. This philosophy is significantly different and less conservative than that which is now utilized by industry, in NEI 97-06, Section 3.4. If what is described above is intended by the proposed discussion, we agree it is appropriate guidance.

Probability of Equipment Malfunction

1) The first two sentences in this section are misplaced and should be deleted. The issue of new failure mode is addressed in Section I. This section deals with the probability of the occurrence of equipment malfunction increasing above that which was previously evaluated in the FSAR. It implies that known malfunctions of either systems, structures, or components were considered and evaluated in the FSAR. The question requires the identification of those previously evaluated FSAR-described malfunctions to determine if said malfunctions may be increased due to the change, test, or experiment.

   The level of detail of the evaluation should be commensurate with the existing level of detail in the FSAR. This means that, if the malfunction evaluations are at a system level, the evaluation of the change (be it a component, system, or structure change), should be conducted at this same system level.

2) The term "Important to Safety," used to describe the equipment for which probabilities and consequences of malfunctions have previously evaluated in the FSAR, is misleading and should be deleted. Within the context of the rule, this term appears to imply that there is a subset of equipment (important to safety) more relevant than the subset of equipment supposedly not "Important to Safety," even though both of these equipment subsets may be described in the FSAR, along with certain malfunctions evaluated.

   If the term is kept, then a definition should be added to clarify exactly what subset of FSAR equipment is being referred to in this regulation.

Consequences of an Accident or Malfunction

1) As we commented previously, a definition for consequences should be provided since it is a key element that is required to be addressed when addressing this criterion. This definition should clearly spell out that the applicable dose is accident-related dose, not normal operating doses.

   The NRC provided a partial 'definition' to NUMARC in it's comments on NSAC-125 sent to NUMARC on May 10, 1989. This 'partial definition' appears to be still valid, at least form the standpoint of what is NOT considered in the 'consequences' questions (i.e., occupational doses). This partial definition, coupled with definitive identification of what specific accident dose(s) are within the purview of the 'consequences' questions, should be delineated in a 'consequences' definition, to provides clear and unambiguous criteria.

2) While the Commission's attempt at trying to establish a quantitative measure for dose, it is unclear as to which dose this measure would be applied to. Is this offsite dose to the public, or control room doses or doses to operators responding to accident situations? Without specifically defining which dose this would apply to, it will lend for confusion when it is applied.

3) Again, changes to a licensee's design basis is only a consideration for 50.59 when it is an FSAR-described design bases. Therefore, line 15 in the third paragraph of this subsection should read " . . . **FSAR described** design bases . . ."

4) If it is the NRC's intent to try to control inputs and assumptions as well as methodologies associated with calculating doses that are not described in the FSAR, it presents the same problems as that now

facing the Margin of Safety, Option 1. Two Commissioners have already expressed concern over this NRC staff direction for margin of safety. In essence, the NRC would want to control inputs, assumptions, and methodologies associated with dose calculations, not described in the FSAR, as rigidly as those described in the FSAR. This goes beyond the scope and intent of the 50.59 rule, and we disagree with the NRC staff proposal.

5) The Two separate questions dealing with 'consequences' should either be combined into one question or the question dealing with the 'consequences of a malfunction' should be deleted. Presently, the 'consequences' of both 'malfunctions' and 'accidents' are to be addressed separately. This is contrary to the derivation of 'consequences,' which is based solely on analyzed Design Basis Events/Accidents. It must be understood that accidents are the source of potential radioactive releases. FSAR analyzed malfunctions that do not initiate or affect mitigation of FSAR analyzed accidents do not produce radiological consequences in and of themselves.

6) Of the three options proposed for defining minimal, we recommend adoption of the third option that defines minimal as being 10% of the remaining margin between current conditions and acceptance guidelines.

7) The NRC discusses changing design basis assumptions and/or analytical methods, to demonstrate that a change in consequence is less than 0.5 rem. The NRC does not view this change as minimal and would expect the licensee to submit a license amendment for such a change, solely on the basis of changing the analytical methods and/or assumptions. It is assumed that the above criteria is also applicable to the other two proposed options discussed in this section, or any other option finally arrived at concerning consequences (dose). While it is understandable why the NRC would want to control these items, the 50.59 rule questions dealing with 'consequences' do not lend themselves well to evaluating assumptions and methodology changes

We fully endorse NEI's comments on this section, regarding the use of regulatory based dose limits. It is our belief that the above criteria is too restrictive considering the amount of acceptable change currently being proposed, either by the NRC or NEI, as compared to what was acceptable industry practice as discussed in NSAC-125 and NRC's letter to NUMARC (C.E Rossi to T.E. Tipton, dated May 10, 1989) on comments to NSAC-125. As discussed in this NRC letter to NUMARC, and echoed in NSAC-125, the accepted industry approach, in the past, was to allow the increase of dose up to the 'acceptance limit' either found in a plant's FSAR or NRC's SER. With this rather lenient approach, it is appropriate to control design basis assumptions and methods of calculating dose because minor changes can cause one value, below the acceptance limit, to be calculated by the licensee and another value, above the acceptance limit, to be calculated by the NRC.

With the more conservative limits being proposed, the specific control of assumptions and methods should be within the purview of the licensee's design control process. The NRC recognizes this fact, for 'Margin of Safety' issues, in their discussions in Section J, Option 3(B)(3), of this proposed rule, where it is stated; "The alternative to this proposed language would be to rely upon a licensee's design control processes under their quality assurance requirements and program, to provide the assurance that any evaluative work has been conducted with methods and techniques commensurate with the safety significance of the analysis being performed." Baltimore Gas and Electric Company believes that this same logic should be applied to 'consequences' issues where the amount of increase is being conservatively controlled.

The NRC should rely on the small fraction of increase allowed for any change to maintain sufficient margins, and allow the design basis assumptions and analytical methods to be controlled by the licensee within their design control processes. This philosophy, coupled with NEI's proposed approach of using regulatory based dose limits, would provides clear, unambiguous meaning of the questions dealing with "consequences."

Cumulative Effect

1) Baltimore Gas and Electric Company strongly agrees with the NEI comments on this issue. This proposed new requirement to perform an evaluation of the overall effects of the changes, approved within that FSAR update cycle, is unreasonable and furthermore not required. It implies that licensees need to perform a safety evaluation of all the safety evaluations. Each change, test or experiment is evaluated against the latest FSAR described facility to ensure cumulative effects of previous changes are accounted for. This new requirement is redundant. This is an ill-fated proposal destined to create confusion and misunderstanding, if implemented.

Section II, H. Possibility of an Accident of a Different Type from any Previously Evaluated in the Safety Analysis Report May Be Created

1) The main confusion regarding this criterion is what is the definition of accident of a different type? Should there be a defined list of types to use in the evaluation or is it left up to the evaluator to determine the type of accidents that have already been evaluated, and then determine if an accident of a different type is created? This is problematic and requires more defined criteria, including examples that could clarify the point. Chairman Jackson's comments on this subject on page 56115 and Commissioner Diaz's comments on page 56116 are along these same lines.

2) Shouldn't the new criteria of "with a different result," applied to 'malfunction of a different type,' also apply to this question?

Need for Definition of Accident

While the Commission's attempt to define accident is worthwhile, the lack of a definition of "different type," as discussed above, will perpetuate the confusion.

Section II, I. Possibility of a Malfunction of a Different Type from any Previously Evaluated in the Safety Analysis Report May Be Created

1) The issue of guidance in NRC Generic Letter 95-02 is addressed in this discussion section. As before, the industry disagrees with the NRC's guidance on replacing analog with digital instrumentation. By letter dated May 18, 1995, NEI issued its position on Generic Letter 95-02. It is apparent that this conflict still exists and requires resolution as part of this rulemaking.

   In this proposed rule, while the NRC recognizes that different FSARs evaluate failures at different levels, for the subject of replacement of analog to digital systems, the NRC migrates back to their GL 95-02 position that disregards the level of evaluation in the FSAR and focuses on "at the level of equipment being replaced." The NRC then goes on to discuss how one would go about such an evaluation. Although BGE agrees that such a design evaluation is required, we disagree that this evaluation should be part of the safety evaluation that determines if a license amendment is required. Typically, the type of technical evaluation described by the NRC in this proposed rulemaking paragraph is done in the design package evaluating the change. Upon completion of this detailed design evaluation, 10 CFR 50.59 is applied and conclusions are reached concerning the impact this change would have on the FSAR-described plant, which allows the engineer to conclude whether the FSAR-described malfunction effects/results are still valid or requires changing. If the FSAR-described malfunction effects/results are not affected, a 50.59 safety evaluation is not required.

2) The proposal to add the term "of equipment to important to safety" is not appropriate and should not be pursued. The purpose of this criteria is to determine if different types of malfunctions than those already evaluated in the FSAR have been created. The presumption here is that the different types of malfunctions being looked for are associated with the same equipment for which there already exists malfunctions evaluated in the FSAR. In order to determine different types of malfunctions, the evaluator first has to have identified those malfunctions and associated equipment already evaluated in the FSAR, which was done when answering the previous questions. The next step is to determine if the change would create a different type of malfunction with a different result than those already identified. With this in mind, the appropriate criteria should be:

   "If a possibility for a malfunction of a different type with a different result, of FSAR-described equipment, than any evaluated previously in the FSAR, is created."

3) The NRC and Industry have had differing views concerning when a malfunction is of a different type. These relate to the appropriate level (system, component) the malfunction evaluation should be focused. This can also be characterized as a difference over what constitutes a malfunction, as distinct from the cause of the malfunction or the effect of the malfunction.

   The industry definition of the term malfunction differs from that of the NRC. Malfunction is defined in NEI 96-07 as the failure of structures, systems and components to perform their intended safety functions described in the SAR. The NRC staff published a broader definition of malfunction in NUREG-1606 as an undesired response of equipment (for example failure to operate, inadvertent operation, operation in an unexpected manner, operation with less than rated capacity, and failure to perform function as designed).

   The baseline to which the 50.59 comparison should be made is what is currently described in the FSAR. In other words, if the FSAR currently describes malfunctions at the component level, then this is the level to which the change should be evaluated; and if the FSAR currently describes malfunctions at the system/plant level, then this is the level to which the change should be evaluated. If the current FSAR description does not address the cause of a malfunction, or the FSAR description is at a level of detail above any new causes identified as a result of the change (e.g., valve malfunction is described in FSAR as valve fails open/close/intermediate, with no causes identified), then the cause (e.g., electrical failure, mechanical failure, controller failure, etc.) is not relevant within the context of 50.59. In such cases, only the effect of the malfunction (on the equipment, associated equipment, and/or system) is of relevance with respect to the FSAR-described facility.

   In this example, if an air-operated valve, described as such in the FSAR, is being replaced by a motor-operated valve, then there **would not** be a malfunction of a different type created even though the motor operator would introduce a **different** cause (motor failure) of the **same** malfunction (valve fails open/close/intermediate). The FSAR-described malfunction evaluation is still valid.

(NOTE: This is not to say that new causes of malfunctions are not to be identified and fully analyzed to ensure that the existing FSAR malfunction evaluations remain valid. This identification/analysis should be done as part of the technical evaluation to ensure that the change is safe.)

In contrast, if the above valve change example results in a new FSAR-described malfunction cause and/or effect (i.e., prior to change; FSAR described valve fails open/close -- after change; valve fails open/close/intermediate), then this new malfunction (intermediate) would need to be added to the FSAR and would be a malfunction of a different type, even if the resultant FSAR described system/plant level malfunction description is not changed.

Section II, J. Margin of Safety as Defined in the Basis for any Technical Specification is Reduced

From the text of this criterion, it is implied that the rules governing the preparation and content of Technical Specifications and their bases (i.e., 10 CFR 50.36) requires each Technical Specification Basis to have a defined margin identified, against which the change could be evaluated. However, there are no such specific requirements in 50.36.

Option 1: Control Inputs to Analyses and Methods that Establish Technical Specifications

The NRC staff's attempt to control inputs and assumptions in the Technical Specification Bases is highly inappropriate. As admitted by the proponents of this option, " . . . this approach would . . . have the effect of giving input values and assumptions the weight of TS *[Technical Specifications]*, which is inconsistent with the philosophy in Sec. 50.36 of establishing TS only on those values of most immediate safety importance." For this reason, this option should not be considered.

Option 2: Delete ``margin of safety'' as a Criterion

This option has the greatest appeal, not because it eliminates a question, but it recognizes the basic premise that the Technical Specification Bases are part of the FSAR. Under this option, changes to the Technical Specification Bases will be evaluated using the other six proposed criteria in 10 CFR 50.59. As we commented earlier, modifying the definition of FSAR to include the Technical Specification and the Technical Specification Basis greatly supports the adoption of this option.

We agree with Commissioner Diaz's comment on this issue and recommend adoption of this option. In fact, there is already historical perspective on the ambiguity of the term "reduction of margin of safety." At a meeting held between NRC and Nuclear Management and Resources Council (NUMARC) on April 6, 1989, an attempt was made to remove the ambiguity in this concept with the issuance of NSAC-125 in June 1989. The existing words in NSAC-125 was the "clarification" agreed to by both the NRC Staff and NUMARC. Almost 10 years later, we are still struggling with this issue. Commissioner Diaz is absolutely correct. Eliminating this question will eliminate this ambiguity once and for all.

Option 3: Control margins associated with results of analyses

This option attempts to determine whether changes to operational characteristics or other FSAR information which would result in reducing the level of protection afforded by the Technical Specifications. The discussion goes on to discuss certain of these characteristics are in the Technical Specifications and others are in the safety analysis.

As can be seen by the various proposed sub-options presented under Option 3, and the various proposed ways of trying to measure minimal margin reduction, it is envisioned that any proposal along these lines will be at least as ambiguous as what is already existing in the 50.59 rule. If the goal is to ensure that the Technical Specifications continue to be complied with, acknowledging the fact that there is inherit margin between the Technical Specifications limits and any Regulatory values, then this 'evaluation' should be part of the review performed to ensure that " A change to the technical specifications incorporated in license is not required," and not embedded in the former USQ questions. In one sense, the 'Margin of Safety' evaluation could be looked at as redundant to the 'Technical Specifications change' evaluation, already required in the 50.59 rule.

There is one discussion, in this section (Option 3 (B) (3); last paragraph, which BGE strongly supports whatever the outcome of this 'Margin of Safety' issue. With the more conservative limits being proposed, the specific control of assumptions and methods should be within the purview of the utility and controlled under the licensee's design control process. The NRC recognizes this fact, in their discussions in Option 3(B)(3), of this proposed rule, where it is stated : " The alternative to this proposed language would be to rely on a licensee's design control processes under their Quality Assurance requirements and program, to provide the assurance that any evaluative work has been conducted with methods and techniques commensurate with the safety significance of the analysis being performed." Baltimore Gas and Electric Company believes that this logic should be applied to situations where the amount of increase / reduction is being conservatively controlled.

<u>**Section II, L: Reporting and recordkeeping Requirements**</u>

As discussed above, under 'cumulative effect,' BGE strongly agrees with the NEI comments on this issue. This proposed new requirement to perform an evaluation of the overall effects of the changes, approved within that FSAR update cycle, is unreasonable and furthermore not required. It implies that licensees need to perform a safety evaluation of all the safety evaluations. Each change, test or experiment is evaluated against the latest FSAR described facility to ensure cumulative effects of previous changes are accounted for. This new requirement is redundant. This is an ill-fated proposal destined to create confusion and misunderstanding, if implemented.

ADDITIONAL COMMENTS

<u>**Section I: Background**</u>

Implementation Guidance

This section discusses only industry-initiated guidance beginning with NSAC-125 in 1989. It must be recognized, to provide a valid historical perspective, that 50.59 guidance was first issued by the NRC in the form of the following documents:

1) NRC IE Circular 80-18; dated August 22, 1980

   This document provided, for the first time, the NRC's insight into the term "Unreviewed Safety Question" and the general principles and philosophy of the 10 CFR 50.59 guidance This document provided specific criteria that needed to be addressed to ensure that a USQ did not exist.

   In Circular 80-18, the NRC stated, "An important part of the 'unreviewed safety question' determination is the evaluation and analysis of the proposed change by the licensee to assure that (1) **potential safety hazards are identified**, and (2) corrective actions are taken to eliminate, mitigate or control the hazards to an acceptable level All realistic failure modes and/or malfunctions must be considered and protection provided commensurate with the potential consequences. All applicable regulatory requirements, including Technical Specifications, must be complied with so that the proposed change shall not represent an 'unreviewed safety question.'" However, later on, in NRC Inspection Procedure 37700, dated September 17, 1990, the NRC states: "It has been found that licensee's philosophical approach to 10 CFR 50.59 safety evaluations has sometimes placed significance on **identifying potential failure modes** instead of examining the potential consequences of system or component failures."

Circular 80-18 provided the industry with the guidance that both the SAR text and drawings are considered "as described in the SAR." This concept still exists and is widely accepted today. In addition, the use of the word "consequences" has a different connotation (i.e., dose) in this NRC document than in others. Much, if not all, of this guidance is still valid today and should be brought forward and placed into current NRC/NEI guidance documents on 50.59.

2) NRC IE Bulletin 80-10; dated May 6, 1980

This document required licensees to "perform an immediate safety evaluation of the operation of a previously non-contaminated system as a contaminated system," even though the licensee has not made the final determination of whether the system will be left as contaminated. This misguided NRC direction still influences utilities today as they feel compelled to follow the requirements of this NRC IE Bulletin, to the letter. It is obvious, today, that non-radioactive systems that become radioactive should be treated as a degraded/non-conforming condition and addressed in accordance with NRC Generic Letter 91-18, Revision 1, and the plant's corrective action program. However, licensees feel compelled to comply with both Generic Letter 91-18 and IE Bulletin 80-10.

3) NRC IE Information Notice 83-64, dated September 29, 1983

This document dealt with installing lead shielding on piping systems. While this Notice correctly identified the need to consider 50.59 when installing lead shielding, even temporarily, it provided misleading NRC philosophy in that it concluded, incorrectly, that "Failure to analyze for possible seismic/structural effects constitutes an unreviewed safety question." This conclusion is flawed in that failure to analyze (i.e., perform an engineering evaluation) is a nonconformance with design basis/criteria, not a USQ.

4) NRC Inspection and Enforcement Manual; Part 9800, dated January 1, 1984

This NRC document provided the applicability (screening) criteria still in use today. This document is essential in understanding the historical reasoning towards establishing the criteria for a 10 CFR 50.59 applicability. The issue of applicability is still in debate today between the NRC and industry. In addition, this document addressed the issue of taking equipment out-of-service for maintenance and the applicability of 50.59 for such activities. The criteria set forth in this document, along with a few clarifications found in NRC Inspection Procedure 37001, provide today's guidance on the issue. This document also provided the concept of "design, function, or method of performing the function" as the criteria used to determine if a proposed change required a safety evaluation.

Many, if not all, of the concepts in this NRC document were utilized in NSAC-125. From a historical perspective, this is the true beginning of "Implementation Guidance," and should be the first document discussed in this rulemaking package.

While this document was a landmark in NRC-issued 50.59 guidance, it also contained misleading information. The flow chart at the end of the guidance document contained a misleading applicability criteria. The criteria, "Could the proposal affect nuclear safety in a way not previously evaluated in the SAR," was not discussed in the text of the document and was not understood by the industry.

These documents formed the set of early 50.59 implementation guidance on 10 CFR 50.59, which industry used in its procedures/training on 50.59. The NRC guidance document, Part 9800 in fact, became one of the main input documents to NSAC-125 on the subject of Applicability (Screening). These documents are important references as many of the concepts under dispute today between the industry and the NRC have their beginnings firmly rooted in these documents.

In addition, the following additional NRC guidance documents on 50.59 were issued following NUMARC's issuance of NSAC-125:

1) NRC Information Notice 89-81, dated December 6, 1989
2) NRC Information Notice 91-63, dated October 3, 1991
3) NRC Information Notice 95-46, dated October 6, 1995
4) NRC Information Notice 95-13, dated November 22, 1995
5) NRC Information Notice 96-17, dated March 18, 1996
6) NRC Information Notice 97-28, dated May 30, 1997
7) NRC Information Notice 97-60, dated August 1, 1997
8) NRC Information Notice 97-71, dated September 22, 1997
9) NRC Information Notice 97-78, dated November 23, 1997
10) NRC Generic Letter 91-18, dated November 7, 1991
11) NRC Generic Letter 91-18, Revision 1, dated October 8, 1997
12) NRC Inspection Manual, Inspection Procedure 37001, dated December 29, 1992
13) NRC Generic Letter 95-02, dated April 26, 1995
14) NRC Inspection Manual, Part 9900, dated October 8, 1997
15) NRC Inspection Manual, Inspection Procedure 37700, dated September 17, 1990

All these NRC-generated documents require review to determine if they need to be revised, rewritten or withdrawn. These documents, in many cases, are still valid and have never been officially superseded or retracted by the NRC. As part of this rulemaking, the NRC needs to either update or supersede these and other guidance documents to the industry to ensure consistent guidance remains with the new regulations.

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December 21, 1998
1900-98-127

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

Secretary
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

RE: Comments on Proposed Rule Concerning "Changes, Tests and Experiments"

Dear Sir:

Pursuant to the Commission's Federal Register Notice (63 Fed. Reg. 56098) concerning "Changes, Tests, and Experiments," or principally 10 CFR 50.59, GPU Nuclear agrees with and fully endorses the industry comments which have been provided by the Nuclear Energy Institute (NEI).

Very truly yours,

John C. Fornicola
Director, NSA

/gba

JAN - 4 1999
Acknowledged by card

36

DOCKETED
USNRC

DOCKET NUMBER
PROPOSED RULE PR 50, 52 & 72
(63FR56098)

'98 DEC 28 P3:11

OFFICE OF SECRETARY
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ADJUDICATIONS STAFF

Lynne Goodman
727 Scarlet Oak Court
Monroe, MI 48162
20 December 1998

Secretary, U.S. NRC
Washington D.C. 20555-0001
ATTN: Rulemakings and Adjudications Staff

SUBJECT: Comments on Proposed Rule on Changes, Tests, and Experiments (RIN 3150-AF94)

I think the subject proposed rule will be helpful in some ways in assuring the NRC has the opportunity to review changes that could truly impact safety before implementation. I think, though, the proposed wording could require NRC review of some very minor changes that are unnecessary. This will tie up NRC and licensee resources, when they could be working on more important issues. This letter submits my comments on the proposed rule. My background is that I have written safety evaluations for about 20 years, both on operating and permanently shutdown plants. These are my personal comments.

I think the NRC proposal that the probability or consequences of an accident or malfunction of equipment important to safety be allowed to not more than minimally increase without prior NRC approval is a beneficial change. I have personally spent many hours trying to determine whether the consequences of an accident could be increased by several mrem, or even less than a mrem, and so need prior NRC approval. I think any one of the NRC proposed options for determining quantitatively what is minimal could work, but think if one of the options involving margin is chosen, the margin should be the margin to the regulatory limit, not the margin to acceptance guidelines, since the latter may be more open to interpretation, depending on wording in a specific SER.

I am especially concerned with some of the proposals for the margin of safety criteria. I think either dropping the criteria or Option 3(B)(3) would be preferable. However, I don't think if Option 3(B)(3) is selected, that this question should apply to plants without fuel. It doesn't make good sense to evaluate fission product barrier response once the fuel is removed from the facility. Also, I do think the licensees design control process and QA program can provide assurance that evaluative work has been conducted appropriately, as discussed as an option under 3(c). To me, this is a requirement of a QA program, as well as needed for good engineering practice.

Acknowledged by card JAN - 4 1999

U.S. NUCLEAR REGULATORY COMMISSION
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My biggest concern would be if Option 1 was selected. Then, if I have a minor nonconservative change to an input assumption, I will need NRC review. This gives assumptions and methods the same weight as Tech Specs. For example, if one new isotope was identified at a shutdown plant, that wasn't included in the accident release calculation, a license amendment would be required even if the increase in dose due to the accident was only 1 mrem. This would undo the benefit of allowing up to minimal increases in consequences.

Regarding the discussion on creating the possibility of an accident of a different type than previously evaluated, I'm concerned about the proposal to define an accident, as discussed on p.56106 of the Federal Register. With that definition, a slightly different initiating event that leads to the same design basis accident would be a new type of accident. The actual proposed wording in 50.59(c)(2)(v) does not raise this concern.

For example, during decommissioning, the initiating event for a liquid waste accident may be different than during operation, but in both cases the event could be that the largest waste tank spills all its contents, and then the event proceeds. The licensee should have to evaluate whether the decommissioning activities will increase the probability of the event more than minimally, but not have to now consider it a different type of accident if the initiator may be different.

Another item I want to comment on is that determining the net effect of all changes made since the last update on the safety analysis, including probabilities, consequences, etc. could be a big burden, especially if numerical results are not calculated for each change as they are made. Such would typically be the case for a decommissioning plant. There is no requirement for a living PSA for a plant undergoing decommissioning. That would be very burdensome. I could see a general summary type paragraph being written in the submittal letter for the SAR update describing the net effect of changes since the last update, but not a determination of the cumulative change in probability of an accident.

Lastly, I'd like to say that the existing or proposed safety evaluation criteria do not often fit well when evaluating changes in a permanently shutdown plant. Yes, the questions can be answered, but they don't fit well. Evaluating fission product barriers when there is no fuel at the facility isn't the most applicable criteria. I'll leave you with the following criteria to think about, which I think would be better for determining what changes the NRC should review for permanently shutdown plants:

- Could the proposed change result in more than a minimal increase in the radiological consequences of an accident?

- Could the proposed change cause a different type of environmental impact than previously evaluated?

These questions plus the existing 50.82 criteria could adequately determine what changes the NRC would want to review prior to implementation or be promptly notified about when the 50.82 criteria require notification.

Thank you for the opportunity to comment on the NRC proposal and options under consideration.

Sincerely,

35

DOCKET NUMBER
PROPOSED RULE PR 50,52+72
(63FR56098)

RG AND E

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AREA CODE 716-546-2700

ROBERT C. MECREDY
Vice President
Nuclear Operations

RGE 150 YEARS OF SERVICE JUST THE BEGINNING

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'98 DEC 28 P1:36

OFFICE OF ... RULEMAKINGS AND ADJUDICATIONS STAFF

December 18, 1998

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTN: Rulemakings and Adjudications Staff

Subject: Comments on Proposed Rulemaking to 10 CFR 50.59, Changes, Tests, and Experiments (63 Fed. Reg. 56098-October 21, 1998)

Dear Mr. Hoyle:

Rochester Gas & Electric (RG&E) wishes to provide comments on the proposed changes to 10 CFR 50.59 and related changes to other sections of Part 50, part 52, and Part 72 as noticed in the Federal Register on October 21, 1998. In addition to our own comments, we wish to support the detailed comments made by the Nuclear Energy Institute (NEI) in regards to this topic. RG&E would like to take this opportunity to commend the Commission on the manner in which this request for public comment was presented, specifically the history of the issue including reference to the industry guidance document NEI 96-07, "Guidelines for 10 CFR 50.59 Safety Evaluations" and the inclusion of the Commission voting record on SECY-98-171.

RG&E agrees with the need to provide definitions of the terms utilized in the rule, though we are concerned that by making them a part of the rule that any subsequent interpretation of the definitions would require further rulemaking. In particular the definition of the term "change" as proposed in the notice could need to be modified in the future. The 10 CFR 50.59 process needs to preserve the ability for utilities to perform a "screening" of proposed changes to determine whether a detailed 10 CFR 50.59 safety evaluation is required and the final rule needs to clearly state the intent of this definition.

We are also concerned with the proposed 10 CFR 50.59 rulemaking with respect to the additional reporting requirements in tandem with 50.71(e) updates. The Federal Register notice discussed the NRC's desire to examine effects of changes, in light of allowing "minimal" increases in probability and consequences. We are particularly interested in the addition of "the net effect of all changes made since the last update on the safety analyses, including probabilities, consequences, calculated values, system or component performance, that are in the FSAR (as updated)...". We disagree that this would not result in a

significantly increased burden. Describing the "net effects of the changes" implies that a 50.59 summary as currently required would not be of any value, because the "effects" of the changes to the FSAR (as updated) would be discussed in the 50.59 evaluation (e.g., how the consequences/probabilities/etc. are affected). We would be summarizing the 50.59 along with FSAR update, and then sending a separate 50.59 summary report. In many cases, this would be redundant. Furthermore, it seems that this additional task would also require a significant amount of effort each updating period to determine the net effects. It could be reasonably implied that for probabilities, all 10 CFR 50.59 safety evaluations would require PSA in order to determine cumulative effects at the end of the reporting period.

We would like to commend the Commission on the conclusion that the terminology "margin of safety" has differing interpretations and for proposing a range of options for consideration. As such, we would like to add our support to the industry proposal for a new approach to margin of safety as presented in the NEI submittal of industry comments. We believe that the industry proposal complements the other criteria in the regulation and preserves the original intent.

RG&E is looking forward to a conclusion to the differences in understanding of 10 CFR 50.59 between the industry and the Commission and highly endorses a single implementation document that can be utilized both by the regulator and utility.

Very truly yours,

Robert C. Mecredy

(34)

DOCKET NUMBER
PROPOSED RULE PR 50,52+72
(63FR56098)

DOCKETED
USNRC

'98 DEC 28 P1:35

OFFICE
RULE
ADJUD STAFF

COMMENTS ON PROPOSED CHANGES TO 10 CFR PARTS 50, 52, AND 72

1. PLEASE **consistently** use the following, recommended conventions:

   - The order of the following words/phrase: STRUCTURES, SYSTEMS, AND COMPONENTS
     or STRUCTURES, SYSTEMS, OR COMPONENTS
     NOT 'systems, structures, and components'

   - Use of the serial comma (i.e., a comma used prior to 'and' or 'or' in a listing of three or more items), as in: structures, systems, and components
     changes, tests, and experiments
     equipment functionality, reliability, and availability

   - When using the plural form of acronyms, use a small 's' after the acronym; for example:
     structure, system, or component >> SSC
     structures, systems, or components >> SSCs
     Technical Specifications >> TSs

   If you choose to not use these conventions, please at least be consistent in applying what you decide.

2. Other (minor) comments are marked up on the attached copy of the FR.

Bill Ellis

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Acknowledged by card

the exposure and frequency of this varietal designation will also increase. Since the purpose of these standards is to expedite the marketing of agricultural commodities, not changing this reference could result in confusion in terms of the proper application of the U.S. grade standards.

This proposed action will make the standards more consistent and uniform with marketing trends and commodity characteristics. This proposed action will not impose any additional reporting or recordkeeping requirements on either small or large grape producers, handlers, or importers. In addition, other than discussed above, the Department has not identified any Federal rules that duplicate, overlap, or conflict with this rule. Accordingly, AMS proposes to amend the United States Standards for Grades of Table Grapes (European or Vinifera Type) as follows.

List of Subjects in 7 CFR Part 51

Agricultural commodities, Food grades and standards, Fruits, Nuts, Reporting and recordkeeping requirements, Trees, Vegetables.

For reasons set forth in the preamble, 7 CFR Part 51 is proposed to be amended as follows:

PART 51—[AMENDED]

1. The authority citation for part 51 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

§ 51.882 [Amended]

2. In part 51, § 51.882 (i)(1)(ii) is amended by removing the words "Superior Seedless" and adding in their place the word "Sugraone."

§ 51.884 [Amended]

3. Section 51.884 (i)(1)(i) is amended by removing the words "Superior Seedless" and adding in their place "Sugraone."

§ 51.885 [Amended]

4. Section 51.885 (h)(1)(i) is amended by removing the words "Superior Seedless" and adding in their place "Sugraone."

§ 51.888 [Amended]

5. In § 51.888, paragraph (a)(2), the words "February 28, 1992" are revised to read "November 16, 1996."

Dated: October 15, 1998.

Robert C. Keeney,

Deputy Administrator, Fruit and Vegetable Programs.

[FR Doc. 98–28238 Filed 10–20–98; 8:45 am]

BILLING CODE 3410–02–P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50, 52 and 72

RIN 3150–AF94

Changes, Tests, and Experiments

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations concerning the authority for licensees of production or utilization facilities, such as nuclear reactors, and independent spent fuel storage facilities, to make changes to the facility or procedures, or to conduct tests or experiments, without prior NRC approval. The proposed rule would clarify which changes, tests and experiments conducted at a licensed facility require evaluation, and the criteria that determine when NRC approval is needed before such changes to a licensed facility can be implemented. The proposed rule would also add definitions for terms that have been subject to differing interpretations, reorganize the rule language for clarity, and revise the criteria for when prior NRC approval is needed. The Commission is also seeking comment on several specific issues as discussed below.

DATES: Submit comments by December 21, 1998. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. ATTN: Rulemakings and Adjudications Staff.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. Federal workdays.

FOR FURTHER INFORMATION CONTACT: Eileen McKenna, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–2189. (emm@nrc.gov) or Naiem Tanious, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001, telephone (301) 415–6103 (nst@nrc.gov).

SUPPLEMENTARY INFORMATION:

I. Background

The existing requirements governing the authority of production and utilization facility licensees to make changes to their facilities and procedures, or to conduct tests or experiments, without prior NRC approval are contained in 10 CFR 50.59. (Comparable provisions exist in 10 CFR 72.48 for licensees of facilities for the independent storage of spent nuclear fuel and high-level radioactive waste. This proposed rulemaking affects the requirements for 10 CFR parts 50, 52 and 72; for simplicity, the discussion will focus primarily on the language in 10 CFR 50.59). These regulations provide that licensees may make changes to the facility or procedures as described in the safety analysis report, or conduct tests or experiments not described in the safety analysis report, without prior Commission approval, unless the proposed change, test or experiment involves a change to the Technical Specifications incorporated in the license or an unreviewed safety question. Section 50.59(a)(2), as currently codified, states:

"A proposed change, test, or experiment shall be deemed to involve an unreviewed safety question (i) if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report may be increased; or (ii) if a possibility for an accident or malfunction of a different type than any evaluated previously in the safety analysis report may be created; or (iii) if the margin of safety as defined in the basis for any technical specification is reduced."

The rule also specifies record keeping and reporting requirements associated with such changes, tests, or experiments.

In order to understand the reasons for the provisions of the current rule, and how the Commission proposes to revise it, it is helpful to understand how this process fits within the overall requirements undergirding licensing and oversight of nuclear reactors.

Overview of Licensing Process

The application for an operating license includes the final safety analysis report (FSAR) which is to contain: a description of the facility; the design bases and limits on operation; and the safety analysis for the structures, systems, and components (SSC) and of the facility as a whole. The safety analysis emphasizes performance requirements, analytical bases and technical justifications, and evaluations that show how safety functions will be accomplished. Design bases include the specific functions that the SSC need to perform, the parameters that need to be controlled to assure the function, and the range of values for these parameters. As part of the FSAR, the applicant is required to propose, for NRC approval, Technical Specifications (TS) that will become part of the license.

The NRC issues a license after finding, among other things, that the plant has been built according to its design and can be operated within its design limits. The NRC prepares a safety evaluation report that documents the basis for its findings, including its review of the design information provided in the FSAR (and supporting documents) and the applicable acceptance criteria (established either in regulations, standards or guidance documents). In some cases, the NRC staff performs independent analyses to confirm the adequacy of the facility design to meet regulatory requirements. One example of this practice is the staff calculation of radiological consequences (doses) for design basis accidents.

The licensee is required to operate the facility in accordance with NRC regulations and with requirements contained in the license. The license describes the facility in general terms, and includes specific conditions imposed on the facility and the licensee, as well as incorporates the TS. Section 50.36 of the regulations defines for inclusion in the TS, those limits and parameters of most immediate significance for protection of public health and safety: safety limits, limiting safety system settings, limiting conditions for operation, surveillance requirements, and design features to which changes would have a significant effect on safety, and administrative controls. The TS are derived from the safety analysis, evaluations, and design bases described in the FSAR. Any changes to the TS must receive NRC review and approval before they are made.

Engineering evaluations demonstrate that the fundamental safety principles of the plant design are met. Design basis events play a central role in plant design. These are a combination of postulated challenges and failure events against which plants are designed to ensure adequate and safe plant response. Design basis events are defined as conditions of normal operation, anticipated operational occurrences and design basis accidents, external events and natural phenomena for which the plant has been designed to ensure the integrity of the pressure boundary, the capability to shutdown safely, and the capability to prevent or mitigate the consequences of accidents. For events with high frequency, NRC requires that consequences be low (such as by preventing fuel damage). For more severe, but less probable accidents, the allowable consequences are higher, but must still meet the regulatory guidelines established in 10 CFR part 100. Adequacy of the reactor design is evaluated by consideration of postulated design basis events viewed as sufficiently credible that the facility should be designed to prevent or mitigate their effects.

During the design process, plant response is evaluated using assumptions that are intended to be conservative to account for uncertainties in analysis or data. In the Final Safety Analysis Report (FSAR), analyses are done conservatively to account for uncertainties in the design, construction, and operation of nuclear power plants. These conservatisms are introduced into FSAR analyses in numerous ways. For example, some computer codes model systems and processes in a simplified but bounding fashion. Analysis input assumptions are typically worst case values (consistent with the design and operating limits) of instrument drift or error, temperature, pressure, fluid volume and enthalpy, flow rate, system response time, heat transfer rate and heat capacity, reactivity coefficients, power history, and decay heat. An FSAR analysis also typically assumes the worst-case single-active failure of equipment.

National standards and other regulatory policies, such as defense-in-depth, constitute additional engineering considerations that influence plant design and operation. Commensurate with expected frequency and consequences of challenges to the system, defense-in-depth could require: (1) Multiple means to accomplish safety functions and prevent release of radioactive material (multiple barriers); (2) reasonable balance among prevention of core damage, prevention of containment failure and consequence mitigation; (3) system redundancy; (4) independence; and (5) diversity.

Various margins exist in a facility design. These margins are based on, for example, assumptions of initial conditions, conservatisms in computer modeling and codes, allowance for instrument drift and system response time, redundancy and independence of components in safety trains, and plant response during operating transient and accident conditions. Margin is provided by meeting codes and standards or alternatives approved for use by NRC, including the safety analysis acceptance criteria in the FSAR and in supporting analyses. Not all margin that exists falls within the purview of "reduction in margin of safety [1] as defined in the basis for any technical specification."

When a plant is licensed, the NRC states in its Safety Evaluation Report (SER) why it found each FSAR analysis acceptable. An FSAR analysis may be accepted because it was considered to be adequately conservative and because the NRC's acceptance criteria for that analysis are met. Frequently, the SER states specific conditions the NRC relied upon for concluding that the analysis was conservative. Examples of such conditions may be the use of an NRC-approved computer code, correlation, or setpoint methodology, specific limitations on one or more input assumptions, or penalties put into a calculation to account for uncertainties. In addition to being stated in a plant-

[1] Margin of safety is not defined in the regulations, although it is mentioned in § 50.34(a) ("the margins of safety during normal operations and transient conditions anticipated during the life of the facility"); § 50.92(c) ("No significant hazards considerations if the proposed amendment would not involve a significant reduction in a margin of safety") as well as § 50.59.

specific SER, these conditions may be found in other safety evaluations such as for an analysis method proposed by a topical report.

Changes to the basis for licensing occur over the life of the plant through promulgation of new rules, plant-specific license amendments and other analyses and reviews that may be conducted, such as in response to NRC bulletins and generic letters. The NRC prepares a safety evaluation for many of these issues based upon either licensee requests for changes or licensee responses to NRC requests for information. The licensee is required to periodically update the final safety analysis report to reflect effects of these changes so that the safety analysis report (as updated) remains a complete and accurate description and analysis of the facility such that it can serve as the reference document for evaluation of changes made under 10 CFR 50.59.

10 CFR 50.59 Evaluation Process

Section 50.59 was promulgated in 1962 to allow licensees to make certain changes that affect systems, structures, components, or procedures described in the SAR without prior approval provided certain conditions were met. In 1968, the rule was revised to modify some of the criteria for when approval was required. The intent of the § 50.59 process is to permit licensees to make changes to the facility, provided the changes maintain the level of safety documented in the original licensing basis, such as in the safety analysis report. The process is thus structured around the licensing approach of design basis events (anticipated operational occurrences and accidents); safety-related mitigation systems, and consequence calculations for the design basis accidents. Margins and equipment functionality, reliability, and availability also may be impacted by facility changes. Therefore, the criteria for requiring NRC approval were directly related to: (1) Preserving licensing assumptions concerning initiation of design basis events by not allowing a different type of initiating event or probability of occurrence larger than previously considered; (2) preserving effectiveness (reliability) of the mitigation systems by not allowing introduction of different equipment malfunctions and by limiting increases in probability of malfunction, or reductions in the margin of safety (which reflects the capability of the system); and (3) preserving acceptability of consequences by limiting increases in consequences of the postulated design basis events.

Implementation Guidance

In 1989, an industry guidance document, NSAC–125, "Guidelines for 10 CFR 50.59 Safety Evaluations" was published to assist licensees in the conduct of the evaluations required under § 50.59. The NRC neither endorsed nor disapproved this document. While the staff concluded that the evaluation process established in NSAC–125 was generally sound, the staff was unable to endorse the document because of some inconsistencies between the implementation guidance and the language of § 50.59.

On October 31, 1997, the Nuclear Energy Institute (NEI) submitted for staff review a revised guidance document, NEI 96–07, "Guidelines for 10 CFR 50.59 Safety Evaluations." This document is an updated version of NSAC–125 that NEI modified in response to some of the staff positions, and other implementation issues arising from licensee use of the NSAC–125 guidance. Along with the submittal of the guidance document, NEI included an industry-wide initiative that would require industry adoption and implementation of the revised guidance by June 1998. The NRC provided comments to NEI concerning this guidance in a letter dated January 9, 1998. This letter noted that certain aspects of this guidance were unacceptable for implementation of § 50.59 as presently written.

Staff efforts to develop guidance on implementation of § 50.59 were prompted by a reassessment of the 10 CFR 50.59 evaluation process, conducted in 1995, that examined existing guidance and practice, with the goal of identifying how the process could be improved, or where additional guidance was needed. The staff provided an action plan to the Commission on April 15, 1996, outlining the actions the staff proposed to complete with respect to guidance and oversight of implementation of § 50.59. The staff review identified a number of areas in which the meaning of the rule language is not clear, or where staff and industry interpretations (such as those in NSAC–125) are different. In SECY–97–035, dated February 12, 1997, the staff forwarded to the Commission proposed regulatory guidance on implementation of § 50.59. In this SECY, the staff presented positions on a number of topic areas. These positions in some cases reaffirmed existing regulatory practice or clarified staff expectations, and in other areas, established positions where guidance did not previously exist. In its proposed guidance, the staff compared its proposed regulatory guidance to industry guidance contained in NSAC–125. In accordance with a Commission Staff Requirements Memorandum dated April 25, 1997, the staff guidance was published in the **Federal Register** as draft NUREG–1606 (Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59), for public comment on May 7, 1997 (62 FR 24947).

In response to the **Federal Register** notice, many comments were submitted that voiced strong opposition to a number of the positions proposed by the staff. These comments were summarized in Attachment 1 to SECY–97–205, Integration and Evaluation of Results from Recent Lessons-Learned Reviews, dated September 10, 1997. Since that time, the NRC has conducted a more detailed review of the comments and concludes that some issues can be resolved through guidance, while in other areas, rulemaking is necessary to clarify the implementation issues. A copy of this analysis of comments is available for review in the NRC Public Document Room. As noted, the staff concluded that rulemaking was necessary to resolve some of the issues associated with implementation of the rule.

II. Proposed Rule Topics and Issues

The NRC is proposing rulemaking on § 50.59 (and § 72.48) to address a number of issues concerning implementation of the current rule, and suitability of the criteria that determine when an unreviewed safety question exists. The implementation issues primarily relate to cases involving judgment as to whether a proposed change requires NRC approval before it can be implemented. The differing interpretations of the rule as it relates to an increase in probability of an accident, or an increase in consequences have contributed to disputed inspection and enforcement findings. Too stringent an interpretation of the meaning of the requirements could result in diversion of licensee and staff resources for review of inconsequential changes. Too high a threshold for NRC review could lead to erosion of safety margins without NRC review, particularly from the cumulative effect of more than one change. In developing the proposed rule, the Commission has carefully weighed these matters in trying to establish an appropriate threshold for NRC review.

Conforming changes are proposed in other portions of the rules, including § 50.66, 50.71(e) for production and utilization facilities licensed under part 50. Conforming changes are also required in § 72.212(b)(4) and Appendices A and B to part 52 (Design Certification Rules for ABWR and System 80+ respectively).

In addition, the Commission is proposing to make parallel changes applicable to facilities for independent spent fuel storage facilities licensed in accordance with part 72. These changes are included in the sections below (in some cases, the discussion of the issue focuses on § 50.59 for simplicity; except where noted, the discussion is also applicable to the changes for § 72.48). As part of the proposed changes to part 72, the Commission is also proposing to extend the change control process authority granted to ISFSI or MRS license holders (in § 72.48) to holders of NRC Certificates of Compliance (CoC) for a spent fuel storage cask design.

In addition to changes to the requirements within §§ 50.59 and 72.48, the Commission is also proposing to rearrange certain provisions of these rules to provide a more logical structure. These changes do not affect the substance of the requirements, but rather affect only where they are located and how they are stated. These organizational changes are discussed first, followed by discussion of each of the issues where revisions to requirements are proposed by this rulemaking. The proposed rule revisions are presented in the order that the issues currently arise in the regulations.

A. Organization of the Rule Requirements

The organizational changes being proposed include the following:

(1) Applicability

In the existing rule, language concerning applicability to different facilities is contained in three different paragraphs. These facilities are: Production and utilization facilities (including power and non-power reactors) that are authorized to operate, and reactors (both power and non-power) that have permanently ceased operations. The Commission proposes to place all of these provisions in one paragraph that is clearly labeled "Applicability." [2]

[2] Section 50.59(a) refers to holders of a license authorizing operation of a production or utilization facility. Section 50.59(d) explicitly refers to power reactor licensees who have submitted certification of permanent cessation of operation required under § 50.82(a)(1)(i). As noted in § 50.82(a)(iii), for power reactors whose licenses were modified to allow possession but not operation, before the effective date of this rule (that is of § 50.82), the certification of § 50.82(a)(1)(i) shall be deemed to have been submitted. Section 50.59(e) refers to non-power reactors whose license no longer authorizes operation. The net effect is that § 50.59 applies to both power and nonpower reactors, whether authorized to operate or no longer authorized to operate (and to other production or utilization facilities).

(2) Form of prior Commission approval

Existing § 50.59(a) refers to the need for prior Commission approval of changes, tests and experiments under certain conditions, but the method of receiving that approval is not discussed until paragraph (c), which states that the licensee shall submit an application for amendment under § 50.90. The Commission proposes to combine these two paragraphs and to revise the regulation to state more clearly that a licensee must apply for and obtain a license amendment, pursuant to § 50.90, before implementing such changes, tests or experiments. This organizational change to the rule of combining (existing) paragraphs (a) and (c) will also facilitate some of the other proposed changes, such as the criteria for when approval is needed.

(3) Criteria for needing Commission approval of changes, tests and experiments and Unreviewed Safety Question (USQ) designation

The Commission proposes to remove the reference in the rule to the term "unreviewed safety question" and instead to refer to the need to obtain a license amendment. The Commission believes that the terminology of "USQ" has sometimes led to confusion about the purpose of the evaluation required by § 50.59. Some licensees have concluded that if they determined a change was safe, there could be no need for NRC approval.

The Commission notes that the purpose of performing evaluations against the criteria specified in § 50.59 is to identify possible changes that might affect the basis for licensing of the facility so that any changes that might pose a safety concern are either reviewed by the NRC or not implemented by the licensee. This evaluation process will thus distinguish those changes which by their nature do not raise safety concerns and therefore do not require prior NRC approval to confirm their safety, from those that must be reviewed by the NRC to independently confirm their safety before implementation. To avoid confusion between a determination of safety and a determination of the need for NRC approval, the Commission proposes to revise § 50.59 to delete use of the term "unreviewed safety question" and instead to list the criteria (in new § 50.59(c)(2)) that require prior Commission approval, in the form of a license amendment. It is also noted that many facility technical specifications refer to unreviewed safety question determinations and such TS should ultimately be revised in accordance with the final wording of § 50.59. The deletion of reference to USQ also requires a number of conforming changes to other parts of the regulations, including Part 52 (Appendices A and B), in which the term is presently used.

This proposed rule would revise the existing compound statements contained with the evaluation criteria to state each specific criterion individually. This will make the regulation more consistent with how it is generally implemented by licensees. Changes to the criteria are discussed in the sections below.

Finally, the Commission would simplify existing § 50.59(c) by removing the following statement: "The holder of a license . . . who desires (1) a change to its technical specifications . . . shall submit an application for amendment of his license pursuant to § 50.90." This statement refers to changes to the TS not associated with a change, test or experiment. The Commission concludes that a more suitable place for this provision is within § 50.90, and therefore as part of this rulemaking, proposes to modify § 50.90 to state that if a licensee wishes to amend its license (including the TS incorporated into it), the licensee must file an application as specified in § 50.90. Revised § 50.59(c)(i) would be revised to state that if a proposed change, test or experiment would involve a TS change, the § 50.90 process must be followed in order to change the technical specification such that the proposed change, test or experiment may be implemented.

B. Change to the Facility as Described in the Safety Analysis Report

Section 50.59 states that "changes to the facility as described in the safety analysis report" must be evaluated to determine whether prior approval is needed before implementation. As discussed in NUREG–1606 and in the comment discussions, a common understanding between the NRC and the industry on what constitutes a "change to the facility as described in the safety analysis report" is necessary for effective functioning of the review process. Guidance on preparation of § 50.59 evaluations provides the means for review of the effects of changes, but these reviews are not conducted if the activity is not considered to be a "change . . ." The Commission concludes that modification of an existing provision (e.g., SSC, design requirement, analysis method or parameter), additions, and removals (physical removals or non-reliance on a system to meet a requirement) are all changes to the facility as described in the final safety analysis. The Commission believes that additions to the facility which were not previously evaluated, could adversely impact facility performance and the bases upon which the NRC previously determined the acceptability of the design as described in the SAR. Accordingly, the Commission concludes that additions should be considered "changes to the facility as described in the SAR" in order to assure that such changes are subject to evaluation using the § 50.59 criteria for determining whether prior NRC review and approval are necessary.

Differences in interpretation have occurred about whether changes that do not actually change the physical plant (the "hardware") require a § 50.59 evaluation. As an example, consider a change being made to the basis (documented in the SAR) for demonstrating adequacy of the facility without a physical change to the facility. Such changes might include changes to evaluative methods, acceptance standards, procurement specifications, or other information for SSC described in the FSAR. The Commission believes that § 50.59 does apply to the requirements for design, construction and operation, and the safety analyses for the facility that are documented in the FSAR. Section 50.34(b), "Final safety analysis report," requires the FSAR to contain a presentation of the design bases and the limits on its operation, a description and analysis of the SSC of the facility, with emphasis upon performance requirements, the bases, with technical justifications therefore, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished. The original licensing decision was based in part upon the margins provided by performance requirements, analysis methods and assumptions described in the SAR, and reviewed by the staff in the SER. Therefore, the Commission concludes that changes to such information (e.g., performance requirements, methods of operation, the bases upon which the requirements have been established, and the evaluations) should be considered to constitute a change to the "facility as described in the SAR" in order to assure that such changes are subject to evaluation using the § 50.59 criteria for determining whether prior NRC review and approval are necessary.

If changes to methods and assumptions were not controlled, a licensee might revise its analyses and then subsequently conclude that a later facility change did not require NRC approval because the results of the (new) analysis with this change were bounded by the previous analysis. This proposed rulemaking would add definitions in § 50.59 of "change" and of "facility as described in the final safety analysis report(as updated)" to more explicitly establish that evaluation is required for changes to the analyses and bases for the facility as well as for physical or hardware changes to the facility.

Accordingly, the Commission proposes to add the following as definitions in section § 50.59:

Change means a modification, addition, or removal.

Facility as described in the final safety analysis report (as updated) means (i) the structures, systems, and components (SSC) that are described in the final safety analysis report (as updated), (ii) design or performance requirements or methods of operation for such SSC required to be included or described in the final safety analysis report (as updated), and (iii) evaluations or methods of evaluation required to be included in the FSAR (as updated) for such SSC that demonstrate that their intended functions will be accomplished or that their design bases can be met.

The Commission endorses the staff's previously stated position (in draft NUREG–1606) about what constitutes a single change, as compared to packaging of several changes with offsetting effects. Interdependent changes (i.e., where a second change is caused by the first, with respect to function or performance), can be treated as a single change, whereas treating as one change the combination of changes (whether to the facility directly or to the safety analysis) to offset one that would otherwise require prior approval is not an appropriate application of § 50.59.

C. Change to the Procedures as Described in the Safety Analysis Report

The Commission proposes to provide a definition of "procedures as described in the safety analysis report" in order to have definitions in the rule for all the major terms and criteria. This definition would include the evaluations demonstrating that requirements are met, such as assumed operator actions and response times.

The Commission also notes that § 50.34(b) states that the final SAR is to contain the managerial and administrative controls to be used to meet Appendix B (Quality Assurance), and plans for coping with emergencies, per Appendix E. Section 50.59 applies to changes to procedures as described in the SAR. Quality assurance and emergency planning program requirements are subject to the change control provisions of §§ 50.54(a) and 50.54(q) respectively. Based on this set of rule provisions, it could be inferred that changes to quality assurance or emergency plans would require both a § 50.59 evaluation and a § 50.54 [either (a) or (q)] evaluation. The § 50.54 [3] regulations provide criteria and reporting requirements specific to the plans and which were promulgated after § 50.59. To reduce duplication of effort, the Commission proposes that changes to these programs be governed by § 50.54 requirements, and that a § 50.59 evaluation would not be required unless other information described in the FSAR is also being changed. The proposed rule would add language to specifically exclude from the scope of § 50.59 changes to procedures where other more specific requirements and criteria have been established by regulation for controlling these changes (e.g., for information required by § 50.34(b)(6) (ii) and (v)), through a provision in the § 50.59(c)(1) of the proposed rule.

The proposed definition for "procedures as described in the final safety analysis report (as updated)" is as follows:

Procedures as described in the final safety analysis report (as updated) means information in the final safety analysis report (as updated) regarding how systems, structures and components are operated and controlled (including assumed operator actions and response times), including assumed operator actions and response times, and information on conduct of operations.

redundant ?

D. Tests and Experiments Not Described in the Safety Analysis Report

Section 50.59 also discusses the conduct of tests or experiments not described in the safety analysis report. "Test" is, of course, subject to many meanings including both routine verifications of function, and also more unusual evolutions. In the former category, there are many tests that are conducted that are not explicitly described in the SAR. For example, a licensee conducts tests of component and system performance that verify the

[3] Section 50.54(p) establishes change control requirements for safeguards contingency plans. While these plans are part of the application submitted pursuant to § 50.34, they are not part of the FSAR, and thus § 50.59 would not apply to these plans.

SSCs perform the functions as described or required. (Performance of tests is typically controlled by procedure.) However, there also may be tests of new materials or means of plant operation that may put the plant in a situation that has not been previously evaluated and that could affect the capability of SSC to perform their required functions. The existing rule was designed to ensure that the latter type of tests would be reviewed before they were conducted. Therefore, to assure that there is clear definition with respect to the tests that are subject to prior NRC review and approval before they are conducted, the Commission proposes that a definition of "tests and experiments not described in the safety analysis report" be provided in § 50.59 as follows:

Tests or experiments not described in the final safety analysis report (as updated) means any activity where the reactor or any of its systems, structures, or components are used or controlled in a manner which cannot be shown to be within (i) the controlling parameters of their design bases as described in the final safety analysis report (as updated) or (ii) consistent with the analyses in the final safety analysis report (as updated).

E. Safety Analysis Report

In developing the proposed rule changes, the Commission noted the varying references to the safety analysis report within related sections of part 50. For example, in § 50.59, the phrase used is "safety analysis report," in § 50.66, the reference is to the "updated final safety analysis report;" and § 50.71(e) refers to the updated FSAR. (Other sections and parts generally refer to the final safety analysis report (e.g. part 55), but this is not universally true (e.g. § 50.54(a)). For purposes of § 50.59, "safety analysis report" refers to the current revision of the FSAR, so that the changes are evaluated against the most complete and accurate description of the facility. When performing evaluations, a licensee needs to consider changes already made for which the FSAR update has not yet been submitted to the NRC. The Commission emphasizes the need for as current a reference base as possible for § 50.59 evaluations, in order that the evaluations appropriately consider other changes already made that may have impacted the facility or procedures. However, a licensee is not required to submit an update to its FSAR in the form specified by § 50.71(e) except at the required frequency. To enhance consistency, the Commission is proposing to revise the rule language in these sections to add a definition of the final safety analysis report (as updated) and to clarify in the evaluation criteria that evaluations need to account for changes made through other processes that have not yet been included in an update to the FSAR. The Commission did not use "Updated FSAR" for this purpose in order to take into account two special circumstances: (1) Nonpower reactors, who are not required to submit updates to the FSAR, although they still need to consider other changes previously made when performing § 50.59 evaluations, and (2) a plant licensed to operate, during the period between initial licensing and the first update. This revision is reflected in the definitions in the earlier sections and in the following sections. The definition also refers to "Final Hazards Summary Report," which is the applicable document for some early plants whose application was submitted before the regulatory term "safety analysis report" was adopted.

The proposed definition is as follows:

Final safety analysis report (as updated) means the final safety analysis report (or Final Hazards Summary Report) submitted in accordance with § 50.34, as amended and supplemented, and as modified as a result of changes made pursuant to § 50.59 and § 50.90, and, as applicable, § 50.71 (e) and (f).

F. Probability of Occurrence or Consequences of an Accident or Malfunction of Equipment Important to Safety Previously Evaluated in the Safety Analysis Report may be Increased

The current language of the rule states that an unreviewed safety question exists when the probability of occurrence or consequences of an accident or malfunction of equipment important to safety previously evaluated may be increased [emphasis added]. Many of the concerns with current implementation relate to the appropriate interpretation of the words "probability of occurrence . . . or consequences . . . may be increased." In the draft NUREG–1606, the NRC staff stated that the plain reading of the words would mean that uncertainty about whether there has been an increase must lead to the conclusion that the criterion is met. As a result of trying to deal with the question of uncertainty, licensees were placed in the position of having to prove there could not be an increase, even when there was no reason to believe that the proposed change, test, or experiment would have that effect. A similar problem was experienced in considering whether the possibility of an accident or malfunction of a different type may be created.

Many of the commenters on the staff's proposed positions viewed this as overly restrictive and stated that it would result in many changes requiring prior NRC approval that are below the level of significance warranting such review. The position espoused in the revised industry guidance document (NEI 96–07) is that an increase in probability or consequences must be discernable in order for approval to be needed. The Commission concludes that the plain reading of the existing rule language is not consistent with this interpretation.

Although the current rule language would not permit discernable increases in probability or consequences, the Commission has concluded that at minimum, this would be a reasonable standard for requiring prior approval of changes, tests, or experiments for increases in probability of occurrence of an accident or malfunction. The existing rule language dates from early in the development of reactor regulation, where with the knowledge base at the time, the then-AEC found it appropriate to set a very low threshold for changes. Over the last thirty years, the Commission has garnered experience with implementation of § 50.59 and insights from probabilistic risk assessments, both of which indicate that this threshold can be adjusted without adversely impacting safety. Further, the analytical capabilities to calculate probabilities have greatly advanced, such that the effect of even minor changes on probabilities can be evaluated. Therefore, the Commission proposes to revise existing paragraph § 50.59(a)(2)(i) of the rule by replacing "may be increased" with "would result in more than a minimal increase," in order to provide that there must be a clearly discernable change to require approval, the "minimal increase" concept is described in the next section. As noted above, the (a)(2) paragraph would be broken into four statements and renumbered as (c)(2)(i) through (iv).

G. More than a Minimal Increase in Probability or Consequences

The Commission notes that § 50.59 permits changes that do not otherwise require approval (such as would be the case if the provisions being changed are in TS or license, quality assurance or emergency plans, or inservice inspection and testing programs). Because the information being revised is of less immediate importance to public health and safety, and in consideration of the conservatisms in NRC design and analysis requirements, acceptance criteria, and the precision with which safety analyses are performed, "minimal" variations in probability of occurrence or consequences of accidents and malfunctions should not affect the basis for the licensing decision. This conclusion is based upon the qualitative consideration of probability during plant licensing; accident probabilities were assessed in relative frequencies; equipment failures were generally postulated to gauge the robustness of the design, without estimating their likelihood of occurrence. Therefore, minimal increases in probability could not even have been identifiable, and could not impact the conclusions reached about acceptability of the facility design. Radiological consequences for accidents are calculated and reported at a level of precision such that minimal increases also would not impact the safety determination. The Commission therefore concludes that the proposed criteria would provide reasonable assurance that those changes that would affect the NRC's basis for licensing would be identified as requiring NRC approval before implementation. The revised criteria would also provide some degree of flexibility for licensees to make changes with smaller impacts without the need to obtain a license amendment.

On the other hand, the Commission intends to limit the amount of increase in probability or consequences of accidents such that it remains substantially less than a "significant increase" as referred to in § 50.92 (in accordance with § 50.92, a license amendment involving a significant increase in the probability or consequences of an accident previously evaluated involves a "significant hazards considerations;" any hearing for an amendment constituting a "significant hazards consideration" must be completed prior to the grant of the amendment.) The standard in the proposed rule is qualitative (probability or consequences no more than minimally increased). The intent of this proposed rule is to allow changes that are small enough that they would not affect the facility's licensing basis, or adversely affect safety performance. While the proposed rule would allow minimal increases, licensee still must meet applicable regulatory limits and other acceptance criteria to which they are committed (such as contained in Regulatory Guides, etc.) Because the "more than minimal" standard allows for there to be a discernable increase, NRC needs to establish a point beyond which one would conclude that the increase is not minimal. The following guidance is offered, including values as to when the Commission would conclude that the revised criteria are not met. Quantitative calculations are not required except for those instances in which a licensee offers other than qualitative arguments as part of its evaluation.

Probability of Occurrence of an Accident

The current guidance in NEI 96–07 states: "Where a change in probability is so small or the uncertainties in determining whether a change in probability has occurred are such that it cannot be reasonably concluded that the probability has actually changed (i.e. there is no clear trend towards increasing the probability), the change need not be considered an increase in probability." The Commission believes this satisfies the proposed NRC standard.

In order to be considered as a minimal increase, the resulting probability (considering the change, test or experiment) must still satisfy the event frequency classification provided in the licensee's FSAR (as updated), e.g., for an anticipated operational occurrence (expected once a year) or for a design basis accident (not expected during life of plant, but sufficiently credible to require mitigation).

Probability of Equipment Malfunction

The Commission believes that the probability of malfunction is more than minimally increased if a new failure mode as likely as existing modes is introduced. The determination should be made either at the component level, or consistent with the failure modes and effects analyses, taking into account single failure assumptions, and the level of the change being made.

Guidance in NEI 96–07 states: "Where a change in probability is so small or the uncertainties in determining whether a change in probability has occurred are such that it cannot be reasonably concluded that the probability has actually changed (i.e. there is no clear trend towards increasing the probability), the change need not be considered an increase in probability." The Commission believes this satisfies this criterion.

The probability of malfunction of equipment important to safety previously evaluated in the FSAR (as updated) is no more than minimally increased if "design bases" assumptions and requirements are still satisfied (i.e., the seismic or wind loadings, qualification specifications, procurement requirements). As part of this guidance, note that NRC concludes that licensees can treat changes in external hazard design requirements as potentially affecting equipment malfunction probability rather than as "accident probability."

Consequences of Accident or Malfunction

Guidance in NEI 96–07 states: "Where a change in consequences is so small or the uncertainties in determining whether a change in consequences has occurred are such that it cannot be reasonably concluded that the consequences have actually changed (i.e. there is no clear trend towards increasing the consequences), the change need not be considered an increase in consequences." The NRC believes this satisfies the revised NRC standard.

If a licensee has performed an analysis with certain bounding assumptions, and the change would increase a specific parameter from its present value to a different value that is still bounded by the value assumed in the analysis, NRC concludes that such a change satisfies the criteria of no more than a minimal increase in consequences.

As a quantitative measure, the Commission is considering some options. One would be to establish that a 0.5 rem increase in calculated dose as a result of the change be used to assess whether a minimal increase has occurred. This range of change would generally be in the decimal place for accident analyses where doses are reported in rem. The facility must still satisfy applicable acceptance values (e.g., the SRP) or regulatory requirements (e.g., part 100) for the particular accident. If a licensee would need to change its design basis assumptions or analytical methods, or both, to demonstrate that the change in consequences is less than 0.5 rem, then the NRC does not view the change as minimal and would expect the licensee to submit a license amendment for such a change.

In addition, the Commission is considering a graduated approach, consistent with the concept of "minimal" being small enough so as not to impact the basis for acceptability. When the facility is far from the limit, a larger increase can be accommodated without concern about impact on the basis for acceptability. The values proposed take into account such factors as differences between licensee calculated values and staff estimation of existing performance, potential for a single change with a large increase, or for several "minimal" increases to approach the regulatory limits. The specific proposal offered for comment is:

Example using 300 rem thyroid dose as the limit.

Existing calculated dose	"Minimal" change	Pre-change	After the change
<50% of limit	≤10% increase	140 rem	170 rem.
≤80% of limit	≤5% increase	205 rem	220 rem.
more than 80%	≤1% increase (NTE limit)	245 rem	248 rem.

A third option under consideration, similar to option 2, would limit the fraction of remaining margin that can be consumed by a particular change. By defining "minimal" as being 10% of the remaining margin between current conditions and acceptance guidelines, the amount of change would decrease as the limit is approached, and the limit could not be exceeded.

Cumulative Effect

The Commission is concerned about the cumulative effect of minimal increases. Since some increases are allowed, the Commission believes that the proposed process would place greater importance on: (1) Complete and accurate SAR updating; (2) the licensee's evaluation process taking into account other changes made since last update; (3) the licensee's screening process examining plant changes to determine whether they are indeed changes requiring evaluation; and (4) reporting requirements so that staff can assess the ongoing nature of cumulative impact.

The issue then becomes how the NRC can best oversee the process such that several "minimal" changes do not result in unacceptable results. The Commission has decided to require licensees to report effects of changes in a different manner to facilitate evaluation of cumulative effect, as discussed in a later section on reporting requirements, in which the Commission proposes to require that the SAR update in accordance with § 50.71(e) discuss the effects of the changes upon calculated doses and other information.

H. Possibility of an Accident of a Different Type from any Previously Evaluated in the Safety Analysis Report may be Created

As noted in Section F above, the uncertainty connected with demonstrating that no accident or malfunction may have been created is a major source of confusion and difficulty in implementing the existing rule; and is unnecessary for purposes of identifying when NRC review of a change is needed. Accordingly, the Commission proposes that the language in existing § 50.59(a)(2)(ii) be revised as discussed below in this section and the following one. As noted earlier, the Commission is proposing to separate the requirements into distinct criteria for clarity. This criterion would now read "if a possibility for an accident of a different type from any previously evaluated in the final safety analysis report (as updated) is created." Under the proposed rule, a license amendment would be needed only if the licensee reasonably concluded that the possibility of an accident of a different type is created. This contrasts with the current rule, which would require a license amendment if the licensee is uncertain or unable to reasonably conclude that a new accident of a different type is not created. The Commission concludes that this proposed rule change will still identify those proposed changes, tests, or experiments that the NRC should review, without also including other changes of lesser significance that may be viewed as meeting the existing criteria.

Need for Definition of Accident

In determining whether a proposed change requires prior NRC approval under § 50.59, the rule refers to whether "accidents" previously evaluated in the SAR are impacted, or whether an accident of a different type may be created (see also § 50.92 criteria for "no significant hazards consideration)". Those accidents evaluated in the SAR, that is, those events that a plant must show that it can withstand, are derived from a number of regulatory requirements, and the safety analyses are included in the FSAR.

The regulations and NRC guidance documents, refer to "a design basis accident" (§ 50.36), to design basis events (§ 50.49), to loss-of-coolant accidents (Appendix A), to anticipated operational occurrences (Appendix A) and to accidents that could result in release of significant quantities of radioactive fission products (part 100). The PSAR, and by extension the FSAR, pursuant to § 50.34, is to contain "analysis and evaluation of the design and performance of SSC of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of (i) the margins of safety during normal operations and transient conditions anticipated during the life of the facility and (ii) the adequacy of SSC provided for the prevention of accidents and the mitigation of the consequences of accidents." RG 1.70 states that the FSAR is to include postulated anticipated operational occurrences; postulated off-design transients that induce fuel failures above those expected for normal operational experience, and design basis accidents. The Standard Review Plan for Chapter 15, refers to anticipated operational occurrences and to postulated accidents, and also to "transients and accidents" (the SRP notes that other events, such as response to external phenomena, are covered in other chapters).

Design basis accident(s) has been used in regulatory practice both singularly and generally. The regulations also include the concept of a design basis accident (DBA), for purposes of evaluating siting, which is an assumed fission product release, based upon a major accident that would result in potential hazards not exceeded by those from any accident considered credible. Such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products. The set of "accidents" that a plant must postulate for purposes of FSAR design and safety analyses, including LOCA, other pipe ruptures, rod ejection, etc., are often referred to as "design basis accidents".

The terms of accidents and transients are often used in regulatory documents (as for example in Chapter 15 of the Standard Review Plan), where transients are viewed as the more likely, low consequence events and accidents as more serious. In the context of probabilistic risk assessment, transients are typically viewed as initiating events, and accidents as the sequences that result from various combinations of plant and safety system response.

However, the meaning of the term "accident" as it is used more generally in Part 50, is somewhat obscured by the use of the term "design basis event." In § 50.49, design basis event is defined as:

normal operations including anticipated operational occurrences, design basis accidents, external events, natural phenomena (earthquakes, tornados, hurricanes, floods, tsunami and seiches), for which the plant must be designed to ensure safety-related functions.

In view of the range of language presently used to describe the types of events evaluated as part of the licensing basis, the Commission is contemplating the need to clarify its intent as to the extent of events that are within the purview of the criteria in § 50.59 and in § 72.48). For purposes of stimulating discussion, the Commission offers two proposals. One would be to set forth a definition for the term "accident" as follows:

an initiating event or combination of events and/or conditions that could occur from equipment failure, human error, natural or manmade hazards which challenges the integrity of one or more fission product barriers (fuel, reactor coolant system, release of radionuclides (confinement/containment)), required to be analyzed and/or accounted for by the Commission and addressed in the licensee's safety analysis report.

Such a definition would make it clear that the Commission's intent in referring to "accidents" in § 50.59 (and in § 72.48) is to refer to the design basis accidents that are addressed in the SAR. The second approach is to add the phrase "design basis accident" into the existing criteria. This could be done for each of the three criteria that refer to "accident" or just for the one on accident of a different type. Since the criteria on probability and consequences also contain language about "previously evaluated in the SAR," there may be less need for a reference to "design basis accident" in these criteria. The proposed rule language includes use of the phrase "design basis accident" in the one criterion, for purposes of obtaining public comment.

I. Possibility of a Malfunction of a Different Type from any Previously Evaluated in the Safety Analysis Report may be Created

In a similar fashion, the Commission proposes to modify the remaining part of existing § 50.59(a)(2)(ii), concerning malfunctions of a different type by creating a new criterion that would read "if a possibility for a malfunction of equipment important to safety with a different result than any evaluated previously in the final safety analysis report (as updated) *is* created." This criterion involves three revisions to the existing rule. The first change is the use of the phrase "is created" which would require a determination that the possibility has been created, rather than uncertainty as to exclusion.

The second change is to insert the words "of equipment important to safety." The existing rule does not provide this characterization within paragraph (ii), but it is included in paragraph (i). It has generally been inferred that the statement in paragraph (ii) is an abbreviated version of that in paragraph (i). A review of the history of the 1968 rulemaking adopting revisions to § 50.59 did not disclose any discussion suggesting that the Commission intended to distinguish between the (a)(2)(i) and the (a)(2)(ii) criteria with respect to the scope of equipment covered. Therefore, the Commission concludes that the rule was intended to apply to the same scope of equipment in each cases, and therefore, proposes to include the words in this criterion to eliminate any doubt.

The final change is being proposed in response to the comments on the staff-proposed guidance (NUREG–1606) on the interpretation of malfunction (of equipment important to safety) of a different type. The commenters believe that the cause of the malfunction should be a consideration in determining whether the probability of the malfunction may have increased, and that a malfunction of a different type would only be created if the effects of the malfunction are not already bounded by the FSAR analysis. The recent industry guidance states that if a component were subject to failure from a new failure mode but the failure of the component is already considered in the safety analysis, then there would not be a failure of a different type. The Commission does not agree that the industry interpretation is consistent with the rule as written, which refers to creation or possibility of a malfunction of a different type, not of a different result. However, the Commission recognizes that in its reviews, equipment malfunctions are generally postulated as potential single failures to evaluate plant performance; thus, the focus of the NRC review was on the result, rather than the cause/type of malfunction. Unless the equipment would fail in a way not already evaluated in the safety analysis, there is no need for NRC review of the change that led to the new type of malfunction. Therefore, as the third change in § 50.59(a)(2)(ii), the Commission is proposing to change the phrase "of a different type" to "with a different result". Therefore, this criterion would read: "if a possibility for a malfunction of equipment important to safety with a different result . . . is created."

In implementing this position, attention must be given to whether the malfunction is evaluated at the component level or the overall system level. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and resulting event initiators or mitigation impacts, it also needs to consider the nature of the change. Thus for instance, if failures were previously postulated on a train level because the trains were independent, a change that introduces a cross-tie might need to be evaluated to see whether new outcomes have been introduced. The staff has provided guidance on this issue in Generic Letter (GL) 95–02, concerning replacement of analog systems with digital instrumentation. The GL states that in considering whether new types of failures are created, this must be done at the level of equipment being replaced—not at the overall system level. Further, it is not sufficient for a licensee to state that since failure of a system or train was postulated in the SAR, any other equipment failure is bounded by this assumption, unless there is some assurance that the mode of failure can be detected and that there are no consequential effects (electrical interference, materials interactions, etc), such that it can be reasonably concluded that the SAR analysis was truly bounding and applicable. Otherwise, the Commission would conclude that there was increase in probability of malfunction or that a malfunction with a different result has been created.

J. Margin of Safety as Defined in the Basis for any Technical Specification is Reduced

Two criteria in the current regulations (§ 50.59) specifically focus upon accidents and equipment malfunction (creation, consequences and likelihood) as the measures for determining when a change requires prior NRC approval. However, the phrases "margin of safety" and "as defined in the basis for any technical specification" in the third criterion have been the subject of differing interpretations because the rule does not define what constitutes a margin of safety or a basis for any technical specification in the context of §§ 50.59 and 72.48. In addition, some have questioned the need for the third criterion on "margin of safety."

The Commission has under consideration a number of proposals on margin. In the proposed rule text specifically being offered for comment, one option has been inserted so that commenters can examine the relationship of this aspect of the proposed rule to other changes being offered. This should not be viewed as meaning that this option is preferred by the Commission. The range of options under consideration is discussed in more detail below.

Questions of margin are commonly judged in terms of the degree of confidence that the response of the facility, or of particular SSC, to postulated challenges is acceptable. Various margins exist in a facility design. These margins are based on, for example, assumptions of initial conditions, conservatisms in computer modeling and codes, allowance for instrument drift and system response time, redundancy and independence of components in safety trains, and plant response during operating transient and accident conditions. Margin to conditions that might be detrimental to safety is also determined by establishing acceptance criteria to be met for response to various accidents and transients. Acceptance criteria are established at a value that accounts for uncertainty about physical properties and other variability and thus provides margin to unacceptable plant conditions. Margins are built into the facility to account for routine plant fluctuations and transients. Margins are also built into the plant to establish the regulatory envelope within which a plant has demonstrated its ability to respond to a spectrum of design basis accidents. It is in this category termed the "regulatory envelope," that the NRC believes that regulatory oversight of changes in margin may be needed from the standpoint of § 50.59. Thus the Commission notes that not all margins fall within the purview in which changes to the margin require prior NRC approval. As part of this rulemaking, the Commission wants to clarify which margins fall within the regulatory envelope and how possible reductions in margin resulting from facility or procedure changes, or from conduct of tests and experiments should be evaluated.

In defining in the rule a standard for NRC review and approval of changes to margins in the regulatory envelope, the Commission may want to preserve the NRC's ability to review changes when there is a potentially significant reduction in a margin of safety,[4] but clearly would not want to unduly affect licensee operations. Therefore, for this proposed rulemaking, the Commission is offering the public the opportunity to comment on a range of options for treating margin. Commenters are requested to present opinions about the merits, or concerns about the specific proposals, or both, and also to offer any other suggestions for wording.

Option 1: Control Inputs to Analyses and Methods that Establish TS

The Commission believes it is reasonable to interpret the specific reference to "basis for any technical specification" in the 1968 rulemaking that added the "margin of safety" criterion as preserving the margins in the analyses that established the TS requirements. For instance, the minimum plant performance conditions and configurations stated in the TS are the limiting conditions for operation, limiting safety system settings, and safety limits. Margins of safety exist within the safety analyses as a result of the specific input assumptions, methods, or other limits that were used. These parameters and methods were proposed by the licensee and reviewed by NRC to account for uncertainties, instrumentation response, and ranges of possible operating conditions. Because § 50.59 requires prior NRC approval for a change to the TS, a change that could invalidate the basis upon which the TS values were established should also receive prior approval. In accordance with this interpretation, changes that invalidate these specific conditions described in the FSAR for analyses that established the TS requirement (such as a limiting condition of operation, or a limiting safety system setting) would reduce the margin of safety associated with the TS.

Under this option, the Commission would conclude that the analyses and information in the FSAR establish the basis for the margins of safety for the TS. Thus, the Commission would propose to add a definition for "reduction in margin of safety associated with any technical specification" and to conform the criterion for needing a license amendment in new § 50.59(c)(2). The existing terminology of "basis for any TS" would be replaced by "associated with any TS."

The following definition would be added:

Reduction in margin of safety associated with any technical specification means that the input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the final safety analysis report (as updated), that established any technical specification requirement, are altered in a nonconservative manner.

Although this option would maintain the safety analyses that underlie the TS, this approach would also have the effect of giving input values and assumptions the weight of TS, which is inconsistent with the philosophy in § 50.36 of establishing TS only on those values of most immediate safety importance. In many instances, changes to inputs can be accommodated by other available margins so that the licensing envelope is preserved.

Option 2: Delete "margin of safety" as a Criterion.

Under this option, the Commission would delete any criterion focusing upon margins. Instead, the Commission would rely upon the other criteria in § 50.59, as well as the regulatory requirement that all changes to TS be reviewed and approved by the NRC, to assure that there are no significant adverse changes to margins in design and operation. The Commission would argue that there is no need for prior review of changes that do not satisfy any of the other evaluation criteria in view of "risk-informed" insights and greater understanding of the margins that exist through meeting the body of regulatory requirements. The Commission seeks comment on whether any of the other evaluation criteria should be revised were this approach to be adopted.

Option 3: Control margins associated with results of analyses

Instead of focusing on the inputs to safety analyses, another interpretation would be to examine the results of the safety analyses, and to determine whether changes to operational characteristics or other information described in the FSAR (as updated) would reduce the level of protection afforded by the TS (i.e., by the limiting safety system settings and limiting conditions of operation), as reflected in the results of safety analyses.

As part of the licensing review for a facility, the NRC established a level of required performance (which will be referred to in this discussion as acceptance criteria) for certain physical parameters, such as those that define the integrity of the fission product barriers (fuel cladding, reactor coolant system boundary, and containment). Satisfying these acceptance criteria (or regulatory limits) produces a margin of safety to loss of barrier integrity. The safety analyses presented in the FSAR (as updated) demonstrate that the response of the barriers to the postulated accidents, transients, and malfunctions meets the acceptance criteria. For

[4] In accordance with 10 CFR 50.92(c)(3), license amendments involving a significant reduction in a margin of safety do not meet the criteria for a "no significant hazards consideration" determination; thus, changes involving a significant reduction in a margin of safety are not to be performed under 10 CFR 50.59.

certain of these parameters, TS safety limits have been established; these safety limits are limits upon important process variables that are found necessary to reasonably protect the integrity of physical barriers that guard against the uncontrolled release of radioactivity.

However, for other parameters, a licensee must determine the licensing basis of the parameter in question by reviewing the plant-specific safety analyses. The acceptance criterion is that value approved by the NRC for a particular parameter or process variable (e.g., ASME Code stress limits, a departure from nucleate boiling ratio limit or maximum critical power ratio limit or containment design pressure). These acceptance criteria may be stated in the FSAR, may be in NRC regulations, or may be presented in the NRC Standard Review Plan. (Note: This approach may require some licensees to revise their FSAR to accurately describe the regulatory values for the set of critical parameters. For example, licensees would need to identify the expected operating or design values and then specify the minimum performance capabilities for the related parameters, which cannot be modified with NRC review).

In constructing the requirements for controlling margin through consideration of results of analyses, there are three aspects to take into account: (a) Which results/parameters are to be controlled through the § 50.59 process, (b) the degree of change to be allowed without review, and (c) how the changes should be evaluated in demonstrating that the criterion is satisfied.

In the sections below, these three aspects are separately discussed in order to amplify upon the issues under consideration. However, any rule language option would need to include some provision for each of the three aspects.

(a) Which parameters should be controlled?

The margins of safety that would be controlled by the 10 CFR 50.59 process can be characterized in different ways.

OPTION 3(A)(1)—Safety and Regulatory Limits

The margin between regulatory limits and the failure of physical barriers is protected in the regulations (and also in the portion of the Technical Specifications (TSs) called "safety limits"). The margin, as reflected in approved safety and accident analyses, between the protection afforded by the TSs (e.g., the limiting safety system settings and limiting conditions of operations) and the associated regulatory limits is a possible interpretation as to "the margin of safety as defined in the basis for any TS", which would be subject to the 10 CFR 50.59 evaluation process. Thus, one proposal under consideration would be to define "margin of safety" as follows:

plural acronyms

The "margin of safety as defined in any technical specification" (margin of safety) is the amount (quantitative or qualitative) of margin between the operation of the facility as described in the technical specifications and the exceedance of safety limits listed in the technical specifications or other regulatory limits. In relation to accident analysis, the margin of safety is typically the difference between calculated parameters (e.g., peak fuel clad temperature, maximum RCS pressure, etc.) and the associated regulatory or safety limit. The margin of safety is a product of specific values and limits contained in the technical specifications (which cannot be changed without NRC approval) and other values, such as assumed accident or transient initial conditions or assumed safety system response times, which are not specifically contained in the technical specifications. Any change to the values not specifically contained in the technical specifications must be evaluated for impact on the margin between the calculated result of an accident or transient and the safety or regulatory limit.

With this option, before changing operational characteristics described in the UFSAR (not directly controlled by TS), a safety evaluation must be performed to determine, among other things, if the change results in a reduction in the level of protection afforded by the TS (margin of safety as defined in any TS). Such a reduction would typically occur only if the operational characteristic had been used as a bounding condition in the analysis upon which the selection of TS was based, or in analysis where the acceptability of selected TS values was demonstrated. Licensees could make desired changes to operational characteristics without prior NRC approval, provided that the change does not result in accident analysis results that are nearer the regulatory, or safety, limits than the corresponding results that the NRC used in evaluating the acceptability of the TS during licensing of the facility.

OPTION 3(A)(2)—Fission product barriers—definition

The NRC notes that § 50.36 (requirements for Technical Specifications) has criteria for when TS are to be provided that specifically are tied to design basis accident or transient analysis that either assumes the failure of or presents a challenge to the integrity of a fission product barrier. Thus, the margin as defined in the basis for any TS can be reasonably viewed as that margin associated with preserving integrity of these barriers. Therefore, the NRC is also considering a more explicit linkage to the response of the three fission product barriers generally relied upon to provide protection from uncontrolled release of radioactive materials from a reactor facility. Under such a proposal, the text of the rule would explicitly state that it is the response of fission product barriers (fuel, reactor coolant system and containment) to accidents, transients and malfunctions that is being controlled.

The following could be given as a definition of margin of safety and of fission product barrier response. Regulatory guidance would explicitly list the parameters (for PWRs and BWRs) that are to be controlled.

The margin of safety for any fission product barrier response is the difference between the calculated value and its associated acceptance criteria. Fission product barrier response means those parameters that must be satisfied in the event of postulated design basis events to demonstrate integrity of the fuel, reactor coolant system and containment system barriers.

The following parameters would be included: Fuel and cladding performance (peak cladding temperature, or energy deposition, DNBR or MCPR, oxidation), RCS performance (pressure, flows, stress), and containment performance (peak pressure, containment leakage).

OPTION 3(A)(3)—Specified Parameters

A variant on the previous option would be to actually list the parameters of interest directly in the criterion for prior review, as for instance, the criterion could read:

(vii) Result in a change to the FSAR (as updated) calculated value of RCS peak pressure, containment peak pressure, or fuel performance (DNBR/MCPR, others), etc.

This variant has the advantage of being more precise, but the rule language would need to be crafted to account for various reactor types.

OPTION 3(A)(4)—Include Mitigation Capability

The Commission is interested in preserving the integrity of both prevention and mitigation capabilities available in the plant, and is therefore considering an option that would include both features within the "margin" criterion if the margin criterion is maintained. If this approach were adopted, the definition or the list of parameters would be supplemented with the performance parameters for the accident mitigation capability of the plant, as for instance, ECCS performance (pressures, flows, actuation values), engineered safety feature performance (flows, pressures, spray effectiveness, system efficiencies).

Finally, in conjunction with any of these approaches, the Commission is also considering whether there are other parameters important to preservation of barriers that should be explicitly defined. For instance, for fuel stored in spent fuel pools, or for the reactor during periods of shutdown or refueling, there may be other analysis results (water level, pool temperature) in lieu of reactor coolant system pressure. Therefore, the Commission seeks input as to whether there are other parameters of interest beyond those previously offered that should be included within the "margin of safety" criterion if that criterion is maintained, and how should the rule language be revised to specify what those parameters might be.

(b) Determination of reduction in margin requiring review

Once the parameters of interest are determined, it is also necessary to define when a reduction in margin warranting NRC review and approval has occurred. The Commission is evaluating options ranging from any "nonconservative change in calculated values," to a "minimal change" standard, and ultimately an option that would allow increases up to "specified limits (acceptance criteria)" for those parameters that may be established in the regulations or NRC guidance (such approaches to the limits might be controlled in a graduated fashion as was discussed in the section of this notice relating to "minimal increases"). An option for the degree of reduction would be paired with an option (such as one of those listed in (a) above) to provide the text of the rule.

OPTION 3(B)(1)—No Reduction

One approach would be require that the safety analysis, considering the effect of the change, must show that the accident analysis results are not nearer to any safety or regulatory limit, thus, a "no reduction in margin" standard. Possible rule text:

Changes, or the net effect of multiple related changes, which result in a reduction in the margin of safety require prior NRC approval. Changes, or the net effect of multiple related changes, which do not cause a reduction in the margin of safety do not require prior NRC approval.

OPTION 3(B)(2)—Minimal Amount—Definition of Margin Reduction

As discussed in other sections of this notice, the Commission concludes that the revised rule should allow licensees some flexibility in making changes, through development of a "minimal increase" standard. In considering margins, the Commission is thus weighing how such a concept could be applied. One option would be that NRC approval would be required for a change, test or experiment if the output values (calculated in the SAR) are altered by more than a minimal amount. The "margin" criterion would be modified to state that a change in calculated result of "more than a minimal amount" would require prior review and approval. Either in the rule itself, or in guidance, the Commission would define "minimal amount", modeled upon the options offered for minimal increases in consequences (see section II.G. of this notice). For example, there could be a fixed amount (percent change) in margin, as long as regulatory limits are still met. If guidance itemizes the parameters, such guidance could also customize how "minimal" should be judged for each particular parameter (allowing greater amounts for certain parameters depending on precision of calculations, sensitivity of results and other considerations).

For instance, the definition of "margin of safety reduction * * *" might be stated as follows:

Reduction in margin of safety means that as a result of a change, the [MARGIN] is altered in a nonconservative manner by more than a minimal amount.

OPTION 3(B)(3)—Minimal Determined With Respect to Acceptance Criteria (Available Margin)

It is also possible to achieve this result by removing the language referring to margin of safety (and to TS), and defining "minimal" in the rule itself in terms of the results or analyses for barrier response, with respect to meeting the acceptance criteria for those barriers. For example, rule language could read as follows:

License amendment needed if as a result of a change, test or experiment:

(vii) there is more than a 10% reduction in the difference between the calculated value and the acceptance criteria for fission product barrier response to accidents evaluated in the SAR.

If such an approach is followed, the Commission would propose to include a definition of acceptance criteria, such as follows:

Acceptance criteria are those values, established by NRC regulation or review guidance, to which the licensee is committed through its FSAR (as updated), as the basis for acceptability of response to the postulated accident, transient or malfunction.

(c) Evaluation of effect of the change upon analysis results.

The Commission also notes that the results of safety analyses are subject to variance depending upon the assumptions, analysis methods or analytical techniques used. In many instances, these factors were reviewed by the NRC during its licensing deliberations, and their use may have formed part of the basis for the conclusion that acceptable safety margins were demonstrated. Therefore, the Commission wishes to ensure that proposed changes by a licensee would not invalidate these conclusions by requiring a demonstration that the evaluation techniques and analyses are suitable.

To accomplish this, the Commission is considering having as part of whichever definition of "margin of safety reduction" is selected the following statement [Option 3(c)]:

All analyses and evaluations for assessing the impacts of proposed changes must be performed using methodology and analytical techniques which are either reviewed and approved by the NRC or which are shown to meet applicable review guidance and standards for such analyses.

The alternative to this proposed language would be to rely upon a licensee's design control processes under their quality assurance requirements and program, to provide the assurance that any evaluative work has been conducted with methods and techniques commensurate with the safety significance of the analyses being performed.

Impacts for Part 72 Changes

Certain of the options discussed above may need to be modified for application to independent spent fuel storage facilities or spent fuel storage cask designs in Part 72. While the overall philosophy would be the same, the particular outputs or barriers that would be specified for reductions in margin would have to be defined in terms of the barriers against release of radioactivity afforded by fuel storage facilities. For instance, these might include calculated fuel temperature or cladding oxidation, and stresses (or pressures) on the cask structure. Comment is also requested on the appropriate parameters for facilities licensed under Part 72.

K. Safety Evaluation

Section 50.59(b)(1) requires licensees to maintain records that must include a written safety evaluation that provides the bases for the determination that the change, test, or experiment does not involve an unreviewed safety question. Section 50.59(b)(2) requires submittal of a report containing a brief description of any changes, tests, or experiment, including a summary of the safety evaluation of each. In the interest of emphasizing the regulatory purpose of the evaluation required under § 50.59, which led the Commission to propose deletion of the term "unreviewed safety question," the Commission proposes to delete the word "safety" in referring to the required evaluation for determining whether the change, test, or experiment requires a license amendment. For purposes of the summary report of tests and experiments submitted to NRC, the staff would propose that the rule specify that a summary of the evaluation be provided (rather than a summary of the safety evaluation).

A similar change is proposed for § 50.71(e), which presently refers to safety evaluations either in support of license amendments or of conclusions that changes did not involve USQs. The Commission proposes to change "safety evaluation in support of license amendments" to "safety analysis in support of license amendments," to reduce confusion between the information prepared by the licensee for the amendment (safety analysis) and the NRC review (safety evaluation). The second part of this phrase would be revised to refer to the "evaluation that changes did not require a license amendment in accordance with § 50.59(c)(2) of this part." (In this case, it is a licensee evaluation against the regulatory criteria in § 50.59 that is being referred to). In addition, other minor wording changes are proposed such as with respect to terminology on "final safety analysis report" and "effects of" (see reporting requirements discussion below). Conforming changes in the appendices to part 52 and in part 72 to revise language to refer to "evaluation" are also proposed.

L. Reporting and Recordkeeping Requirements

In view of the "minimal increase" criteria in § 50.59, the Commission concludes that the reporting requirements for the SAR update should be enhanced to enable the NRC to better understand the potential cumulative impact of changes that might have been made since the last update. Therefore, the Commission proposes to supplement the reporting requirements on "effects" of changes to require that in the FSAR update submittal (with the replacement pages), the licensee shall include a description of each change affecting that part of the SAR that provides sufficient information to document the effect of the change upon the probability or consequences of accidents or malfunctions, or reductions in margin associated with that part of the SAR. Accordingly, the Commission proposes to revise § 50.71(e) to read as follows:

"(e) Each person licensed to operate a nuclear power reactor pursuant to the provisions of § 50.21 or § 50.22 of this part shall update periodically, as provided in paragraphs (e)(3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the operating license, to assure that the information included in the FSAR (as updated) contains the latest information developed. The submittal must describe the effects [1] of: (1) All changes made in the facility or procedures as described in the FSAR; (2) all safety analyses and evaluations performed by the licensee either in support of requested license amendments, or in support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2) of this part; (3) all analyses of new safety issues performed by or on behalf of the licensee at Commission request; and (4) the net effect of all changes made since the last update on the safety analyses, including probabilities, consequences, calculated values, system or component performance, that are in the FSAR (as updated). The updated information shall be appropriately located within the update to the FSAR.

Finally, the Commission is proposing a change to the record retention requirements in existing § 50.59 (b)(3) (renumbered by this rulemaking to (c)(3)). The change would add to the requirement that the records of changes to the facility be maintained until the termination of the license, the statement "or until the termination of a license issued pursuant to 10 CFR part 54, whichever is later." This change would make more clear the requirement that records must be maintained through the life of the facility so that they will remain available until such time as they are no longer needed (that is, when the license is terminated, not just at the end of the initial licensing term).

M. Part 72 Changes

In part 72 the Commission is proposing to make conforming changes to § 72.48 with those made to § 50.59 and to expand the scope of § 72.48 so that holders of a Certificate of Compliance (CoC) are also subject to it. In addition to the proposed changes to § 72.48, the Commission proposes to make changes in other sections of part 72. When subpart L—Approval of Spent Fuel Storage Casks, was originally added to part 72, no provisions were included to address potential amendments of CoCs. However, regulations in this area are necessary to provide requirements for certificate holders in instances where a proposed change does not meet the tests of § 72.48, and an amendment to the CoC is necessary. Therefore §§ 72.244 and 72.246 would be added to subpart L, to provide regulations on applying for, and approving, amendments to CoCs. Section 72.248 would also be added to provide regulations for the certificate holder submitting an updated final safety analysis report, which would document the changes it made to procedures or structures, systems, and components under the provisions of § 72.48. The Commission notes that a general licensee is not precluded from loading spent fuel into an approved spent fuel storage cask during the 90-day period allowed for the certificate holder to submit a final safety analysis report. This approach is the same as that required for part 72 license holders to update their final safety analysis report under § 72.70. The Commission also notes, that for dual-purpose spent fuel casks (i.e., casks which have been issued CoCs for transportation and storage under parts 71 and 72, respectively), no regulation equivalent to § 72.48 exists in part 71. Consequently, a certificate holder could make changes to the design of a spent fuel storage cask under the authority of § 72.48 (i.e., without prior NRC approval); however, if the change also affected the transportation aspects of the cask's design and involved a modification to the part 71 certificate, then NRC approval and amendment of the transportation CoC would be required before the cask could be used to transport spent fuel to another site. Additionally, a transportation cask CoC has a term of 5 years, compared to the 20-year term for a storage CoC. Consequently, the Commission envisions that most of this type of change would be captured during the periodic renewal of a transportation CoC and this delay would not have a significant adverse impact on a licensee's ability to transport spent fuel in a dual purpose cask.

In § 72.3 the definition for *independent spent fuel storage installation (ISFSI)* would be revised to remove the tests for evaluation of the acceptability of sharing common utilities and services between the ISFSI and other facilities. The existing requirement in § 72.24(a)—Contents of application: Technical Information,

[1] Effects of changes includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate.

would be revised to reference shared common utilities and services in the applicant's assessment of potential interactions between the ISFSI and another facility. The Commission would remove the existing requirement in § 72.3 for the applicant to evaluate the impact of sharing common utilities and services on the "other facility." The Commission believes that evaluation of the impact on the "other facility" should not be part of the licensing process for an ISFSI. Rather, such evaluation should be part of the license amendment process for that "other facility" and should be performed under the regulations used to license that "other facility."

Changes to § 72.56 would be conforming changes to those made to § 50.90. Changes to § 72.70 are also conforming changes to those made to § 50.71(e); additionally, requirements would be added to § 72.70 on standards for submitting revised Final Safety Analysis Report (FSAR) pages. The Commission notes that the proposed § 72.70 would retain the requirement that the site-specific licensee submit a final safety analysis report at least 90 days prior to the planned receipt of spent fuel or high-level waste. The Commission has not received any requests for exemption from this regulation and believes that this regulation does not impose an undue burden or schedule impact on licensees. The proposed rule also modifies the requirements for filing of updates (through reference to § 72.4) to be consistent with other changes being made to part 72. Changes to § 72.216 for a general licensee are similar to the changes made to § 72.70 for a site-specific licensee and are also conforming changes to those made to § 50.71(e). The Commission also envisions that a general licensee who wishes to adopt a change to the design of a spent fuel storage cask it possesses—which was previously made to the generic design by the certificate holder under the provisions of § 72.48—would be required to perform a separate evaluation under the provisions of § 72.48 to determine the suitability of the change for itself. The changes to §§ 72.9 and 72.86 are conforming changes due to the addition of new §§ 72.244, 72.246, and 72.248.

Changes to part 72 Record keeping requirements would include the clarification that records required by § 72.48 shall also include determinations that significant increases in occupational exposure or unreviewed environmental impacts did not exist, such that a license amendment would have been required. (The existing language linked the written evaluation only to the "unreviewed safety question" determination, and thus did not explicitly require Record keeping for the determinations of whether the change would cause a significant increase in occupational exposure or a significant unreviewed environmental impact). Certificate holders would also be required to keep records of such changes as would be allowed under § 72.48.

Requirements in § 72.70 would be established for reporting changes to procedures. The Commission notes that § 72.70 presently requires that the update include[5] a description and analysis of changes in the structures, systems, and components with emphasis upon performance sp? requirements; the bases, with technical justification therefor, upon which such requirements are based; and evaluations showing that safety functions will be accomplished. It also requires an analysis of the significance of any changes to codes, standards, regulations or regulatory guides which the licensee has committed to meeting the requirements of which are applicable to the design, construction or operation of the facility. New reporting requirements for certificate holders would be added in §§ 72.244 and 72.248, similar to existing requirements imposed on licensees in §§ 72.56 and 72.70, respectively. New reporting requirements for general licensees would be added as § 72.216(d), similar to existing reporting requirements for site-specific licensees in § 72.70 and proposed requirements for certificate holders in § 72.248. In both of these sections, the Commission is adding a requirement that the entity making a change to the cask, either the general licensee or the certificate holder, provide a copy of the submittal to the other party for their information.

III. Section By Section Analysis

10 CFR Part 50

10 CFR 50.59

As discussed in more detail above, § 50.59 would be restructured and revised to have the following components.

Paragraph (a)—This is a new paragraph that provides definitions of terms such as "change", "facility as described * * *," in order to specify more clearly which changes, tests and experiments require further evaluation and how reductions in margin of safety are to be determined. The references to "safety analysis report" are being revised to "final safety analysis report (as updated)" to state that the evaluations are to be performed that take into account other changes made that have affected the final safety analysis report since its original submittal.

Paragraph (b)—Relocation of existing applicability provisions.

Paragraph (c)(1)—Relocation of existing provisions establishing which changes, tests, or experiments require evaluation, using the defined terms. The terminology of "unreviewed safety question" has been replaced by referring to the need to obtain a license amendment. This paragraph also clarifies that the licensee must submit its request for license amendment, and obtain the amendment prior to implementing those changes, tests or experiments that involve TS or otherwise meet the criteria for prior NRC approval as specified in (new) paragraph (c)(2).

Paragraph (c)(2)—Reformatting of the evaluation requirements into seven distinct statements of the criteria and revision of the criteria for when prior NRC approval of a change, test or experiment is required. Specifically, language of "more than a minimal increase" was inserted in the criteria concerning increases in probability and consequences, and revisions to the rule requirements were made concerning creation of accidents of a different type and malfunctions of equipment with a different result. Clarification is also being provided that the margins of safety are those associated with TS requirements established by the FSAR analyses, and are not confined to the BASES section of the TS. These revisions clarify the criteria for when prior approval is needed and allow some flexibility for licensees to make changes that would not affect the NRC basis for licensing of the facility.

Paragraph (d)(1)—Renumbered paragraph with record keeping requirements. Also includes change from "safety evaluation" to "evaluation."

Paragraph (d)(2)—Renumbered paragraph with reporting requirements.

Paragraph (d)(3)—Renumbered and revised paragraph on retention of records, to cover the term of any renewed license.

10 CFR 50.66

The proposed changes for § 50.66 are to conform existing language referring to unreviewed safety questions, and references to updated final safety analysis report, to the language

[5] The similarity in the language between §§ 72.24 and 50.34(a) and between §§ 72.70 and 50.34(b)(2) is noteworthy.

proposed in revised § 50.59 for consistency.

10 CFR 50.71(e)

The proposed changes to this section are to conform language with respect to unreviewed safety question, safety evaluation, and reference to final safety analysis report (as updated), with the proposed language in § 50.59, and to clarify reporting requirements relating to "effects of" changes such that cumulative effects of minimal increases in probability and consequences are included in the update to the FSAR.

10 CFR 50.90

A portion of existing § 50.59(c) would be relocated into this section. This change would place the requirements for changes to technical specifications in the rule section on amendments to licenses.

10 CFR Part 52

Appendix A and Appendix B to 10 CFR Part 52

The proposed changes to these sections are to conform references to unreviewed safety question, safety evaluation and the evaluation criteria concerning when prior NRC approval is needed, to the language in the proposed revision to § 50.59.

10 CFR Part 72

10 CFR 72.3

The definition for independent spent fuel storage installation would be revised to remove the tests for evaluation of the acceptability of sharing common utilities and services between the ISFSI and other facilities. (Section 72.24 is also proposed to be revised to include this evaluation).

10 CFR 72.9

Paragraph (b) would be revised as a conforming change to include in the list of information collection requirements the new reporting requirements in §§ 72.244 and 72.248 for reports of changes made by CoC holders and for updates to the safety analysis reports by CoC holders.

10 CFR 72.24

This section would be revised to reference shared common utilities and services in the applicant's assessment of potential interactions between the ISFSI and another facility (previously covered by § 72.3).

10 CFR 72.48

New definitions have been added for terms such as "change" and "facility as described in the Final Safety Analysis Report (as updated)." The specific criteria in existing paragraph (a)(2) have been revised to separate out the various statements, to insert the language of "more than a minimal increase," and to modify the criterion from "malfunction of a different type" to "malfunction of a different result." The text for Record keeping requirements was revised to refer to the need for license or certificate of compliance (CoC) amendments, rather than involving an unreviewed safety question. As part of this revision, the Commission is also clarifying that the records shall also provide a basis for why a proposed change, test, or experiment did not require a license or CoC amendment with respect to significant increases in occupational exposure or significant unreviewed environmental impacts. Additionally, the term "Final Safety Analysis Report (FSAR) (as updated)" has been used to provide greater clarity and consistency with § 50.59 and other sections of Part 72. The filing requirements for the summary reports are modified to be consistent with § 72.4 (Communications).

10 CFR 72.56

Existing § 72.48 (c)(2) is being relocated into this section. This is a parallel change to that proposed for § 50.59 and § 50.90, wherein the Commission would place the requirements for changes to license conditions in the rule section on amendments to licenses.

10 CFR 72.70

Paragraphs (a) and (b) would be revised to use the terms "Final Safety Analysis Report," "FSAR," and "as updated." Paragraph (b)(2) would be revised to add changes to procedures to the annual updates of the FSAR. New paragraph (c) would be added to provide requirements on submitting revisions to the FSAR.

10 CFR 72.86

Paragraph (b) currently includes those sections under which criminal sanctions are not issued. This paragraph would be revised by adding §§ 72.244 and 72.246 as a conforming change to reflect that certificate holders who fail to comply with these new sections would not be subject to the criminal penalty provisions of section 223 of the Atomic Energy Act (AEA). New § 72.248 has not been included in paragraph (b) to reflect that certificate holders who fail to comply with this new section would be subject to the criminal penalty provisions of section 223 of the AEA.

10 CFR 72.212(b)(4)

The change to this section is to conform the reference to 10 CFR 50.59 provisions, specifically to change from the terminology of unreviewed safety question to referring to need for license amendment for the facility (that is, the reactor facility at whose site the independent spent fuel storage installation is located).

10 CFR 72.216

New paragraph (d) provides requirements for a general licensee to submit annual updates to a final safety analysis report (FSAR) for the cask or casks approved for spent fuel storage cask that are used by the general licensee. The general licensee is also required to provide a copy of its submittal to the certificate holder. This section is similar to the requirements in §§ 72.70 and 72.248 for submission of annual updates to the FSAR associated with a site-specific Part 72 licensee or a certificate holder, respectively.

10 CFR 72.244

This new section provides requirements for a certificate holder to submit an application to amend the certificate of compliance (CoC). This section is similar to the requirements in § 72.56 for licensees to apply for an amendment to their license.

10 CFR 72.246

This new section provides requirements for approval of an amendment to a CoC. This section is similar to the requirements in § 72.58 for approval of an amendment to a license.

10 CFR 72.248

This new section provides requirements for submittal of annual updates to a FSAR associated with the design of a spent fuel storage cask which has been issued a CoC. This new section also provides that the changes to procedures and structures, systems, and components associated with the spent fuel storage cask and which are made pursuant to § 72.48 would be included in the annual update. The proposed revisions would also require that the certificate holder provide a copy of the FSAR submittal to each general licensee using that cask. This section is similar to the requirements in § 72.70 for submission of annual updates to the FSAR associated with a site-specific part 72 license and new section 72.216 for general licensees to provide updates to the FSAR.

IV. Commission Voting Record on SECY–98–171

The staff forwarded to the Commission a proposed rulemaking package on § 50.59 and related regulations in SECY–98–171, dated July 10, 1998. This document was placed in the Public Document Room on July 29, 1998. Subsequently, the Commission voted to approve issuance of a proposed rule for public comments with several additions and changes that are reflected in this notice. The Commission also directed that the record of their decision on SECY–98–171 be included as part of this notice to clearly inform stakeholders on preliminary positions taken by the Commission. The text of the resultant staff requirements memorandum and of the individual Commissioner vote sheets, is presented below.

Commission SRM on SECY–98–171, Dated September 25, 1998

The Commission has approved publication, for a 60 day public comment period, the proposed rulemaking that would revise 10 CFR 50.59 and related provisions in parts 50, 52 and 72 concerning the processes controlling licensee changes, tests and experiments for production and utilization facilities and for facilities for independent storage of spent nuclear fuel and high-level radioactive waste. The Voting Record, which includes the Commissioner votes and this Staff Requirements Memorandum, should be published in the **Federal Register** notice to clearly inform stakeholders on preliminary positions taken by the Commission (Enclosed).

The Commission also approves the staff's recommendations for handling violations of 10 CFR 50.59 and 72.48, including staff plans for exercise of enforcement discretion, while rulemaking is underway.

The Commission requested that the staff specifically solicit public comment in the **Federal Register** notice on:

1. A wide array of options for the margin of safety criterion (50.59(c)(2)(vii) in the proposed rule) and its definition including: (a) Deleting the criterion and definition, (b) a new definition as described in Chairman Jackson's vote, and (c) an option which would decouple the last criterion from technical specifications and focus instead on a new criterion relating to performance of fission product barriers (e.g., reactor coolant system pressure, containment pressure, etc), with minimal changes being allowed up to specified limits, perhaps utilizing a graduated approach similar to the approaches proposed for other criteria.

2. Options for defining "minimal" as it pertains to "probability of occurrence of an accident" or "probability of equipment malfunction."

3. The definitions of "facility," "procedures," and "tests or experiments," including elimination of the definitions.

4. A clear definition of "accident."

(This action scheduled for completion October 9, 1998).

The Commission requests the staff to complete the revised 50.59 rule on an expedited schedule.

(This action scheduled for completion February 19, 1999).

All Commissioners approved in part and disapproved in part the proposed rulemaking on 10 CFR parts 50, 52 and 72 requirements concerning changes, tests, and experiments and staff recommendations on changes to other regulations and enforcement policy, and provided additional comments. In their vote sheets, all Commissioners approved the staff's recommendations to approve publication of the proposed rule for public comment, and use of the enforcement discretion guidance in its assessment of severity levels for violations while the rulemaking is underway, and provided some additional comments. In particular, all Commissioners disapproved the staff's proposed margin of safety criterion (§ 50.59(c)(2)(vii) in the proposed rule) and its definition and each Commissioner provided an option for evaluation during the comment period. The Commissioners also specifically requested comments on a number of other issues. Because of the need to finalize this rule as expeditiously as possible and because SECY–98–171 has already been publicly available since July 29, 1998, the Commission agreed to a 60 day comment period, and that the staff complete the revised § 50.59 rule by February 19, 1999. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on September 25, 1998.

Chairman Jackson's Comments on SECY–98–171

I approve, in part, and disapprove, in part, the staffs proposal for rulemaking. I approve the staff's proceeding with issuance of the proposed rule language for public comment in order to support the expedited finalization of a revision to these processes. I disapprove of the specific language proposed by the staff for § 50.59(c)(2)(vii), "reductions in the margin of safety."

I agree with the recent letter from ACRS on this rulemaking, in that: (1) 10 CFR 50.59 can accommodate risk-informed decisionmaking, (2) the positions, as presented, on margin of safety may add regulatory burden without a commensurate safety benefit.

I disagree with ACRS in that I believe:

(1) The rulemaking should go out for public comment to foster comment on this high priority issue, and

(2) The regulatory guidance can be worked in parallel with the rulemaking.

I note that a further reason for issuing this package for public comment at this time is that the paper calls for the proper use of enforcement discretion as this rulemaking progresses, thereby providing further stability in the implementation of this rule in the industry.

Further, I propose that the SRM on this SECY, and the voting record, be placed in the FR notice to clearly inform stakeholders on preliminary positions taken by the Commission.

Giving Definition to Minimal

Attached to the recent ACRS letter was "A Proposal for the Development of a Risk-Informed Framework for 10 CFR 50.59 and Related Matters." The proposal forwarded by the ACRS parallels an existing risk-informed approach described in Regulatory Guide 1.174. Regulatory Guide 1.174 describes a method for determining the level of review, based on severe accident implications, for proposed licensing actions. The proposal forwarded by the ACRS describes methodology for creating frequency-consequence curves for Class 1–8 accidents. The proposal states that existing processes could be extended to provide appropriate context for whether the results of a change are "minimal." The proposal also notes that aspects of this type of approach are in use in the international regulatory community. The approach utilized in the proposal forwarded by the ACRS is consistent with the Commission guidance in the Staff Requirements Memorandum of March 24, 1998 on SECY–97–205.

Without commenting on the specifics of the proposal forwarded by the ACRS, I am convinced that changes to nuclear plants can be evaluated in a risk-informed context. Any such approach would benefit from paralleling existing methodology. Careful consideration would be required to ensure that the "consequence" and "frequency" standards are appropriate for a § 50.59 type application. For instance, "consequences" could be evaluated at one of the following levels: Fractional releases, off-site or on-site doses, or challenges to fission product release barriers. "Frequency" could be evaluated for Class 1–8 accidents or for design basis accidents using existing guidelines for risk-informed regulation. The level at which consequences and frequency of events were tracked would also impact the type of parallel, deterministic (e.g., protection of redundancy, defense in depth, etc.), considerations against which changes would have to be evaluated. For instance, evaluating consequences at the level of the loss of a single barrier, or occurrences of accident sequence initiators, might allow elimination of parallel, deterministic, considerations such as "margin."

It is of some concern to me that the whole staff has pursued risk-informed approaches to issues like the review of TSs, the use of Graded Quality Assurance, and programs like Inservice Inspection and Inservice Testing, the staff appears to be more reluctant to allow risk-informed approaches if the result is the relinquishment of review and approval authority. Because prior NRC review and approval impacts the cost and schedule of licensed activities, we must ensure that we require such prior review and approval only when justified or required by mandate. We should not limit the application of risk-informed regulation as a means to ensure continued NRC reviews and approvals of licensed activities. This message is complimentary to my oft repeated message to industry that the use of risk information is "double-edged," that is that relief and additional regulatory scrutiny may both result from its use.

Margin of safety

The staff proposes to provide a specific definition of "Reduction in margin of safety associated with any technical specification," and to revise the current provisions of 10 CFR 50.59(a)(2)(iii) to explicitly refer to this definition. While I commend the staff on its efforts to provide clear, definitive, requirements in this proposed rulemaking, I am concerned that the proposed rule is not consistent with policy direction established by the Commission in the SRM dated March 24, 1998. I concur that it is important that the staff has the independence to (and, I believe, has the responsibility to) inform the Commission when there are concerns with Commission guidance (as it did in COMSECY 98–013). However, I believe that when the staff proposes to take action that is inconsistent with Commission direction, it is obliged to provide a clear and complete rationale for the proposed departure. I do not feel that the staff has met that obligation for the "margin of safety" aspect of this proposed rule. However, this said, I do not disagree with the staff's conclusion that we should be careful to understand, and maintain, a consistent regulatory basis on "margin of safety." We must proceed in a manner that does not call into question the existing deterministic basis for "reasonable assurance" of public safety embodied in plants Technical Specifications (TSs).

My previous discussions with the staff have indicated that it is extremely difficult (and probably not legally defensible) to allow decreases in the "margin of safety" when the upper and lower limits between which "margin" may exist are not defined in relation to the regulatory requirements for safe operation. Based upon these discussions, I can only assume that the staff is hesitant to allow direct reductions in margin within the "basis" for TSs because some such changes could create a de-facto change in the TSs themselves. The staff may also be concerned by the lack of consistency in the "margin of safety in the basis for TSs" associated with the different generations of existing licenses (e.g., older customized TSs compared to improved standardized TSs), and associated with the different methods utilized in the technical review and approval of the TS (e.g., some TSs might be based on maintaining margin between accident analysis results and acceptance limits, while other TSs might be based on margin which was built into analytical techniques and methodologies used in the accident and safety analysis, with no "margin" between the results and the acceptance limits, etc.).

The staff's proposed method of requiring prior agency approval to changes of input assumptions, analytical methods, etc., for those parameters which affected the selection of TSs, results in the newly controlled parameters being treated essentially the same way as values in the TSs. It also appears that implementation of the staffs proposed control over a broad range of parameters used in the safety analysis would effectively prevent any change to the facility that would result in a "minimal change in consequence," a condition allowed elsewhere in the proposed rule. In other words, it is not clear what type of changes would successfully pass the 10 CFR 50.59 test for allowed "minimal increases in consequences," without failing the test for "no reductions in the margin of safety." I do not believe that the potential safety significance of *all* the parameters to be covered under the proposed definition of a reduction in the margin of safety *always* justify the requirement of prior NRC approval.

The staff should continue to work to establish a technically sound method for allowing licensees to make plant changes where there is only "minimal" impact on safety. If fundamental conflicts exist with allowing reductions in some "margins of safety," especially those on which the validity of TSs are based, then staff should provide a clear explanation of this, and should address how other changes to the structure of the regulation, which do not create fundamental conflicts, can be made in a manner which achieves the Commission's objective of removing unnecessary burdens from licensees.

Attachment "A" to this vote describes one alternate method for addressing the issue of "margin of safety." This alternative would maintain existing margins of safety (associated with TSs), while providing greater flexibility to licensees in implementing changes to their facilities. This alternative is based on methodology similar to that described in NEI 96–07. This methodology requires evaluating the effect of proposed tests and changes on the accident analysis *results* (rather than inputs, as proposed by the staff), in cases where TSs are based on accident analysis considerations. Prior NRC approval of changes, tests, and experiments would be limited to those cases where there was a net effect on the accident analysis results. The alternative also recognizes the significance of the analytical techniques used in the safety or accident analysis, and would require some form of prior approval for analytical methods used to support changes when the change did not have prior NRC approval. This approach could provide staff reasonable assurance that the assumptions made by the license reviews are not invalidated. The staff should evaluate this option, along with other comments in this area, during the comment period.

In considering the technical and regulatory underpinning of this clause of § 50.59, I have become concerned that we are evaluating incremental changes to a provision which is not well suited to such changes. I am concerned that the result may be the addition of yet another layer of regulatory process rather than the elimination of any unnecessary layers. For this reason, the staff should be receptive to internal or public comments on feasible alternatives which eliminate the discussion of "the margin of safety in the basis of TSs," while maintaining the integrity of the plant's licensing basis. I envision that it may be possible to eliminate the rule

plural acronym

language criteria on "margin of safety" if evaluations of "frequency" and "consequences" are performed at a level of significance which bounds allowable "minimal" reductions in margin.

Accident of a Different Type

In determining the effect of any proposed change to § 50.59, it will be necessary to more clearly understand what an "accident of a different type" is. The staff should provide a more definitive definition of an accident than was included in COMSECY–98–013. The information provided by the staff should address, as a minimum, the following:

(1) What is an "accident" under this section, and is it consistent with other existing regulations (e.g., § 50.92, § 50.34, Appendix A of part 50, etc.)?

(2) Is an "accident of a different type" better described as an "initiating event (e.g., loss of feedwater, loss of offsite power, new common mode failure mechanism, etc.) of a different Type?"

(3) What are the bounds which limit those "accidents" which are the subject of this Section (e.g., only those initiating events which, when evaluated using approved analytical techniques, result in transients with the potential to challenge fission product barriers, etc.)?

Procedures

I commend staff on inserting a definition for the term "Procedures as described in the final safety analysis report (as updated)." However, I am concerned that the definition provided may cloud the distinction between: (1) Those procedures which must be screened, or evaluated, under § 50.59, and (2) the criteria which necessitates a full safety evaluation. I believe that staff seeks to indicate that all procedures which are described as being required in the FSAR are subject to a § 50.59 screening. The screening would identify the need for a full safety evaluation only if a proposed procedure change created a change to the "information in the FSAR regarding how structures, systems, and components are operated and controlled. . . ." Staff should solicit comment on this definition and clarify the proposed definition, as required, in the final rule.

Making the Rule Risk Informed

I note with interest that members of the ACRS believe that there are substantial barriers in the existing deterministic framework of 10 CFR part 50 to the concept of allowing "minimal" changes in accident probabilities or consequences. In my previous vote on SECY–97–205, "Integration and Evaluation of Results from Recent Lessons-Learned Reviews," I approved the staff's proposal to develop the framework for risk-informed regulatory processes. In particular, I called for the staff to develop a series of milestones by which the Commission could "chart its course in its move to more risk-informed regulatory processes." Additionally, I promoted the idea of promulgating a new regulation in 10 CFR part 50, that would make clear how the Commission uses risk information in its decision-making. In proceeding with the "short-term" changes to 10 CFR 50.59 (and related regulations; "short-term" actions from SECY–97–205), and in responding to the ACRS, the staff should re-evaluate whether the Agency should initiate action to provide for a risk-informed framework that would allow for the efficiencies to be gained through use of risk-informed, performance-based revisions to our regulatory processes.

Attachment "A" to Chairman Jackson's vote sheet on SECY–98–171

"Straw Man" on Margin of Safety

Regarding margin:

• The margin between regulatory limits and the failure of physical barriers is protected in the regulations (and also in the portion of the Technical Specifications (TSs) called "safety limits").

• The margin, as reflected in approved safety and accident analyses, between the protection afforded by the TSs (e.g., the limiting safety system settings and limiting conditions of operations) and the associated regulatory limits is "the margin of safety as defined in the basis for any TS."

• The margin between normal plant or system operation used and the "bounding" assumptions used in accident analysis is below the threshold of safety significance that requires NRC prior approval for changes.

• The results of safety and accident analyses are subject to significant variance, depending on the analytical techniques and methods used in the analysis. Where a licensee wishes to make a change in their facility without prior NRC approval, the effects of the change must be evaluated using analytical techniques and methods which are NRC approved for the application, or which are reviewed and vetted (but not subject to specific NRC approval) in a NRC approved manner.

Direct changes to technical specifications require prior NRC approval. Before changing other operational characteristics described in the UFSAR, a safety evaluation must be performed to determine, among other things, if the change results in a reduction in the level of protection afforded by the TS (margin of safety as defined in any TS). Such a reduction would typically occur only if the operational characteristic had been used as a bounding condition in the analysis upon which the selection of TS was based, or in analysis where the acceptability of selected TS values was demonstrated. Licensees can make desired changes to operational characteristics without prior NRC approval, provided that the change does not result in accident analysis results that are nearer the regulatory, or safety, limits than the corresponding results that the NRC used in evaluating the acceptability of the TS during licensing of the facility.

This regulatory position could be codified by adding the following footnote to Section 50.59(a)(2)(iii):

The "margin of safety as defined in any technical specification" (margin of safety) is the amount (quantitative or qualitative) of margin between the operation of the facility as described in the technical specifications and the exceedance of safety limits listed in the technical specifications or other regulatory limits. In relation to accident analysis, the margin of safety is typically the difference between calculated parameters (e.g., peak fuel clad temperature, maximum RCS pressure, etc.) and the associated regulatory or safety limit. The margin of safety is a product of specific values and limits contained in the technical specifications (which cannot be changed without NRC approval) and other values, such as assumed accident or transient initial conditions or assumed safety system response times, which are not specifically contained in the technical specifications. Any change to the values not specifically contained in technical specifications must be evaluated for impact on the margin between the calculated result of an accident or transient and the safety or regulatory limit. Changes, or the net effect of multiple changes, which result in a reduction in the margin of safety require prior NRC approval. Changes, or the net effect of multiple changes, which do not cause a reduction in margin of safety do not require prior NRC approval. All evaluatory work in assessing the impact of proposed changes must be performed using methodology and analytical techniques which are either reviewed and approved by the NRC or which are reviewed and vetted in a manner approved by the NRC.

Commissioner Diaz's Comments on SECY–98–171

I consider this rulemaking effort to be our short term fix for the 50.59 rule, not the longer term risk-informed rule enhancement discussed in SECY–97–205.

I approve the publication of this rulemaking package for a 90-day public comment period, contingent upon the additions described in the last paragraph of my comments. I propose that the package also include the Commissioners' votes for public consideration. The purpose of issuing the rulemaking package is to expedite rulemaking by opening the process for public comments during the Commission's continuing deliberation on this matter. It should be made very clear to all stakeholders that publication of the package is an invitation to participate in improving the rulemaking. In fact, I do not agree with several of the proposed positions in this paper, as delineated in my specific comments below.

I agree with the staff's recommendation to remove the reference to "unreviewed safety question" from § 50.59 and to make conforming changes in parts 50, 52, and 72. I also agree with staff's proposal to allow a minimal increase in the probability of occurrence or consequence of an accident or malfunction previously evaluated, and to *not allow* the creation of an accident of a different type or malfunction of equipment important to safety with a different result than any previously evaluated.

I agree with the ACRS comments in their June 16, 1998, letter regarding the definition of "reduction in margin of safety." Notwithstanding the staff's suggestion of a possible Commission interpretation, the language "altered in a nonconservative manner" can still be interpreted as a de facto "zero increase" standard for the 50.59 criterion on margin of safety. I believe the risk-informed § 50.59 approach suggested in the ACRS letter deserves serious consideration as part of longer term improvements and should be considered in the staff's response, due in February 1999, to the SRM for SECY–97–205.

The current language in 50.59(a)(2)(iii) ("margin of safety as defined in the basis for any technical specification") is, in fact, defined and bounded by the technical specifications. Therefore, as long as the licensee proposed change, test, or experiment under § 50.59 is not in violation of the technical specification requirements, the requisite margin of safety is maintained, and it is possible to eliminate "reduction of margin of safety" from the rule as a condition requiring prior staff approval. This change will eliminate the existing ambiguity in the use of § 50.59 for changes with minimal safety significance. This alternative should also be published for public comment; it is consistent with the safety envelope provided by the technical specifications and is a straightforward improvement that will match with the eventual conversion to a risk-informed rule.

I support the staff's recommended changes in the reporting and record keeping requirements relating to § 50.59. The enforcement policy and its corresponding implementation guidance should be changed in accordance with the revised § 50.59 rule. I recommend that, during the rulemaking period, the enforcement policy be revised to grant discretion (i.e., suspend issuance of Level IV violations) under Section VII.B.6 for those § 50.59 violations of little or no safety significance.

I do not agree with the recommended definitions of "facility", "procedures", "reduction in margin of safety", and "tests or experiments." These definitions appear to increase prescriptiveness at the input of the licensees' change process instead of the output, and therefore, are more broad-based than the definitions to date. I believe that these definitions will create more burden for the NRC and licensees, are not consistent with the original intent of the § 50.59 rule, i.e., to evaluate whether the licensee proposed changes will result in inadequate protection of public health and safety, and therefore, are not necessary.

On the other hand, the "accident" in the proposed revisions to § 50.59 should be defined. The "accident of a different type than any previously evaluated" as described in the proposed § 50.59(c)(2)(v) should be of the same safety significance as the "accident" in the proposed § 50.59(c)(2)(I) and (c)(2)(iii). The staff should determine if the anticipated operational transients and the postulated design basis accidents described in the FSAR form a sufficient basis for the § 50.59 evaluation.

The staff should continue its interactions with NEI in resolving the differences between the NRC's position on § 50.59 implementation guidance and that contained in NEI 96–07. The regulatory guide for § 50.59 that endorses a revised NEI 96–07, with exceptions and clarifications, as appropriate, should be developed concurrently with the rulemaking process.

In summary, the staff should proceed with publishing the existing rulemaking package, and concurrently solicit public comment on the following alternatives: (1) eliminate "reduction of margin of safety" as a condition requiring prior staff approval, (2) eliminate the broadened definitions of "facility", "procedures", "reduction in margin of safety", and "tests or experiments," and (3) clearly define "accident" in the proposed revisions to § 50.59. I urge the staff to complete the revised § 50.59 rule and the associated regulatory guide by the end of March, 1999.

Commissioner McGaffigan's Comments on SECY–98–171

I approve publishing this rulemaking package for a ninety-day public comment period. However, like my colleagues, I do not agree with the staff proposal regarding "reduction in the margin of safety associated with any technical specification."

As the Chairman points out, the definition of "reduction in margin of safety * * *" would extend the requirements for prior agency approval to underlying aspects (e.g., input assumptions) of parameters that affected the selection of technical specifications, and result in the newly controlled parameters being treated essentially the same way as values in the technical specifications. This is the wrong way to go.

It is clear from my colleagues' and my vote that the margin of safety criterion (§ 50.59(c)(2)(vii) in the proposed rule) and the definition will need to be fixed in the final rule. My concern at this point is that the staff discuss a wide enough array of options in the **Federal Register** notice to ensure that the proposed rule will not have to be renoticed before being finalized. Commissioner Diaz has proposed to simply delete the criterion and definition as not needed. The Chairman has proposed essentially a new definition. Another option would decouple the last criterion from technical specifications and focus instead on a new criterion relating to performance of fission product barriers (e.g., RCS pressure, containment pressure. etc), with minimal changes being allowed up to specified limits, perhaps utilizing a graduated approach similar to the approaches proposed for other criteria. Comment should be solicited on this option as well.

I believe that the staff has done a good job in proposing options for defining "minimal" for consequences of an accident or malfunction. On probability, however, the staff has essentially only said that NEI 96–07 satisfies the proposed NRC standard for a "minimal" increase. That is a good step forward, and will bring regulatory stability. I believe that in choosing the word "minimal" the Commission intended to grant greater flexibility than the NEI 96–07 "so small" or negligible standard. The staff should continue to try to give better definition to "minimal" as it pertains to "probability of occurrence of an accident" or "probability of equipment malfunction" and solicit comment on this.

Finally, I endorse the use of enforcement discretion under Section

VII of the Enforcement Policy as the rulemaking proceeds for those § 50.59 violations of little or no safety/risk significance. The staff should treat (vice "consider treating" as proposed by staff) as minor violations cases where the violation of existing rule requirements would not constitute a violation under the rule were it revised as proposed. I do not object to documenting such minor violations in inspection reports because the rule is still in a proposed revision stage.

V. Rule Language Proposed by The Nuclear Energy Institute

In a letter dated November 14, 1997, the Nuclear Energy Institute provided to the NRC suggested language for revising 10 CFR 50.59 that they believed would enable the NRC to endorse NEI 96–07. This language is included here in this Statement of Considerations so that interested parties can offer comment on whether this language should be adopted by the NRC. The supporting information for NEI's proposal is contained in the referenced letter which is available for review in the Public Document Room.

Specifically, NEI proposed that [existing] section 50.59(a)(2) be revised to read:

(a)(2) A proposed change, test, or experiment shall be deemed to involve an unreviewed safety question: (i) If there is more than a negligible increase in the probability of occurrence of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report; or (ii) if the consequences of an accident or malfunction important to safety previously evaluated in the safety analysis report exceeds the established acceptance limit; or (iii) if a possibility for an accident of a different type or malfunction with a different result from any evaluated previously in the safety analysis report may be created; or (iv) if the margin of safety provided by any technical specification is reduced.

In this rulemaking, the Commission is proposing to adopt certain aspects of the changes offered by NEI (e.g., on malfunction with a different result). The Commission is seeking comment as to whether other aspects of this proposal should be adopted. The Commission also offers the following observations about this proposal for consideration as part of the comment process:

A. Negligible Increase in Probability of Occurrence

NEI proposes that the rule be revised to state that a change would be an USQ "if there is more than a negligible increase in the probability of occurrence of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report." As discussed above, the Commission is proposing a "more than minimally increased" criterion, which is considered comparable in overall intent to what was proposed by NEI.

B. Increase in Consequences of an Accident or Malfunction

NEI proposes that the rule be revised such that a change would be a USQ if the consequences of an accident or malfunction previously evaluated exceed the established acceptance limit. As NEI discusses further in its letter, the established acceptance limit would be the value that was previously reviewed and approved by the NRC generally as documented in the staff's safety evaluation report (SER).[6]

The current industry guidance, NEI 96–07, would permit, in some instances, increases in consequences up to the regulatory thresholds (such as Part 100), without review. As discussed in (draft) NUREG–1606, the staff typically performs independent evaluations of radiological consequences of accidents, rather than an in-depth review of the licensee's calculations, during licensing of the plant. As a result, the degree of conservatism in the licensee calculations differs from that used in the staff's assessments. As noted above, the Commission is proposing to revise the rule to allow "minimal" increases in consequences without prior approval, provided that the regulatory limits are still met. The Commission has some concerns about allowing licensee changes without review, which when evaluated with licensee assumptions and methods, result in doses at or very close to the regulatory guidelines (e.g., part 100). This is because such changes, if reviewed with staff assumptions (or starting from the staff's previous estimation of the accident dose), might result in the regulatory guidelines not being met. Rather than allowing one change to result in an increase in consequences up to the guidelines, the Commission concludes that minimal increases, along with NRC oversight of cumulative effects, is the appropriate standard for review.

[6] Attempting to use values from the staff's SER as acceptance limits would be difficult since SERs were not written for the purpose of establishing such limits. In a literal sense, neither the SAR nor the SER set an "acceptance *limit*." Rather, the SAR documents an applicant's/licensee's analytically derived conclusion that a given event has a certain consequence which is within the regulatory bounds set by NRC regulations. The SER is intended only to confirm or modify that conclusion. The SAR value as modified through the staff's review and approval then becomes the baseline for future analyses.

C. Malfunction with a Different Result

As discussed above, the Commission is proposing to adopt this particular proposed change to the rule.

D. Margin of Safety Provided by Any Technical Specification

NEI proposes to replace the existing language of "as defined in the basis for any technical specifications," with "as provided by any technical specification" with respect to reductions in the margin of safety. The proposed change is intended to clarify that the margin of safety is not necessarily limited to information in the BASES section of the technical specification. NEI 96–07 guidance notes that the SAR, staff SERs and other licensing basis documents should be reviewed to determine if a proposed change would result in a reduction in margin of safety. NEI intended to use this rule language in conjunction with guidance that the margin of safety is the range of values between the acceptance limit reviewed by the NRC (e.g., ASME code stress limits, containment design pressure, etc.) and the failure point. The Commission is seeking comment on a range of options relating to margin of safety, including the option proposed by NEI.

VI. Request for Comment

The Commission requests comments on the proposed rule, as discussed in Section II above. In addition, the Commission is seeking comment on a number of specific issues related to this rulemaking. All commenters are encouraged to provide specific comments on the following issue areas:

1. The Commission is seeking input on a number of options relating to the criterion of margin of safety reduction, and its definition. Some possible alternatives are presented in Section II.J as being representative of the range of approaches under consideration, but the Commission is open to other proposals that commenters may wish to put forth as representing the best means to provide a clear understanding of which margins should fall within the regulatory envelope of requiring approval if they would be reduced as a result of a change, test or experiment, if the margin of safety criterion were to be retained.

2. The Commission is interested in options for defining what constitutes a "minimal" increase in the probability of occurrence of an accident previously evaluated in the FSAR or in the probability of equipment malfunction (refer to Section II.G). This might include suggested examples of changes

that commenters believe represent only a "minimal increase" in probability.

3. The Commission is interested in comments upon the proposed definitions for such terms as "facility as described in the FSAR," "procedures as described in the FSAR," and "tests or experiments" (refer to Sections II.B, C, and D). The Commission is soliciting views on whether (1) definitions are necessary, (2) the proposed definitions are desirable, even if not necessary, and (3) whether the suggested definitions are clear and focused upon the appropriate changes that should be evaluated. In this light, the Commission is also interested in comments on a broader view of the scope of changes that should be evaluated; for instance, should the scope be linked to the SAR, or should the focus of changes to the facility be linked to another set of regulatory information?

4. As part of the present rulemaking, the Commission is seeking comment on the need for a clear definition of accident as it is used in § 50.59 to reflect the Commission's intent that the "accidents" referred to are those dealt with in the safety analysis report (see Section II.H of this notice for discussion of issues related to definition of accident).

5. In addition to the NRC proposals in Sections II and III, the Commission is also interested in receiving comments on the proposals and language suggested by NEI (Section V).

VII. Availability of Documents and Electronic Access

Certain documents related to this rulemaking, including comments received and the regulatory analysis, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC NRC documents also may be viewed and downloaded electronically via the interactive rulemaking website established by NRC for this rulemaking.

You may also provide comments via the NRC's interactive rulemaking web site through the NRC home page (http://www.nrc.gov). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301) 415-5905; e-mail CAG@nrc.gov.

VIII. Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this rule, if adopted, will not have a significant impact on the environment. The proposed rule changes are of two types: those that relate to the processes for evaluating and approving changes to licensed facilities and those that involve the degree of potential change in safety for which changes can proceed without NRC review. The process changes being proposed will make it more likely that planned changes are properly reviewed and approved by NRC when necessary. With respect to the criteria changes, only minimal increases in probability or consequences of accidents (still satisfying regulatory limits) would be allowed without prior NRC review. All changes to the Technical Specifications, which are the operating limits and other parameters of most immediate concern for public health and safety, will continue to require prior NRC review and approval. Changes to the facility that would involve an accident of a different type from any already analyzed, or reductions in defined margins of safety require prior approval. Further, changes which result in more than minimal increases in radiological consequences will continue to require prior NRC approval, including NRC consideration of potential impact on the environment. Therefore, the Commission concludes that there will be no significant impact on the environment from this proposed rule. This discussion constitutes the environmental assessment and finding of no significant impact for this proposed rule.

IX. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements. Existing requirements were approved by the Office of Management and Budget approval numbers 3150-0011 and 3150-0132.

The proposed rule changes would affect information collection requirements through the existing reporting requirements in § 50.59 for a summary report of changes, tests and experiments, performed under the authority of § 50.59 and in § 50.71(e) for submittal of updates to the FSAR, as well as record keeping requirements. To the extent that the definitions provided in the proposed revisions would require evaluations that are not presently being performed, there may be an increase in record keeping and reporting. The Commission estimates that this is a small increment over the existing burden. On the other hand, some changes might be screened out as not needing evaluation on the basis of these definitions, and thus there would overall be at most a small increase in the record keeping required.

In addition, the requirements under § 72.48 are also being revised to explicitly require records of determinations concerning occupational dose and environmental impact (the existing rules required the evaluations but did not explicitly specify record retention requirements for these evaluations). The Commission does not believe this that this change will significantly impact record keeping burden because records of evaluations of changes are already required (as to whether they involve a USQ), and the evaluation itself is already required by the rule. The part 72 burden associated with the definitions of when evaluations are required should be significantly less than for § 50.59 since the number of licensees is smaller and the expected number of changes is also smaller. Further, there is a recordkeeping requirement established for CoC holders who make changes to an approved storage cask design in accordance with § 72.48.

With respect to reporting requirements, the Commission is proposing to modify the FSAR update requirement to state that the updates must include specific information on the effects of changes made. This was not explicitly stated in the current rule, although it could be inferred that this was what the update rule intended, as follows. In the Statement of Considerations for § 50.71(e),(45 FR 30615), the NRC commented on the relationship between changes made under § 50.59 and FSAR updating, stating: "The § 50.59(b) reporting may not be detailed sufficiently to be considered adequate to fulfill the FSAR updating requirement. The degree of detail required for updating the FSAR will be generally greater than a 'brief description' and a 'summary of the safety evaluation'." Thus, the Commission clearly expected the update submittal to include sufficient information to appropriately reflect the changes that were made. The burden associated with explicitly documenting in the update the effects of the changes on event probabilities and consequences is therefore small.

The public reporting burden for this information collection request is estimated to average 3100 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The Commission estimates that there is only a slight increase in burden associated with these proposed changes over the existing burden. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the collection of information contained in the proposed rule and on the following issues:

1. Is the proposed collection of information necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of the burden correct?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the collection of information be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed collection of information, including suggestions for reducing the burden, to the Information and Records Management Branch (T–6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202, (3150–0017, –0020, –0011, –0009, and –01320), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the collections of information or on the above issues should be submitted by November 20, 1998. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

X. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the values and impacts of the alternatives considered by the Commission and includes the backfit analysis required by § 50.109 (and § 72.62). The alternatives considered in this analysis include no action, issuance of guidance only, or rulemaking. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC and is available through the NRC interactive rulemaking website. Single copies of the analysis may be obtained from Eileen McKenna, EMM@NRC.GOV (301) 415–2189, Mail stop O–11–F–1, U.S. Nuclear Regulatory Commission, Washington DC 20555.

The Commission requests public comment on the draft analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the **ADDRESSES** heading.

XI. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, (5 U.S.C. 605(b)), the Commission 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 and decommissioning of nuclear power plants, nonpower reactors, and independent spent fuel storage facilities. The companies that own these facilities 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.

XII. Backfit Analysis

As required by § 50.109 and § 72.62, the Commission has completed a backfit analysis for the proposed rule, which is included within the regulatory analysis. The Commission has determined, based on this analysis, that in most respects, the proposed rule does not impose new requirements, but provides more flexibility or clarification of existing requirements. In other respects, such as the definitions of change to the facility and "reduction of margin of safety* * *", some licensees may view the revised rule as imposing new requirements. Therefore, the Commission has prepared an analysis considering the factors in § 50.109(c), which is included in the Regulatory Analysis.

XIII. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act (AEA), the Commission is issuing the proposed rule to amend 10 CFR part 50 : 50.59,: 50.66, and : 50.71; and 10 CFR part 72: 72.48,: 72.70,: 72.212, and : 72.248, under one or more of sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

XIV. Compatibility of Agreement State Regulations

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the **Federal Register** (62 FR 46517, September 3, 1997), this rule is classified as compatibility Category "NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of Title 10 of the Code of Federal Regulations, and although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws, but does not confer regulatory authority on the State.

List of Subjects

10 CFR Part 50

Antitrust, Classified Information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and record keeping requirements.

10 CFR Part 52

Administrative practice and procedure, Antitrust, Backfitting, Combined license, Early site permit, Emergency planning, Fees, Inspection, Limited work authorization, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Reporting and record keeping requirements, Standard design, Standard design certification.

10 CFR Part 72

Manpower training programs, Nuclear materials, Occupational safety and health, Reporting and record keeping requirements, Security measures, Spent fuel

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR parts 50, 52 and 72.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for part 50 continues to read as follows:

Authority: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955 as amended (42 U.S.C. 2131, 2235), sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, and 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Section 50.37 also issued under E.O. 12829, 3 CFR 1993 Comp., P. 570; E.O. 12958, Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80—50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C 2237).

2. Section 50.59 is revised to read as follows:

§ 50.59 Changes, tests and experiments.

(a) Definitions for the purposes of this section:

(1) *Change* means a modification, addition or removal.

(2) *Facility as described in the final safety analysis report (as updated)* means:

(i) The systems, structures, and components that are described in the final safety analysis report (as updated),

(ii) The design, performance requirements and methods of operation for such systems, structures and components required to be included or described in the final safety analysis report (as updated), and

(iii) The evaluations or methods of evaluation required to be included in the FSAR (as updated) for such SSC and which demonstrate that their intended function(s) will be accomplished.

(3) *Final safety analysis report (as updated)* means the Final Safety Analysis Report (or Final Hazards Summary Report) submitted in accordance with § 50.34, as amended and supplemented, and as modified as a result of changes made pursuant to § 50.59 and § 50.90, and, as applicable, § 50.71 (e) and (f).

(4) *Procedures as described in the final safety analysis report (as updated)* means information in the final safety analysis report (as updated) regarding how structures, systems and components are operated and controlled (including assumed operator actions and response times) and information describing the conduct of operations.

(5) *Reduction in margin of safety associated with any technical specification* means that the input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the final safety analysis report (as updated), that established any technical specification requirement, are altered in a nonconservative manner.

(6) *Tests or experiments not described in the final safety analysis report (as updated)* means any condition where the reactor or any of its systems, structures or components are utilized or controlled in a manner which is either:

(i) Outside the controlling parameters of the design bases as described in the final safety analysis report (as updated) or

(ii) Inconsistent with the analyses in the final safety analysis report (as updated).

(b) Applicability. The provisions of this section apply to each holder of a license authorizing operation of a production or utilization facility, including the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required under § 50.82(a)(1) or a reactor licensee whose license has been permanently modified to allow possession but not operation of the facility.

(c)(1) A licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) without obtaining a license amendment pursuant to § 50.90 only if:

(i) A change to the technical specifications incorporated in the license is not required, and

(ii) The change, test or experiment does not meet any of the criteria in paragraph (c)(2) of this section. The provisions in this section do not apply to changes in procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(2) A licensee shall obtain an amendment to the license pursuant to § 50.90 prior to implementing a change, test or experiment if it would:

(i) Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to § 50.90 after the last final safety analysis report was updated pursuant to § 50.71 of this part;

(ii) Result in more than a minimal increase in the probability of occurrence of a malfunction of equipment important to safety previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to § 50.90 after the last final safety analysis report was updated pursuant to § 50.71 of this part;

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to § 50.90 after the last final safety analysis report was updated pursuant to § 50.71 of this part;

(iv) Result in more than a minimal increase in the consequences of a malfunction of equipment important to safety previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to § 50.90 after the last final safety analysis report was updated pursuant to § 50.71 of this part;

(v) Create a possibility for a design basis accident of a different type than any previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to § 50.90 with respect to design basis accidents after the last final safety analysis report was updated pursuant to § 50.71 of this part;

(vi) Create a possibility for a malfunction of equipment important to safety with a different result than any previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to § 50.90 after the last final safety analysis report was updated pursuant to § 50.71 of this part;

(vii) Result in a reduction in the margin of safety associated with any Technical Specification.

(d)(1) The licensee shall maintain records of changes in the facility and of changes in procedures made pursuant to this section, to the extent that these changes constitute changes in the facility as described in the final safety analysis report (as updated) or to the extent that they constitute changes in procedures as described in the final safety analysis report (as updated). The licensee shall also maintain records of tests and experiments carried out pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test, or experiment does not require a license amendment pursuant to paragraph (c)(2) of this section.

(2) The licensee shall submit, as specified in § 50.4, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. The report may be submitted annually or along with the FSAR updates as specified by § 50.71(e), or at such shorter intervals as may be specified in the license.

(3) The records of changes in the facility must be maintained until the termination of a license issued pursuant to this part or the termination of a license issued pursuant to 10 CFR part 54, whichever is later. Records of changes in procedures and records of tests and experiments must be maintained for a period of five years.

3. In § 50.66, paragraph (b), introductory text, paragraphs (b)(4), (c)(2), and (c)(3)(iii) are revised to read as follows:

§ 50.66 Requirements for thermal annealing of the reactor pressure vessel.

* * * * *

(b) *Thermal Annealing Report.* The Thermal Annealing Report must include: a Thermal Annealing Operating Plan; a Requalification Inspection and Test Program; a Fracture Toughness Recovery and Reembrittlement Trend Assurance Program; and Identification of Changes Requiring a License Amendment.

(1) * * *

(4) *Identification of changes requiring a license amendment.* Any changes to the facility as described in the final safety analysis report (as updated) which requires a license amendment pursuant to § 50.59(c)(2) of this part, and any changes to the technical specifications, which are necessary to either conduct the thermal annealing or to operate the nuclear power reactor following the annealing must be identified. The section shall demonstrate that the Commission's requirements continue to be complied with, and that there is reasonable assurance of adequate protection to the public health and safety following the changes.

(c) * * *

(2) If the thermal annealing was completed but the annealing was not performed in accordance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program, the licensee shall submit a summary of lack of compliance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program and a justification for subsequent operation to the Director, Office of Nuclear Reactor Regulation. Any changes to the facility as described in the final safety analysis report (as updated) which are attributable to the noncompliances and which require a license amendment pursuant to § 50.59(c)(2) and any changes to the technical specifications, shall also be identified.

(i) If no changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to Technical Specifications are identified, the licensee may restart its reactor after the requirements of paragraph (f)(2) of this section have been met.

(ii) If any changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to the Technical Specifications are identified, the licensee may not restart its reactor until approval is obtained from the Director, Office of Nuclear Reactor Regulation and the requirements of paragraph (f)(2) of this section have been met.

(3) * * *

(iii) If the partial annealing was not performed in accordance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program, the licensee shall submit a summary of lack of compliance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program and a justification for subsequent operation to the Director, Office of Nuclear Reactor Regulation. Any changes to the facility as described in the final safety analysis report (as updated) which are attributable to the noncompliances and which require a license amendment pursuant to § 50.59(c)(2) and any changes to the technical specifications which are required as a result of the noncompliances, shall also be identified.

(A) If no changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to technical specifications are identified, the licensee may restart its reactor after the requirements of paragraph (f)(2) of this section have been met.

(B) If any changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to technical specifications are identified, the licensee may not restart its reactor until approval is obtained from the Director, Office of Nuclear Reactor Regulation and the requirements of paragraph (f)(2) of this section have been met.

* * * * *

4. In § 50.71 paragraph (e) is revised to read as follows:

§ 50.71 Maintenance of records, making of reports.

* * * * *

(e) Each person licensed to operate a nuclear power reactor pursuant to the provisions of § 50.21 or § 50.22 of this part shall update periodically, as provided in paragraphs (e)(3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the operating license, to assure that the information included in the report contains the latest information developed. This submittal must contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submission of the original FSAR, or as appropriate the last update to the FSAR under this section. The submittal must include the effects[1] of:

(1) All changes made in the facility or procedures as described in the FSAR;

(2) All safety analyses and evaluations performed by the licensee either in support of requested license amendments, or in support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2) of this part;

(3) All analyses of new safety issues performed by or on behalf of the licensee at Commission request; and

(4) The net effect of all changes made since the last update on the safety analyses, including probabilities, consequences, calculated values, system or component performance, that are in the FSAR (as updated). The updated information shall be appropriately located within the update to the FSAR.

* * * * *

5. Section 50.90 is revised to read as follows:

§ 50.90 Application for Amendment of license or construction permit.

Whenever a holder of a license or construction permit desires to amend the license (including the Technical Specifications incorporated into the license) or permit, application for an amendment must be filed with the Commission, as specified in § 50.4, fully describing the changes desired, and following as far as applicable, the form prescribed for original applications.

[1] Effects of changes includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate."

PART 52—EARLY SITE PERMITS, STANDARD DESIGN CERTIFICATIONS; AND COMBINED LICENSES FOR NUCLEAR POWER PLANTS

6. The authority citation for part 52 continues to read as follows:

Authority: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2133, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5546).

7. Appendix A to Part 52 is amended by revising Section VIII.B, paragraphs 5.a,b,d, and Section X.A.3 as follows:

Appendix A—Design Certification Rule for the U.S. Advanced Boiling Water Reactor

VIII. Processes for Changes and Departures

* * * * *

B. Tier 2 information

5. * * *

a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the technical specifications, or otherwise requires a license amendment as defined in paragraphs B.5.b and B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would—

(1) Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the probability of occurrence of a malfunction of equipment important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of equipment important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for a design basis accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of equipment important to safety with a different result than any evaluated previously in the plant-specific DCD; or

(7) Result in a reduction in the margin of safety associated with any Technical Specification for an application or license referencing this design certification.

* * * * *

d. If a departure requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

* * * * *

X. Records and Reporting

A. Records.

* * * * *

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

8. Appendix B to part 52 is amended by revising Section VIII.B, paragraphs 5.a,b,d, and Section X.A.3 to read as follows:

Appendix B—Design Certification Rule for the System 80+ Design

VIII. Processes for Changes and Departures

* * * * *

B. Tier 2 information.

* * * * *

a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the technical specifications, or otherwise requires a license amendment as defined in paragraphs B.5.b and B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would—

(1) Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the probability of occurrence of a malfunction of equipment important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of equipment important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for a design basis accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of equipment important to safety with a different result than any evaluated previously in the plant-specific DCD; or

(7) Result in a reduction in the margin of safety associated with any Technical Specification for an application or license referencing this design certification.

* * * * *

d. If a departure requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

* * * * *

X. Records and Reporting

A. Records.

* * * * *

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE

9. The authority citation for part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); Secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

10. Section 72.3 is amended by revising the definition for *independent spent fuel storage installation or ISFSI* to read as follows:

§ 72.3 Definitions.

* * * * *

Independent spent fuel storage installation or ISFSI means a complex designed and constructed for the interim storage of spent nuclear fuel and other radioactive materials associated with spent fuel storage. An ISFSI which is located on the site of another facility licensed under this part or a facility licensed under part 50 of this chapter and which shares common utilities and services with such a facility or is physically connected with such other facility may still be considered independent.

* * * * *

11. In § 72.9, paragraph (b) is revised to read as follows:

§ 72.9 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 72.7, 72.11, 72.16, 72.19, 72.22 through 72.34, 72.42, 72.44, 72.48 through 72.56, 72.62, 72.70 through 72.82, 72.90, 72.92, 72.94, 72.98, 72.100, 72.102, 72.104, 72.108, 72.120, 72.126, 72.140 through 72.176, 72.180 through 72.186, 72.192, 72.206, 72.212, 72.216, 72.218, 72.230, 72.232, 72.234, 72.236, 72.240, 72.244, and 72.248.

12. In § 72.24, paragraph (a) is revised as follows:

§ 72.24 Contents of application: Technical information.

* * * * *

(a) A description and safety assessment of the site on which the ISFSI or MRS is to be located, with appropriate attention to the design bases for external events. Such assessment must contain an analysis and evaluation of the major structures, systems and components of the ISFSI or MRS that bear on the suitability of the site when the ISFSI or MRS is operated at its design capacity. If the proposed ISFSI or MRS is to be located on the site of a nuclear power plant or other licensed facility, the potential interactions between the ISFSI or MRS and such other facility—including shared common utilities and services—must be evaluated.

* * * * *

13. Section 72.48 is revised to read as follows:

§ 72.48 Changes, tests and experiments.

(a) *Definitions*—As used in this section:

(1) *Change* means a modification, addition or removal.

(2) *Final Safety Analysis Report (as updated)* means:

(i) For site-specific licensees, the Safety Analysis Report for a ISFSI, MRS or spent fuel storage cask, submitted in accordance with § 72.24, as modified as a result of changes made pursuant to § 72.48, and as updated in accordance with § 72.70;

(ii) For general licensees, the Safety Analysis Report for a ISFSI, MRS or spent fuel storage cask, as modified as a result of changes made pursuant to § 72.48, and as updated in accordance with § 72.216; and

(iii) For certificate holders, the Safety Analysis Report for an approved cask, modified by as a result of changes made pursuant to § 72.48 and as updated in accordance with § 72.248.

(3) The ISFSI, MRS, or spent fuel storage cask as described in the Final Safety Analysis Report (as updated) means:

(i) The systems, structures, and components that are described in the Final Safety Analysis Report as updated in accordance with §§ 72.70, 72.216 or § 72.248,

(ii) The design, performance requirements and methods of operation for such systems, structures, and components required to be included or described in the Final Safety Analysis Report (as updated), and

(iii) The evaluations for such systems, structures, and components required to be included in the Final Safety Analysis Report (as updated) and which demonstrate that their intended function(s) will be accomplished.

(4) *Procedures as described in the Final Safety Analysis Report (as updated)* means information in the Final Safety Analysis Report (as updated) regarding how structures, systems, and components are operated or controlled and information describing conduct of operations.

(5) *Reduction in margin of safety associated with any technical specification* means that the input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the Final Safety Analysis Report (as updated), that established any technical specification requirement, are altered in a nonconservative manner.

(6) *Tests or experiments not described in the Final Safety Analysis Report (as updated)* means any condition where the ISFSI, MRS or spent fuel storage cask or any of its systems, structures, or components are utilized or controlled in a manner which is either:

(i) Outside the controlling parameters of the design bases as described in the Final Safety Analysis Report (as updated) or

(ii) Inconsistent with the analyses in the Final Safety Analysis Report (as updated).

(b)(1) A licensee or certificate holder may make changes in the ISFSI, MRS, or spent fuel storage cask as described in the Final Safety Analysis Report (as updated), make changes in the procedures as described in the Final Safety Analysis Report (as updated), and conduct tests or experiments not described in the Final Safety Analysis Report (as updated), without obtaining either a license amendment pursuant to § 72.56 (for licensees), if a change in the conditions incorporated in the license is not required, and the change, test, or experiment does not meet any of the criteria in paragraph (b)(2) of this section or a Certificate of Compliance (CoC) amendment pursuant to § 72.244 (for certificate holders), if a change in the terms, conditions or specifications incorporated in the CoC is not required; and the change, test, or experiment does not meet any of the criteria in paragraph (b)(2) of this section. The provisions in this section do not apply to changes in procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(2) A licensee shall obtain a license amendment pursuant to § 72.56 and a certificate holder shall obtain a CoC amendment pursuant to § 72.244, prior to implementing a change, test, or experiment if it would:

(i) Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 72.56 or 72.244 after the last Final Safety Analysis Report was updated pursuant to §§ 72.70, 72.216 or § 72.248, of this part, as applicable;

(ii) Result in more than a minimal increase in the probability of occurrence of a malfunction of structures, systems, and components important to safety which were previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 72.56 or 72.244 after the last final safety analysis report was updated pursuant to §§ 72.70, 72.216 or § 72.248, of this part, as applicable;

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 72.56 or 72.244 after the last final safety analysis report was updated pursuant to section 72.70, 72.216 or § 72.248, of this part, as applicable;

(iv) Result in more than a minimal increase in the consequences of a

singular, not plural

malfunction of structures, systems, and components important to safety which were previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to § 72.56 or § 72.244 after the last final safety analysis report was updated pursuant to § 72.70, § 72.216, or § 72.248, of this part, as applicable;

(v) Create the possibility for a design basis accident of a different type than any evaluated previously in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 72.56 or § 72.244 with respect to design basis accidents after the last final safety analysis report was updated pursuant to § 72.70, § 72.216 or § 72.248, of this part, as applicable;

(vi) Create the possibility for a malfunction of structures, systems, and components important to safety with a different result than any evaluated previously in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 72.56 or § 72.244 after the last final safety analysis report was updated pursuant to § 72.70, § 72.216 or § 72.248, of this part, as applicable;

(vii) Result in a reduction in the margin of safety associated with any technical specification; (viii) Result in a significant increase in occupational exposure;

(ix) Result in a significant unreviewed environmental impact.

(c)(1) Each licensee or certificate holder shall maintain records of changes in the ISFSI, MRS, or spent fuel storage cask and of changes in procedures it has made pursuant to this section if these changes constitute changes in the ISFSI, MRS, or spent fuel storage cask or procedures described in the Final Safety Analysis Report (as updated). The licensee or certificate holder shall also maintain records of test and experiments carried out pursuant to paragraph (b) of this section. These records shall include a written evaluation that provides the bases for the determination that the change, test, or experiment does not require a license or CoC amendment pursuant to paragraph (b)(2) of this section. The records of changes in the ISFSI, MRS, or spent fuel storage cask and of changes in procedures and records of tests and experiments shall be maintained until spent nuclear fuel is no longer stored in the ISFSI, MRS or spent fuel storage cask, and the Commission terminates the license or CoC. For a holder of cask Certificate of Compliance who permanently ceases operation, any such records shall be provided to the new holder of cask Certificate of Compliance or to the Commission, as appropriate, in accordance with § 72.234(d)(3).

(2) Annually, or at such shorter interval as may be specified in the license or CoC, each holder of a license or cask Certificate of Compliance shall submit a report containing a brief description of changes, tests, and experiments made by the license or certificate holder under paragraph (b) of this section, including a summary of the evaluation of each. Licensee and certificate holders shall submit their reports in accordance with § 72.4. Any report submitted by a licensee or certificate holder pursuant to this paragraph will be made a part of the public record pertaining to the license or CoC.

14. Section 72.56 is revised to read as follows:

§ 72.56 Application for amendment of license.

Whenever a holder of a license desires to amend the license (including a change to the license conditions), an application for an amendment shall be filed with the Commission fully describing the changes desired and the reasons for such changes, and following as far as applicable the form prescribed for original applications.

15. In § 72.70, paragraphs (a), (b), introductory text, and (b)(2) are revised to read and a new paragraph (c) is added to read as follows:

§ 72.70 Safety analysis report updating.

(a) The design, description of planned operations, and other information submitted in the Safety Analysis Report for an ISFSI or MRS shall be updated by the licensee and submitted to the Commission at least once every six months after issuance of the license during final design and construction, until preoperational testing is completed, with a Final Safety Analysis Report (FSAR) completed and submitted to the Commission at least 90 days prior to the planned receipt of spent fuel or high-level radioactive waste. The FSAR shall include a final analysis and evaluation of the design and performance of structures, systems, and components that are important to safety taking into account any pertinent information developed since the submittal of the license application.

(b) After the first receipt of spent fuel or high-level radioactive waste for storage, the FSAR shall be updated annually and submitted to the Commission by the licensee. This submittal shall include the following:

* * * * *

(2) A description and analysis of changes in procedures or in structures, systems, and components of the ISFSI or MRS, as described in the FSAR (as updated), with emphasis upon:

* * * * *

(c) The licensee shall submit revisions of the FSAR to the Commission in accordance with § 72.4, on a replacement-page basis that is accompanied by a list which identifies the current pages of the FSAR following page replacement. Each replacement page shall include both a change indicator for the area changed (e.g., a bold line vertically drawn in the margin adjacent to the portion actually changed) and a page change identification (date of change or change number or both).

16. In § 72.86, paragraph (b) is revised to read as follows:

§ 72.86 Criminal penalties.

* * * * *

(b) The regulations in this part 72 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 72.1, 72.2, 72.3, 72.4, 72.5, 72.7, 72.8, 72.9, 72.16, 72.18, 72.20, 72.22, 72.24, 72.26, 72.28, 72.32, 72.34, 72.40, 72.46, 72.56, 72.58, 72.60, 72.62, 72.84, 72.86, 72.90, 72.96, 72.108, 72.120, 72.122, 72.124, 72.126, 72.128, 72.130, 72.182, 72.194, 72.200, 72.202, 72.204, 72.206, 72.210, 72.214, 72.220, 72.230, 72.238, 72.240, 72.244, and 72.246.

17. In § 72.212, paragraph (b)(4) is revised to read as follows:

§ 72.212 Conditions of general license issued under § 72.210.

* * * * *

(b) * * *

(4) Prior to use of this general license, determine whether activities related to storage of spent fuel under this general license involve a change in the facility Technical Specifications or require a license amendment for the facility pursuant to § 50.59(c)(2) of this chapter. Results of this determination must be documented in the evaluation made in paragraph (b)(2) of this section.

18. In § 72.216, new paragraph (d) is added to read as follows:

§ 72.216 Reports.

* * * * *

(d) The final safety analysis report (FSAR) for each approved cask used by the general licensee shall be updated annually and submitted to the Commission by the general licensee.

The submittal shall include the following:

(1) A description and analysis of changes in procedures or in structures, systems, and components of the spent fuel storage cask, as described in the FSAR (as updated), with emphasis upon:

(i) Performance requirements,

(ii) The bases, with technical justification therefor upon which such requirements have been established, and

(iii) Evaluations showing that safety functions will be accomplished.

(2) An analysis of the significance of any changes to codes, standards, regulations, or regulatory guides which the general licensee has committed to meeting the requirements of which are applicable to the design, construction or fabrication of the spent fuel storage cask.

(3) The general licensee shall submit revisions containing updated information to the Commission, in accordance with § 72.4, on a replacement-page basis that is accompanied by a list which identifies the current pages of the FSAR following page replacement. The general licensee shall also provide a copy of the submittal to the holder of the certificate for the cask. Each replacement page shall include both a change indicator for the area changed (e.g., a bold line vertically drawn in the margin adjacent to the portion actually changed) and a page change identification (date of change or change number or both). Each replacement page shall also indicate the cask FSAR, including the certificate holder's revision number, upon which the general licensee's update is based.

19. Section 72.244 is added to read as follows:

§ 72.244 Application for amendment of a certificate of compliance.

Whenever a certificate holder desires to amend the CoC (including a change to the terms, conditions or specifications of the CoC), an application for an amendment shall be filed with the Commission fully describing the changes desired and the reasons for such changes, and following as far as applicable the form prescribed for original applications.

20. Section 72.246 is added to read as follows:

§ 72.246 Issuance of amendment to a certificate of compliance.

In determining whether an amendment to a CoC will be issued to the applicant, the Commission will be guided by the considerations that govern the issuance of an initial CoC.

21. Section 72.248 is added to read as follows:

§ 72.248 Safety analysis report updating.

(a) The design, description of planned operations, and other information submitted in the Safety Analysis Report for a spent fuel storage cask shall be updated by the certificate holder and submitted to the Commission after the design of the spent fuel storage cask has been approved pursuant to § 72.238. This Final Safety Analysis Report (FSAR) shall be completed and submitted to the Commission within 90 days after approval of the cask design. The FSAR shall incorporate all changes and requirements contained in the CoC and the staff's safety evaluation report (SER) associated with approval of the cask's design.

(b) The FSAR shall be updated annually and submitted to the Commission by the certificate holder. This submittal shall include the following:

(1) A description and analysis of changes in procedures or in structures, systems, and components of the spent fuel storage cask, as described in the FSAR (as updated), with emphasis upon:

(i) Performance requirements,

(ii) The bases, with technical justification therefor upon which such requirements have been established, and

(iii) Evaluations showing that safety functions will be accomplished.

(2) An analysis of the significance of any changes to codes, standards, regulations or regulatory guides which the certificate holder has committed to meeting the requirements of which are applicable to the design, construction or fabrication of the spent fuel storage cask.

(c) The certificate holder shall submit revisions containing updated information to the Commission, in accordance with § 72.4, on a replacement-page basis that is accompanied by a list which identifies the current pages of the FSAR following page replacement. The certificate holder shall also provide a copy of the submittal to each general licensee using the spent fuel storage cask. Each replacement page shall include both a change indicator for the area changed (e.g., a bold line vertically drawn in the margin adjacent to the portion actually changed) and a page change identification (date of change or change number or both).

Dated at Rockville, Maryland, this 14th day of October, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 98–28066 Filed 10–20–98; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–269–AD]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model MD–90–30 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain McDonnell Douglas Model MD–90–30 series airplanes. This proposal would require modification of the right and left main landing gear (MLG) hydraulic damper assemblies or replacement of the MLG hydraulic damper assemblies with modified and reidentified hydraulic damper assemblies. This proposal is prompted by reports indicating that, during overhauls, the MLG hydraulic dampers assemblies failed or had damaged spring retainers due to insufficient material thickness of the spring retainers. The actions specified by the proposed AD are intended to prevent failure of the hydraulic damper assemblies of the MLG, which could result in vibration damage and collapse of the MLG.

DATES: Comments must be received by December 7, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–269–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from The Boeing Company, Douglas Products Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Dept. C1–L51 (2–60). This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California.

FirstEnergy

Perry Nuclear Power Plant
10 Center Road
Perry, Ohio 44081

Lew W. Myers
Vice President

440-280-5915
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USNRC

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December 17, 1998
PY-CEI/NRR-2341L

DOCKET NUMBER
PROPOSED RULE PR 50,52+72
(63FR56098)

United States Nuclear Regulatory Commission
Rulemakings and Adjudications Staff
Washington, D.C. 20555-0001

Comments on Proposed Rule, 10CFR50.59, "Changes, Tests, and Experiments"

Ladies and Gentlemen:

On October 21, 1998, the Nuclear Regulatory Commission (NRC) issued a proposed rule for public comment on "Changes, Tests, and Experiments" (Federal Register Notice, Volume 63, Number 203). The Perry Nuclear Power Plant (PNPP) staff has reviewed the proposed rule, and based upon this review is submitting comments regarding the proposed rule. The comments are contained in Attachment 1.

If you have questions or require additional information, please contact Mr. Henry L. Hegrat, Manager - Regulatory Affairs, at (440) 280-5606.

Very truly yours,

Lew W. Myers

Attachment

FirstEnergy 10 Center Road, Perry, Ohio 44081

Regulatory Affairs Section
Mail Zone A210

Acknowledged by card JAN - 4 1999

Comments Regarding Proposed Rule: Changes, Tests, and Experiments Federal Register, October 21, 1998, Volume 63, Number 203

1. II.G. "More than a Minimal Increase in Probability or Consequence"
   Subitem Entitled, "Consequences of Accident or Malfunction"

The Perry Nuclear Power Plant (PNPP) staff recommends the third option be selected. It will be easier to implement and control, especially in light of the Nuclear Regulatory Commission (NRC) concerns on "cumulative effects."

2. II.G. "More than a Minimal Increase in Probability or Consequence"
   Subitem Entitled, "Cumulative Effect"

The PNPP staff disagrees with the "additional" reporting requirements. In Item II.E, the NRC defined what is meant by the "Safety Analysis Report." The definition states, "... a licensee needs to consider changes already made for which the FSAR update has not yet been submitted to the NRC." The concept of cumulative changes is contrary to this definition. Changes will be made considering what changes were previously made. Since changes to the plant, procedures, and tests described in the FSAR require the performance of a 10CFR50.59 safety evaluation, the summary of the safety evaluation pursuant to 10CFR50.59(b)(2) will provide the NRC information regarding the changes' effects upon accident and equipment malfunction probabilities, consequences, etc. 10CFR50.71(e) requires changes made to the FSAR (updated) be periodically submitted to the NRC. The 10CFR50.71(e) submittal will contain the actual revised designs, analyses, etc. Therefore, additional reporting requirements is not necessary.

3. II.H. "Possibility of an Accident of a Different Type from any Previously Evaluated in the Safety Analysis Report may be Created"
   Subitem Entitled, "Need for Definition of Accident"

The options the NRC presents for defining the term "accident" are vague and subject to interpretation. These options are contrary to the use of the term "accident" in latter parts of the proposed rule, e.g., Option 3A1 and Option 3A2. However, in supporting their arguments, the NRC used the definition currently contained in 10CFR50.49. This definition would be acceptable. It is clear and concise with respect to the type of language already used within Regulatory Guide 1.70, the Standard Review Plan, and the PNPP Updated Safety Analysis Report. The definition would also be consistent with the contents of Nuclear Energy Institute (NEI) 96-07, "Guidelines for 10CFR50.59 Safety Evaluations."

4. II.J. "Margin of Safety as Defined in the Basis for any Technical Specification is Reduced"

Select Option 2. Since the proposed rule clarifies when a Technical Specification change is required, this question should not need to be addressed. Furthermore, the other six questions (e.g., probability of an accident, consequences of an accident) would more than adequately address any issue that could be associated with any type of margin not already contained within the Technical Specifications.

The selection of this option is consistent with Commissioner Diaz's counterpoint to the proposed rule.

5. II.L. "Reporting and Recordkeeping Requirements"

See comments under Item #2.

6. III. "10CFR50.71(e)"

NRC is discussing the proposed "cumulative effect" reporting. See comments under Item #2.

7. IX. "Paperwork Reduction Act Statement"

NRC stated that the additional reporting requirements would have minimal impact upon licensees. They state the requirements would add 3100 man-hours per response. When one considers that the NRC receives summaries of all safety evaluations, receives all FSAR changes, and given the industry will use FSAR changes as they become approved, the additional reporting requirements associated with the "cumulative effect" serve no useful purpose other than waste valuable NRC and industry resources.

YANKEE ATOMIC ELECTRIC COMPANY

Telephone (508) 779-6711
TWX 710-380-7619

580 Main Street, Bolton, Massachusetts 01740-1398

(32)

December 17, 1998
BYR 98-043

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

OFFICE ... RULEMAKINGS AND ADJUDICATIONS STAFF

'98 DEC 28 P1:34

DOCKETED
USNRC

The Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attention: Rulemakings and Adjudications Staff

Subject: Proposed Rule: Changes, Tests, and Experiments; 10 CFR Parts 50, 52, and 72 (63 Fed. Reg. 56098, October 21, 1998)

Yankee Atomic Electric Company would like to commend the NRC for its efforts to improve the regulatory process by issuing the proposed rule pertaining to "Changes, Tests, and Experiments; 10 CFR Parts 50, 52 and 72." Yankee Atomic Electric Company appreciates the opportunity to provide constructive input and, as a result, has enclosed comments concerning the authority for licensees to make changes to the facility or procedures, or to conduct experiments without prior NRC approval in response to the subject notice.

Should you have any questions regarding our comments, please do not hesitate to contact me at (978) 568-2767.

John M. Oddo

John M. Oddo
Manager, Regulatory Affairs

DY/

Enclosure

Acknowledged by card JAN - 4 1999

ENCLOSURE

Section	Comment
General	Historically, the six evaluation criteria of paragraph (a)(2) (i) and (a)(2) (ii) have been easy to understand, but frequently difficult to answer because of the literal translation of the phrases. To answer any question with a "YES" does not require a positive finding, but is invoked in the absence of a negative finding. Licensees are placed in the position of having to prove there cannot be an increase, even when there are no reasons to believe that the proposed change, test, or experiment would have that effect. Margin of safety, per paragraph (a)(2)(iii), has demonstrated to be both difficult to understand and answer. Inspection of the basis for a technical specification will seldom, if ever, reveal a definition of a margin of safety. As a result, changes to the existing rule for purposes of clarification and reduction of complexity are welcome. The proposed administrative changes to 50.59 (and 72.48) pertaining to definition of terms, and restructuring of text for clarification purposes will aid in reducing the various rule interpretations that have existed in the past. However, the number of options provided for in the proposed rule regarding evaluation criteria creates a wide range of variability in the final rule language. Therefore, the proposed rule should be renoticed in the federal register once the rule language has been narrowed following incorporation of initial stakeholder input.
II.A.(1)\2\	Consolidation of the applicability statements from three different paragraphs to one clearly labeled paragraph is appropriate as it supports the overall clarification effort associated with this proposed rule revision.
II.A.(3)	Replacing the term "Unreviewed Safety Question" (USQ) with a list of criteria which require prior Commission approval via license amendment should aid in clarifying the underlying purpose of the regulation. Focus would then be placed on the 50.59 evaluation determining how a change compares to the regulatory threshold of requiring prior NRC approval. In addition, revising the existing compound statements which delineate the evaluation criteria into separate distinct criteria will provide a format which is clear and typically in agreement with the way many utilities already have their evaluations procedurally formatted.
II.B	The rule should clearly indicate that "Changes to the facility as described in the SAR" does include additions to the facility. It's also important to state that changes subject to evaluation under 50.59 (or 72.48) are not limited to only physical changes since changes to acceptance standards, procedures or calculation methodologies can potentially affect the design bases.

ENCLOSURE

Section	Comment
II.C	The rule will be enhanced by clarifying that changes to programs such as quality assurance or emergency plans do not fall within the scope of 50.59 as they have their own change control processes included within the provisions of 50.54(a) and 50.54(q) respectively. The proposed new definition of procedures as described in the SAR (as updated) is more definitive than the current rule and appropriately emphasizes operator actions and response times, which can affect critical factors in the safety analysis. Delete the phrase "including assumed operator actions and response times," as it appears twice in the last sentence of the last paragraph.
II.D	The proposed clarifying definition regarding special tests or experiments does not deviate from Yankee's historical understanding of the term and is acceptable.
II.E	It is appropriate for the proposed rule to include a statement indicating the need for the licensee to review changes already made, for which the FSAR update has not yet been submitted. This ensures that the facility reference base review, in support of the 50.59 (or 72.48) evaluation, is based on the most up to date information available.
II.F	As indicated in industry guidance document NEI 96-07, the need to demonstrate a discernable change in order to require prior approval is provided by replacing "may be increased" with "would result in more than a minimal increase."
II.G	Criteria for determining when probabilities or consequences exceed a "minimal increase" are more understandable when the minimal thresholds are clearly codified as quantitative versus qualitative. For example, a change affecting the event frequency classification for DBAs in the licensee's SAR provides a clear minimum threshold for probability of occurrence of an accident. Regarding minimal increases in consequences, only the graduated approach seems to capture the spectrum of potential licensee scenarios while not impacting the basis for acceptability. This option provides the maximum flexibility by allowing for larger "minimal" changes when a licensee is far from an acceptance limit and smaller changes when the licensee has less radiological dose margin remaining.
II.H	Adding the phrase "design basis accident" to the three criteria referring to accidents adequately defines accident as those DBAs that are addressed in the SAR. Adding a lengthy definition to the term "accident" is unnecessary.
II.I	The revised text "if a possibility for a malfunction of equipment important to safety with a different result…..is created" is superior to the current rule text. Results based evaluation criteria maintain focus on whether the change evaluated is still bound by the analysis in the SAR.

ENCLOSURE

Section	Comment
II.J	The proposed rule provides several options on how to address the issue of "margin of safety". Of the various options provided, the most appropriate, and least burdensome, is to delete "margin of safety" as an evaluation criterion (option 2). There is no need for prior review of changes which do not satisfy the other evaluation criteria in a 50.59 (or 72.48) evaluation (i.e., the margin of safety criterion is redundant to the other evaluation criteria). Current rule language on margin of safety is defined and bounded by the technical specifications. As a result, if the licensee's proposed change, as evaluated per 50.59, does not exceed their technical specifications then the required margin of safety is maintained. This improvement will also simplify evaluations performed for changes that have little safety significance.
II.M	The possibility exists that in a given year there may be no facility changes impacting an ISFSI FSAR and thereby not requiring an evaluation under 72.48 (or 50.59). This is especially true at an ISFSI located at the site of a permanently shutdown nuclear power plant. In such a situation the site-specific ISFSI licensee should merely issue a submittal [similar to 50.71(e)(2)] indicating that site activities resulted in no changes to the FSAR. The proposed rule contains some discussion regarding dual purpose casks and changes impacting the storage cask as well as the transportation cask. Transportation casks, as governed under Part 71, have no regulatory equivalent to 72.48. This results in the need for NRC approval and amendment of the transportation Certificate of Compliance (CoC). The proposed rule text glosses over this burden by stating that licensee impact is minimized due to the 5 year renewal frequency associated with the transportation cask CoC and the need to amend the CoC prior to renewal. A clarification under Part 72, which would provide guidance to a certificate holder as to circumstances that would affect a transport certificate would be beneficial.

31

PSEG

DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63FR56098)

Public Service Electric and Gas Company P.O. Box 236 Hancocks Bridge, New Jersey 08038-0236

Nuclear Business Unit

DOCKETED
DEC 23 1998
RULEMAKINGS AND ADJUDICATIONS STAFF
SECY-NRC

DEC 21 1998
LR-N980595

Mr. John C. Hoyle
Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Attn: Rulemakings and Adjudication Staff

COMMENTS ON PROPOSED RULEMAKING TO 10CFR50.59, CHANGES, TESTS, AND EXPERIMENTS, 63 FED. REG. 56098 (OCTOBER 21, 1998)
SALEM AND HOPE CREEK GENERATING STATIONS
DOCKET NOS. 50-272, 50-311 AND 50-354

Dear Mr. Hoyle:

On October 21, 1998, the Nuclear Regulatory Commission (NRC) issued a proposed Rulemaking to 10CFR50.59, Changes, Tests, and Experiments for public comment. This letter submits PSE&G's comments regarding the proposed rulemaking. In addition to these specific comments, PSE&G supports the comments submitted by the Nuclear Energy Institute (NEI) in their letter dated December 21, 1998.

PSE&G's specific comments are as follows:

The proposed rulemaking adds several definitions. The definition of "Facility" in the Notice of Public Register (NOPR) includes those systems, structures, and components that are described in the FSAR. Many plants have systems, structures, and components described in the FSAR that are not related to nuclear safety. The definition in the NOPR notes that the systems, structures, and components in question are those required to be included or described in the FSAR. The use of "required to be included or described" is not sufficiently defined. PSE&G recommends the phrase "required to be included or described" be replaced with reference to the definition of Safety-Related Structures, Systems and Components contained in 10CFR 50.2.

Acknowledged by card DEC 31 1998

PSE&G concurs that the phrase "margin of safety" should be eliminated. The NEI recommendation to address design basis limits associated with the integrity of the fuel cladding, RCS pressure, or containment boundary is more appropriate. However, this change needs careful consideration to ensure proper understanding and implementation of new terminology.

The discussion in the Probability of Occurrence of an Accident contained within the NOPR provides guidance on what constitutes a small change. The NOPR states that this determination should be made at the component level or consistent with the failure modes and effects analyses, taking into account single failure assumptions, and the level of the change being made. PSE&G believes the determinations for the probability should be commensurate with the existing analyses without reference to the component level. PSE&G supports the NEI proposed description of a minimal increase in the Probability of Occurrence of an Accident which provides a better approach to this issue.

We appreciate the opportunity to comment on the proposed revision and request your careful consideration of the issues.

Sincerely,

David R. Powell

David R. Powell
Director –
Licensing/Regulation & Fuels

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Mr. S. Morris (X24)
USNRC Senior Resident Inspector - Salem

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Mr. K. Tosch, Manager IV,
Bureau of Nuclear Engineering
PO Box 415
Trenton, NJ 08625

U.S. Nuclear Regulatory Commission
Document Control Desk
Washington, DC 20555

December 22, 1998

NOTE TO: Emile Julian
Chief, Docketing and Services Branch

FROM: Carol Gallagher Carol Gallagher
ADM, DAS

SUBJECT: DOCKETING OF COMMENT ON PROPOSED RULE, "CHANGES, TESTS AND EXPERIMENTS (10 CFR PARTS 50, 52, 72)"

Attached for docketing is a comment letter related to the subject proposed rule. This comment was received via the rulemaking forum website on December 21, 1998. The submitter's name is David R. Powell, PSE&G, PO Box 236, Hancocks Bridge, NJ 08038. Please send a copy of the docketed comment to Eileen McKenna (mail stop O11-F-1) for her records.

Attachment:
As stated

cc w/o attachment:
E. McKenna

(30)

DOCKETED
USNRC

'98 DEC 23 P3:06

December 21, 1998
MN-98-76 GAZ-98-66

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Secretary, U.S. Nuclear Regulatory Commission

Washington, D.C. 20555-0001

DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63FR56098)

Reference: (a) License No. DPR-36 (Docket No. 50-309)

Attention: Rulemakings and Adjudications Staff

Subject: Maine Yankee comments on Notice of Proposed Rulemaking to Amend 10 CFR 50.59, 56098 Federal Register/Volume 63, No. 203/ Wednesday, October 21, 1998

Maine Yankee has reviewed the subject rulemaking and concurs with industry comments being submitted by the Nuclear Energy Institute.

Sincerely,

George A. Zinke, Director
Nuclear Safety & Regulatory Affairs Dept.
Maine Yankee Atomic Power Company
Bailey Point Road
Wiscasset, ME 04578

Acknowledged by card DEC 31 1998

U.S. NUCLEAR REGULATORY COMMISSION
RULEMAKINGS & ADJUDICATIONS STAFF
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OF THE COMMISSION

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December 22, 1998

NOTE TO: Emile Julian
Chief, Docketing and Services Branch

FROM: Carol Gallagher
ADM, DAS

Carol Gallagher

SUBJECT: DOCKETING OF COMMENT ON PROPOSED RULE, "CHANGES, TESTS AND EXPERIMENTS (10 CFR PARTS 50, 52, 72)"

Attached for docketing is a comment letter related to the subject proposed rule. This comment was received via the rulemaking forum website on December 21, 1998. The submitter's name is George Zinke, Maine Yankee Atomic Power Company, Bailey Point Road, Wiscasset, ME 04578. Please send a copy of the docketed comment to Eileen McKenna (mail stop O11-F-1) for her records.

Attachment:
As stated

cc w/o attachment:
E. McKenna

(29)

BNFL
Fuel Solutions Corporation

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December 21, 1998
BFS/NRC 98-026
Docket No. 72-1023
72-1007
File No. SNC-109

Secretary
US Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Attn: Rulemakings and Adjudications Staff

Subject: Proposed Amendment to 10 CFR Parts 50, 52, and 72, Changes, Tests and Experiments

Dear Sir,

In Federal Register dated October 21, 1998, a proposed amendment to 10 CFR Parts 50, 52, and 72 was published concerning the authority for licensees of production or utilization facilities, such as nuclear reactors, and independent spent fuel storage installations (ISFSIs), to make changes to the facility or procedures, or to conduct tests or experiments, without prior NRC approval. As part of the proposed changes to Part 72, the Commission also proposed to extend the change control process authority granted to ISFSI license holders (in §72.48) to the holders of NRC Certificates of Compliance (CoC) for a spent fuel storage cask. BFNL Fuel Solutions (BFS), which is doing business as Sierra Nuclear Corporation, holds the CoC for the Ventilated Storage Cask System (Model VSC-24), and has submitted an application for the TranStor™ Storage Cask System CoC. As such, BFS provides the following general comments below and provides more specific comments and recommendations relative to the Part 72 amendments, in the attachment to this letter.

GENERAL COMMENTS

In summary, BFS supports the intent of the proposed revisions to 10 CFR Part 72. The purpose is to clarify which changes, tests and experiments conducted at a licensed facility require evaluation, and the criteria that determine when NRC approval is needed before such changes to a licensed facility can be implemented.

BFS also finds that the proposed amendment improves the regulatory expectations for licensees and certificate holders, which should provide each the opportunity to enhance safety and regulatory performance.

Not proposing changes to Part 71 equivalent to those of §72.48 would impose a significant burden on vendors of dual-purpose cask designs. The §72.48 requirements can be used to screen minor Part 72 changes, while the same changes must be formally submitted as a Safety Analysis Report (SAR) amendment under Part 71.

If any questions exist relative to this submittal, please contact me at (831) 438-6444.

Sincerely,

E. D. Fuller
President & CEO

cc)

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Mr. Dan Ropson
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Russellville, AR 72801

ATTACHMENT

BFS respectfully provides the following specific comments to the proposed amendment to 10 CFR Part 72.

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§72.48(3)(ii) and §72.48(3)(iii) propose that the ISFSI or spent fuel storage cask as described in the Final Safety Analysis Report (as updated) means:

(ii) "The design, performance requirements and methods of operation for such systems, structures, and components required to be included or described in the Final Safety Analysis Report (as updated)," and

(iii) "The evaluations for such systems, structures, and components required to be included in the Final Safety Analysis Report (as updated) and which demonstrate that their intended function(s) will be accomplished."

Comment: The inclusion of the phrase "required to be included" in subparagraphs (ii) and (iii) potentially expands the scope of licensee controlled documents subject to the evaluation purview of §72.48 beyond the intended licensing basis as defined in the FSAR. "Required to be included" has a judgmental open-ended bound to it. Such a requirement would necessitate continual re-assessments of the appropriate content of the SAR with each §72.48 evaluation. Such reviews would be a non-productive use of resources and would delete the intended purpose of the §72.48 revision.

Recommendation: The phrase "required to be included" should be deleted from subparagraphs (ii) and (iii).

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§72.48(b)(2)(i), (ii), (iii), and (iv) propose that a licensee obtain a license amendment prior to implementing a change, test, or experiment if it would "result in more than a minimal increase" in the probability or consequences of specified detrimental occurrences.

Comment: The phrase "more than a minimal increase" is subjective. Unless specific guidelines are established, uniform and unambiguous application of the regulations will not be achieved. A minimal increase could be interpreted as no increase. Additionally, it is not practical to quantify individual changes in probability or consequences for all issues of the licensing basis.

Recommendation: Establish Regulatory Guidelines or a NUREG to provide some guidance or examples in this area.

§72.48(b)(2)(viii), and (ix) propose that a licensee obtain a license amendment prior to implementing a change, test, or experiment if it would "result in a significant increase in occupational exposure, or would "result in a significant unreviewed environmental impact."

Comment: The descriptor "significant" is subjective. Unless specific guidelines are established, uniform and unambiguous application of the regulations will not be achieved.

Additionally, the requirement to evaluate increases in occupational exposures and unreviewed environmental impacts for §72.48 detracts from the goal of consistency with the requirements of §50 59.

Recommendation: The phrase "more than minimal" should be used instead of significant, subject to the comments and recommendation of §72.48(b)(2)(i) above.

Delete the §72.48 requirement for the evaluation of increases in occupational exposures and unreviewed environmental impacts. Given that these requirements are not necessary for changes made under §50.59, they ought not be necessary for changes made to Part 72 facilities.

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§72.216(d) proposes that the final safety analysis report (FSAR) for each approved cask used by the general licensee be updated annually and submitted to the Commission.

Comment: The requirement for reactor SAR updates, as prescribed by §50.72(4), is no greater than 24 months. The updating frequency should be equivalent, if not longer than allowed for reactor SARs, given the lesser potential safety consequences for casks versus reactors.

Recommendation: Establish the SAR update requirement to be consistent with the reactor SAR timetable, i.e. a maximum of every 24 months.

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§72.248 (b) proposes that the FSAR be updated annually and submitted to the Commission by the certificate holder.

Comment: The requirement for reactor SAR updates, as prescribed by §50.72(4), is every 24 months. The updating frequency should be equivalent, if not longer than allowed for reactor SARs, given the lesser potential safety consequences for casks versus reactors.

Recommendation: Establish the SAR update requirement to be consistent with the reactor SAR timetable, i.e. a maximum of every 24 months.

Docket Number
Proposed Rule <u>50, 52 & 72</u>
(63FR56098)

CHANGES, TESTS, AND EXPERIMENTS

Please note:

Comment Number 28 is a duplicate of
Comment Number 23

(28)

1400 L Street, NW
Washington, DC 20005

December 21, 1998

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Re: Comments on *Changes, Tests, and Experiments*,
63 Federal Register 56,098 (October 21, 1998)

Dear Mr. Hoyle:

The Nuclear Utility Group on Equipment Qualification ("NUGEQ")[1] hereby submits the following comments on the Nuclear Regulatory Commission's ("NRC") proposed rule to revise the current provisions of 10 C.F.R. Part 50.59.[2] Overall, we conclude that the proposed rule is positive and responsive to concerns regarding the difficulties experienced with the current rule. Nevertheless, the proposal raises certain potential concerns for its application to equipment qualification programs and processes implemented pursuant to 10 C.F.R. § 50.49.

As background, we note that each licensee is required pursuant to 10 C.F.R § 50.49 to qualify certain equipment to perform its intended safety function in the event of a design basis event. Those requirements and applicable guidance establish explicit standards for qualification which include specific margins in testing and analysis (e.g. 10 C.F.R. § 50.49(e)(8)). In addition, the rule includes provisions for assuring qualification of replacement equipment (see 10 C.F.R. § 50.49(l)). Notably, while licensees are required to maintain qualification of equipment, the rule does not anticipate prior NRC approval of changes to qualification bases, although records of qualification are to be maintained in auditable form (10 C.F.R. § 50.49(j)).

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1 The NUGEQ is comprised of 35 electric utilities in the United States and Canada, including NRC licensees authorized to operate over 100 nuclear power reactors. The NUGEQ was formed in 1981 to address and monitor topics and issues related to equipment qualification, particularly with respect to the environmental qualification of electrical equipment pursuant to 10 C.F.R. 50.49.

2 "Changes, Tests, and Experiments," Proposed Rule 63 Fed. Reg. 56,098 (October 21, 1998).

In the terminology of the proposed rule, we submit that the maintenance of qualification in accordance with 10 C.F.R. § 50.49 assures that licensees maintain the "regulatory envelope" surrounding equipment qualification. In this light, we believe that many of the proposed changes to 10 C.F.R. § 50.59, if properly applied, will assure that unnecessary burdens and potential adverse impacts on plant operation do not occur in connection with the implementation of EQ programs. To assure such clarity of purpose and intent, we provide some comments below which, in effect, seek NRC Staff clarification or affirmation of intent with respect to the application of the proposed rule in the context of EQ.

"Margin of Safety":

It is not clear as to whether the proposed rule would broaden the scope of the "margin of safety" definition. We are concerned with the possibility that a broader definition might be applied such that all safety analysis "input" and "assumed" parameters which are "altered in the nonconservative direction" would be construed as "reductions" in margin of safety. Specifically, while we do not believe it is intended, we are concerned that this definition could potentially be applied inappropriately to equipment and qualification changes performed under the Equipment Qualification (EQ) program pursuant to 10 C.F.R. § 50.49.

For example, a licensee's safety analysis will assume that certain equipment must maintain operability during design basis events. As such, the equipment must be "qualified" to operate under the harsh environment created during accident conditions. In the context of equipment qualification, pursuant to 10 C.F.R. §50.49 equipment is qualified based on testing and/or analyses which take into account many different post-accident parameters such as temperature, humidity and radiation levels. This testing and/or analytical data will be compared to the assumed/analyzed plant accident profiles to determine whether the equipment is "qualified" to operate in the post-accident environment. Under the proposed rule, we are concerned with a potential interpretation that if the test profile for new equipment, including replacement equipment, is closer to the assumed/analyzed accident profile than the original equipment, one might mistakenly conclude that the "margin of safety" has been reduced. However, the underlying assumption for the EQ design bases is that the equipment will maintain its operability under the adverse post-accident conditions. By definition, the equipment maintains such operability if it is qualified pursuant to 10 C.F.R. § 50.49. Therefore, the underlying assumption for operability under accident conditions would be met and review under 10 C.F.R. 50.59 should not be warranted as a reduction in the margin of safety. Indeed, as the Commission indicates in the Statements of Consideration with respect to the "probability of equipment malfunction" criterion,

> The probability of malfunction of equipment important to safety . . . is no more than minimally increased if 'design bases' assumptions and requirements are still satisfied (i.e., . . . qualification specifications).[3]

Similarly we believe it should be noted that where specific qualification specifications continue to be met, the underlying design bases assumptions continue to be met and there would be no reduction in the margin of safety.

As a further example, a plant may alter its accident profile as a result of various plant modifications or reanalyses. These new accident profiles may move closer to existing test EQ profiles. Nonetheless, so long as EQ equipment remains qualified by nature of test and/or analytical information, in accordance with the requirements of 10 C.F.R. § 50.49, there is no impact to the overall level of plant safety and qualification margins built into the EQ rule itself. Indeed, in addition to the point above regarding assurance of qualification of replacement equipment without prior NRC review, the NRC has recognized that because of new information or analyses a licensee may need to reverify or conduct new analyses to assure the qualification of certain equipment, but such determination is up to the licensee, subject only to NRC audit not prior NRC review. *See* Generic Letter 91-18 "Information To Licensees Regarding Two NRC Inspection Manual Sections On Resolution OfDegraded And Nonconforming Conditions And On Operability." As such, we urge the Commission to recognize that revisions to individual equipment qualification bases, in accordance with the requirements of 10 C.F.R. § 50.49, should not be construed as a "reduction in the margin of safety" that requires prior NRC approval under 10 C.F.R. § 50.59.

Definition of "Change":

The proposed rule defines "change" as a "modification, addition, or removal."[4] A literal application of this definition could be construed as requiring a 50.59 evaluation for all replacements (both identical and non-identical) of qualified equipment. The NUGEQ believes that this is not the intent of the proposed rule.

Further, we are concerned that there may be some confusion as to whether replacement equipment would be considered as either an "addition" or "removal" that could be construed to be a "change" to the plant. (In addition, NUREG-1606 seemingly reinforces the position that non-identical replacements are "changes." In NUREG-1606, the NRC Staff had interpreted "change" to "include any modification or replacement of something . . . with

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[3] 63 Fed. Reg. at 56104.

[4] 63 Fed. Reg. at 56,120.

something that is not identical to the original in design requirements."[5]) The NUGEQ urges the Commission to clarify that equipment replacements, which are qualified under 10 C.F.R. § 50.49 do not alter the underlying design bases with respect to qualification and should not, therefore, be construed as "changes" to the underlying qualification design bases under 10 C.F.R. § 50.59.

In summary, the NUGEQ urges that the Commission clarify that whether dealing with equipment replacements, or otherwise modifying equipment qualification analyses, so long as the equipment installed in the plant is qualified in accordance with 10 C.F.R. § 50.49 there is no reduction in the margin of safety or change to the plant that requires prior NRC review of 10 C.F.R. § 50.49 qualification determinations. Absent such a determination, virtually innumerable instances of changes to equipment or qualification bases, all still demonstrating qualification under 10 C.F.R. § 50.49, could require prior NRC review. Any other result would have adverse safety and operational consequences by delaying the timeliness of plant assurances of qualification (e.g., delaying operability/qualification determinations) and likely resulting in unnecessary plant shutdowns while awaiting NRC review of changes to qualification bases, as well as discouraging the availability of alternative equipment which may have operational advantages over existing equipment.

We appreciate the opportunity to comment on this proposed rule.

Respectfully submitted,

Malcolm H. Philips, Jr.
William A. Horin

Counsel to the
Nuclear Utility Group on
Equipment Qualification

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5 NUREG-1606, "Proposed Regulatory Guidance Related to Implementation of 10 C.F.R. § 50.59 (Changes, Tests, or Experiments)" 7 (May 7, 1997). (Although not adopted by the proposed rule, we wish to obtain clarification as to the underlying intent of the proposed rule in light of the comments in NUREG-1606.)

December 23, 1998

NOTE TO: Emile Julian
Chief, Docketing and Services Branch

FROM: Carol Gallagher
ADM, DAS
Carol Gallagher

SUBJECT: DOCKETING OF COMMENT ON PROPOSED RULE, "CHANGES, TESTS AND EXPERIMENTS (10 CFR PARTS 50, 52, 72)"

Attached for docketing is a comment letter related to the subject proposed rule. This comment was received via the rulemaking forum website on December 22, 1998. The submitter's name is William A. Horin, 1400 L Street, N.W., Washington, DC 20005. Please send a copy of the docketed comment to Eileen McKenna (mail stop O11-F-1) for her records.

Attachment:
As stated

cc w/o attachment:
E. McKenna

(27)

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December 21, 1998

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTN: Rulemakings and Adjudication Staff

Re: Comments on Proposed Rule Concerning "Changes, Tests and Experiments"

Dear Sir:

Pursuant to the Commission's Federal Register Notice of October 21, 1998 (63 Fed. Reg. 56,098), we are pleased to submit these comments on the Nuclear Regulatory Commission's ("NRC") proposed rule concerning "Changes, Tests, and Experiments," or principally 10 C.F.R. § 50.59. These comments are being submitted on behalf of Shaw Pittman Potts & Trowbridge ("Shaw Pittman") as well as Boston Edison Company, Detroit Edison Company, FirstEnergy Corp., GPU Nuclear, Inc., Northern States Power Company, Vermont Yankee Nuclear Corporation, and Wisconsin Electric Power Company (referred to hereinafter as the "Utilities").

At the outset, we agree with many of the changes that the NRC is proposing. In particular, we strongly support the elimination of the phrase "may be increased" from various sections of the rule (which previously led the staff to view any uncertainty about the effect of a change on accident probability or consequences as an unreviewed safety question (USQ)); the proposal to allow instead changes with minimal increases in accident probability or consequences without NRC approval; and the proposal to replace "malfunctions of a different type" with "malfunctions with a different result" in the section 50.59 evaluation criteria. As a general matter, we agree with and endorse the comments submitted by the Nuclear Energy Institute. In addition, we offer the following recommendations.

A. <u>Eliminate the Link Between USQs and License Amendments</u>

The NRC should eliminate the link between changes determined to involve USQs and the need for license amendments. Under the current rule, if a proposed change involves a

USQ, the licensee must obtain NRC approval in the form of a license amendment before proceeding with the change. Instead of requiring this burdensome license amendment process, the NRC should simply require licensees to provide advance notice and justification to the NRC prior to implementing changes constituting USQs. If more control is needed, the rule might require the licensee to obtain the NRC's approval for a change in the event that, within thirty days after a submittal, the NRC staff determined the proposed change to be of safety significance warranting further NRC review and approval. In such cases, however, the approval should be granted by letter, similar to the approvals under 10 C.F.R. §§ 50.54(a)(3), (p)(2), (q), and 50.55a(a)(3).

There are a number of reasons for this recommendation. First, license amendments should be reserved for changes to the actual technical specifications or license conditions. The technical specifications establish those limits and conditions that are so directly related to safety that they must be controlled by the license. It follows that changes not affecting the technical specifications do not warrant the same degree of control.

Second, the current requirement to obtain approval of USQs through license amendments results in a considerable amount of paperwork and administrative effort to approve changes that often have little real safety significance. In this regard, the NRC staff is required to prepare multiple federal register notices, safety evaluation reports, and environmental assessments, and pass these documents through a number of layers of management and legal review. At a time when NRC staff efficiency and staffing levels are being questioned by Congress, the NRC should reconsider these procedures and adopt a less burdensome approach.

Finally, the NRC should recognize that the administrative burden, delay, and hearing risk associated with the current procedures creates a disincentive to characterize a change as a USQ and submit information concerning the change to the NRC staff. While licensees strive to make correct determinations, this disincentive may lead to unnecessarily complicated evaluations in an attempt to analyze a USQ away, or debatable engineering judgments in close cases. Eliminating the requirement for license amendments would eliminate these disincentives.

B. The Proposal to Allow Minimal Increases in Probability or Consequences Is Appropriate and Will Decrease Unnecessary Regulatory Burden

The NRC proposes to change the language of 10 C.F.R. § 50.59 to expressly allow "a minimal increase" in the probability of occurrence or consequences of an accident previously evaluated and the probability of occurrence or consequences of a malfunction of equipment important to safety previously evaluated, without requiring a license amendment. Utilities fully agree with the NRC's conclusion that such minimal increases should not require prior

NRC approval. As set forth in Utilities' comments on NUREG 1606,[1] prior NRC approval for such minimal changes was never the intent of 10 C.F.R. § 50.59 and could prove counterproductive to reactor safety by diverting licensee and staff resources from more important safety issues.

Thus, although Utilities do not believe that amending the rule is necessary to implement this long-standing interpretation and application of 10 C.F.R. § 50.59, as set forth in their comments on NUREG-1606, Utilities fully endorse the proposed rule to expressly allow such minimal increases without requiring prior NRC approval. Utilities do, however, believe that several clarifications and modifications should be made to the proposed rule to clarify and better define what is meant by minimal.

The Statement of Considerations sets forth proposed guidance for defining a "minimal" increase in probability of occurrence of an accident and an equipment malfunction. For both, the NRC quotes the current guidance in NEI-96-07 and states that the "Commission believes this satisfies the proposed NRC standard." 63 Fed. Reg. at 56,104. However, as noted in Commissioner McGaffigan's comments on the proposed rule, the Commission "in choosing its word 'minimal' . . . intended to grant greater flexibility than the NEI 96-07 'so small' or negligible standard." 63 Fed. Reg. at 56,116. The guidance in the final rule should expressly reflect Commissioner McGaffigan's comments, and expressly state that, although the current NEI guidance certainly satisfies the rule, the rule affords greater flexibility than that provided for by the current NEI guidance. As stated elsewhere in the Statement of Considerations, the proposed rule is intended to allow a "discernable increase," 63 Fed. Reg. at 56,104, which does reflect greater flexibility than the current NEI guidance.

Of course, the question is how to provide a quantitative definition of what constitutes a minimal increase. The NRC has proposed options for giving some quantitative meaning to "minimal increase" in the context of consequences, (discussed further below). Utilities urge the Commission to develop similar quantitative standards for "minimal increase" in the context of probability of occurrence of accidents and equipment malfunctions. In this regard, the NRC has proposed one semi-quantitative standard with respect to equipment malfunctions, which is that the probability of an equipment malfunction is "no more than minimally increased if 'design bases' assumptions and requirements are still satisfied." 63 Fed. Reg. at 56,104. Industry guidelines have long taken the position, however, that there is no increase in the probability not only of an equipment malfunction but also of an accident where design basis requirements and assumptions are still met. The NRC staff has

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[1] Letter from D. Lewis and P. Gaukler to D. Myer, "Comments on NUREG-1606 -- 'Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests and Experiments)'" dated July 7, 1997.

previously indicated its acceptance of this position in NUREG-1606 at 28. The NRC should adopt the same position under any amended rule.

Utilities urge more broadly, however, that consistent with the Commission's goal of shifting to more risk-informed regulation, the terms "minimal increase in the probability of occurrence of an accident" and "minimal increase in the consequences of an accident," in the proposed amendment to 10 C.F.R. § 50.59 (new sections (c)(2)(i) and (iii)), be defined in terms of the regulatory criteria for the accident in question. As a general matter, Utilities believe that the magnitude of a "minimal increase" should depend on a plant's current condition and should be larger where the plant is well below the regulatory threshold and smaller where the plant is closer to the threshold. Such would reflect the Commission's specific intent to allow changes small enough that they would not adversely affect plant safety performance and the Commission's general intent to eliminate unnecessary regulatory burdens on licensees.

Consistent with the foregoing, the Commission should promulgate quantitative definitions of "minimal" so that licensees may employ probabilistic risk assessment methods to show that a change has a minimal impact. (Such quantitative standards should clearly be identified as being in addition to – and not in lieu of – the current prevailing industry practice of using qualitative engineering assessments to make such judgments.) Such a quantitative approach would be consistent with the example of the "graduated approach" for consequences that the Commission included in the proposed rule (63 Fed. Reg. at 56,104-05). The Commission has determined the relevant probabilities, in the context of promulgating Regulatory Guide 1.174, for accidents leading to core damage or a large early release of radioactivity. Thus, the Commission could define as minimal those changes that have a very small impact on those probabilities, e.g., those that fell within Region III of its Acceptance Guidelines for Core Damage Frequency and Large Early Release Frequency (RG 1.174, Figures 3 and 4).[2] The Commission could also define as minimal those changes that have a somewhat greater impact on the probability of core damage and large early release, where a licensee could show that its plant's existing probabilities for those accidents were well below the Commission's thresholds.[3] Thus, such changes would fall within some portion of Region II of the Commission's Acceptance Guidelines.

The above approach does not take into account the impact of a change on the probability and consequences of potential lesser accidents. It should not be necessary, however, to consider these lesser accidents in the context of 10 C.F.R. § 50.59, for the public

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[2] Such a change would increase the probability of core damage by less than 10^{-6} per reactor year and the probability of large early release by less than 10^{-7} per reactor year.

[3] The Commission's threshold probabilities of core damage and large early release are 10^{-4} per reactor year and 10^{-5} per reactor year, respectively. See Regulatory Guide 1.174.

health and safety under the Atomic Energy Act will be protected regardless of the impact on these lesser accidents by requiring changes to the Core Damage Frequency and Large Early Release Fraction to be minimal, as described above. Moreover, current probabilistic risk assessments generally do not evaluate lesser accidents probabilistically. Accordingly, a requirement by the Commission to take into account under 10 C.F.R. § 50.59 the impact of a change on the probability and consequences of potential lesser accidents would limit the use of probabilistic methods for determining what constitutes a "minimal increase" under the proposed rule. Should the Commission determine, however, that it is necessary for licensees using probabilistic methods to demonstrate probabilistically the acceptability of minimal increases with respect to such lesser accidents, the Commission should develop and set threshold probabilities for them to enable the use of probabilistic methods for determining minimal increases under the proposed rule.[4]

In addition, consistent with the above, Utilities urge the Commission to eliminate the requirement that licensees independently assess the impact of a change in the facility on the probability and consequences of a malfunction of equipment important to safety in those circumstances where a licensee has incorporated the possibility of equipment malfunction in a probabilistic assessment of the probability and consequences of the accidents that the malfunction would affect. In such circumstances, there is no need, from the perspective of plant safety, to require a separate showing that a change has a minimal impact on the probability or consequences of malfunction. Accidents are the relevant safety concern. Demonstrating by probabilistic methods that a change has a minimal impact on accident probability and consequences <u>necessarily</u> assesses as well, and shows the minimal impact of, the change on potential equipment malfunctions that could in turn affect the probability and consequences of accidents. Therefore, in such circumstances the requirement that the licensee make separate demonstrations with respect to the effect of a change on the probability and consequences of equipment malfunction would be redundant and unnecessary.

The above risk informed approaches would encompass both the probability of occurrence and consequences of an accident in the same evaluation. Therefore, it would be unnecessary, where such risk informed approaches were used, to utilize the quantitative standards proposed by the Commission for determining whether an increase in consequences is minimal. However, the Commission should nevertheless definitely adopt such a standard, particularly given the current industry practice of utilizing qualitative engineering assessments for 10 C.F.R. § 50.59 evaluations. Moreover, even as probabilistic risk

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[4] One such an approach has been proposed by ACRS member Dr. George Apostolakis in a July 16, 1998 letter from the ACRS to Chairman Jackson. Dr. Apostolakis advocates developing metrics, or quantitative indices, for the consequences of lesser accidents, defining probability-consequence curves for them (which would quantify acceptable risk), and then determining what would constitute a "minimal" impact on those curves.

informed approaches become more widely used, there will still be circumstances where the use of risk informed approaches may not be possible or cost effective.

Accordingly, Utilities strongly urge the Commission to adopt a quantitative standard for defining a minimal increase in consequences. Such a standard should, however, acknowledge and recognize the long standing interpretation and implementation of 10 C.F.R. § 50.59, by both the NRC staff and the industry, that changes in consequences within acceptance limits established in a facility's SER do not involve an increase in accident consequences (discussed in the following section). In such circumstances, any quantitative standard should apply only to changes between the acceptance limit established in the SER and the regulatory limit. Where no acceptance limit is established in the SER, the quantitative standard would apply to changes between current conditions and the regulatory limit.

Of the three approaches suggested by the Commission in the proposed rule, the second approach would generally allow larger changes in the consequences to be considered minimal. We believe, however, that the third approach proposed by the NRC -- "defining 'minimal' as being [a percentage or fraction] of the remaining margin" (63 Fed. Reg. at 56,105) -- is simpler in concept and implementation and therefore generally the preferable approach. However, Utilities believe that the percentage or fraction that should be allowed as being minimal should be up to 20% of the remaining margin instead of the 10% proposed by the NRC. An allowance of 20% would still constitute a small fraction of the remaining margin while allowing licensees greater flexibility to make changes without the burden on NRC and utility resources of having to go through the license amendment process.

Further, the remaining margin should not be the difference "between current conditions and acceptable guidelines" as suggested by the NRC. Rather, the remaining margin should be defined as the difference between current conditions and the applicable regulatory limit except where the current conditions fall within an acceptance limit established in the SER. In such circumstances, any changes in consequences up to the acceptance limit provided for by the SER should not be considered a change subject to 10 C.F.R. § 50.59 as discussed below. Changes beyond this point would be subject to 10 C.F.R. § 50.59 and should be considered minimal if limited to less than 20% of the remaining margin between the acceptance limit (or current conditions if greater) and the applicable regulatory limit.

C. The NRC Should Recognize NRC Acceptance Limits <u>For Evaluations Considering Increases In Accident Consequences</u>

Proposed sections 50.59(c)(2)(iii) and (iv) require NRC approval if a proposed change results in more than a minimal increase in the consequences of an accident or malfunction evaluated either in the FSAR or certain other licensee evaluations. This language fails to recognize the effect of acceptance limits established in the safety evaluation report for a facility. Where an SER establishes specific acceptance limits and a proposed change does not affect those limits, the change should not be considered to involve an increase in accident consequences.

The effect of acceptance limits established in an NRC's SER was previously recognized by the NRC staff and applied by licensees for many years. A May 10, 1989 letter from C. Rossi to T. Tipton (NEI), providing NRC comments on the final draft of NSAC-125, stated:

> [I]f in licensing the plant the staff explicitly found that the plant's response to a particular event was acceptable because the dose was less than the SRP guidelines (without further qualification) then the staff implicitly accepted the SRP guideline as the licensing basis for the plant and the particular event, and the licensee may make changes that increase the consequences for the particular event, up to this value, without NRC approval. However, if the staff cited some value other than the SRP guideline in its SER as its criteria for licensing the plant then that value is considered the licensing basis for the plant.

Id., Encl. 1 at 3. In NUREG-1606, the NRC staff determined that a literal reading of the rule no longer permitted this position, because the rule referred only to increases in consequences of an accident evaluated in the SAR. NUREG-1606 at 30.

The NRC should restore the previously accepted interpretation, and recognize the effect of acceptance limits established in a facility's SER, by adding "unless within acceptance limits established in an NRC safety evaluation report for the facility" at the end of proposed sections 50.59(c)(2)(iii) and (iv).

D. Comments on Reduction of Margin

The Statement of Considerations to the proposed rule sets forth three options for modifying the third criterion for a USQ. The first option would redefine reduction in margin to be any circumstance where "the input assumptions, analytical methods, acceptance conditions, criteria and limits of safety analyses" presented in the SAR establishing any technical specification "are altered in a non-conservative manner." 63 Fed. Reg. at 56,107.

Such an approach would greatly expand the requirements for prior NRC review and approval through license amendments "to underlying aspects (e.g., input assumptions) of parameters that affected the selection of the technical specifications and result in the newly controlled parameters being treated essentially the same way as values in the technical specifications." 63 Fed. Reg. at 56,116 (Commissioner McGaffigan's Comments on SECY-98-171). As Commissioner McGaffigan goes on to state, "[t]his [option] is the wrong way to go." It would greatly increase the burden of 10 C.F.R. § 50.59 with no clear safety benefit and prove counterproductive to reactor safety by diverting scarce licensee and staff resources from more important safety issues. Accordingly, Utilities strongly oppose this option.

The second option set forth in the proposed rule is to delete this criterion in its entirety.[5] Such an approach is suggested by Commissioner Diaz in his comments on SECY-98-171. As noted by Commissioner Diaz, "as long as the licensee proposed change, test, or experiment under § 50.59 is not in violation of the technical specification requirements, the requisite margin of safety is maintained, and it is possible to eliminate 'reduction of margin of safety' from the rule as a condition requiring prior staff approval." 63 Fed. Reg. 56,116. As Commissioner Diaz observed, this alternative "is consistent with the safety envelope provided by the technical specifications and is a straightforward improvement that will match with the eventual conversion to a risk-informed rule." Id.

Utilities agree with the logical clarity of Commissioner Diaz's analysis, particularly once risk informed approaches are in place and commonly utilized. In such circumstances, any unacceptable reduction of margin in safety would be captured in more than minimal increases to the probabilities and consequences of accidents, discussed above. The industry has generally determined, however, as reflected in NEI's comments on the proposed rule, that there is in the meantime a need to retain the reduction in margin criterion in limited respects concerning calculated design basis limits associated with the integrity of fission product barriers -- i.e., the fuel cladding, RCS pressure boundary and containment boundary. Accordingly, NEI proposes that the scope of the reduction in margin criterion be limited to these design bases limits.

NEI's proposed approach would greatly reduce the scope of the reviews currently under reduction in margin of safety criterion. Accordingly, Utilities strongly support the limitation of this criterion to fission products barriers as proposed by NEI.

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[5] As an alternative to the second option, it would be reasonable to interpret "margin of safety as defined in the basis for any technical specification" literally, as applying only to those margins that are explicitly set forth in the "Bases" section of a licensee's Technical Specifications. As discussed in our July 7, 1997 comments on NUREG-1606, this approach would restore the original intent of the rule. It would inject certainty into the evaluations, because each licensee would know exactly what to look at to determine the "margin" requiring preservation. As stated by the Commission when it proposed adding the "Bases" section to the technical specifications, one of the reasons for the Bases section was to "present a sound basis for analysis and assessment of changes." Report by the Director of Regulation, "Proposed Amendment to 10 CFR 50: Technical Specifications; Technical Information Required of Applicants," AEC-R 2/50 at 8 (June 30, 1966).

E. Incredible Accidents Should Not Be Considered In the Evaluations

Proposed section 50.59(c)(2)(v) requires evaluation of changes that create the possibility of "design basis" accident of a different type than any previously evaluated. We agree with reference to design basis accidents (as opposed to just "accidents" as in the current rule), because the term denotes only those accidents that are considered credible. Evaluations should not be required to consider the possibility of accidents that could only occur as a result of multiple failures (such as the failure of a single-failure proof crane) or are so unlikely as to be outside the realm of reasonable engineering judgment. This approach is consistent with the NRC staff's position in NUREG-1606, at 28, and should be reflected in the supplementary information published with any final rule.

F. Comments on Definitions as to Scope of 50.59.

1. Definition of "Facility as described in the final safety analysis report"

The new definition of "facility as described in the final safety analysis report" raises several concerns and should be changed. First, proposed section 50.59(a)(2)(i) would define the "facility as described in the final safety analysis report" to include "systems, structures and components that are described in the final safety analysis report." This wording appears to expand the rule considerably. Read literally, it would require an evaluation of any change to a system, structure or component (SSC) that is described in the FSAR, even if the FSAR description is unaffected. Consequently, the proposed definition appears to eliminate a licensee's ability to screen out changes that do not affect the FSAR description, and thus to require many more full blown evaluations. To avoid this undesirable and burdensome result, the proposed definition should be changed so that "facility as described in the final safety analysis report" includes only "those aspects of systems, structures and component as are explicitly described in the final safety analysis report."

Similarly, proposed section 50.59(a)(2)(ii) would define "facility as described in the final safety analysis report" to include "the design, performance requirements and methods of operation for such systems, structures or components required to be included or described in the final safety analysis report." If the phrase "described in the final safety analysis report" modifies "systems, structures and components" (which would be the correct grammatical construction), this proposed definition could be interpreted literally as requiring an evaluation of any aspect of the design, performance or operation of an SSC in the FSAR, even though no aspect of the FSAR description is affected. Again, this would prevent licensees from screening out changes that do not affect the FSAR description.

The phrase "required to be included" in proposed sections 50.59(a)(2)(ii) and (iii) also injects substantial uncertainty into the regulation. A licensee performing evaluations under 50.59 should not be required to perform additional research to determine whether additional information should have been included in its FSAR, particularly given the differences in FSAR content between older and newer plants. This proposed provision could also lead to frequent disputes concerning what is "required" to be in the FSAR. While there may be issues concerning the completeness of an FSAR, those issues should be addressed through enforcement of 10 C.F.R. 50.71(e), and not through new provisions in section 50.59.

2. Definition of "Procedures as described in the final safety analysis report"

The NRC's proposed definition of procedures includes information in the SAR "describing the conduct of operations." Utilities urge the Commission to delete this requirement because information concerning the conduct of operations found in the SAR is generally managerial and administrative information not suited to evaluation under 10 C.F.R. § 50.59. Moreover, such information is generally governed by administrative procedures which are typically controlled by licensee QA programs.

3. Definition of "Tests or Experiments not described in the final safety analysis report"

Proposed section 50.59(a)(6) defines tests or experiments not described in the FSAR as any condition where the plant is outside its design bases or inconsistent with the FSAR. This proposed definition greatly expands the commonly understood meaning of a "test and experiment," so that the phrase covers any operational activity or evolution that is inconsistent with the FSAR. Its effect would be to make virtually any operational error a prohibited "test or experiment." To avoid this over-breadth, the definition should remain limited to actual tests and experiments.

4. The NRC's concept of "Single Changes" is too narrow

In the supplementary information, the NRC proposes to endorse the staff's position in NUREG-1606 about what constitutes a single "change" that must be evaluated without considering offsetting effects from other changes. The staff's position is that only "interdependent changes" (i.e., situations where one change requires another for performance or function) may be evaluated collectively. See 63 Fed. Reg. at 56,102; NUREG-1606 at 38.

We believe that the NRC's staff's position is unduly narrow. For example, under this guidance, if a licensee proposed a series of modifications as part of an upgrade project and the project as a whole clearly decreased the probability or consequences of accidents, the project would still be considered a USQ requiring NRC approval under the NRC's position if any element of the project, viewed in isolation, caused more than a minimal increase in the probability or consequences of an accident. This position could therefore act as a considerable impediment to complex upgrade or performance improvement projects. As a practical matter, the industry is mature enough and licensees are sophisticated enough to plan complex modifications that maintain the licensing basis and plant safety without the need for multiple NRC approvals.

We therefore recommend that the NRC adopt the following alternative position on single changes:

> Multiple changes to the facility or its procedures may be evaluated collectively (i.e., may be considered elements of a single change for purposes of review under section 50.59) if they are interrelated. Changes are considered interrelated if (1) they are interdependent, as in the case where a modification to a system or component necessitates additional changes to other systems and components (or procedures) in order for the modified system to perform its function or comply with its design or licensing basis; (2) they are proposed collectively to address a design or operational issue, such as the correction of a degraded or nonconforming condition; or (3) they are otherwise planned as elements of a single project undertaken to restore, maintain or improve plant performance or safety.

CONCLUSION

The Utilities and Shaw Pittman appreciate this opportunity to provide these comments on the proposed changes to 10 C.F.R. § 50.59. The proposed rule takes significant steps, as noted, towards eliminating unnecessary NRC review of proposed changes of little or no potential safety significance. The NRC's adoption of the recommendations made in these comments will constitute further major steps towards this common goal of the Commission and its licensees.

Sincerely,

Paul Gaukler

David R. Lewis
Paul A. Gaukler

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Detroit Edison

DOCKET NUMBER
PROPOSED RULE PR 50, 52 & 72
(63FR56098)

December 21, 1998
NRC-98-0154

Mr. John C. Hoyle
Secretary of the Commission
U. S. Nuclear Regulatory Commission
Attention: Rulemakings and Adjudication Staff
Washington D C 20555-0001

References: 1) Fermi 2
NRC Docket No. 50-341
NRC License No. NPF-43

2) Federal Register, Volume 63, Number 203
"Proposed Rulemaking to 10 CFR 50.59, "Changes, Tests and Experiments," dated October 21, 1998

Subject: Detroit Edison Comments on Proposed Rulemaking to 10 CFR 50.59

Detroit Edison offers the following comments on the proposed rulemaking in Reference 2. We fully agree with and support many of the changes being proposed to 10 CFR 50.59.

Detroit Edison fully supports the comments being submitted on this proposed rule by the Nuclear Energy Institute (NEI). Detroit Edison has been involved in the development of these comments through participation in the industry workshop in October 1998 and the 10 CFR 50.59 Task Force. We also participated in the formulation of comments submitted by the Nuclear Utility Backfitting and Reform Group (NUBARG) and the law firm of Shaw Pittman, Potts & Trowbridge. Rather

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than reiterating these positions in this letter, we are limiting our comments to the two issues discussed below. Specifically, we have additional comments on the "Margin of Safety" options and the definition of "Accidents," contained in Reference 2.

The thrust of our comments is to develop rule language that will meet both the industry and NRC objectives and at the same time minimize the expenditure of resources in performing and documenting reviews which do not have any substantial impact on the health and safety of the public. We believe that these comments are consistent with the comments submitted by NEI and feel confident that they can be resolved in the industry guidance document, NEI 96-07.

With regard to the "Margin of Safety" options, Detroit Edison fully supports the NEI position that any form of the criterion should focus solely on the integrity of the fission product barriers rather than all Technical Specifications. Furthermore, we agree that any changes to the other six criteria should be limited to those discussed in the proposed rule and comments (i.e., we do not favor modification of these criteria to compensate for modification or elimination of the "Margin of Safety" criterion).

Detroit Edison's position is that further consideration should be given to a form of Option 2; the Deletion of the Margin of Safety Criterion. As stated above, we do not feel this to be inconsistent with the industry proposal presented by NEI. The final form of the rule, for example, might recognize the seventh criteria as proposed by NEI, but it should also be clear that for specific licensees or types of plants this criteria may in fact be totally unnecessary as suggested by Option 2 proposed by the Commission. We acknowledge that, as stated by NEI, there may be some cases where outright elimination of the criteria could "create gaps" in comparison to the area currently covered by 10 CFR 50.59. It is possible, however, that for some plants like Fermi 2 or possibly Boiling Water Reactors (BWRs) as a class of plants it could be shown by Detroit Edison or the Owners Group that the existing six criteria, Technical Specifications and regulations are adequate without the margin of safety (or equivalent) criteria. We strongly recommend that the final rule not preclude this option and leave the flexibility for further development of this approach in NEI 96-07, the detailed guidance for implementing the rule.

With regard to the definition of "Accidents," Detroit Edison notes that NEI has proposed a definition that is consistent with industry practice in NEI 96-07 and its predecessor document, NSAC-125. We concur with this definition compared to the one proposed by the NRC, but believe that it should be resolved in the guidance documents and not included directly in the rule. We are in agreement that the safety evaluations performed as required by 10 CFR 50.59 should apply to the entire licensing basis envelope including events, new regulations, operational transients, etc., that are included in the SAR We are concerned, however, that the application of a single definition to all criteria including the term "accidents" would still be confusing and may result in an unnecessarily high number of changes necessitating referral to the Commission for approval. For example, we do not believe there is any value in requiring that a proposed change be analyzed to determine if it affects the probability of a non-limiting operational transient that may be included in Chapter 15 of the UFSAR.

Should you have any questions or require additional information, please contact me at (734) 586-4258.

Sincerely,

Norman K. Peterson
Director - Nuclear Licensing

cc: A. J. Kugler
A. Vegel
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December 21, 1998
MFN-053-98

Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63FR56098)

Attention: Docketing and Service Branch

Subject: Comments on Proposed Rulemaking to Amend 10 CFR 50.59

On October 21, 1998, the NRC published a Notice of Proposed Rulemaking to 10 CFR 50.59, Changes, Tests, and Experiments (63 Fed. Reg. 56098 - October 21, 1998). The following comments are being provided by GE Nuclear Energy (GE).

Over the years, Section 50.59 has served the industry well and resulted in industry's ability to make changes having no significant impact on safety without the need for prior NRC approval. However, more recently, stringent interpretations by the staff have contributed to an increased number of enforcement actions and have narrowed the types of changes that licensees can make. This, in turn, has resulted in an increased number of license amendment requests, requiring additional resource allocations to resolve matters that do not have a significant impact on safety.

GE believes that many of the rule changes proposed would restore the Section 50.59 process to its former usefulness and would provide a step toward a more risk-informed approach to regulation of plant changes. As such, GE supports the intent of the proposed changes to Section 50.59. However, in some cases, we have concerns with regard to the language of the proposed rule changes and see the need to offer specific comments thereon. In this regard, GE Nuclear Energy strongly endorses the positions advocated in Nuclear Energy Institute's (NEI) formal submittal dated December 21, 1998, transmitting its comments on NRC's proposed rule to amend Section 50.59.

GE would further emphasize three (3) specific areas: 1) NRC's proposed definition of an accident, 2) the proposed definition of "margin of safety", and 3) the NRC's intent to revise regulations governing the change process for other types of facilities, including the design certification rule for the ABWR.

As regards the first, GE agrees with NEI that the NRC's proposed definition of an accident should be replaced. The event categories defined in Regulatory Guide (RG) 1.70 provide a well-defined use of the terms "Accident" and "Anticipated Operational Occurrences ". The proposed regulation should utilize the same definitions, rather than apply the term accident to essentially all unplanned occurrences. For purposes of 10CFR50.59 evaluation, assessment of potential impact of proposed plant changes with respect to anticipated operational occurrences should be focused on the potential impact on margin of safety (defined appropriately). This path will avoid an unnecessary increase in the number of utility license amendment requests of evaluations that currently do not require prior NRC review. Additional discussion concerning this comment is provided in Attachment 1.

Regarding margin of safety, GE does not agree with the definitions or the options provided at FR 56106 to 9. NEI's Enclosure dealing with margin of safety methodology is more consistent with GE's position. Adequacy of the margin of safety remaining after a plant change should be primarily evaluated with respect to the applicable Safety Limit(s). This evaluation should **not** be with respect to plant changes which may change design or operating margin, but do not impact the plant so that performance fails to remain in compliance with the required licensing criteria. The following definition is recommended: "The margin of safety" (in the basis for any Technical Specification) is the difference between the assumed, analyzed or design basis failure point (as available) and the item's Licensed Acceptance Limit (if specified) or the FSAR acceptance criteria (if specified)." The resulting 50.59 evaluations should continue to preserve the primary concept that the margin of safety is ensured by compliance with the licensing criteria, whether or not there is "extra" margin built into the design to allow for operational flexibility. Attachment 1 provides additional discussion of margin of safety and how it should be used in the 50.59 evaluations.

Attachment 2 provides specific suggested changes to the regulation pertaining to these areas.

Finally, in preparing the rulemaking package, the NRC explicitly considered whether the regulations governing the change process for other types of facilities, including the design certification rule for the ABWR, should be modified to be consistent with the proposed changes to Section 50.59. The proposed rule would revise the ABWR design certification rule to make it consistent with the proposed revisions to Section 50.59. Of interest, not all of the relevant revisions to Section 50.59 are included in the proposed revision to the ABWR design certification rule. For example, NRC is proposing to add a subsection of definitions to Section 50.59 but not to the corresponding sections in the design certification rules. It appears that the exclusion of these definitions from the proposed revision of the ABWR design certification rule is an oversight, rather than an intentional omission. It is our position that the substantive provisions that are in the proposed revisions to Section 50.59, but not in the proposed revision to the ABWR design certification rule, be incorporated directly or by reference into the design certification rules.

We would be pleased to discuss with you any questions you may have with regard to these comments.

Sincerely,

JF Quirk

J. F. Quirk

Attachment 1

Comments To The 10/21/98 FR Vol. 63, No 203 Proposed Rule,

"Changes, Tests, and Experiments," Related Changes To 10 CFR 50.59

This attachment provides comments on the NRC's 10/21/98 proposed revision of 10 CFR 50.59, and supplies information to help the NRC develop positions that are consistent with the safety bases of the BWR. Changes to § 50.59 should maintain consistency and retain the licensed safety bases of the BWR.

GE's comments primarily address the definitions associated with the term "accident" and "safety margin" because a clear agreement on the meaning of both of these terms is essential for the effective use of the proposed regulation. If the application of these terms is misused, the result can be a large escalation in the number of utility and NRC reviews required for plant changes which affect non-limiting events, but which do not affect the design and licensing basis accidents that are considered in protecting the health and safety of the public.

Specific suggested changes to portions of the 10/21/98 proposed revision of § 50.59 (in particular, definitions) are provided in Attachment 2. An explanation of each of the suggested changes, and comments on other 10 CFR 50.59 related statements from the 10/21/98 Federal Register (Vol. 63, No. 203) are provided below.

Comments To The 10/21/98 FR Vol. 63, No 203 Proposed Rule,

"Changes, Tests, and Experiments," Related Changes To 10 CFR 50.59

1. Accidents Versus Other Design and Licensing Events

Assessment of "Accidents" has always focused on those postulated events which have been identified in the Final Safety Analysis Report (FSAR) and which potentially result in a radiological consequence greater than the 10CFR 20 allowable release limit. These events are included and evaluated, with other category events, in Chapter 15 of a typical plant FSAR. Because of their potentially serious consequences, plant design is such that the expected frequency of occurrence of such a postulated accident is very low (typically interpreted to be ~<10E-4/yr), and mitigation functions are carefully designed to ensure their success in limiting the consequences of such an event.

The potential for radiological release during postulated Accidents is the reason why the 10CFR50.59 review focuses on the important goal of identifying any possibility that a plant change could affect one or more events in this very important category. They challenge the modification reviewers to truly access all aspects of a change, including if the change will have an impact on any of these previously identified events from the viewpoint of frequency of occurrence, radiological consequences, and proper operation of the equipment assumed to mitigate the postulated event. 10CFR50.59 also requires the reviewers of the modification to evaluate if the change would create a new event in this category, or produce a new kind of failure of the equipment used in event mitigation. GE has no argument with continuing the thorough evaluations of plant modifications in this context.

The proposed changes to the regulation and the accompanying elaboration contain an undesirable extension of the use of the term "accident" to any unplanned or abnormal event. A typical plant FSAR also includes other events, most of which are typically included in Chapter 15. They are primarily identified as Anticipated Operational Occurrences (AOOs) (as defined in the NRC Regulatory Guide 1.70). Because these anticipated events do occasionally occur during the operation of a plant, the plant is designed to mitigate them so that no adverse affects to the health and safety of the public or any damage to the plant occurs; the plant is usually restarted as soon as possible after such an occurrence.

A plant modification which only affects an event other than an Accident (e.g., an AOO event) should only be evaluated in terms of whether it adequately maintains the appropriate "margin of safety" of the unit. That term also needs a clear meaning as discussed in the next section. For this section, the main point is that plant changes should be primarily evaluated with respect to potential impact on the Accident category events, and the 10CFR 50.59 evaluation questions which address the potential for a change of the frequency, radiological consequences, a new event or failure are effectively directed toward this goal. The potential impact of the plant change on FSAR events other than Accidents is adequately addressed by proper consideration of margin of safety.

Comments To The 10/21/98 FR Vol. 63, No 203 Proposed Rule,

"Changes, Tests, and Experiments," Related Changes To 10 CFR 50.59

Economic success of the plant depends strongly on controlling plant changes so that the number of such AOO events is minimized - in fact that is the explicit goal of many plant changes. Significant utility and vendor efforts have been and continue to be extended to accomplish this goal. The continued reduction of the shutdown (scram) rate for the nuclear fleet is strong evidence of the attention being paid to this area of plant performance. It should not be the goal of the 10CFR50.59 evaluation and review to address the frequency or potential for different AOOs, except from the viewpoint of their potential effect on margin of safety.

For a plant change to create an Accident of a different type, the change must create the potential for a new failure with resulting radiological release of such safety significance (>0.5 rem whole body dose or 1.5 rem thyroid dose) that, if the plant was being licensed for the first time, the failure would be included in the plant FSAR accident chapter. That is, *the change must create the potential for a new fission product release path, result in a new fission product barrier failure mode, or create a new sequence of events that results in significant fuel cladding failures.* The calculated consequences should be within the guideline exposures of 10 CFR 100.

For a change to create a malfunction of a different type, the change must create the potential for a new failure of equipment used to mitigate and/or limit the consequences of a previously identified Accident. Such a new failure is considered because it could change the radiological consequences of a previously identified Accident and thereby have safety significance.

Related Suggested Changes To The 10/21/98 Proposed Version of 50.59:

(a) A definition of the term "accident" should be included in the regulation; however, the proposed accident definition in FR 56106 is too broad to be interpreted and applied consistently. A more "straight forward" definition is provided in Attachment 2. Accidents are very low frequency (<10^{-4}/year) events addressed in Chapter 15 of a Reg Guide 1.70 FSAR, and have potential radiological doses for consequences. The associated doses may exceed 10 CFR 20 for an event of such low frequency so as to be categorized as an accident.

(b) As shown in Attachment 2, the phrase "*accident of a different type*" should be defined in the regulation. For a new event to be classified as an *accident*, the *accident* must cause potential radiological dose via a new release path, causes a new fission product barrier failure mode, or creates a new sequence of events that results in significant fuel cladding failures. A "design basis accident of a different type" also results in plant design change(s) with corresponding change(s) to the plant's 10 CFR 50.2 design bases.

Comments To The 10/21/98 FR Vol. 63, No 203 Proposed Rule,

"Changes, Tests, and Experiments," Related Changes To 10 CFR 50.59

2. Margin of Safety

Required margin of safety must be primarily evaluated with respect to compliance with the applicable Safety Limit(s), **not** with respect to parameter changes which may change design margin, but do not impact the plant so that performance fails to remain in compliance with the required licensing criteria. Variations of calculated results should be considered as precursor indicators related to the Safety Margin, but not variations of the margin of safety itself. The difference between a calculated result and the applicable criterion is a measure of "extra" margin or "design margin". The concept of evaluating the importance and/or severity of the impact of a plant change by using the relative change of this design margin could be developed as an acceptable method of determining a threshold of increased attention, similar to the method described for Radiological consequences on FR Page 56105. However, such an evaluation should continue to preserve the primary concept that the Margin of Safety is ensured by simple compliance with the licensing criteria, whether or not there is "extra" margin.

Of the options in the 10/21/98 FR, the Option 1, input parameter method (Page 56107), for evaluation of the effect of a change on the margin of safety is much like the conservative analysis methods used in the past. However, the definition of margin of safety should be consistent with the discussion presented above, and the phrase "such that compensating change(s) are required to maintain compliance with the subject Technical Specification Safety Limit" should be added to the end of the last sentence.

The discussion concerning Option 3, analysis results evaluation, (10/21/98 FR 56106&7) is useful and similar to most licensing analysis evaluations currently in use. Again, an appropriate definition of margin of safety is necessary. However, some of the characterizations are technically incorrect. For example, peak fuel cladding temperature (PCT) calculation results are not governed by 50.59. PCT results (including their reportability requirements to the NRC) are governed by 10 CFR 50.46. PCTs are not addressed in the Technical Specifications. The margin of safety related to PCT is based on the LOCA Radiological accident analysis and not the ECCS performance analysis.

FR 56107 Option 2 is not considered acceptable. The "margin of safety" criterion should remain within 50.59, and be stated as shown in the 10/21/98 proposed version of 50.59. The deletion of the use of margin of safety is non-conservative, while use of the term beyond the basis of a Technical Specification Safety Limit is not needed. Deleting the term is non-conservative, because non-accident events involving malfunctions of equipment not important to safety may not be adequately covered by 50.59. For, example, the limiting transient for most BWRs is the generator load rejection. This event is a malfunction of equipment **not** important to safety, and does not result in a radiological consequence. Therefore, 50.59 criteria that address equipment important to safety, accidents and consequences do not cover all types of abnormal events. However, the BWR transient analyses form the bases for a number of Technical Specifications Safety Limits, and are properly covered by the criterion addressing a reduction of margin of safety in the basis for any Technical Specification Safety Limit.

In summary, the margin of safety always starts from the regulatory acceptance or design (code) limit, not the calculated results. An actual calculated value demonstrates that the plant design will remain within an applicable acceptance limit. Therefore, the difference between the calculated value and its acceptance limit is, by definition, design margin. If this position is changed by the NRC, the concept and use of regulatory acceptance and design (code) limits become meaningless, and the NRC will be flooded with license amendment requests generated by the 50.59 process, relating to changes that do not affect the bases of NRC acceptance of plant designs. It is recommended that all forms of this aspect of the 3(A) options be dropped.

The following practical definition of *Margin of Safety* is provided for 50.59 evaluations.

The "margin of safety" (in the basis for any Technical Specification Safety Limit) of an item is the difference between the assumed, analyzed or design basis failure point (as available) and the item's Licensed Acceptance Limit (if specified) or the FSAR acceptance criteria (if specified).

Attachment 2

Suggested Changes To 10/21/98 Proposed 10CFR 50.59

50.59 Changes, tests and experiments

(a) Definitions for the purposes of this section:

.........(Only specific changes to the proposed regulation are provided)

***Accident* means** an abnormal **event that is not expected to occur during the life of a plant** (frequency of occurrence <10^{-4}/year). The consequences of such an event may **result in an offsite radiological consequence greater than § 20 limits (>0.5 rem whole body dose or 1.5 rem thyroid dose);** however. mitigation of the event must limit consequences to be less than the requirements of 10CFR100.

An *accident of a different type* means an accident that results in a new fission product release path, results in a new fission product barrier failure mode, or creates a new sequence of events that results in significant fuel cladding failures. A *design basis accident of a different type* also requires a change to the plant's design with a corresponding change to the plant's § 50.2 design bases.

The "margin of safety" (in the basis for any Technical Specification Safety Limit) of an item is the difference between the assumed, analyzed or design basis failure point (as available) and the item's Licensed Acceptance Limit (if specified) or the FSAR acceptance criteria (if specified).

Reduction in margin of safety associated with any Technical Specification Safety Limit means that the input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the final safety analysis report (as updated), that established a Technical Specification Safety Limit, are altered in a nonconservative manner**, such that compensating changes are required to maintain compliance with the subject Technical Specification Safety Limit.**

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DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63FR56098)

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ComEd

December 21, 1998

OFFICE OF SECRETARY
RULEMAKINGS AND
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Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
ATTN: Rulemakings and Adjudications Staff

Subject: Comments on Proposed Rulemaking, "Changes, Tests, and Experiments"

References: (1) Volume 63, Federal Register, Page 56098 (63FR56098), dated October 21, 1998

(2) Letter from A. Pietrangelo (NEI) to U.S. NRC, "Industry Comments on Proposed Rulemaking to 10 CFR 50.59, Changes, Tests, and Experiments," dated December 21, 1998

This letter provides Commonwealth Edison (ComEd) Company comments on the subject Nuclear Regulatory Commission (NRC) proposed rulemaking published in the Federal Register (i.e., 63FR56098.)

ComEd fully endorses the industry comments submitted in Reference 2. The industry comments were developed with the assistance of the Nuclear Energy Institute (NEI) through the NEI Regulatory Process Working Group and 10 CFR 50.59 Task Force. Our personnel have been an integral part of both these groups and assisted in developing the comments.

There are two major issues associated with the proposed rule that ComEd considers to warrant special attention. The first issue is the proposed industry review process to replace the existing Margin of Safety concept. This change is a significant improvement over the other options in the proposed rule. Should the industry proposal not be endorsed, we recommend that implementation of Option 2 in the proposed rule, "Delete "margin of safety" as a Criterion," would be appropriate.

The second issue involves the wording of the proposed rule that can be interpreted to foreclose the ability to "screen" out changes and tests or experiments that do not warrant full 10 CFR 50.59 evaluations. We strongly urge that the supplementary information in the rulemaking should make clear that the new rule does not preclude a screening process and therefore is not a new requirement in this sense.

Respectfully,

R. M. Krich

R. M. Krich
Vice President - Regulatory Services

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NUCLEAR UTILITY GROUP
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December 21, 1998

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

DOCKET NUMBER
PROPOSED RULE PR 50, 52 & 72
(63FR56098)

Re: Comments on *Changes, Tests, and Experiments*, <u>63 Federal Register 56,098 (October 21, 1998)</u>

Dear Mr. Hoyle:

The Nuclear Utility Group on Equipment Qualification ("NUGEQ")[1/] hereby submits the following comments on the Nuclear Regulatory Commission's ("NRC") proposed rule to revise the current provisions of 10 C.F.R. Part 50.59.[2/] Overall, we conclude that the proposed rule is positive and responsive to concerns regarding the difficulties experienced with the current rule. Nevertheless, the proposal raises certain potential concerns for its application to equipment qualification programs and processes implemented pursuant to 10 C.F.R. § 50.49.

As background, we note that each licensee is required pursuant to 10 C.F.R § 50.49 to qualify certain equipment to perform its intended safety function in the event of a design basis event. Those requirements and applicable guidance establish explicit standards for qualification which include specific margins in testing and analysis (e.g. 10 C.F.R. § 50.49(e)(8)). In addition, the rule includes provisions for assuring qualification of replacement equipment (see 10 C.F.R. § 50.49(l)). Notably, while licensees are required to maintain qualification of equipment, the rule does not anticipate prior NRC approval of changes to qualification bases, although records of qualification are to be maintained in auditable form (10 C.F.R. § 50.49(j)).

1/ The NUGEQ is comprised of 35 electric utilities in the United States and Canada, including NRC licensees authorized to operate over 100 nuclear power reactors. The NUGEQ was formed in 1981 to address and monitor topics and issues related to equipment qualification, particularly with respect to the environmental qualification of electrical equipment pursuant to 10 C.F.R. 50.49.

2/ "Changes, Tests, and Experiments," Proposed Rule 63 Fed. Reg. 56,098 (October 21, 1998).

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In the terminology of the proposed rule, we submit that the maintenance of qualification in accordance with 10 C.F.R. § 50.49 assures that licensees maintain the "regulatory envelope" surrounding equipment qualification. In this light, we believe that many of the proposed changes to 10 C.F.R. § 50.59, if properly applied, will assure that unnecessary burdens and potential adverse impacts on plant operation do not occur in connection with the implementation of EQ programs. To assure such clarity of purpose and intent, we provide some comments below which, in effect, seek NRC Staff clarification or affirmation of intent with respect to the application of the proposed rule in the context of EQ.

"Margin of Safety":

It is not clear as to whether the proposed rule would broaden the scope of the "margin of safety" definition. We are concerned with the possibility that a broader definition might be applied such that all safety analysis "input" and "assumed" parameters which are "altered in the nonconservative direction" would be construed as "reductions" in margin of safety. Specifically, while we do not believe it is intended, we are concerned that this definition could potentially be applied inappropriately to equipment and qualification changes performed under the Equipment Qualification (EQ) program pursuant to 10 C.F.R. § 50.49.

For example, a licensee's safety analysis will assume that certain equipment must maintain operability during design basis events. As such, the equipment must be "qualified" to operate under the harsh environment created during accident conditions. In the context of equipment qualification, pursuant to 10 C.F.R. §50.49 equipment is qualified based on testing and/or analyses which take into account many different post-accident parameters such as temperature, humidity and radiation levels. This testing and/or analytical data will be compared to the assumed/analyzed plant accident profiles to determine whether the equipment is "qualified" to operate in the post-accident environment. Under the proposed rule, we are concerned with a potential interpretation that if the test profile for new equipment, including replacement equipment, is closer to the assumed/analyzed accident profile than the original equipment, one might mistakenly conclude that the "margin of safety" has been reduced. However, the underlying assumption for the EQ design bases is that the equipment will maintain its operability under the adverse post-accident conditions. By definition, the equipment maintains such operability if it is qualified pursuant to 10 C.F.R. § 50.49. Therefore, the underlying assumption for operability under accident conditions would be met and review under 10 C.F.R. 50.59 should not be warranted as a reduction in the margin of safety. Indeed, as the Commission indicates in the Statements of Consideration with respect to the "probability of equipment malfunction" criterion,

> The probability of malfunction of equipment important to safety . . . is no more than minimally increased if 'design bases' assumptions and requirements are still satisfied (i.e., . . . qualification specifications).[3]

Similarly we believe it should be noted that where specific qualification specifications continue to be met, the underlying design bases assumptions continue to be met and there would be no reduction in the margin of safety.

As a further example, a plant may alter its accident profile as a result of various plant modifications or reanalyses. These new accident profiles may move closer to existing test EQ profiles. Nonetheless, so long as EQ equipment remains qualified by nature of test and/or analytical information, in accordance with the requirements of 10 C.F.R. § 50.49, there is no impact to the overall level of plant safety and qualification margins built into the EQ rule itself. Indeed, in addition to the point above regarding assurance of qualification of replacement equipment without prior NRC review, the NRC has recognized that because of new information or analyses a licensee may need to reverify or conduct new analyses to assure the qualification of certain equipment, but such determination is up to the licensee, subject only to NRC audit not prior NRC review. *See* Generic Letter 91-18 "Information To Licensees Regarding Two NRC Inspection Manual Sections On Resolution Of Degraded And Nonconforming Conditions And On Operability." As such, we urge the Commission to recognize that revisions to individual equipment qualification bases, in accordance with the requirements of 10 C.F.R. § 50.49, should not be construed as a "reduction in the margin of safety" that requires prior NRC approval under 10 C.F.R. § 50.59.

Definition of "Change":

The proposed rule defines "change" as a "modification, addition, or removal."[4] A literal application of this definition could be construed as requiring a 50.59 evaluation for all replacements (both identical and non-identical) of qualified equipment. The NUGEQ believes that this is not the intent of the proposed rule.

Further, we are concerned that there may be some confusion as to whether replacement equipment would be considered as either an "addition" or "removal" that could be construed to be a "change" to the plant. (In addition, NUREG-1606 seemingly reinforces the position that non-identical replacements are "changes." In NUREG-1606, the NRC Staff

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[3] 63 Fed. Reg. at 56104.

[4] 63 Fed. Reg. at 56,120.

had interpreted "change" to "include any modification or replacement of something . . . with something that is not identical to the original in design requirements."[5/]) The NUGEQ urges the Commission to clarify that equipment replacements, which are qualified under 10 C.F.R. § 50.49 do not alter the underlying design bases with respect to qualification and should not, therefore, be construed as "changes" to the underlying qualification design bases under 10 C.F.R. § 50.59.

In summary, the NUGEQ urges that the Commission clarify that whether dealing with equipment replacements, or otherwise modifying equipment qualification analyses, so long as the equipment installed in the plant is qualified in accordance with 10 C.F.R. § 50.49 there is no reduction in the margin of safety or change to the plant that requires prior NRC review of 10 C.F.R. § 50.49 qualification determinations. Absent such a determination, virtually innumerable instances of changes to equipment or qualification bases, all still demonstrating qualification under 10 C.F.R. § 50.49, could require prior NRC review. Any other result would have adverse safety and operational consequences by delaying the timeliness of plant assurances of qualification (e.g., delaying operability/qualification determinations) and likely resulting in unnecessary plant shutdowns while awaiting NRC review of changes to qualification bases, as well as discouraging the availability of alternative equipment which may have operational advantages over existing equipment.

We appreciate the opportunity to comment on this proposed rule.

Respectfully submitted,

William A. Horin

Malcolm H. Philips, Jr.
William A. Horin

Counsel to the
Nuclear Utility Group on
Equipment Qualification

5/ NUREG-1606, "Proposed Regulatory Guidance Related to Implementation of 10 C.F.R. § 50.59 (Changes, Tests, or Experiments)" 7 (May 7, 1997). (Although not adopted by the proposed rule, we wish to obtain clarification as to the underlying intent of the proposed rule in light of the comments in NUREG-1606.)

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December 21, 1998

Mr. John C. Hoyle
Secretary of the Commission
Attention: Rulemakings and Adjudications Staff
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555-0001

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

SUBJECT: Industry Comments on Proposed Rulemaking to 10 CFR 50.59, Changes, Tests, and Experiments (63 Fed. Reg. 56098 – October 21, 1998)

PROJECT NUMBER: 689

Dear Mr. Hoyle:

The Nuclear Energy Institute[1] offers the following comments in response to the subject *Federal Register* notice which solicited public comments on proposed changes to 10 CFR 50.59 and related changes to other sections of Part 50, Part 52 and Part 72.

We commend the Commission for its initiative to simplify and clarify 10 CFR 50.59. This rulemaking should provide licensees with the intended flexibility to make changes that have little or no impact on plant design or operation without prior NRC approval. We also share the Commission's priority on expediting rule changes to restore regulatory stability in this important area.

As indicated in the enclosures, the industry supports many of the proposed changes to 10 CFR 50.59. Several comments and recommendations are offered to further clarify the rule. Most significantly, we are recommending a modified approach to the existing margin of safety criterion. Our alternative complements the other 10 CFR 50.59 evaluation criteria by focusing on design parameters associated with the integrity of fission product barriers (fuel cladding, RCS pressure boundary and

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[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including regulatory aspects of generic operational and technical issues. NEI members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

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containment). The industry proposal is outlined in Comment III.C of Enclosure 1 and is fully described in Enclosure 2. The industry comments in Enclosure 1 are organized as follows:

I. Rule Reorganization and General Clarifications
II. Definitions
III. Clarification of Evaluation Criteria
IV. Recordkeeping and Reporting Requirements
V. Improving the Scope of 10 CFR 50.59 and Other Long-Term Changes
VI. Enforcement Policy and Rule Implementation
VII. Conforming Changes to 10 CFR 50.66, 50.90 and Part 52, Appendices A & B
VIII. Industry-Recommended Rule Language for 10 CFR 50.59

Enclosure 3 provides industry comments on proposed changes to Part 72.

Several of the changes to the rule will require conforming changes to NEI 96-07 [Revision 0], *Guidelines for Performing 10 CFR 50.59 Safety Evaluations*. We intend to expedite revision of NEI 96-07 so that the guideline is available to support implementation of the new rule when it becomes effective. We have already begun this task. However, certain aspects of the revision must necessarily await Commission disposition of the public comments, including selection of options related to defining "minimal" and the existing margin of safety criterion.

As part of the transition to the new rule requirements, we intend to request NRC endorsement of the revised NEI 96-07 in a regulatory guide. We expect the endorsement process to be completed within one year after the final rule is published in the *Federal Register*. During this time, other important aspects of the transition will be accomplished, including:

- Licensee conforming changes to their 10 CFR 50.59 programs;
- NRC adjustment of training and inspection programs; and
- One or more industry workshops to support implementation of the new regulation and guidance.

We look forward to working with the NRC staff and Commission on the resolution of rulemaking issues, revision and endorsement of NEI 96-07 and a smooth transition to the new rule requirements. We also look forward to discussing plans for making further, longer term improvements to 10 CFR 50.59, including better focusing the rule's scope of applicability.

If you have questions concerning these comments, please contact me at (202) 739-8081 or Russ Bell at (202) 739-8087.

Sincerely,

Anthony R. Pietrangelo

Anthony R. Pietrangelo

Enclosures
ARP/RJB/ngs

c:	Ashok Thadani	RES/NRC
	Samuel Collins	NRR/NRC
	Stewart Magruder, Jr.	NRR/NRC

Enclosure 1

Industry Comments in Response to Notice of Proposed Rulemaking to Amend 10 CFR 50.59 56098 Federal Register / Vol. 63, No. 203 / Wednesday, October 21, 1998

I. Rule Organization and General Clarifications

The industry provides the following comments and recommendations concerning proposed changes to reorganize and clarify the rule:

1. We agree with the proposal to add a new Section (a) on Definitions. See specific comments in Section II below on the definitions proposed in the NOPR.

2. We agree with the proposal to consolidate existing 10 CFR 50.59 applicability statements into a new Section (b) on Applicability as discussed in NOPR Section A.

3. We agree with the proposal to split the three existing compound evaluation criteria in 10 CFR 50.59(a)(2) into seven separate criteria in new Section (c)(2). See also our specific comment concerning the proposed rule structure in Section II (definition of "FSAR (as updated)"), below.

4. We agree with the proposal to relocate the existing requirement in 10 CFR 50.59(c)(3) on control of technical specifications to 10 CFR 50.90.

5. We agree with the removal of the term "safety evaluation" in favor of simply "evaluation." Likewise, we agree with the removal of the term "unreviewed safety question" and instead simply refer to the "need to obtain a license amendment." As noted in the proposed rule, the terminology has sometimes led to confusion about the purpose of the evaluation required by Sec. 50.59.

   a. The change in terminology however should not alter previous guidance and accepted practices that have used the term "unreviewed safety question" or "USQ." For example, Revision 1 to GL 91-18, published on October 8, 1997, resolved the concerns with the role of 10 CFR 50.59 for resolution of degraded or nonconforming conditions. In particular, the revision established that decisions regarding continued operation should be determined on the basis of operability, conformity with the license, and safety significance, not on whether a USQ has been identified. The Statement of Considerations that accompanies the final rule should clearly point out that the guidance and resolutions obtained in Revision 1 to GL 91-18 and in other previous guidance remains unaltered. The terminology "unreviewed safety question" or "USQ" is equivalent to the wording in Section (c)(2) of the proposed rule.

b. The term "unreviewed safety question" is found in the Technical Specifications of many licensees. The NRC staff should establish a streamlined process for approving Technical Specification changes to conform to the new terminology for 10 CFR 50.59.

6. We agree with the proposal to clarify the form of prior Commission approval (license amendment) required if a proposed change, test or experiment requires a change to the technical specifications or meets one or more of the criteria in new Section (c)(2).

   Specifically, the industry agrees with proposed Section (c)(2) which states, "A licensee shall obtain an amendment to the license pursuant to Section 50.90 prior to implementing a change, test or experiment if it would: ...." However, the supplementary information for the final rule should make clear that the licensee may design, plan, install, and test a modification prior to NRC approval of the license amendment provided (1) appropriate evaluation under 10 CFR 50.59 is performed, and (2) these activities are consistent with applicable Technical Specifications. This is consistent with the industry interpretation that a modification is considered "implemented" only once it provides its intended function, that is, when it is placed in service and declared operable.

7. We agree with the proposal to clarify that changes controlled by 10 CFR 50.54 (a or q) need not also be evaluated under 10 CFR 50.59. Because such changes may include modifications to the plant as well as to procedures, we recommend the proposed language for Section (c)(1)(ii) of final rule be modified as indicated below:

   The provisions in this section do not apply to changes in <u>the plant or</u> procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

II. Definitions

In general, the industry agrees that adding definitions of key terms used in 10 CFR 50.59 will add clarity to the rule. The following are specific comments and recommendations on the definitions (in italics) proposed in the NOPR:

A. *"Change" means a modification, addition, or removal.*

We agree that a common understanding of when a proposed modification constitutes a "change" to the facility or procedures as described in the safety analysis report is key to an effective and efficient change process. We also agree that the term "change" includes modifications and additions to, and removal from, the facility or procedures. This is consistent with the industry guidance in NEI 96-07.

We also agree with the discussion of the "interdependent change" concept as discussed in the Section II.B of the proposed rule. We understand the staff's view on this point to be consistent with NEI 96-07 and concur that it is more appropriately handled in the guidance document than the rule.

The definition of "change" is central to the "screening" step that is implicit in the 10 CFR 50.59 process. Proposed modifications that do not constitute a change for purposes of 10 CFR 50.59 are "screened out" and do not require evaluation and reporting to NRC under the rule. Thus, defining the term "change" presents the opportunity to markedly improve the effectiveness and efficiency of the revised rule. The screening process can be enhanced with no adverse affect on regulatory oversight by:

- Making the screening process more clear, objective and efficient, thus conserving licensee resources with no reduction in safety or regulatory control of significant changes
- Eliminating the need to perform full 10 CFR 50.59 evaluations for changes that have no impact on design functions or method of performing or controlling design functions
- Enhancing the focus of licensees and the NRC on significant changes, allowing for more effective resource allocation

To achieve these objectives, it is essential that the final rule preserve the capability that licensees have under the current rule to screen out changes for which evaluation under 10 CFR 50.59 is not necessary and beyond the intent of the regulation. Specifically, evaluation against the seven criteria of proposed Section (c)(2) should not be required for changes to design details that do not impact design functions or method of performing or controlling design functions. For example, minor changes that do not alter or affect the design function of a system, structure or component should "screen out," i.e., not require evaluation against the seven criteria of proposed Section (c)(2). (In addition, removal of equipment from service for maintenance, or to support maintenance activities, does not constitute a change and should be assessed, as appropriate, under technical specification limiting conditions for operation or 10 CFR 50.65.)

The proposed definition could be interpreted as requiring a full 10 CFR 50.59 evaluation for <u>any</u> modification or change in a design detail of a system, structure or component that is described or identified in the FSAR. Such an interpretation would result in the expenditure of licensee and NRC resources on numerous 10 CFR 50.59 evaluations for minor drawing changes and other changes that have no impact on the performance of design functions and no potential to meet the evaluation criteria for determining that prior NRC approval is required.

<u>Industry Recommendations:</u>

1. The following alternative definition for "change" should be included in the new rule:

    Change means a modification or addition to, or removal from, the facility or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

2. Furthermore, the supplementary information accompanying the final rule should clearly state that removal of equipment from service for maintenance, or to support maintenance activities, does not constitute a change and should be assessed, as appropriate, under technical specification limiting conditions for operation or 10 CFR 50.65.

3. The supplementary information should identify the intent of this definition to improve the efficiency of the licensee screening process, thus enhancing the focus of 10 CFR 50.59 evaluations on significant changes and conserving licensee and NRC resources.

4. The supplementary information should also make clear that for a proposed change to require a full 10 CFR 50.59 evaluation, it must meet the definition of change and either the definition of "facility" or "procedures" as described in the FSAR.

In addition to defining the term "change" as part of this rulemaking, we intend to propose appropriate clarifications to the industry guidance in NEI 96-07 to ensure that the screening process is clearly understood.

B. *"Facility as described in the FSAR (as updated)" means:*
   (i) The systems, structures, and components that are described in the final safety analysis report(as updated),
   (ii) The design, performance requirements and methods of operation for such systems, structures and components required to be included or described in the final safety analysis report (as updated), and
   (iii) The evaluations or methods of evaluation required to be included in the FSAR (as updated) for such SSC and which demonstrate that their intended function(s) will be accomplished.

Industry Recommendations:

1. The phrase: *"required to be included or"* should be deleted from subparagraphs (ii) and (iii). Requirements for FSAR content originate from 10 CFR 50.34(b) and 50.71(e) and are not appropriate for definitions in 10 CFR 50.59.

2. *"Methods of operation"* should be excluded from paragraph (ii) of the definition of "facility as described..." because this information is captured by the definition proposed for "procedures as described in the FSAR (as updated)."

C. *"'Final safety analysis report (as updated)" means the Final Safety Analysis Report (or Final Hazards Summary Report) submitted in accordance with Section 50.34, as amended and supplemented, and as modified as a result of changes made pursuant to Section 50.59 and Section 50.90, and, as applicable, Section 50.71 (e) and (f).*

Industry Recommendations:

1. The phrase *"as modified as a result of changes made pursuant to Section 50.59 and Section 50.90, and, as applicable, Section 50.71 (e) and (f),"* should be replaced with the simpler equivalent language, *"as updated per the requirements of 10 CFR 50.71(e)."* This is consistent with the definition of "U*pdated FSAR*" provided in NEI 98-03, *Guidelines for Updating FSARs,* which the NRC has indicated it will endorse.

2. To shorten and simplify proposed Section (c)(2), the definition of "FSAR (as updated)" should be expanded to encompass the intent of the following lengthy and cumbersome phrase repeated in each of the evaluation criteria i through vi:

, or evaluations performed pursuant to this section and analyses performed pursuant to Section 50.90 after the last final safety analysis report was updated pursuant to Section 50.71 of this part.

This repeated language should then be deleted from Section (c)(2)(i - vi).

3. The recommendations above result in the following proposed alternative definition for FSAR (as updated):

   "Final safety analysis report (as updated)" means the current revision of the FSAR (or Final Hazards Summary Report) submitted in accordance with Section 50.34, as amended and supplemented, and as updated per the requirements of 10 CFR 50.71(e).

   For purposes of implementing this section, the FSAR (as updated) is considered to include evaluations performed pursuant to this section and analyses performed pursuant to Section 50.90 after the last update of the final safety analysis report pursuant to Section 50.71 of this part.

D. *"Procedures as described in the final safety analysis report (as updated)" means information in the final safety analysis report (as updated) regarding how structures, systems, and components are operated and controlled (including assumed operator actions and response times) and information describing the conduct of operations.*

While not defined in the proposed rule, the phrase "*conduct of operations*" is generally interpreted as encompassing the following types of information typically found in Chapter 13 of the FSAR:

- Operations and maintenance activities such as control of equipment status (tag outs),
- Organizational structure, including shift staffing and personnel qualifications
- Control of plant procedures
- Training programs
- On-site safety review committees
- Emergency plan
- Security plan

While included in the FSAR to meet the requirements of 10 CFR 50.34(b)(6)(ii), (iv) and (v) and required to be updated per 10 CFR 50.71(e), it is inappropriate to consider such information to be within the meaning of *"procedures as described in the FSAR (as updated*) and thus within the scope of information subject to 10 CFR 50.59. This is because:

- Administrative procedures governing these activities are typically controlled by licensee QA Programs, changes to which are controlled under 10 CFR 50.54. Consistent with the discussion in paragraph II.C of the proposed rule, changes to information controlled by more specific NRC requirements need not also be evaluated under 10 CFR 50.59.

- Proposed changes to this type of managerial and administrative information is not suited to evaluation under the seven criteria of proposed Section (c)(2) of 10 CFR 50.59.

- Proposed changes to this type of managerial and administrative information do not meet the definition of "change" recommended above and thus would screen out, i.e., not require evaluation under 10 CFR 50.59.

Industry recommendation:

The phrase "conduct of operations" should be deleted from the definition of *"procedures as described in the FSAR (as updated)."*

E. *"Reduction in margin of safety associated with any technical specification" means that the input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the final safety analysis report (as updated), that established any technical specification requirement, are altered in a nonconservative manner.*

Industry Recommendation:

The proposed definition would substantially reduce the flexibility of licensees to make needed changes and substantially increase the number of changes requiring a license amendment. We agree with the NOPR conclusion that "this approach would also have the effect of giving input values and assumptions [in FSAR safety analyses] the weight of Technical Specifications, which is inconsistent with the philosophy in 10 CFR 50.36 of establishing Technical Specifications only on those values of most immediate importance." Accordingly, this definition should not be included in the final rule. In comment III.C below, an industry-recommended alternative approach to the existing "margin of safety" criterion of 10 CFR 50.59 is presented for Commission consideration.

F. *"Tests or experiments not described in the final safety analysis report (as updated)" means any condition where the reactor or any of its systems, structures or components are utilized or controlled in a manner which is either:*

(i) *Outside the controlling parameters of the design bases as described in the final safety analysis report (as updated) or*
(ii) *Inconsistent with the analyses in the final safety analysis report (as updated).*

Industry Recommendation:

We note that the definition presented in Section II.D of the NOPR uses the word "activity" where the definition in the proposed rule language uses the word "condition." We recommend use of "activity" for the final rule so that tests and experiments are not confused with discovered "conditions" (which are addressed per the guidance of Generic Letter 91-18, Revision 1).

G. Definition of "accidents"

Industry Recommendation:

We believe it is appropriate to continue to define the term "accidents" as part of guidance for implementing 10 CFR 50.59, and that is not necessary to include a definition in the final rule.

Since 1989, the following definition has been part of the industry guideline for implementing 10 CFR 50.59, first as part of NSAC-125 and presently as part of NEI 96-07:

> *The term "accidents" refers to the anticipated operational transients and postulated design basis accidents that are analyzed to demonstrate that the plant can be operated without undue risk to the health and safety of the public. The accidents considered for a plant typically are found in SAR Chapter 15 for most plants.*

In connection with conforming revisions to NEI 96-07, we intend to work with the NRC staff to clarify the industry guidance as appropriate to ensure a clear, common understanding of the term "accident" as it is used in 10 CFR 50.59.

III. Clarification of Evaluation Criteria

A. General

The industry agrees with the following clarifications to the evaluation criteria in proposed Section (c)(2) of the rule:

- elimination of the existing problematic phraseology "may be created" in favor of "*Create the possibility for ...*" in criteria v and vi of Section (c)(2)
- inclusion of the phrase "*important to safety*" in proposed criteria ii, iv, and vi of Section (c)(2)
- adoption of the industry recommended language in criterion vi of Section (c)(2) regarding "*malfunctions with a different result*" in place of the existing language, "*malfunctions of a different type.*"

B. Minimal Increase Standard

The industry strongly supports the Commission's intent to adopt rule changes that clearly provide licensees with the flexibility to make changes that have minimal impact on plant design or operation without the need to obtain a license amendment. We agree with the rationale presented in the proposed supplementary information and the conclusion that minimal increases in probability or consequences could not impact NRC conclusions reached about the acceptability of the facility design or associated safety determinations.

We concur in the language proposed for Section (c)(2)(i), (ii), (iii) and (iv) except for the recommended relocation of repetitive language to the definition of "*FSAR (as updated)*" as discussed in industry comment II.3. We offer the following comments with respect to the options presented for implementing the new minimal increase standard reflected in the proposed criteria.

1. Minimal Increase in Probability of Accidents or Malfunctions

   a. The NOPR identifies the current guidance in NEI-96-07 and states "[T]he Commission believes this satisfies the proposed NRC (minimal increase) standard." This guidance is as follows:

      ``*Where a change in probability is so small or the uncertainties in determining whether a change in probability has occurred are such that it cannot be reasonably concluded that the probability has actually changed (i.e. there is no clear trend towards increasing the* *probability), the change need not be considered an increase in probability."*

In addition to stating that the "negligible increase" standard of NEI 96-07 satisfies the proposed NRC minimal increase standard, we agree with the following additional guidance concerning probability of an accident provided in the NOPR. We recommend this guidance be included with the final rule (with the minor modification indicated):

In order to be considered as a minimal increase, the resulting probability (considering the change, test or experiment) must still satisfy the event frequency classification provided in the licensee's FSAR (as updated), e.g., for an anticipated operational occurrence (anticipated during life of the plant, up to once per year) or for a design basis accident (not expected during life of the plant, but sufficiently credible to require mitigation).

It should be noted, however, that not all licensees have event frequency classifications identified in their FSARs.

b. The industry recommends that the following discussion on probability of equipment malfunction in Section II.G of the NOPR be modified as indicated for inclusion in the supplementary information for the final rule:

   The probability of malfunction of equipment important to safety previously evaluated in the FSAR (as updated) is ~~no more than minimally increased~~ not increased if "design bases" assumptions and requirements are still satisfied (i.e., the seismic or wind loadings, qualification specifications, procurement requirements). As part of this guidance, note that NRC concludes that licensees can treat changes in external hazard design requirements as potentially affecting equipment malfunction probability rather than as "accident probability."

c. The evaluation of a change against the probability of malfunction criterion should be performed at a level consistent with the existing analyses in the FSAR. We believe the following discussion in Section II.G of the NOPR may be subject to other interpretations, and we recommend it be modified for the final rule as indicated:

   ~~The Commission believes that the probability of malfunction is more than minimally increased if a new failure mode as likely as existing modes is introduced.~~ The determination of whether the probability of malfunction is more than minimally increased should be made ~~either~~ at a ~~c component~~ level~~, or~~ consistent with the failure modes and effects analyses in the FSAR. ~~taking into account single failure assumptions, and the level of the change being made.~~

d. Some have expressed concern that the minimal standard as applied to probability increases indicates a new 10 CFR 50.59 emphasis on quantitative evaluations over qualitative evaluations. The supplementary information should clearly state that the NRC recognizes and accepts that it is prevailing industry practice consistent with NEI 96-07 that probability increase determinations are typically based on reasonable engineering practices, engineering judgment, and other qualitative assessments. Qualitative evaluations continue to be acceptable for determining that a change does not result in more than a minimal increase in the probability of occurrence of an accident or equipment malfunction.

e. The supplementary information for the final rule should reflect the intent of the proposed rule language and the Commission to provide greater licensee flexibility to make changes without prior NRC approval. As Commissioner McGaffigan stated in his comments on the proposed rule, "in choosing the word 'minimal' the Commission intended to grant greater flexibility than the NEI 96-07 'so small' or negligible standard." As stated in Section II.G of the NOPR, the minimal increase standard "allows for there to be a discernible increase" in probability.

   The industry believes that quantitative methods (e.g., PRA) could be used to better define when a change involves more than a "negligible"—but less than a "minimal"—increase in probability and thus may be implemented without obtaining a license amendment. The supplementary information should provide that licensees may use their PRAs and appropriate regulatory guidance to determine whether specific changes involve more than a minimal increase in probability of an accident or malfunction.

   We will work with the NRC staff and Commission to further clarify "minimal" as applied to increases in probability as part of conforming revisions to NEI 96-07.

2. Minimal Increase in Consequences of Accidents or Malfunctions

   a. We recommend that the Commission clearly state in the supplementary information for the final rule that the term "consequences" refers to radiological dose.

   b. With regard to consequences of an accident or malfunction of equipment, Option 1 as presented in the NRC proposed rule does not take into consideration how far or close a licensee's current FSAR calculated dose is from the regulatory limit. The 0.5 rem standard would not provide sufficient flexibility for licensees to make changes without the need to obtain a license amendment. This would result in an increase in regulatory burden with no commensurate safety benefit.

The concept behind the second and third options presented in the proposed rule offers the advantage over the first of providing greater flexibility to make changes in cases where there is more margin to the limit established in the regulations (e.g., 10 CFR Part 100, GDC 19). The third option—defining "minimal" as a fraction of the remaining margin between the current condition (as calculated in the updated FSAR) and the regulatory limit—is the simpler of the two to implement. Another desirable feature of this option is that it would be self-limiting. Because regulatory limits could not be exceeded, adoption of this approach would obviate the need for new reporting requirements to track the net effect of changes (see Comment IV, below). Except as discussed below, the industry supports the third option discussed in the proposed rule for defining minimal increases in consequences.

<u>NRC Use of "Acceptance Guidelines"</u>

For many licensees, "acceptance guidelines"—that are themselves a small fraction of regulatory limits—have been used by the NRC as the basis for safety determinations. "Acceptance guidelines" have been applied by the NRC staff as conservative criteria for approving licensee analyses of those accidents assumed to occur relatively more frequently than others, i.e., Class 1 and 2 accidents. For example, while the regulatory limit for thyroid dose based on Part 100 is 300 rem, the NRC staff has established "acceptance guidelines" of 30 rem and 75 rem for Class 1 or 2 accidents, respectively. Except for the earliest licensees, these "acceptance guidelines" have typically been identified in NRC safety evaluation reports[1]. "Acceptance guidelines have also been reflected in the Standard Review Plan. Analyses of higher frequency events and associated acceptance guidelines are typically the limiting factors in determining whether a proposed change requires prior NRC approval.

While not clear from the proposed rule, we understand that the NRC intends that these lower acceptance guidelines be used to determine the available margin as follows:

minimal increase in consequences $\leq$ *10% x (acceptance guideline minus calculated dose)*

The industry strongly disagrees with this approach as discussed below.

[1] SERs for the earliest licensees are typically based solely on the regulatory limits in 10 CFR.

Industry Recommendation

Where the NRC has applied acceptance guidelines in approving safety analyses, licensees have long accepted them as limits that may not be exceeded without prior NRC approval. However, they are not appropriate to use as the basis for margin calculations as the staff has suggested. As discussed below, we recommend that (1) only limits defined in the regulations, e.g., Part 100 and GDC 19, be used in the above equation to determine the available margin, and (2) this calculation should be used in tandem with acceptance guidelines (where applicable) to determine when a proposed change requires prior NRC approval. The effect of the industry-recommended approach is that licensees may make changes without prior NRC approval that increase calculated dose by the lesser of the following:

- 10% of the margin to 10 CFR limits, or
- the applicable acceptance guideline (if any)

Examples of Industry-Recommended Approach

Case 1 - No acceptance guideline; regulatory limit is 300 rem thyroid

- The current calculated dose in the UFSAR is 150 rem
- 10% of the available margin = 15 rem
- The licensee may make a change without prior NRC approval that results in a new calculated dose of 165 rem or less

Case 2 - Acceptance guideline of 30 rem applies

- The current calculated dose in the UFSAR is 24 rem
- 10% of the margin to the regulatory limit is 27.6 rem (10% of (300 rem—24 rem)
- The licensee is limited by the applicable acceptance guideline and therefore may make a change without prior NRC approval that results in a new calculated dose of no more than 30 rem

Case 3 - Acceptance guideline of 75 rem applies

- The current calculated dose in the UFSAR is 30 rem
- 10% of the margin to the regulatory limit is 27 rem (10% of (300 rem—30 rem)
- The licensee may make a change without prior NRC approval that results in a new calculated dose of 57 rem or less

Concerns Regarding the NRC Staff Approach and Rationale for the Industry Recommendation

The NRC staff approach would be unduly restrictive.

Use of acceptance guidelines for determining available margin would undermine key goals of this rulemaking by unduly restricting licensee changes and requiring numerous license amendments to be obtained where they are clearly not warranted. Where "acceptance guidelines" have been applied, the NRC staff has effectively built in a large cushion between the maximum allowable calculated dose and the limits established in the regulations for protecting public health and safety. In addition to these large, built-in margins to regulatory limits, the staff's approach would take away from licensees 90% of the remaining margin between the plant-specific calculated dose and the acceptance guideline.

Based on long-standing industry guidance, licensees have considered the margin to applicable regulatory limits or acceptance guidelines to be their own. Dose calculation results could move up or down within this region of "operating margin" without prior NRC approval. Only if an applicable limit was exceeded would a proposed change have been identified as a USQ. Only recently has this long-standing industry practice been called into question by the NRC staff, and thus the staff proposal would significantly reduce the flexibility licensees have historically had.

Example:

- acceptance guideline of 30 rem thyroid applies
- current calculated dose in UFSAR is 24 rem
- 10% of margin to acceptance guideline = 0.6 rem

Any proposed change that results in a calculated dose > 24.6 would require a license amendment even though this value is less than the acceptance guideline established by the NRC staff, and the increase of 0.6 rem is merely 0.2% of the limit established in the regulations for protecting public health and safety. Long-standing industry practice based on NEI 96-07 as well as the industry recommended approach (see Case 2 above) would allow changes to be implemented under 10 CFR 50.59 provided the resulting calculated dose does not exceed the acceptance guideline of 30 rem.

The NRC staff approach can produce illogical and unintended results.

1. Under the NRC staff approach, in cases where multiple independent changes are proposed, the need for a license amendment can depend on the order in which the changes are evaluated.

   Example:

   - acceptance guideline = 30 rem
   - current calculated dose in UFSAR is 24 rem
   - two unrelated changes, A and B, are proposed in roughly the same time frame
   - change A results in a dose decrease of 6 rem
   - change B results in an increase of 1 rem

     Case 1: Change B is evaluated first:

     - 10% of margin to acceptance guideline = 0.6 rem
     - Because Change B results in more than a 10% increase in dose, the change requires a license amendment

     Case 2 - Change A is evaluated first:

     - The calculated dose as a result of Change A is 18 rem
     - 10% of margin to acceptance guideline is 1.2 rem
     - Because Change B does not result in more than a 10% increase in dose, the change may be implemented under 10 CFR 50.59

     Case 3 - Both changes are evaluated against the most recent calculated dose in the UFSAR

     - Change A results in a decrease in dose and thus may be implemented under 10 CFR 50.59 without prior NRC approval
     - Change B results in an increase of more than 0.6 rem (10% of the margin to the acceptance guideline) and thus requires a license amendment

   Obviously, given this situation and assuming use of consistent methodology for all analyses, change B should not require a license amendment under any circumstances.

2. Problems also arise with the staff's approach in cases where the calculated dose goes down as a result of one change and up as a result of a later change.

   Example:

   - Acceptance guideline = 30 rem
   - Current calculated dose in UFSAR = 24 rem
   - In many cases, the SER may state that the calculated dose of 24 rem is acceptable because it is less than 30 rem.
   - Change A results in a calculated dose of 18 rem
   - Two years later, change B results in a calculated dose of 22 rem

     Under the staff approach, change B would require a license amendment because the 4 rem increase in dose exceeds 10% of the available margin (1.2 rem). A license amendment would be required for change B even though the calculated dose is less than that which had been previously reflected in UFSAR and less than the dose specifically approved in the SER. Under these circumstances, assuming use of consistent analyses for all calculations, it is inappropriate and wasteful of licensee and NRC resources to require a license amendment for change B.

   The industry proposal to allow calculated dose consequences to increase up to the lesser of (1) 10% of the margin to 10 CFR limits, or (2) the applicable acceptance guideline (if any) would:

   - Provide licensees with the appropriate level of flexibility consistent with long-standing industry practice tacitly approved by the NRC
   - Ensure that neither 10 CFR limits nor NRC staff established acceptance guidelines are exceeded without prior Commission approval
   - Preclude implementation problems such as those identified above
   - Avoid the additional burden that would result from having to seek license amendments for minor changes where prior NRC approval is clearly not required

3. <u>"Acceptance guidelines" lack regulatory standing.</u>

The staff proposal also suffers because acceptance guidelines, which are typically found in NRC safety evaluation reports or the Standard Review Plan, lack regulatory standing and thus may not be suited to the purpose intended by the staff. Accordingly, we recommend that 10 CFR limits be used in tandem with acceptance guidelines as described above to determine whether a license amendment must be obtained to prior to implementing a proposed change.

We look forward to working with the NRC staff on appropriate revisions to NEI 96-07 concerning the definition of minimal increases in consequences.

C. A Modified Approach to Margin of Safety

The industry has evaluated a wide range of options for a new approach to margin of safety evaluations under 10 CFR 50.59, including those identified in the proposed rule. To meet the Commission's objective to clarify and simplify the rule, we believe that action is needed to address longstanding implementation issues including the following:

- The existing scope given by the phrase "any technical specification" is overly broad, making margin of safety evaluations largely redundant to those for the other criteria of 10 CFR 50.59.

- Terminology central to implementation has not been defined and is subject to differing interpretation, including the terms "basis for any technical specification" and "margin of safety."

Based on long-standing practice and the guidance in NEI 96-07 (formerly NSAC-125), the industry has defined margin of safety as the margin between the "acceptance limit" for a particular technical specification-related parameter identified in docketed licensing correspondence and the failure point for that parameter. Under this approach, any change that would cause an acceptance limit to be violated was considered a reduction in margin of safety and identified as a unreviewed safety question. This approach ensured that acceptance limits established in the regulation or plant-specific licensing interactions were not violated without prior Commission approval.

The NRC staff has recently made clear that its interpretation of margin of safety differs from that of the industry, necessitating action in this rulemaking to resolve these differences and restore regulatory stability. To address these concerns, the industry has returned to first principles to define a more focused approach to margin of safety. We believe we have developed an approach that

- Is more effective and efficient than the existing approach
- Is consistent with the original intent of margin of safety evaluations
- Compliments the role of technical specifications and the regulations in controlling plant changes
- Provides the appropriate level of regulatory control

The industry proposal presented in Enclosure 2 for Commission consideration includes:

- A review of the purpose of margin of safety evaluations under 10 CFR 50.59 and the industry experience in performing them
- Evaluation of options and basis for the industry recommended alternative
- Description of the industry proposal to focus margin of safety evaluations solely on ensuring the integrity of fission product barriers
- Several examples illustrating the proposed approach and how it complements the other criteria of 10 CFR 50.59 and other change controls, e.g., 10 CFR 50.90

The industry proposal reflects elements from several of the options presented in the proposed rule, including a significant reduction in the scope of margin of safety evaluations, albeit not elimination of the review criterion altogether as proposed in Option 2 of the NOPR; emphasis on results of safety analyses and associated limits espoused in Option 3.A.1 of the NOPR; and a focus on controlling parameters and design basis limits for ensuring the integrity of fission product barriers as proposed in Options 3.A.2 and 3.A.3. The proposal provides for appropriate control of both accident prevention and mitigation capabilities, consistent with the original intent of the margin of safety concept.

While appealing on its face, the industry ultimately could not recommend elimination of the margin of safety criterion because our analysis determined that doing so would leave gaps in the coverage of existing 10 CFR 50.59 evaluations and may lead to compensating expansion of the probability and consequence criteria. Thus, elimination of the criterion could actually undermine the objective of the rulemaking to clarify and simplify the rule.

Our recommended approach would narrow the scope of current margin of safety reviews by focusing solely on parameters directly related to the integrity of fission product barriers (fuel cladding, RCS pressure boundary and containment) rather than all technical specifications. The scope of review would include aspects of fission product barrier design that are not adequately addressed by the other criteria of 10 CFR 50.59, Technical Specifications or NRC regulations. The industry recommendation presented in Enclosure 2 also eliminates terminology that has been subject to differing interpretation, including "basis for any technical specification" and "margin of safety[2]."

[2] Because the industry-recommended proposal for Criterion vii of proposed 10 CFR 50.59(c)(2) does not involve a definition for "margin of safety," this term would no longer be used in the context of requirements for plant change evaluations (although the term may continue to be used in guidance). Therefore, a conforming change is necessary to delete the corresponding "margin of safety" criterion from 10 CFR 50.92(c)(3).

The industry recommends that the existing 10 CFR 50.59(a)(2)(iii) for evaluating the effect of proposed changes on margin of safety be replaced with the following language for 10 CFR 50.59(c)(2)(vii) in the final rule:

(c)(2) A licensee shall obtain an amendment to the license pursuant to 10 CFR 50.90 prior to implementing a change, test or experiment if the change would:

(vii) *result in a design basis limit directly related to the integrity of the fuel cladding, RCS pressure boundary, or containment boundary being exceeded or altered.*

It should be noted that the industry recommendation is not based on the concept of allowing minimal changes that has been proposed for the probability and consequence criteria of 10 CFR 50.59. This is because the fission product barrier design parameters of interest are not suited to this approach. As discussed in Enclosure 2, design basis limits are integral to the design of the barriers, and conservative margins were built in when the limits were established. Because plants are routinely designed and operated at or near these limits, there is typically little or no margin—and thus little meaning to the minimal increase concept.

Enclosure 2 describes the four basic steps for implementing this provision and provides examples to illustrate their application to a range of proposed plant changes. The four steps are as follows:

<u>Step 1</u>

Determine the design parameters that would be affected by the proposed change.

<u>Step 2</u>

Determine if the parameter(s) identified in Step 1 meet all five of the following criteria, thus indicating that the change must be evaluated under 10 CFR 50.59(c)(2)(vii):

- Part of Design Basis, per 10 CFR 50.2
- "Controlling parameter" that is a reference bound for design (not a functional description)
- Located in the updated FSAR
- Not the direct subject of a rule or technical specification limiting condition for operation
- Directly linked to the integrity of a fission product barrier

Step 3

For each parameter meeting the above criteria, identify the associated design basis limit.

Step 4

Determine if, as a result of the proposed change, whether a design basis limit will either be exceeded or altered. If "yes", then a license amendment must be obtained prior to implementing the proposed change. (As described in Enclosure 2, certain changes in analytical methodology would also require a license amendment.)

Implicit in this process is the option for licensees to incorporate into the technical specifications, as appropriate, parameters satisfying the five criteria in Step Two. If such parameters are added to the technical specifications, licensees need not perform evaluations under proposed 10 CFR 50.59(c)(2)(vii) for future changes affecting those parameters. If licensees incorporate all such parameters in the technical specifications, this approach converges with Option 2 presented in the NOPR in that control of technical specifications would indeed then ensure that there are no significant adverse changes to margins in design and operation.

We look forward to the opportunity to discuss the fission product barrier approach with the Commission and the NRC staff, including the language proposed for the final rule and the nature of implementation guidance that would be included in a revision to NEI 96-07.

IV. Recordkeeping and Reporting Requirements

A. The industry agrees with the proposed language for 10 CFR 50.59(d)(3) clarifying that records of changes in the facility must be retained throughout any license renewal term.

B. Aside from the proposal to expand recordkeeping requirements (discussed below), the proposed rule includes a reorganization of existing 10 CFR 50.71(e) requirements. These changes are unnecessary. The industry and NRC have just completed a long interaction that has led to the first-ever guidance for implementing the FSAR update rule, NEI 98-03. These interactions were based in part on the premise that no changes to 10 CFR 50.71(e) were necessary. The proposed changes to existing 10 CFR 50.71(e) requirements are not necessary, and we request that they be removed for the final rule.

C. As discussed below, no expansion is necessary or appropriate to 10 CFR 50.71(e) to address NRC concerns regarding cumulative effects of minimal increases. The industry strongly opposes the proposed expansion of 10 CFR 50.71(e).

Safety evaluation summaries and the effects of changes on the updated FSAR are already reported to the NRC per 10 CFR 50.59(b)(2) and, as appropriate, 10 CFR 50.71(e). In the future, safety evaluation summaries will continue to reflect the determination that changes made under 10 CFR 50.59 satisfied all evaluation criteria.

In addition, licensee procedures controlled under 10 CFR 50 Appendix B ensure that the latest design and analytical information is used in evaluating each new proposed change, including the analytical results and effects of changes pending or implemented since the last required report was made to the NRC.

1. No expansion of 10 CFR 50.71(e) is necessary to address increases in probability of occurrence of an accident or malfunction.

   As discussed in comment III.B.1, above, the industry intends to seek NRC endorsement of NEI 96-07 which provides a "negligible" increase standard for evaluating changes under 10 CFR 50.59. Guidance in NEI 96-07 states:

   > Where a change in consequences is so small or the uncertainties in determining whether a change in consequences has occurred are such that it cannot be reasonably concluded that the probability has actually changed (i.e. there is no clear trend towards increasing the probability), the change need not be considered an increase in probability[3].

   Because implementation of NEI 96-07 ensures that only changes that have negligible impact on the probability of accidents or malfunctions, i.e., changes for which there is no clear trend towards increasing the probability, it is unnecessary to add new NRC requirements for tracking the cumulative effects of such changes.

   Likewise, no additional reporting requirements are necessary for changes that cause an accident to cross into a higher event classification frequency than that specified in the updated FSAR. This is because such changes would be considered more than a minimal increase in probability and would require the licensee to obtain a license amendment prior to implementing the change.

[3] A proposed revision to this guidance to conform to the revised 10 CFR 50.59 is as follows: "...the change is considered to meet the minimal increase standard of 10 CFR 50.59(c)(2)(i & ii), and may be implemented without a license amendment."

Moreover, determinations concerning the impact of a change on the probability of accidents or malfunctions will continue to be largely qualitative in nature, consistent with prevailing industry practice and the guidance of NEI 96-07. Such qualitative determinations do not, by their nature, lend themselves to determining and reporting of net effects as envisioned by the staff proposal.

In the future, experience gained from use of quantitative evaluations in conjunction with R.G 1.174 or other guidance to determine whether changes meet the 10 CFR 50.59 minimal increase standard may indicate a need for additional guidance or requirements relative to tracking and reporting of cumulative effects. When the need for such actions becomes apparent, we will be prepared to discuss appropriate steps with the NRC staff.

2. No expansion of 10 CFR 50.71(e) is necessary to address increases in the consequences of an accident or malfunction.

   As discussed in Comment III.B.2, above, the industry recommends that the Commission define minimal increases so as to allow a given change to consume up to 10% of the remaining margin to the applicable regulatory (10 CFR) limit. Limiting increases to a small fraction of the available margin, such as 10%, ensures that any approach toward an applicable regulatory limit would be, at most, a slow one. As described in the industry comment, licensees would be further limited by any applicable acceptance guidelines.

   As noted in the NOPR, this approach ensures that applicable regulatory limits cannot be exceeded. Based on this self-limiting feature, and the small fractional steps (a maximum of 10% of available margin) permitted under this approach, we conclude that it is unnecessary to add new NRC requirements for tracking the cumulative effects of such changes.

3. Despite the potential to substantially increase burden associated with updating FSARs, the specific proposal in the NOPR is presented with virtually no discussion about how the new requirement would be implemented. In particular, licensees are deeply concerned about what is meant by *"the net effect of all changes made since the last update on the safety analyses, including probabilities* [which are typically not found in FSARs], *consequences, calculated values, system or component performance" and how the updated information is to be "appropriately located in the FSAR."* Prior to the NOPR, there had been no discussion with stakeholders about potential need for new reporting requirements or possible alternatives.

   We understand that the proposal to track cumulative effects via expanded 10

CFR 50.71(e) reporting requirements was included in the NOPR because such tracking and reporting might be appropriate depending on the direction selected for implementing the minimal increase standard. Because of the way the minimal increase standard is to be structured in the rule and supporting implementation guidance, as discussed above, it is unnecessary to expand the existing reporting requirements for the purpose of tracking cumulative effects.

In summary, the industry strongly opposes the proposed changes to 10 CFR 50.71(e). This notwithstanding, if the Commission elects to establish new reporting requirements in connection with this rulemaking, we request that the industry be given appropriate opportunity to work with the NRC staff to address the significant associated implementation concerns.

V. Improving the Scope of 10 CFR 50.59 and Other Longer-Term Changes

We appreciate the Commission's interest in receiving input concerning changes beyond those proposed in the NOPR that would better focus the scope of 10 CFR 50.59. As we have expressed to the Commission, the industry places a high priority on achieving this objective so that this highly resource intensive regulation can become more efficient and effective.

Because FSARs contain significant descriptive, supporting and historical information beyond the design bases, operational and design requirements, and safety analyses that are the intended target of NRC change controls, the FSAR is a blunt instrument for defining the scope of 10 CFR 50.59. As a result of the current overly broad scope of the rule, limited licensee resources are expended screening and evaluating proposed changes that affect FSAR information of little or no safety significance. Compounding the situation, licensees are required to expend additional resources reporting these changes to the NRC thus consuming equally limited agency resources that could be focused on more significant matters.

Furthermore, while some violations of 10 CFR 50.59 concern the quality of the evaluations performed, most violations concern failure to perform a 10 CFR 50.59 evaluation for changes that clearly were not unreviewed safety questions. Better focusing the scope of 10 CFR 50.59 would substantially reduce the number of wasteful disagreements with the NRC about when an evaluation must be performed.

The proposed definitions of "change," "facility as described in the FSAR," and "procedures as described in the FSAR" reflect a welcome recognition on the part of the

NRC of the need to clarify the scope of changes that require 10 CFR 50.59 evaluations. These definitions, as modified by the industry comments herein, will lead to noticeably more effective licensee screenings and overall improvement in the efficiency of the 10 CFR 50.59 process.

However, we believe that more fundamental changes are possible and necessary in the longer term, including further change to risk inform 10 CFR 50.59 by better focusing its scope of applicability.

In connection with making further improvements to 10 CFR 50.59, there is at least one other change that is important to maximizing the effectiveness and efficiency of the rule going forward. A graded approach should be established for obtaining prior NRC approval of changes that meet one or more of the criteria in Section (c)(2), but do not involve a technical specification change or other significant safety issue. For example, such changes could be approved by the Executive Director for Operations or the Director of Nuclear Reactor Regulation based on licensee submittal of appropriate information concerning the proposed change. This approach would maintain NRC control of significant changes but would reserve the formal license amendment process—and the substantially greater licensee and NRC resources required—for changes involving significant safety issues, such as changes affecting the technical specifications.

We understand that the NRC staff will provide a paper to the Commission in February 1999 on options for better focusing the scope of 10 CFR 50.59 on significant changes to the plant or procedures. We look forward to discussing the options paper with the NRC staff and Commission, as well as the need for a graded approach for obtaining prior NRC approval of changes.

VI. Enforcement Policy and Rule Implementation

While enforcement is not specifically discussed in the statement of considerations for the proposed rule change, it is discussed in SECY-98-171 under Item 4. The staff proposed to exercise enforcement discretion during the rulemaking period, for violations of the existing rule that are not safety significant and do not pose regulatory concerns that warrant escalated action. The staff considered exercising discretion to not take enforcement action for violations of the existing rule that would not be violations of the proposed rule. However, the staff concluded that such an approach would in essence implement the rule without rulemaking. Therefore the staff intends to reduce the severity level of violations in such instances. The staff proposes to consider whether to exercise enforcement discretion based on weighing the following factors:

- Was the safety and risk significance of the change low?

- Would the change (had it been submitted) likely have been approved by the staff without modification and with little need for clarification (e.g., because it clearly meets established NRC guidance such as contained in Standard Review Plans).

The staff proposes that in cases where the licensee on its own initiative identifies and appropriately corrects the 10 CFR 50.59 failure, which does not reflect current performance, discretion under section VII.B.3 of the policy may be warranted. In addition, for cases where the violation of existing rule requirements would not constitute a violation under the rule were it revised as proposed (e.g., in that it involved only a minimal increase in probability or consequences), the staff will consider treating such instances as minor violations; however, they would be documented in inspection reports because the rule is still in a proposed revision stage.

A. For the following reasons, the industry believes that the staff should reconsider its dismissal of a policy of refraining from issuing notices of violation during the rulemaking period for violations of the existing rule that would not be violations of the proposed rule:

1. The NRC staff has previously determined the proposed changes to the rule to be appropriate or the staff would not be proposing them for implementation. Further, many of the rule changes proposed are consistent with current industry practice based on NRC staff interpretations of the existing 10 CFR 50.59 rule, and thus any violations identified would represent "current performance" under the staff's proposal. Implementation of the staff's proposal would mean continued wasteful expenditure of licensee and NRC resources on issues having no nexus to safety.

2. The current enforcement policy has sufficient flexibility to allow the staff to make such an enforcement discretion policy and disseminate it via an Enforcement Guidance Memorandum (EGM) on other vehicle as an interim change to existing policy. This action would be consistent with EGMs 96-005 and 98-007 with respect to FSAR enforcement discretion.

3. A policy of refraining from issuing violations would be clearer and less open to interpretation than the staff's proposal which involves ambiguous terms such as "regulatory concern" and subjective evaluation criteria such as "would the change have likely been approved by the staff?" The industry believes this clarity is needed to bring much needed stability to the industry's effort associated with performing the reviews required by 10 CFR 50.59.

4. Refraining from issuing violations would allow the industry and NRC to focus on accomplishing a smooth transition to the new rule requirements. Revision

and endorsement of NEI 96-07, licensee modification of 10 CFR 50.59 programs, and retraining of NRC and licensee staffs on the new requirements could proceed without concern for interim enforcement issues. We estimate that these activities can be completed within one year from the date that the final rule is published in the *Federal Register.*

5. A policy of refraining from issuing violations is consistent with the comments made by the commissioners on SECY-98-171.

B. Grandfathering of Past Enforcement Issues

Concerns have been expressed that pre-rule change 10 CFR 50.59 evaluations, performed in good faith consistent with industry guidance tacitly accepted by the NRC, may continue to be subject to enforcement under current regulations. In most cases, such a course would be inappropriate and wasteful of both industry and NRC resources. To allay this concern and promote a complete transition to the new requirements when the rule changes are issued, the industry requests that the Commission express a policy such as the following in the supplementary information that will accompany the final rule:

> *Except in cases of willful noncompliance, the NRC will not take enforcement action related to licensee 10 CFR 50.59 evaluations performed prior to issuance of this revision to 10 CFR 50.59 based on interpretations of NRC requirements then in effect.*

VII. Conforming Changes to 10 CFR 50.66, 50.90 and Part 52, Appendices A & B

A. 10 CFR 50.66 - No comments

B. 10 CFR 50.90 - No comments

C. Part 52, Appendices A & B - No comments

VIII. Industry-Recommended Language for 10 CFR 50.59

10 CFR 50.59 Changes, tests and experiments.

(a) Definitions for the purposes of this section:

(1) Change means a modification or addition to, or removal from, the facility or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

(2) Facility as described in the final safety analysis report (as updated) means:

(i) The systems, structures, and components that are described in the final safety analysis report(as updated),

(ii) The design and performance requirements for such systems, structures and components described in the final safety analysis report (as updated), and

(iii) The evaluations or methods of evaluation required to be included in the FSAR (as updated) for such SSC and which demonstrate that their intended function(s) will be accomplished.

(3) Final safety analysis report (as updated) means the Final Safety Analysis Report (or Final Hazards Summary Report) submitted in accordance with Sec. 50.34, as amended and supplemented, and as updated per the requirements of 10 CF 50.71(e). For purposes of implementing this section, the FSAR (as updated) is considered to include evaluations performed pursuant to this section and analyses performed pursuant to Section 50.90 after the last update of the final safety analysis report pursuant to Section 50.71 of this part.

(4) Procedures as described in the final safety analysis report (as updated) means information in the final safety analysis report (as updated) regarding how structures, systems, and components are operated and controlled (including assumed operator actions and response times).

(5) Tests or experiments not described in the final safety analysis report (as updated) means any activity where the reactor or any of its systems, structures or components are utilized or controlled in a manner which is either:

(i) Outside the controlling parameters of the design bases as described in the final safety analysis report (as updated) or

(ii) Inconsistent with the analyses in the final safety analysis report (as updated).

(b) Applicability. The provisions of this section apply to each holder of a license authorizing operation of a production or utilization facility, including the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required under Sec. 50.82(a)(1) or a reactor licensee whose license has been permanently modified to allow possession but not operation of the facility.

(c)(1) A licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) without obtaining a license amendment pursuant to Sec. 50.90 only if:

(i) A change to the technical specifications incorporated in the license is not required, and

(ii) The change, test or experiment does not meet any of the criteria in paragraph (c)(2) of this section. The provisions in this section do not apply to changes in the plant or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(2) A licensee shall obtain an amendment to the license pursuant to Sec. 50.90 prior to implementing a change, test or experiment if it would:

(i) Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in the final safety analysis report (as updated);

(ii) Result in more than a minimal increase in the probability of occurrence of a malfunction of equipment important to safety previously evaluated in the final safety analysis report (as updated);

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the final safety analysis report (as updated);

(iv) Result in more than a minimal increase in the consequences of a malfunction of equipment important to safety previously evaluated in the final safety analysis report (as updated);

(v) Create a possibility for a design basis accident of a different type than any previously evaluated in the final safety analysis report (as updated);

(vi) Create a possibility for a malfunction of equipment important to safety with a different result than any previously evaluated in the final safety analysis report (as updated);

(vii) Result in a design basis limit directly related to the integrity of the fuel cladding, RCS pressure boundary, or containment boundary being exceeded or altered.

(d)(1) The licensee shall maintain records of changes in the facility and of changes in procedures made pursuant to this section, to the extent that these changes constitute changes in the facility as described in the final safety analysis report (as updated) or to the extent that they constitute changes in procedures as described in the final safety analysis report (as updated). The licensee shall also maintain records of tests and experiments carried out pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test or experiment does not require a license amendment pursuant to paragraph (c)(2) of this section.

(2) The licensee shall submit, as specified in Sec. 50.4, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. The report may be submitted annually or along with the FSAR updates as specified by Sec. 50.71(e), or at such shorter intervals as may be specified in the license.

(3) The records of changes in the facility must be maintained until the termination of a license issued pursuant to this part or the termination of a license issued pursuant to 10 CFR part 54, whichever is later. Records of changes in procedures and records of tests and experiments must be maintained for a period of five years.

Enclosure 2

Industry Comments on Proposed Changes to 10 CFR 50.59
A Modified Approach to Margin of Safety Evaluations

1. Introduction

This enclosure presents and provides the rationale for the industry-recommended replacement of the following existing language in 10 CFR 50.59 a(2)iii:

> A proposed change, test, or experiment shall be deemed to involve an unreviewed safety question if the margin of safety as defined in the basis for any technical specification is reduced.

While implementation of this criterion has been generally sound and effective based on industry guidance documents NSAC/125 and NEI 96-07, this language has been found to be problematic because:

- The scope given by the phrase "any technical specification" is overly broad and unwieldy
- Common understanding does not exist for the phrase " basis for any technical specification"
- "Margin of safety" is not defined

This rulemaking seeks to address these problems and several options have been presented for public comment. The industry, through NEI, has carefully evaluated these options and has developed a recommended alternative. The industry recommendation draws heavily from elements of the options presented in the October 21 notice of proposed rulemaking (NOPR).

The balance of this enclosure includes:

- A review of the purpose of margin of safety evaluations under 10 CFR 50.59 and the industry experience in performing them
- Description of the industry proposal to focus margin of safety evaluations solely on ensuring the integrity of fission product barriers
- Evaluation of options and basis for the industry recommended alternative
- Several examples illustrating the proposed approach and how it complements the other criteria of 10 CFR 50.59 and other change controls, e.g., 10 CFR 50.90

2. Purpose of Existing "Margin of Safety" Evaluations

As a foundation for the industry recommendation, it is useful to revisit the logic behind the original "margin of safety" concept as it was promulgated in 1968.

The underlying purpose of "margin of safety" evaluations was summarized in the Federal Register (Vol. 33, No 244, 10891-18612) when 10 CFR 50.59 was amended to reflect the new concept in 1968. That discussion identifies the underlying purpose of the rule revision as maintaining the integrity of the fission product barriers.

> In the revised system, emphasis is placed on two general classes of technical matters: (1) Those related to prevention of accidents, and (2) those related to the mitigation of the consequences of accidents. By systematic analysis and evaluation of a particular facility, each applicant is required to identify at the construction permit stage, those items that are directly related to maintaining the integrity of the physical barriers designed to contain radioactivity.

NEI 96-07, *Guidelines for 10 CFR 50.59 Safety Evaluations,* and NSAC-125 before it, provide guidance that is clearly consistent with the NRC view outlined above and specifically identified the three radiological barriers: fuel cladding, reactor coolant system (RCS) pressure boundary, and containment. Additionally, the industry guidance defines "margin of safety" as the region between the limit used as the basis for NRC approval of specific values in the FSAR ("acceptance limit") and the value that would cause failure of one of the three principle barriers (failure point) The following Figure 3-2 from the industry guideline illustrates the definition of "margin of safety."

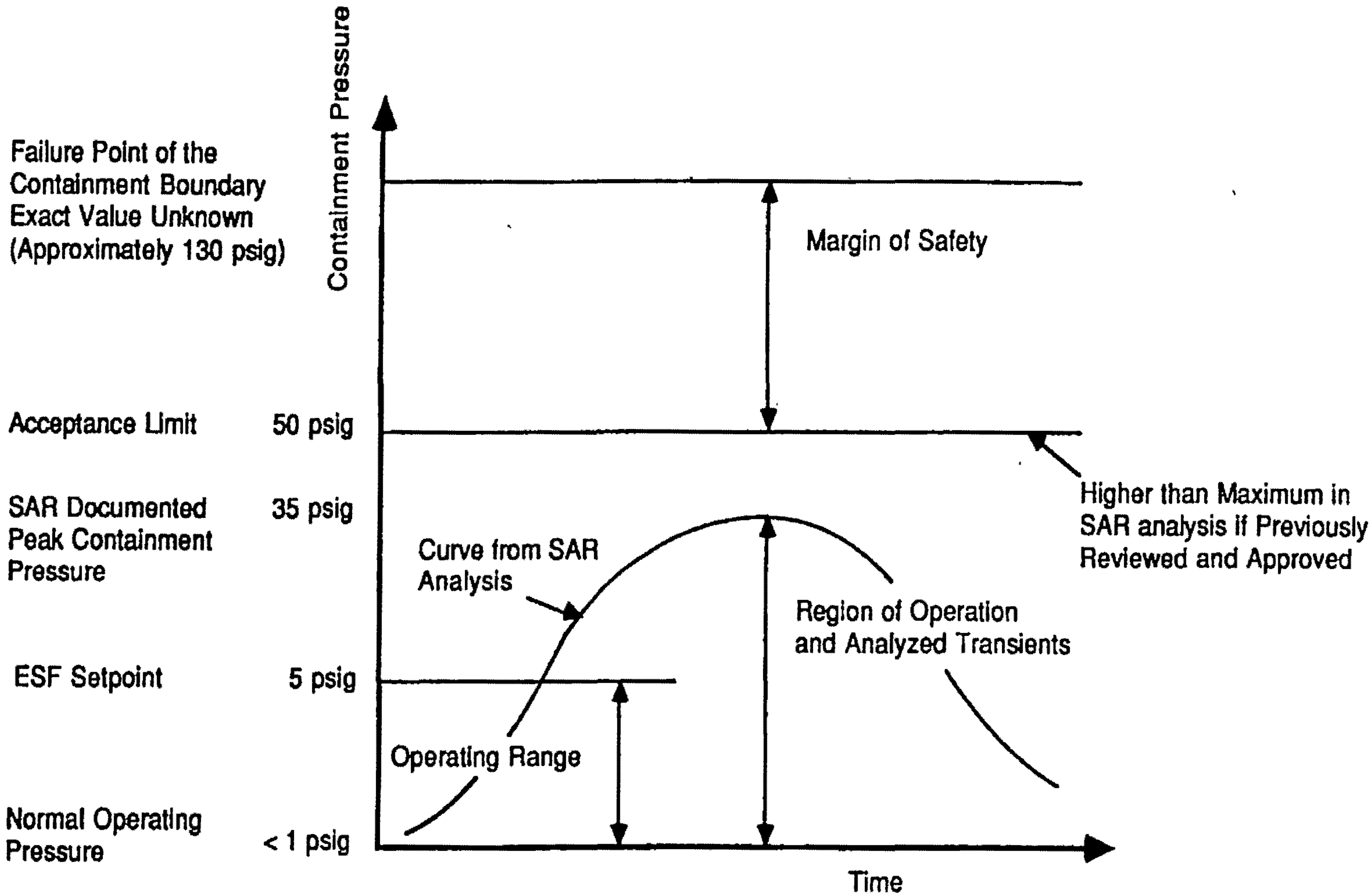

Figure 3-2. Example of Margin of Safety Using Containment Pressure Transient

The same 1968 Federal Register Notice cited above also makes clear that the scope of a "margin of safety" review is the information that forms the foundation of the technical specifications and is distinct from the technical specifications themselves.

> The analysis and evaluation of the facility required under 50.34 must provide (1) the necessary information from which technical specifications will be selected, and ***(2) the detailed bases for the specifications derived.*** (emphasis added)

These two characteristics ensured that the "margin of safety" reviews under 10 CFR 50.59 complemented the existing control of technical specifications and were focused on technical specification-related matters, in particular, the technical information defining the performance of fission product barriers.

Based on these "first principles," we conclude that the purpose of "margin of safety" evaluations within 10 CFR 50.59 is the proper identification and review, prior to any change, test, or experiment, of that technical information that forms the foundation for the continued integrity of the three fission product barriers.

3. Industry Experience

The current "margin of safety" concept has been a part of the10 CFR 50.59 safety evaluation process since 1968. Experience since that time has demonstrated that "margin of safety" is not typically the determining factor when evaluating proposed changes. Further, it is rare that "margin of safety" is solely responsible for determining that an unreviewed safety question (USQ) exists. These observations are consistent with premise of Option 2 of the NOPR that reliance on the other six review criteria of 10 CFR 50.59, technical specifications and NRC regulations is adequate to avoid adverse changes in design or operational margins.

On the other hand, the industry also endorses the original purpose for the "margin of safety" concept as provided in 1968 and summarized above. To the extent that there is information concerning the bases for the fission product barriers that is <u>not</u> directly controlled by a technical specification or rule and <u>not</u> adequately covered by the other six review criteria of 10 CFR 50.59, it may be necessary to maintain a margin of safety evaluation criterion to control this information.

4. Industry Selection Criteria to Test NOPR Option 2

The industry developed a set of criteria to effectively challenge the premise of Option 2 that the "margin of safety ... is defined and bounded by the technical specifications."

The five criteria provided below are intended to capture any information that both forms the technical foundation for a fission product barrier and is not otherwise controlled. Note that this logic is consistent with the 1968 genesis of "margin of safety" and tests the hypothesis that Option 2 is based upon. That is, if Option 2 is well founded, then there should be little or no information that meets all five criteria.

As discussed above, information that meets all five of these criteria would be most effectively controlled via a properly focused "margin of safety" evaluation under 10 CFR 50.59.

Criterion	Description	Basis for criterion
1.	Part of Design Bases, per 10 CFR 50.2	Ensures that information is safety significant.
2.	"Controlling parameters" that are reference bounds for design.	Focuses the review on design information that supports technical specifications, not on functional descriptions or actions.
3.	Located in the UFSAR	Reflects that the information must have been part of NRC license review.
4.	Not the subject of a rule or technical specification limiting condition for operation.	Ensures that safety evaluation review is not redundant.
5.	Directly linked to integrity of fission product barriers	Ensures that information is focused on barrier performance.

5. Application of Selection Criteria

NEI 96-07, and NSAC-125 before it, provided a set of nine parameters that defined the performance of fission product barriers. That list is provided below.

BARRIER	PHYSICAL PARAMETER
Fuel Cladding	• DNBR/MCPR • Fuel Temperature • Fuel Enthalpy • Clad Strain • Clad Temperature • Clad Oxidation
RCS Pressure Boundary	• Pressure • Stresses
Containment	• Pressure

Based upon the discussion in the preceding section, information (i.e., parameters) meeting all of the selection criteria identified in Section 4 would benefit from a "margin of safety" evaluation. Applying these five criteria to the list of parameters above would eliminate clad temperature and clad oxidation due to the requirements of 10 CFR 50.46. Also, RCS pressure boundary stresses would be eliminated because ASME code compliance is ensured by technical specifications.

The remaining six parameters satisfy all five characteristics, and therefore, may not be adequately controlled if the "margin of safety" review criterion was deleted from 10 CFR 50.59. Examples of this potential loss of control include:

- ➢ The maximum allowable fuel assembly burn-up could be increased until rod internal pressure exceeds that required for clad lift-off.
- ➢ Core loading patterns could be modified such that the clad enthalpy limit for fuel dispersion following reactivity addition accidents is exceeded.
- ➢ The size of the reactor coolant flywheels could be reduced, altering coast-down flow characteristics and resulting in more extensive departure from nucleate boiling.

6. Industry Recommendation

Based on the determination that important information concerning the technical foundation of fission product barriers might not be adequately controlled in the absence of margin of safety evaluations, an alternative industry proposal was developed to focus on parameters/analyses that satisfy the five criteria presented in Section 4.

The selection criteria of Section 4 provide an objective method to identify parameters that comprise the scope of evaluations under 10 CFR 50.59(c)(2)(vii) for each facility. Changes that adversely affect the parameters satisfying all five criteria, including six of the nine parameters identified in NEI 96-07 (as discussed in the previous section), would require evaluation in accordance with the industry proposal. These criteria ensure that the review scope of the industry proposal would be design parameters that are safety-significant, readily definable, and complementary to the balance of the regulatory framework, including NRC regulations, technical specifications and the other evaluation criteria in 10 CFR 50.59.

The industry-recommended approach is consistent with the purpose and fission product barrier focus of margin of safety reviews as reflected in the genesis of the existing 10 CFR 50.59 criterion and industry guidance. In addition, the approach represents a substantial—although not complete—validation of NOPR Option 2 in that the scope of information that does not meet all five of the selection criteria presented in Section 5 appears to be quite small. Thus, while we are not recommending elimination of the margin of safety criterion, the industry proposal does represent a significant narrowing of the scope for margin of safety evaluations.

In NEI 96-07/NSAC-125, the term "acceptance limit" was used to describe the point beyond which a change would require prior NRC approval. Generally speaking, acceptance limits denote the parameter values corresponding to the point beyond which confidence in the integrity of fission product barriers decreases. The new proposal defines the point beyond which prior NRC approval is required based on the design basis limits contained in the UFSAR. Specifically, the proposal focuses on the underlying technical information that provides assurance that the three principle barriers remain intact. The following discussion of the industry proposal is divided into two portions of the envisioned review:

- Focus of Evaluation
- Acceptance Criteria for Evaluation

Associated with this proposal is the following proposed rule language for 10 CFR 50.59(c)(2)(vii):

> A licensee shall obtain an amendment to the license pursuant to 10 CFR 50.90 prior to implementing a change, test or experiment if it would:
>
> > *Result in a design basis limit directly related to the integrity of the fuel cladding, RCS pressure boundary, or containment boundary being exceeded or altered.*

6.1 <u>Focus of Evaluation</u>

Consistent with the overall purpose of the review, information that forms the technical foundation of the three barriers' integrity is the focus of the envisioned evaluation under Section (c)(2)(vii). This information is part of the design bases for the fission product barriers as defined in 10 CFR 50.2:

> Design bases means that information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design.

Design bases, along with supporting design descriptions and evaluations, are included in the FSAR, in accordance with 10 CFR 50.34. The term "design basis limit" in the proposed rule language above is intended to focus the evaluation on quantitative "reference bounds for design" of "controlling parameters". Design basis limits do not refer to actions, programs, or functional descriptions that might have been candidates for Technical Specifications, but were not selected. The focus on design basis limits is a significant advantage of the industry proposal because these values are located in the FSAR. While design basis limits may also be relied upon in an associated SER, the values would have been extracted from the FSAR.

Examples of typical design basis limits applicable to fission product barriers are provided below. This table reflects elimination of the three parameters identified in NEI 96-07 that were found to be adequately controlled by other means and therefore did not meet all five selection criteria presented in Section 4 above. Parameters meeting meet all five criteria, such as those below, are the focus of the envisioned evaluation.

Fission Product Barriers with Typical Design Basis Limits

BARRIER	PHYSICAL PARAMETER	TYPICAL DESIGN BASIS LIMIT
Fuel Cladding	• DNBR/MCPR	• 95/95 DNB
	• Fuel Temperature	• Temp. associated with centerline melt
	• Fuel Enthalpy	• Enthalpy associated with fuel dispersion
	• Clad Strain	• Strain associated with clad lift off
RCS Pressure Boundary	• Pressure	• RCS design pressure
Containment	• Pressure	• Containment design pressure

6.2 Acceptance Criteria for Evaluation

There are three acceptance criteria associated with the envisioned review. The first ensures that the calculated parameter always remains below the design basis limit. The second ensures that any change to a fundamental design basis limit is properly controlled. Finally, the third ensures that the analytical methodology utilized remains consistent with the approved methodology.

The first two criteria are embodied directly in the proposed rule language, and all three will be clarified in a conforming revision to NEI 96-07. Each is discussed below.

Acceptance Criteria 1 & 2

The purpose of the envisioned review would be to require a license amendment be obtained for changes that reduce the confidence in the continued integrity of one of the fission product barriers. This could occur when:

- analysis of the proposed change predicts that a design basis limit for a parameter within the scope of review will be exceeded as a result of a change, or
- a design basis limit has been altered

Thus, the proposed rule language providing that a design basis limit may not be "exceeded or altered" provides the needed assurance. Confidence in the integrity of the fission product barriers is not reduced unless one of the two conditions described above exists. Therefore, the requirement that a license amendment be sought when design basis limits are "exceeded or altered" ensures the continued high confidence in the integrity of the barriers.

The term "altered" ensures that any change in design basis limits for fission product barriers would trigger prior NRC review, even if in a conservative direction, because such a change involves a fundamental alteration of the facility's design that warrants prior NRC review. In addition, such changes typically stem from use of an analytical methodology other than that approved by the NRC. As discussed below regarding Acceptance Criterion 3, such a change in methodology would also need to be approved by the NRC.

An example of the application of Acceptance Criteria 1 & 2 is provided below:

Containment Pressure

- Failure point = 140 psia
- NRC-approved Design Basis Limit = 50 psia
- Bounding analysis result = 37 psia

Prior NRC approval would be required if either (1) the bounding analysis result **exceeds** the design basis limit, or (2) the design basis limit itself is **altered** in any fashion. Note that "alteration" of the design basis limit in this example would involve changing the containment design pressure. This a fundamental design change that is rarely performed.

Acceptance Criterion 3

A critical element of the envisioned review process is to ensure that the analytical method utilized to determine the parameter's value is appropriate. NEI 96-07, and NSAC-125 before it, has recognized this concern and have considered the methodology used to be part of the "margin of safety" in some cases. Specifically, the analytical methodology utilized may have been submitted to the NRC and become a critical part of the review and approval process. This consideration is also a valid concern for evaluations envisioned under the industry proposal.

In the discussion of Option 3.C in the Notice of Proposed Rulemaking (NOPR), the following statement addresses this concern:

> All analyses and evaluations for assessing the impacts of proposed changes must be performed using methodology and analytical techniques which are either reviewed and approved by the NRC or which are shown to meet applicable review guidance and standards for such analyses.

The industry understands this to be consistent with the following guidance in NEI 96-07:

> It is recognized that there are "margins" associated with SAR analyses to account for uncertainties in the design, construction, and operation of a nuclear power plant (e.g., conservatisms in computer modeling and codes, allowances for instrument drift and system response time). These "margins" may be reduced by licensees without prior NRC approval provided the specific acceptance conditions, criteria and limits (including models, tests, uncertainties, penalties, methodology, etc.) are not invalidated. For example, assume the licensee performed, but did not submit to the NRC, analysis to determine the peak pressure for a system (perhaps as a function of time) following an accident. Further, assume the licensee then asked the NRC to license the plant based on a more conservative (bounding) limit or curve (because of analyses uncertainties), and the NRC reviewed and approved the bounding limit or curve. In this case, the licensee could make a change which would increase the peak system pressure provided a more precise analysis, with reduced uncertainties, left the bounding limit or curve valid. The licensee should apply the same methodology, with and without the proposed change, when evaluating a change to determine its effect upon the margin of safety. However, if the specific methodology for computing the bounding limit or curve or combining uncertainties (such as instrument errors) was submitted to the NRC in support of the licensing action, reductions in margin associated with this methodology would constitute an USQ.
>
> The determination of whether or not a reduction in margin is involved is based on the results of the analysis and not on the change itself. For example, an increase in initial conditions (not already limited by technical specifications) in the non-conservative direction can be compensated for by lowering a setpoint or reallocating analysis conservatisms. If the analysis results continue to be bounded by the acceptance limit, a reduction of margin is not involved. In this respect, the evaluation of reduction in margin of safety is performed in a way analogous to the way changes to the LOCA analysis are evaluated to determine if NRC review is required. The criterion for seeking prior review and approval is based on the extent of the change in LOCA analysis results and not on the input change per se.

We believe that discussion of when proposed changes to analytical methodology require prior NRC approval continues to be most appropriately addressed in the implementing guidance for the rule. In connection with conforming revisions to NEI 96-07, we are prepared to work with the staff on appropriate revisions to the existing industry guidance to ensure a clear, common understanding in this area.

At the same time, we also intend to clarify NEI 96-07 to better distinguish "analytical methodology" from input assumptions and descriptions of design. Among other things, these revisions will clarify the treatment of multiple changes. The envisioned content of these revisions is outlined below:

- "Methodology" means the techniques used in performing the analyses. Examples of elements that would be considered part of the methodology include:

    - Methods for reducing data
    - Statistical treatment of results
    - Correlations
    - Physical constants
    - Dose commitment factors
    - Mathematical modeling techniques

- Proposed changes to analytical methodology should be evaluated separately
    - The existing guidance of NEI 96-07, as modified above, would apply to methodology changes
    - Multiple changes may be evaluated as a single change if they are interdependent, as described in NEI 96-07

- Non-methodology changes would be treated as facility or procedure changes, as appropriate. Examples of elements that would not be considered part of "methodology" include:

    - Input assumptions
    - System characteristics, such as valve stroke times
    - Operator response times
    - Uncertainties in setpoints or instrument performance

7. Comparison of the Industry Proposal with NOPR Options

In order to facilitate the integrated review and comparison of all of the NOPR options with the alternative industry proposal, the matrix provided on the next page was developed. The matrix characterizes each of the proposed options by listing the following attributes of each:

- Scope—What material would be reviewed as part of an evaluation conducted under that option?
- Focus of review—Within the identified "Scope," what specifically is examined?
- When is a license amendment required?
- Would FSAR safety analyses methodologies be controlled?
- Option-specific comments

The options described in the matrix include:

- The current 10 CFR 50.59 for reference/comparison
- NOPR Options 1 through 14
  - Option 1 is the option proposed by the staff in SECY-98-171
  - Option 2 is the option to delete the "margin of safety" criterion
  - Options 3 through 14 are combinations of four scope and three options for determining when a license amendment is required
- NEI 96-07 (for reference/comparison)
- Current NRC staff position (for reference/comparison)
- Recommended Industry Approach

SUMMARY OF OPTIONS TO REPLACE THE "MARGIN OF SAFETY" REVIEW CRITERION

		NOPR Options								
	Current 50.59	1 (SECY-98-171)	2	3.A.1	3.A.2	3.A.3	3.A.4	NEI 96-07	NRC Staff Position	Industry Proposal
Scope	basis of any TS	FSAR safety analyses that establish TS	TS	basis of any TS	fission product barrier parameters (generic)	fission product barrier parameters (specified)	fission product barrier parameters (plus ECCS, ESF)	basis of any TS	basis of any TS	Specific fission product barrier parameters
					Scope may include parameters for shutdown, SFP cooling, fuel handling, etc.					
Focus of Review	none stated	• input assumptions • methodology • acceptance conditions	TS	Calc'd values in FSAR	Calculated values in FSAR			Calculated values & acceptance limits	Calculated values in FSAR	Calculated values for fpb & db limits
When is a LAR required?	any reduction in M of S is a USQ	Any non-conservative change	TS change involved? (Y/N)	Any non-conser-vative change	• 3.B.3 - minimal change (% of margin to regulatory limit) • 3.B.1 - any adverse change • 3.B.2 - minimal change (% of calculated value)			any reduction in M of S* is a USQ	any reduction in M of S* is a USQ	design basis limits exceeded or altered?
FSAR safety analyses methodology controlled?	Yes (?)	Yes	Not unless specified in TS	Yes	Yes			Yes	Yes	Yes
Comment	• lacks clarity	• large scope • controls S/A inputs like TS	• methods control ? • gaps	• large scope • rigid	• review criteria incompatible with scope and focus of review			* Differing interpretations of "margin of safety"		

As the option matrix illustrates, the industry proposal has a scope that draws upon a combination of Options 2 and 3.. The industry proposal's review focus is very similar to Options 3.A.1, 2, 3, and 4. However, the industry proposal's criterion for determining that a license amendment is required is distinct from all other options.

That difference highlights one of the industry's primary concerns with Options 3.A.1, 2, 3, and 4. Specifically, each of those options requires a license amendment when a calculated parameter increases, but remains below the design basis limit.

There are numerous instances when existing industry design practices routinely increase the calculated parameter values up to the design basis limit. This treatment is consistent with 10 CFR 50.46 and the practices specified in industry design codes. Examples of these parameters include departure from nucleate boiling ratio (DNB) or minimum critical power ratio (MCPR), clad strain, and RCS pressure boundary stresses. Therefore, none of the review criteria described in options 3.B.1, 3.B 2, or 3.B 3 are compatible with accepted industry practices.

Options 1 and 3.A.1 both continue to carry the technical specifications as the scope for the evaluation. This characteristic would result in the retention of the broad, unwieldy scope that is problematic with of the existing rule.

In contrast, the scope of the industry proposal is focused on the parameters that satisfy all five of criteria presented in Section 4:

- Part of Design Basis, per 10 CFR 50.2
- "Controlling parameter" that is a reference bound for design (not a functional description)
- Located in the updated FSAR
- Not the direct subject of a technical specification LCO or rule
- Directly linked to the integrity of a fission product barrier

Applying these criteria ensures that the review scope of the industry proposal would be safety significant, readily definable, and complementary to the balance of the regulatory framework, including NRC regulations, technical specifications, and the other evaluation criteria in 10 CFR 50.59.

8. Evaluation Process and Examples

The industry-recommended process is straightforward in practice. Note that the terms "margin of safety," and "basis for any technical specification" are eliminated. Ten examples are provided below to illustrate the revised process.

Example #	Description of proposed change
1	Routine reload reanalysis of DNB-related transients
2	Extending maximum allowable assembly burn-up
3	Change design of condenser make-up pumps
4	Increasing post-accident battery loading
5	Redesigning allowable steam generator tube stress
6	Decreasing the UET (unacceptable evaluation time) for ATWS
7	Delaying Auxiliary Feedwater pumps response slightly
8	Decreasing ECCS pump flow capacity slightly
9	Reducing the size of RCP flywheels
10	Changing the DNB correlation used in fuel assembly design

There are four steps to the process proposed by the industry.

Step 1

Determine the parameters that would be affected by the proposed change.

Step 2

Determine if the parameter(s) identified in Step 1 meet all five of the selection criteria from Section 4, thus indicating that the change requires further evaluation under 10 CFR 50.59(c)(2)(vii).

Step 3

For each parameter warranting further review, identify the associated design basis limit.

Step 4

Determine if, as a result of the proposed change, whether a design basis limit will either be exceeded or altered. If "yes", then a license amendment must be obtained prior to implementing the proposed change. As discussed in

Section 6 above, proposed changes in analytical methodology may also require a license amendment.

Steps 1, 2, 3, and 4 are performed below for the ten examples provided, along with comments regarding the features of the revised review process.

Step 1

The affected parameters for the ten examples are listed below.

Example	Description of proposed change	Affected parameter
1.	Routine reload DNB reanalysis	Post-accident DNB
2.	Extending assembly burn-up	Fuel rod clad stress
3.	Change condenser make-up pumps	Make-up flowrates
4.	Increasing post-accident battery loading	Battery capacity
5.	Allowable steam generator tube stress	Post-accident stress
6.	Decreasing the UET	UET
7.	Delaying Auxiliary Feedwater pumps	Post-accident pressure
8.	Decreasing ECCS pump flow capacity	Post-LOCA PCT
9.	Reducing the size of RCP flywheels	Post-accident DNB
10.	Changing the DNBR correlation	DNBR limit

Step 2

Apply the five selection criteria to the ten parameters above. (A reviewer might select different, or additional, parameter(s) than the list above. If so, then those parameters would be included in this step to determine if further review under 10 CFR 50.59(c)(2)(vii) is warranted.)

SUMMARY OF PARAMETER SELECTION

	Selection Criteria				
Affected parameter for each example	Part of Design Basis, per 10 CFR 50.2?	Numerically based "controlling parameter"?	Located in FSAR\ UFSAR?	Not the **direct** subject of a technical specification LCO or rule?	**Directly** linked to the integrity of a fission product barrier?
1. DNB	Yes	Yes	Yes	Yes	Yes
2. Clad stress	Yes	Yes	Yes	Yes	Yes
3. flow	No	No	Yes	Yes	No
4. amp-hours	Yes	Yes	Yes	Yes	No
5. tube stress	Yes	Yes	Yes	Yes	Yes
6. UET	Yes	Yes	Yes	Yes	No
7. RCS press.	Yes	Yes	Yes	Yes	Yes
8. PCT	Yes	Yes	Yes	No	Yes
9. DNB	Yes	Yes	Yes	Yes	Yes
10. DNBR limit	Yes	Yes	Yes	Yes	Yes

Examples 1,2,5,7,9, and 10 all warrant further evaluation under the proposed 10 CFR 50.59(c)(2)(vii) by virtue of having five "Yes" answers.

Example 3 (condensate make-up pumps) do not have any design basis involvement, nor any direct effect on a fission product barrier. There are no technical specifications associated with the condensate make-up pumps. Therefore, the existing "margin of safety" criteria could not result in a determination of a USQ. This change would be properly evaluated by the remaining six criteria of 10 CFR 50.59.

Example 4 (battery capacity) involves a parameter that does not directly affect a fission product barrier. The 10 CFR 50.59 evaluation will address this change under 10 CFR 50.59(c)(2)(ii), i.e., the "probability of malfunction" of the battery and its connected loads.

Example 6 alters the value of UET, which has no direct bearing on any fission product barrier. Therefore, no further evaluation under the proposed 10 CFR 50.59(c)(2)(vii) would be needed. However, UET is an important parameter, which has an indirect effect on plant performance. It also may be important to compliance with 10 CFR 50.62. As a result, the remaining six review criteria and/or the individual utility's commitment management system may restrict this proposed change.

Example 8 involves compliance with parameters directly controlled by 10 CFR 50.46. Also the pump's "probability of malfunction" would continue to be evaluated.

Importantly, all eliminated examples will be appropriately evaluated as a result of a regulatory requirement other than 10 CFR 50.59(c)(2)(vii). Summarizing the above comments:

Example	Description of proposed change	Evaluation comments
3	Change condenser make-up pumps	No current margin of safety concern. Other six criteria would adequately address evaluation.
4	Increasing post-accident battery loading	The other six criteria would adequately address evaluation. "Probability of malfunction" would be of interest.
6	Decreasing the UET for ATWS	10 CFR 50.62 compliance governs.
8	Decreasing ECCS pump flow	10 CFR 50.46 compliance governs. "Probability of malfunction" would also be of interest.

Step 3

For the parameters that warrant further evaluation under the proposed 10 CFR 50.59(c)(2)(vii), identify the associated design basis limit.

Examples 1,2,5,7,9, and 10 all warrant further evaluation, and their design basis limits (typical) are listed below.

Example	Description of proposed change	Design Basis Limit
1.	Routine reload DNB reanalysis	95/95 DNB
2.	Extending assembly burn-up	Fuel rod clad lift-off
5.	Allowable steam generator tube stress	Code compliance
7.	Delaying Auxiliary Feedwater pumps	Design pressure
9.	Reducing the size of RCP flywheels	95/95 DNB
10.	Changing the DNBR correlation	DNBR limit

Example 1 simply identifies the design basis limit normally used in reload analyses.

Example 2 identifies a design basis limit that is typically found in a vendor topical report and reported in the FSAR. Currently, the topical report requires NRC approval as part of a "margin of safety" review.

Example 5 would reflect the design basis limit for the steam generator tubes found in the UFSAR.

Example 7 would identify the applicable RCS pressure design basis limit for each accident affected. Therefore, the design basis limit for ATWS would be different that the design basis limit for Loss of Normal Feedwater. Both limits could be affected by a delay in AFW pump start.

Example 9 captures the appropriate design basis limit in a manner similar to the normal reload process.

Example 10 is changing the design basis limit itself.

Step 4

Identify whether, as a result of the proposed change, the design basis limit would either be exceeded or altered.

Examples 1, 2, 5, 7, and 9 cannot be pre-judged. That is, whether each proposed change is significant enough to cause a design basis limit to be exceeded is the determining factor and would be evaluated on a case by case basis.

Example 10 involves changing the design basis limit. This is a fundamental change that could reduce confidence in the integrity of the fuel cladding and may indicate a change in analytical methodology. As a result, a license amendment would have to be submitted to obtain NRC review and approval.

9. Conclusion

The industry proposal provides an alternative to the current "margin of safety" review criterion in 10 CFR 50.59. This proposal satisfies the Commission's original intent of the existing criterion by preserving the technical foundation upon which fission product barrier integrity resides. The proposal has the following attributes:

- Refined and focused review scope
- Elimination of reference to "basis for any technical specification"
- Elimination of reference to "margin of safety"
- Review scope is complementary to balance of regulatory structure
- Review criteria are clear and objective
- Elimination of reference to information or limits not docketed in the FSAR, i.e., no reliance on SERs
- Independent of plant/FSAR vintage, use of plant-specific vs standard technical specifications, and SER format/content

We look forward to detailed discussion of the industry recommendation with the NRC staff and Commission.

The industry recommends that the existing 10 CFR 50.59(a)(2)(iii) for evaluating the effect of proposed changes on margin of safety be replaced with the following language for 10 CFR 50.59(c)(2)(vii) in the final rule:

(c)(2) A licensee shall obtain an amendment to the license pursuant to 10 CFR 50.90 prior to implementing a change, test or experiment if the change would:

(vii) *result in a design basis limit directly related to the integrity of the fuel cladding, RCS pressure boundary, or containment boundary being exceeded or altered.*

It should be noted that the industry recommendation is not based on the concept of allowing minimal changes that has been proposed for the probability and consequence criteria of 10 CFR 50.59. This is because the fission product barrier design parameters of interest are not suited to this approach. As discussed in Enclosure 2, design basis limits are integral to the design of the barriers, and plants are routinely designed and operated at or near these limits. Thus, there is typically little or no margin and thus little meaning to the minimal increase concept.

with conservative margins built in when the limits were established,

Enclosure 2 describes the four basic steps for implementing this provision and provides examples to illustrate their application to a range of proposed plant changes. The four steps are as follows:

Step 1

Determine the design parameters that would be affected by the proposed change.

Step 2

Determine if the parameter(s) identified in Step 1 meet all five of the following criteria, thus indicating that the change must be evaluated under 10 CFR 50.59(c)(2)(vii):

- Part of Design Basis, per 10 CFR 50.2
- "Controlling parameter" that is a reference bound for design (not a functional description)
- Located in the updated FSAR
- Not the direct subject of a rule or technical specification limiting condition for operation
- Directly linked to the integrity of a fission product barrier

Enclosure 3

Comments on Proposed Part 72 Changes Associated With 50.59 Rulemaking

General comment related to Part 72: Accident consequences (potential offsite dose) for casks licensed under Part 72 are a very small percentage of that possible for reactors, yet many requirements in Part 72 for evaluations, reporting requirements, and SAR updates are more restrictive. As a minimum, these requirements, as discussed below, should be made equivalent to their Part 50 counterparts. The current and planned requirements which are more restrictive do not conform with a policy of placing emphasis in areas with higher safety significance.

1. Proposed change to 50.71(e) to discuss the effects of the changes upon calculated doses and other information. The current 50.71(e) requires the SAR update to "**contain** all the changes necessary to reflect ..." The wording of the proposed revision for the update to "**describe the effects** of ..." changes can be interpreted as requiring each SAR update to include an analysis of each change included in the update, separate from the revised wording in the SAR and in addition to the summaries of the analysis included in a 72.48 report or in any certificate of compliance amendment requests. This interpretation would cause a significant increase in burden associated with SAR updates over that currently performed that is discounted in the analysis for the proposed rule and in the paperwork reduction act statement. This comment also applies to the similar changes proposed in 72.70 and 72.248. If this is not the intended interpretation, it is not clear how the added requirement to discuss the net effect of all changes made since the last update would be included in the SAR update (this added requirement even taken by itself would be a significant additional burden over those currently imposed for SAR updates).

2. A request for parameters to be considered for Part 72 licensees for margin of safety was made in the proposed rulemaking. These items should include only those with potential to increase the probability or consequence of an offsite release. Items potentially to be included would be containment of fuel and fission products within the cask or facility. Sub-items would include fuel and cladding temperature, cask temperature, cask internal pressure and atmosphere, and cask materials/stresses. The release/accident limits utilized for Part 50 facilities should also be used for Part 72 facilities. Utilizing more stringent requirements for Part 72 facilities does not conform with the

policy to channel resources toward more safety-significant activities.

3. The NRC decision not to add an equivalent to 72.48 to Part 71 is questionable. Under the scenario proposed by the staff, a licensee or vendor could make a change to a dual purpose cask internally under 72.48 and then need to have the same change formally approved by the staff under Part 71 at a later date after the change has already been made. This results in the need for NRC approval and amendment of the transportation Certificate of Compliance (CoC). The proposed rule text glosses over the burden by stating that the licensee impact is minimized due to the 5 year renewal frequency associated with the transportation cask CoC and the need to amend the CoC prior to renewal. A licensee or vendor should be allowed the same flexibility to make changes to both storage and transportation casks. The safety considerations for a transportation cask are not of such a significant difference that the NRC could not allow a process like 72.48 to exist. The lack of uniformity in regulations provide additional burden to licensees that is not commensurate with safety significance. The absence of a 72.48 equivalent in Part 71 creates a situation where cask users will be reluctant to implement changes approved under 72.48 until the same change is approved by CoC for dual-purpose cask systems.

4. The wording for 72.70, 72.216, and 72.248 should be revised to conform entirely with 50.71(e). Current wording stresses different items for Part 72 SAR updates that are not included in Part 50 SAR updates. The underlying safety basis for SAR updates are not different, therefore the wording of the actual regulations do not need to differ. The differences in wording increases the burden on licensees who have to perform both Part 50 and Part 72 SAR updates by requiring different systems to be in place for the updates.

5. Part 72.48 contains additional burden over 50.59 because of additional criteria for review of environmental impacts and occupational exposure. In the finding of no Significant Environmental Impact included in the proposed rulemaking, the staff states that the amount of reviews required to make changes under the proposed 50.59 process is sufficient to determine that the rule will not cause a significant environmental impact. If the 72.48 review processes are revised to conform with that of 50.59 it is logical to draw the conclusion that a significant environmental impact will not occur by utilizing 72.48. However, the current and proposed 72.48 includes an additional requirement to evaluate the potential for a significant unreviewed environmental impact. If this requirement is not necessary for reviews of changes made to production and utilization facilities made under 50.59 with their higher potential for environmental impacts , it ought not to be necessary for changes made to Part 72

facilities.

Similarly, the current and proposed 72.48 requires an evaluation for significant increase in occupational exposure. This requirement is not included in 50.59. No justification exists for the difference in requirements. Additionally, both Part 50 and Part 72 facilities are subject to Part 20, therefore ALARA reviews are already included in site processes. These additional nonconforming requirements should be deleted from 72.48 due to the additional burden imposed on Part 72 licensees over Part 50 licensees without any additional safety benefit.

6. The wording for the seven criteria in 72.48 have not been revised to conform with 50.59. Specifically, 72.48 and other Part 72 regulations use the term "structures, systems and components important to safety" while Part 50.59 uses "equipment important to safety." Absent any safety based reason for the wording differences, the wording between 50.59 and 72.48 should not be different.

7. The new requirement for SAR updates by general licensees in 72.216(d) is a new significant reporting burden. Previously the SARs utilized by general licensees were considered to belong to the cask vendor and SAR updates were not provided to the NRC by the general licensees. The impact of this new requirement has not been specifically addressed in the paperwork reduction act statement, the regulatory analysis or the backfit analysis.

   We do recognize there may be operational, maintenance or other items in the cask SAR that general licensees may still need to change. In this case, they would perform the appropriate 72.48 evaluation and send proposed SAR changes to the cask certificate holder to collect and incorporate with their own, and other users' changes in the periodic submittals required by the proposed regulations. Licensee-initiated changes which do not meet the 72.48 criteria for implementation without prior NRC approval would be submitted by the cask certificate holder as an amendment to the certificate.

   General licensees should be obligated to maintain their 72.212 evaluation to the same level as their other plant-specific design and licensing basis documents. This includes maintaining records of the written evaluations of changes made under 72.48 and periodic updates of the entire evaluation. We would need to ensure that 72.48 applies to the licensees' 72.212 evaluations as well as the cask SAR.

8. While some merit exists in requiring general licensees to update SARs to account for plant-specific differences, no consideration has been given to

an implementation schedule for the new requirement. When SAR updates were initially imposed on reactor licensees, a schedule for the 1st update was included in the regulation which considered the greater than normal burden associated with the 1st update. A similar schedule should be added to the proposed 72.216(d).

9. 10CFR72.70, proposed 72.216(d), and proposed 72.248 would require an annual SAR update. However, a reactor SAR update can be as long as 24 months. No justification is given for requiring the more frequent updates for cask or MRS SARs than for reactor SARs. Since the potential safety consequences for casks are orders of magnitude less than reactors, the updating frequency should be equivalent, if not longer than allowed for reactor SARs using the CoC anniversary as the submittal date.

   Additionally, in 72.70 the requirement to update every six months after issuance of the license and 90 days prior to planned receipt is overly restrictive. NRC is currently in the process of deleting the requirement in 72.82(e) to perform a notification to the staff after preoperational testing and 30 days before loading. Many changes related to cask loading included in the SARs will not be identified or analyzed until preoperational testing is performed. Thus the 90 day SAR update requirement could be interpreted as another holdpoint before loading. Any changes made under 72.48 should not be considered of such a safety significance to require a SAR update three months prior to loading. Additionally the preloading SAR update requirements should be clarified to state if applicable to site-specific licensees, general licensees, or both. It should be noted 50.71(e) does not include similar requirements for production and utilization facilities.

10. 50.71(e) states that SARs must be updated to reflect all changes made up to six months before the submittal date. Changes to the cask design or supporting SAR should be made using the CoC anniversary submittal date. The existing and proposed SAR updating requirements included in Part 72 do not state a cutoff date for changes to be included in the updates. The Part 72 licensee could be considered in noncompliance if a change made two days prior to submittal is not included in the SAR update. The Part 72 SAR updating requirements should be revised to conform with those in Part 50, this should be consistent to accommodate cask certificate holders and cask activities..

11. The possibility exists that in a given year there may be no facility changes impacting an ISFSI FSAR and thereby requiring evaluation under 72.48 (or 50.59). This is especially true at an ISFSI located at the site of a permanently shutdown nuclear power plant. In such a situation the site-specific ISFSI licensee should merely issue a submittal [similar to

50.71(e)(2)] indicating that site activities resulted in no changes to the FSAR.

12. 10CFR72.48 requires an annual report of changes made. However 10CFR50.59 allows a similar report to be made at up to 24 month intervals. Similar to the above comment, no justification is given for requiring more frequent reporting for changes made under 72.48 than that required by 50.59. Since the potential safety consequences for casks are orders of magnitude less than reactors, the updating frequency should be equivalent, if not longer than allowed for changes to Part 50 facilities.

13. 10CFR72.48 is being revised to make distinctions between site-specific licensees and general licensees. This regulation states that if an amendment is required to utilize 72.56, cask vendors may make amendments under the proposed 72.244. However, 72.56 is not being revised to specifically define if it applies to both site-specific and general licensees. If it is intended that 72.56 not apply to general licensees, no current regulation specifies what actions a general licensee may take if its 72.48 review indicated that a license amendment is required.

14. Proposed 72.216 and 72.248 include requirements for general licensees and certificate holders to provide copies of SAR updates to each other. No guidance is provided for a timetable for internal reviews and incorporation or rejection of the changes made by the other party. Additionally, site-specific licensees may utilize cask types that have also received general approval. No requirements are given for site-specific licensees to provide updates to their respective cask vendors or general licensees that utilize the same general type casks. These discrepancies should be clarified.

15. The NRC should create rules allowing exigent and emergency processing of cask certificates under certain circumstances. The criteria of 10CFR50.91(a)(5) and (6) for operating reactor license amendments as a baseline for what general licensee or certificate holder circumstances warrant exigent or emergency processing.

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North Atlantic

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The Northeast Utilities System

December 18, 1998

NYN-98143

AR#98019093

Mr. John C. Hoyle
Secretary of the Commission
Attention: Rulemakings and Adjudications Staff
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555-0001

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

Seabrook Station
Comments on Proposed Rulemaking to 10 CFR 50.59
Changes, Tests and Experiments
(63 Fed. Reg. 56098 - October 21, 1998)

This letter provides the North Atlantic Energy Service Corporation (North Atlantic) comments on proposed Rulemaking to 10 CFR 50.59, Changes, Tests and Experiments (63 Fed. Reg. 56098 - October 21, 1998).

North Atlantic has reviewed and provided input to the comments being submitted separately by the Nuclear Energy Institute (NEI) on behalf of the industry, and enthusiastically endorses those comments. The industry comments being submitted by NEI address North Atlantic concerns with the proposed rulemaking. We are, however, particularly concerned with two areas of the proposed rule and wish to reinforce the NEI comments in these areas. The following provides specific comments on the two areas of concern.

North Atlantic strongly opposes the proposed changes which represent an expansion of the reporting requirements contained in 10 CFR 50.71(e). We are particularly concerned with the rule language that would require the reporting of "The net effect of all changes made since the last update on the safety analysis, including probabilities, consequences, calculated values, system or component performance". This new and undefined requirement would result in additional burden and would be in addition to the information provided for each individual evaluation summary and the effects of changes on the updated FSAR which are already

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reported to the NRC under the requirements of 10 CFR 50.59(b)(2) and 10 CFR 50.71(e). The determinations concerning the impact of a change on the probability of accidents or malfunctions are largely qualitative in nature. North Atlantic is concerned that the process used to determine the net effect of a number of qualitative assessments can not be accurately defined and would be the subject of debate between the industry and the Staff. Further, even if agreement could be reached on an acceptable process for assessing the net effects of changes, the results would be largely qualitative and would not provide measurable or meaningful information such that a quantitative conclusion could be reached. The qualitative process employed in the evaluations performed for changes under 10 CFR 50.59 simply does not lend itself to the quantitative assessment process implied by the language of the proposed rule.

The second area of concern relates to the addition of definitions of key terms used in 10 CFR 50.59. Specifically, North Atlantic believes that clear, precise definitions of "change", "facility as described" , "procedures as described" and "tests and experiments not described" are essential to an effective screening process. The North Atlantic experience with 10 CFR 50.59 is consistent with the industry experience and the observations of the Staff. That is, the largest percentage of issues related to improper application of the 10 CFR 50.59 rule involve the failure to identify the need to perform a 10 CFR 50.59 evaluation. Providing unambiguous definitions for the key terms used in 10 CFR 50.59 represents one of the most important improvements of the proposed rulemaking. We fully support the clarifications to the proposed definitions as discussed in the comments presented by NEI. These important clarifications are absolutely necessary to add clarity to the rule and improve the effectiveness, accuracy and efficiency of the screening process.

If you have any questions regarding these comments, please contact Mr. Terry L. Harpster, Director of Licensing Services at (603) 773-7765.

Very truly yours,

NORTH ATLANTIC ENERGY SERVICE CORP.

Ted C. Feigenbaum

Ted C. Feigenbaum
Executive Vice President and Chief Nuclear Officer

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DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63FR56098)

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RULEMAKINGS AND
ADJUDICATIONS STAFF

CP&L

Carolina Power & Light Company
PO Box 1551
411 Fayetteville Street Mall
Raleigh NC 27602

Serial: PE&RAS-98-112

December 18, 1998

Mr. John C. Hoyle
Secretary of the Commission
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Comments on Proposed Rulemaking, Parts 50, 52 and 72, *Changes, Tests, and Experiments* (63 FR 56098)

Dear Sir:

Carolina Power & Light Company (CP&L) offers the following comments regarding the proposed rulemaking:

- CP&L concurs with comments submitted by the Nuclear Energy Institute (NEI) for this proposed rulemaking. This proposed rulemaking presents the NRC and the industry with a unique opportunity to push forward the concept of risk-informed, performance-based regulation in an area that stands to be mutually beneficial by focusing the resources of both on matters that have the largest potential to impact the public health and safety.

- In general, CP&L concurs with the NRC's proposed reorganization of the rule. In particular, providing a new section on Definitions will be of great benefit to the industry and the NRC in establishing the clear meaning of the related terminology. Also, the movement away from the terms "safety evaluation" and "unreviewed safety question" and toward the "need to obtain a license amendment" refocuses the intent of the review.

- The proposed definition of "change" should be redirected toward a focus on change in <u>design function</u>.

- With regard to probability of occurrence of an accident, CP&L concurs with NEI that implementation of the rule should continue to allow for qualitative engineering judgments to be acceptable regarding such probabilities.

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- Regarding minimal increase in consequences of accidents and malfunctions, the term "consequences" should be related clearly to radiological dose.

- CP&L also favors the use of some percentage of the remaining margin between the regulatory limit and the calculated results as an acceptable means of assuring a minimal increase and concurs with NEI's suggested 10% value. In this light, CP&L does not favor the proposed changes in reporting requirements in 10 CFR 50.71(e) that would require addressing the cumulative effect of changes on risk. However, if the deletion of the "margin of safety" criterion is adopted, CP&L supports NEI's proposed alternative evaluation criteria.

CP&L appreciates the opportunity to comment on this issue of vital importance. If you have any questions regarding these comments, please contact me at (919) 546-6901.

Sincerely,

Donna B. Alexander

Donna B. Alexander
Manager, Performance Evaluation
and Regulatory Affairs

(19)

UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899

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RULEMAKINGS AND
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18 Dec 1998

DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63FR56098)

Secretary
NRC
Washington, D.C. 20555-0001
Attention: Rulemakings and Adjudications Staff

Ref: RIN 3250-AF94

Dear Sir:

The proposed changes to 10CFR50.59 (and related sections) are in general well thought out and represent an incremental improvement to the rules. However, in the context of research and test reactors, as opposed to power reactors, the process and methods for implementing this proposed rule as described in the proposal are clearly onerous and excessive in light of the minimal risks to the public posed by these facilities and in view of the provisions of the Atomic Energy Act for this class of reactors. Other than writing a separate Part 50 for these reactors, specific changes to this proposal that would be appropriate for both types of reactor licensees are not evident. What is needed is clearer guidance, both in the statement of consideration and from the Commission in other guides, e.g., ANSI standards, that clarifies the methods for implementation appropriate to non-power reactors in a manner similar to that of the power reactor community via the NEI guidance.

In regard to the alternatives for defining *minimal increase in probability or consequences* the statements of consideration should explicitly acknowledge that in the case of non-power reactors these risks are already minimal so that the primary thrust of a 50.59 analysis in this instance is more in terms of consistency with the SAR than quantitative assessment. Specifically, the analysis of incrementally small changes to an already small risk is an unnecessary exercise and a diversion of limited resources of both the NRC and the licensee.

In particular the Commission should emphasize that documentation related to this implementation should be commensurate with the risks posed by these facilities and proposed actions. This is consistent with the provisions of the Atomic Energy Act that requires the Commission to impose only the minimum of regulation on this class of reactors to assure the public health and safety and permit widespread and diverse research and application of these facilities.

Sincerely,

Lester A. Slaback, Jr.

Lester A. Slaback, Jr. C.H.P.
Supervisory Health Physicist

Acknowledged by card DEC 31 1998

UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899

18 Dec 1998

Secretary
NRC
Washington, D.C. 20555-0001
Attention: Rulemakings and Adjudications Staff

Ref: RIN 3250-AF94

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Sincerely,

Lester A. Slaback, Jr. C.H.P.
Supervisory Health Physicist

(18)

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December 18, 1998

Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
ATTN: Rulemakings and Adjudications Staff

DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63FR56098)

Subject: Comments on Proposed Rule 10 CFR Parts 50, 52 and 72, RIN 3150-AF94, Changes, Tests and Experiments

I provide these comments in response to the Federal Register notice of proposed rulemaking on 10 CFR 50.59 and other regulations related to evaluations to determine the need for Commission approval of proposed changes, tests and experiments at nuclear power plants and other licensed facilities. My background with 10 CFR 50.59 includes preparing safety evaluations, consulting on safety evaluation issues, numerous reviews of programs and evaluation at plants throughout the United States and training approximately 4,000 individuals on 10 CFR 50.59 application. Many of my comments result from a desire to assure agreement on interpretations and application of the changes.

The need to achieve agreement between NRC staff interpretations and industry interpretations is well known. The Commission and NRC staff should be commended for moving forward with that objective.

We have seen the result of literal interpretation of words in a regulation. This draft change in 10 CFR 50.59 and the proposed statement of consideration include several new opportunities for similar interpretation problems in future application of 10 CFR 50.59. My comments will attempt to identify some of these areas that are at risk of different interpretations. Many of the proposed changes to 10 CFR 50.59 could result in significant increases in the burden on licensees and the NRC staff. These would completely fail to meet an objective stated in the regulatory analysis "to clarify and slightly relax the criteria for when prior NRC approval is needed for such changes."

Although these comments focus on 10 CFR 50.59, they should be applied to other regulations where appropriate. Please call if further clarification of my comments is needed.

Sincerely,

Larry A. Grime

Larry A. Grime, PE

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TESTS AND EXPERIMENTS NOT DESCRIBED IN THE SAR — II.D

It is important that tests and experiments criteria be provided that limit the evaluations to just those tests that represent a potential risk to public health and safety. **The proposed definition of tests and experiments might better serve both the licensee and the regulator if it focuses on the concept of performing evaluations for those proposed tests and experiments that would have been included in the SAR if they had been planned at the time the SAR was written.** Licensees that are committed to RG 1.70 would use that and other applicable guidance. Non-RG 1.70 plants would use guidance that they are committed to and their existing SAR described tests and any experiments as guidance.

FINAL SAFETY ANALYSIS REPORT DEFINITION — II.E and Proposed Rules

The phrase 'or in evaluation performed pursuant to this section and safety analyses performed pursuant to section 50.90 after the last final safety analysis report was updated pursuant to section 50.71 of this part' should be incorporated into the definition. It is ridiculous to repeat it with each of the criteria in the rule. I can envision licensee forms that carry this extra baggage, which distracts from the issue when performing evaluations.

PROBABILITY OF OCCURRENCE OF AN ACCIDENT II.G

The accident frequency classifications should recognize the moderate frequency, infrequent incidents and limiting faults system used by some licensees for frequency classifications. **It is not clear from the presentation if the change in accident classification is intended as the definition of a more than minimal increase in probability of an accident or an example of such an increase.** If the Commission intent is to define 'minimal' as more than 'negligible,' then unless this is considered the definition of a more than minimal increase, the definition would become the NEI 96-07 negligible approach.

PROBABILITY OF EQUIPMENT MALFUNCTION — II.G

The staff recommended criteria, "the probability of malfunction is more than minimally increased if a new failure mode as likely as existing modes is introduced," is unacceptable. This could easily be interpreted to require a license amendment for nearly all proposed activities. For example, if a component is added to the plant, it would have a failure mode that could be considered new since the component did not previously exist. Even if the new component had a very low probability of failure, there would be other components that had similar probabilities of failure that could trigger the criteria. New failure modes should be evaluated against the 'different malfunction' criteria. This failure modes discussion should be deleted from application to equipment malfunction probability.

The statement, "The probability of malfunction ... is no more than minimally increased if 'design bases' assumptions and requirements are still satisfied [i.e. the seismic or wind loadings, qualification specifications, procurement requirements]," is a good approach that appears to be consistent with NEI 96-07. However, **the reference to 'procurement requirements' as a design basis assumption or requirement must be deleted**. Procurement requirements normally are in excess of the design bases requirements, and procurement requirements do not establish the design basis; the design basis helps determine the procurement requirements. As written, this statement would make failure to meet a procurement requirement an issue requiring a license amendment instead of an issue between a purchaser and a supplier.

DEFINITION OF MINIMAL CONSEQUENCES — II.G

The option to use a percentage of the difference between regulatory limit and the SAR reported value would be much better than a complicated variable percentage or a fixed difference. I support the NEI recommended percentage guidance of 20% versus 10% as presented in the draft guidance. When placed into perspective with the present industry guidance (100% of the difference between the SAR value and the acceptance limit) a 20% criteria is 80% below the NEI 96-07 criteria. I find that licensees tend to avoid changes that increase radiation releases of any amount. This results in a very low occurrence of changes that result in increases in calculated radiological releases.

The option to use a fixed 0.5 rem increase includes a prohibition on changing design basis assumptions or analytical methods, or both, to demonstrate that the change is less than 0.5 rem. Licensees using an approved methodology should not be held to this restrictive approach. Since the design bases definition is not well understood, this would also tend to prohibit credit for any action to limit releases through actions such as a reduced fuel cycle length, delaying the start of fuel handling, or installing a faster containment isolation valve.

The graduated approach option would add unnecessary complication to the evaluation process.

Comments on the reporting needs are discussed in my comments on reporting and recordkeeping requirements.

MARGIN OF SAFETY — II.J

This issue has gotten entirely out of control! The staff change to claim that the interpretation of criteria such as peak clad temperature is from the value reported in the UFSAR — never the regulatory requirement of 2200° F — is a giant step backwards in progress toward resolving 10 CFR 50.59 conflicts. Staff testimony before the ACRS gave no indication that this issue was about to be completely reinterpreted.

After considering the various proposals from both the Federal Register publication and NEI comments on a barrier focus, **I fully support deleting the margin of safety question**, Option 2. The question on increasing the probability of failures can adequately address issues that would be addressed under margin of safety. The guidance could include reference to the barriers for this question. In what situations would reducing a margin of safety not increase the probability of a malfunction of equipment important to safety?

Although I prefer deleting the margin of safety question, I could also support the NEI 'New Approach to Margin of Safety' if design basis limit is interpreted to be the commonly used criteria for barrier performance parameters such as peak clad temperature of 2200° F, fuel enthalpy of <280 cal/gm and 110% or 120% of ASME code pressure. If design basis is interpreted to be the calculated post accident or post transient values, the NEI approach would be an unacceptable and an unnecessary burden on both the NRC staff and licensees.

Margin of Safety Option 1

The proposed NRC staff definition in Option 1 of a reduction in margin of safety is unacceptable for many reasons. Many of these reasons are expressed in the comments from the Commissioners. My additional comments on this option follow.

1. It expands the present concept of acceptance limits applied to margins of safety to include 'input assumptions, analytical methods, criteria and limits of the safety analysis.' Changes in analytical methods should be evaluated using various methods other than 10 CFR 50.59.

   The inclusion of input assumptions in the reduction of margin of safety definition is inconsistent with the stated objective of "would not want to unduly affect licensee operations." There are numerous parameters that are controlled by the technical specifications. A single parameter may have tens to hundreds of input assumptions associated with it. This definition would result in numerous issues that have nonconservative changes in input assumptions requiring a license amendment — even when there is no safety significance to the change. For example, the specific current load for all post accidents required circuits connected to a diesel generator supplied electric bus is an input assumption associated with a technical specification. Increasing the current from 200.35 amps to 200.36 amps would appear to be a nonconservative change. Although the load handling capability of the diesel generator and associated requirements for fuel consumption, cooling etc. could be found to still be conservative, the change would require advance Commission approval.

   Criteria and limits of the safety analysis are not clearly defined. If these terms were defined, they should be redundant to the definition of acceptance conditions. This comment assumes that the term 'acceptance conditions' means 'acceptance limits' as currently defined in NEI 96-07.

2. The limit on finding acceptance criteria only in the final safety analysis report is too limiting. Acceptance criteria are much more likely to be found either directly or through reference in the staff safety evaluation reports. Regulation 10 CFR 50.34 does not require the safety analysis report to include acceptance criteria (and other items in the proposed list of items to evaluate for potential margin of safety reductions).

3. Alteration is yet another term that is subject to interpretation. The nonconservative manner concept would be easier to implement if it followed the currently used approach with NEI 96-07 that focuses on acceptance limit being exceeded versus a nonconservative alteration.

In addition, Option 1 is likely to trigger a backfitting argument from licensees. This could result in delays in implementing the final regulation should a licensee decide to mount a legal challenge to the change.

Margin of Safety Option 2

I prefer this option. As suggested in the proposed rule publication, other criteria — particularly the question on the probability of failures of equipment important to safety — can assure no significant adverse changes to margins in design and operation.

The options on criteria for margin of safety that are not a significant and ultraconservative change in its treatment would result in treating it as is currently done with NEI 96-07, or similar to NEI 96-07, but with a reduced set of parameters to evaluate (i.e. Focus on technical specification controlled parameters or barriers and use the acceptance criteria concept). The ultraconservative suggestions are discussed with my options 1 and 3 comments.

This results in licensees demonstrating that they would not reduce a margin of safety by demonstrating that acceptance criteria such as peak clad temperature limits, reactor coolant system pressure limits and other applicable standards would be met. This is essentially the same justification that will be used to address potential increases in the probability of a malfunction of equipment important to safety. Meeting peak clad temperature and reactor coolant system pressure requirements are part of the design bases related to the proposed activity. If the components continue to meet their design bases, we would also expect a finding that the proposed activity would not increase accident or malfunction consequences due to a barrier failure.

Option 2 is the only option that would not trigger a backfitting response from licensees.

Margin of Safety Option 3

Margin controls on the results are preferred over controlling the inputs discussed in Option 1. However, this option still retains a very big risk of a 'zero increase' interpretation. Concepts discussed in 3(A)(1) are a totally new approach to treating margin of safety. Concepts 3(A)(2), 3(A)(3) and 3(A)(4) also are new; they just focus on fewer issues. The only acceptable variation would be the approach mentioned in the section b discussion on margin of safety. Specifically, "The Commission is evaluating options ranging from ... to an option that would allow increases up to 'specified limits (acceptance criteria).'" This option without limits on percentage changes as discussed later in the proposed rule notice is comparable to the present approach. As such, that approach would be the only approach not subject to backfitting challenges. It also would be the only approach that keeps the resources focused on the most significant issues.

It appears that the statement in the third paragraph of the Option 3 discussion should read 'which cannot be modified *without* NRC review.'

REPORTING AND RECORDKEEPING REQUIREMENTS II.L

The reporting requirement proposed to be added to 50.71(e) could place an excessive burden on licensees with no benefit. The suggested (e)(4) section should not be added.

If licensees must include the net effect of increases in probability, for example, this could result in excessive pressure to calculate the probabilities. Even if the licenses would be expected to note that the accident category is not changed, several licensees currently have events categorized as being more likely to occur than they would be if they were calculated. This would result in excessive focus on issues that are not important to nuclear safety. From my review of several SARs I have found it very rare to have an accident probability quantified. Usually only select external hazards have calculated probabilities. Several, but not all, SARs categorize events based on the probability of occurrence. The fact that the probability increase did not trigger the need for a licenses amendment should be an adequate indication of the present status of the accident probability.

The net effect of changes on accident consequences, calculated values and system or component performance, if it is different that the previous SAR description, would be revised without this added requirement. If it is not different than the previous description, there would still be nothing to report. Changes in the SAR description are labeled by the licensees. If the staff or Commission is interested in the net effect of all changes made since the last update, they can compare the current and previous revisions to the SAR for the specific need information.

If implemented, this added requirement would essentially require that an evaluation be reported three times to the regulator: once under the new 10 CFR 50.59 (d)(2); a second time when the SAR is changed to reflect the effects of the safety evaluation; and a third time when reporting the net effect of the safety evaluation. One report should be enough.

Instead of adding this effective third report of changes made, the Commission should consider eliminating the requirement in 10 CFR 50.59(d)(2) to separately report changes that is currently required by 10 CFR 50.59.

ACCIDENT AND MALFUNCTION CONSEQUENCES — Proposed Rules

I suggest combining these two issues. Some of our clients currently address these two questions together. Accidents are the source of potential radioactive releases. SAR analyzed malfunctions that do not initiate or affect mitigation of SAR analyzed accidents do not produce radiological consequences.

We find that keeping them separate tends to put people in the 'creative writing' mode which can lead to misstatements. Writers attempt to give completely different answers to the two questions.

If the questions appear separately in the regulation, I fear no licensee would have the option to combine the response to the two questions.

DESIGN BASES — Various sections

If 'design bases' is used anywhere in the publication, it must be defined in terms that are not subject to the varying interpretations we have recently witnessed. The NRC staff has demonstrated that the industry and their interpretation of the definition in the regulations is not consistently understood.

IMPLEMENTING CHANGES WITH LICENSE AMENDMENTS PENDING — SECY 98-171

Although the reference is not in the Federal Register publication, SECY 98-171 included a comment that the NRC staff would prohibit licensees from initiating any effort to make physical changes in the plant without an approved license amendment request. This is not in the best interest of the licensees or, in some cases, the regulator. **Licensees should in nearly all cases be permitted to procure and construct proposed facility changes associated with a pending license amendment request.** They should only be required to wait for the approved amendment to put the equipment into service. This is essentially a hardware version of a procedure change that is fully written but not implemented until the approval arrives.

(17)

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USNRC

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OFFICE OF SECRETARY
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Operations Support

DOCKET NUMBER
PROPOSED RULE PR 50,52+72
(63FR56098)

December 17, 1998

Secretary
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001
Attn: Rulemakings and Adjudications Staff

Subject: Comments on Proposed Rulemaking, 10 CFR Parts 50, 52, and 72, "Changes, Tests, and Experiments"

CNRO-98/00027

Ladies and Gentlemen:

Entergy Operations, Inc. (Entergy) appreciates the opportunity to comment on the proposed rulemaking of 10CFR Parts 50, 52, and 72, "Changes, Tests, and Experiments," as published in the Federal Register, October 21, 1998, Volume 63, Number 203. Specific comments are provided in the accompanying attachment. Entergy also endorses the comments submitted to the NRC by the Nuclear Energy Institute (NEI), the Nuclear Utility Backfitting and Reform Group (NUBARG), the Region IV Utilities Group, and the Licensing and Design Bases Clearinghouse.

Again, thank you for the opportunity to provide our comments.

Sincerely,

Steve Bethay for MRK

MRK/SJB/GHD/baa
attachment

cc: Mr. C. M. Dugger (W-3)
Mr. R. K. Edington (RBS)
Mr. W. A. Eaton (GGNS)
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Acknowledged by card DEC 31 1998

COMMENTS ON PROPOSED RULEMAKING
10 CFR Parts 50, 52, and 72

Entergy's comments on the proposed rulemaking are provided below under the associated rulemaking section.

I. **Background**, Implementation Guidance

Even though the NRC never endorsed NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations," the NRC provided comments to NUMARC in a letter dated May 10, 1989 from Charles Rossi, Director, Division of Operational Events Assessment. The NRC comments were incorporated almost verbatim including those associated with dose consequences and Margin of Safety. Most of the current NRC concerns with NSAC-125 (and later with NEI 96-07, "Guidelines for 10 CFR 50.59 Safety Evaluations") goes directly against previous NRC comments and positions.

II. **Proposed Rule Topics and Issues**

1. Practical application of the §50.59 rule has been in process for over 30 years with continuing improvements. Associated training is given at almost all industry sites. The NSAC-125 guidance (recently modified and updated in NEI 96-07) has been a significant industry primer for conducting 50.59 Reviews. With the NEI initiative in mid-1998 to ensure that all sites use the guidance of NEI 96-07, this guidance provides the industry with a stable approach to meet the 50.59 rule. Concerns raised due to the Millstone and Maine Yankee events were associated with failing to recognize that FSAR changes and associated 50.59 Reviews were needed rather than having conducted inadequate 50.59 Reviews or not meeting NRC current guidance of Part 9900 of the Inspection Manual.

   In a November 30, 1995, memo to the Executive Director of Operations and the General Counsel, Chairman Shirley Jackson noted that her 50.59 concerns were based on ensuring:

   1) facility changes undergo 50.59 review

   2) there is a consistent interpretation of the 50.59 process.

   The latter issue has been addressed by NEI through the mandatory industry initiative to adopt the NEI 96-07 guidance. The former issue relates to entry into the 50.59 process (i.e., the same as the issues at Millstone and Maine Yankee), and thus does not take issue with the NEI 96-07 or previous NSAC-125 guidance how to perform 50.59 reviews.

   In a December 16, 1995, memo to Chairman Jackson, the Executive Director of Operations stated the process, as currently implemented, provides reasonable assurance that plant safety has not been decreased. Also, there is currently no indication that implementation of §50.59, as it is carried out today, has led to decreased safety based upon NRC's inspection experience. Therefore, from a safety perspective, the level of effort expended by both the NRC and the industry in the last two years to reach a common 50.59 rule implementation perspective is not warranted based on the issues identified. As stated in Ms. Jackson's comments on the proposed rulemaking in the October 21, 1998 Federal Register notice regarding margin of safety, "I am concerned that that [sic] the result may be the addition of yet another layer of regulatory process rather than the elimination of any unnecessary layers." This was also a concern in a letter from the Advisory Committee on Reactor Safety (ACRS) letter to Ms. Jackson, dated July 16, 1998. The application of unnecessary staff and licensee burden is also considered applicable to the entire rule for other departures from the current industry established guidance.

The primary goal of the current 50.59 rulemaking should be to establish consistent and uniform guidance for determining an unreviewed safety question (USQ) by modifying the rule language to implement NEI 96-07. The industry has identified and submitted USQs for NRC review and approval via the guidance of NEI 96-07. Even though the NRC has identified certain cases they believed should have been USQs, these are limited and can be handled in examples of further guidance under NEI 96-07. Additional, longer-term rulemaking (2 - 3 years) should address the needed insights of "risk-informed" changes with a more objective evaluation process for determining a USQ. Minor changes in terminology, approaches, and other short-term improvements may only add additional licensee burden to modify their programs and NEI guidance with no real gained benefit. These minor changes should be part of a more exhaustive rule change, if determined necessary, to "wipe the slate clean" and develop a more effective 50.59 process. We agree with the approach recommended by Ms. Jackson that a short-term clarification be pursued with a longer-term approach to modify the 50.59 rule and other related rule sections [i.e. 50.59, 50.71(e), 50.62, etc.]

If the NRC Commission determines that broader rulemaking is appropriate at this time (a one-shot rulemaking), then NRC enforcement should only be applied during the interim rulemaking period for deviations to the established guidance of NEI 96-07. A task force made up of both industry and NRC members should convene regularly to establish a mutually acceptable 50.59 rule. **Given there is no safety concern, stability within the industry and NRC is the foremost near-term concern for §50.59 application.** See also ACRS letter of July 16, 1998.

2. As part of issuing any revision to §50.59, the NRC should define a period in which utilities are to revise their 50.59 processes to implement changes to the 50.59 rule (as well as implementing any changes required in the industry guidance of NEI 96-07).

3. It is clear that much of the difficulty involved with 50.59 is in the detailed application of the regulatory philosophy to specific cases. NRC and NEI should work together to provide examples, including those from actual precedents at plants, that do and do not meet the 50.59 Evaluation criteria that will result from any rulemaking. This would greatly enhance regulatory stability and reduce burden by making the expectations for 50.59 Evaluation criteria clear.

II.A(3) Criteria for needing Commission approval of changes, tests and experiments and Unreviewed Safety Question (USQ) designation

1. Entergy agrees with NRC's proposal to remove the term "unreviewed safety question" from the rule. However, as discussed in the general comments above, the need to obtain NRC and industry regulatory stability is foremost. Deleting this term should not interfere with achieving the ultimate goal of this rulemaking effort.

2. NRC recognizes that many facility Technical Specifications (TS) refer to USQ determinations and such TS should be revised in accordance with the final wording of §50.59. Entergy recommends the NRC streamline the approval of such change requests via the appropriate processes to decrease the burden on licensees and NRC staff personnel.

3. Entergy agrees with the proposed change to state each specific criterion individually.

4. Entergy agrees with the proposed change revising 50.59(c)(i) to state if a proposed change, test, or experiment would involve a TS change, 50.90 process must be followed in order to change the TS such that the change may be implemented. This is an acceptable change for clarification; however, the level of effort to modify §50.90 for this change is not warranted at this time.

II.B Change to the Facility as Described in the Safety Analysis Report

1. As discussed in the industry comments to NUREG-1606, changes to the safety analysis report (SAR) whether to procedures or the facility require a 50.59 Review (unless it is an inconsequential change). Adding definitions to the rule is not necessary and only adds confusion and additional details to the rule. The definition for this is appropriately contained in NEI 96-07. This is consistent with Mr. Diaz's comments for issuance of the rule.

2. A change to an "analysis method or parameter" is a change to the facility only if that "analysis method or parameter" is described, explicitly or implicitly, in the SAR.

3. If the level of discussion within the FSAR is unaffected by the proposed change and there is no change to the results of any underlying design analysis, then there is no requirement to perform a 50.59 evaluation.

4. The NRC should provide detailed guidance, or endorse detailed industry guidance, on the treatment of nominal values contained in the SAR under 50.59. If the SAR mentions a nominal value, there is inherently some control band associated with that value. For example, if the SAR specifies that a turbine oil pressure is maintained at 8 psig, would a procedure change to specify that the oil is to be maintained at 8 +/- 2 psig be considered a change to the plant as described in the SAR? Would it be considered a change to the plant as described in the SAR (thus requiring a 50.59 evaluation) if the control band in plant procedures were to be "8 to 10 psig" such that an argument could be made that 8 psig is no longer a nominal value?

5. Entergy understands NRC is planning to endorse NEI 98-03, "Guidelines for Updating Final Safety Analysis Reports." We agree with the treatment of information "incorporated by reference" in the SAR that is contained in NEI 98-03. By relying on "incorporated by reference," licensees may simplify their SARs by removing information that is duplicated in separate, controlling program documents such as the Emergency Plan, Offsite Dose Calculation Manual, and Technical Requirements Manual.

   Much information incorporated by reference in the SAR consists of fuel vendor topical reports or standardized analyses, such as the General Electric GESTAR document for BWRs (and similar documents for other reload vendors). Documents such as GESTAR are under fuel vendor control, rather than direct utility control. Information in such documents is referred to in licensee SARs providing methodology information required in the SAR (e.g., for Sections 4 or 15, amongst others). It would benefit licensees and the NRC if the 50.59 process could be expanded (or a parallel process developed) to allow reload vendors to evaluate changes to their high level documentation to determine whether or not such changes require NRC review or can be instituted without requiring NRC approval.

6. If a change is made in direct response to issues raised in generic communications from the NRC, such as Information Notices or Generic Letters, should such a change require a 50.59 evaluation? Some persons within the industry and NRC have wondered if such changes, provided acceptance limits from the SRP are not exceeded, could be construed as having been previously approved by the NRC because they are in response to NRC regulatory correspondence.

7. The proposed position on what constitutes a single change is consistent with the guidance in NEI 96-07. However, there is no need to develop a definition in the rule as discussed above.

8. As discussed at the October, 1998, NEI Licensing Issues Workshop, NRC should provide specific examples of cases where activities normally viewed as maintenance (outside the scope of 50.59) <u>do</u> involve a change to the plant as described in the SAR.

II.C <u>Change to the Procedures as Described in the Safety Analysis Report</u>

1. NEI 96-07 states the Emergency Plan and the QA Program Plan are not part of the 50.59 Review requirements since they are controlled under 10CFR50.54. However, if the Staff believes the rule should be clarified to avoid duplicative effort, then we agree with the proposed change.

2. As discussed in the industry comments to NUREG-1606, changes to the SAR, whether to procedures or the facility, require a 50.59 Review (unless it is an inconsequential change). Adding definitions to the rule is not necessary and only adds confusion and additional details to the rule. The definition for this is appropriately contained in NEI 96-07. This is consistent with Mr. Diaz's comments for issuance of the rule.

3. Entergy agrees with footnote 3: that 50.54(p) establishes change control requirements for safeguards contingency plans; 50.59 does not apply to these plans.

II.D Tests and Experiments not described in the Safety Analysis Report

There does not appear to be a disagreement with the approach to applying "tests and experiments" within the proposed definition. However, as discussed above, a similar definition provided in NEI 96-07 accomplishes the same purpose. Adding this definition to the rule is not necessary and should be controlled by a guidance document.

II.E Safety Analysis Report

No comment.

II.F Probability of Occurrence or Consequences of an Accident or Malfunction of Equipment Important to Safety Previously Evaluated in the Safety Analysis Report may be Increased

1. Each plant has a set of events for which it must respond. Each event is assigned to one of the following frequency classifications:

   - Incidents of moderate frequency – may occur during a calendar year to once per 20 years
   - Infrequent incidents – may occur once in 20 years to once in 100 years
   - Limiting faults – are not expected to ever occur.

   The events and their frequency classifications are typically identified in each facility's SAR. The NRC should recognize changes within the frequency classification do not constitute an increase in probability. An increase in probability would be realized only if the event moved into a more frequent classification (e.g., from "infrequent incidents" to "incidents of moderate frequency"). This position would not require the term "minimal increases in probability" to be defined while still maintaining assurance of public health and safety.

2. For each frequency classification identified above, the NRC has established acceptance criteria pertaining to dose consequences each event must meet. These criteria are typically identified and discussed in the SAR. The NRC should recognize changes in dose consequences that continue to meet these acceptance criteria do not represent an increase in consequences. This position would not require the term "minimal increase in consequences" to be defined while maintaining assurance of public health and safety.

3. If the above approaches are not acceptable, the NRC should endorse the existing industry positions presented in NEI 96-07.

4. The NRC's attempt to tie "increase in consequences" to values reported in the SAR rather than to acceptance limits in the SER (usually from the SRP) will clearly penalize those plants that maintain a greater level of detail in the SAR, and would prove counterproductive to NRC's interest in SAR integrity. Plants that have provided more detailed information in their SARs would be penalized under the draft guidance, as any use of the design margin between what is reported in the SAR and the SRP/SER acceptance limits would result in failing 50.59 Evaluation Criteria. For example, one plant may have reported consequences in a less specific manner than others, reporting that the consequences of a certain accident (e.g., Reactor Coolant Pump Shaft Seizure) is less than a small fraction of 10CFR100 limits (e.g., 30 Rem thyroid). In contrast, a plant that maintains a higher level of detail in its SAR would have placed actual numerical results for the event in its SAR. Thus, if there is a change resulting in a slight increase in calculated dose for this event, the plant that maintains more detail in its SAR would have to make a submittal to the NRC, whereas the plant with less detail in its SAR could make the change without NRC approval. Thus, paradoxically, the NRC approach on "increase in consequences" would penalize those plants that attempt to maintain a greater level of detail and fidelity to the actual plant in their SARs. Thus, the discussion in Attachment 1 of SECY-98-171 that there is no "penalty" for plants that do a better job of maintaining their SAR would be incorrect.

   NRC agreement with the fact that the SAR is not the baseline for determining if there is an increase in consequences is documented in the May 10, 1989, NRC letter from C. E. Rossi to T. E. Tipton of NUMARC. In this letter, the NRC states:

   > "If a proposed change, test, or experiment, would result in an increase in dose from an accident or equipment malfunction above that previously reviewed and approved by the staff as part of the licensing basis for the plant (i.e., the acceptance limit), then the proposed change, test or experiment involves an unreviewed safety question and would require prior NRC approval."

   The NRC also states in this letter:

   > "...if in licensing the plant the staff explicitly found that the plant's response to a particular event was acceptable because the dose was less than the SRP guidelines (without further qualification) then the staff implicitly accepted the SRP guideline as the licensing basis for the plant and the particular event, and the licensee may make changes that increase the consequences for the particular event, up to this value without NRC approval. However, if the staff cited some value other than the SRP guideline as its criteria for licensing the plant then that value is considered the licensing basis for the plant."

   By these statements, the NRC has clearly established the acceptance basis in the SER, which is often that of the SRP, is the proper licensing basis for the plant. Thus, any value for dose consequences which remains less than the acceptance basis has been reviewed by the NRC as within the plant licensing basis and, hence, is not a USQ.

An example exists where NRC has explicitly used the SRP alone as the basis for limits on a plant's licensing basis. In 1992, a PWR submitted to the NRC, as a potential USQ, a case where the calculated percent of fuel rods experiencing departure from nucleate boiling (DNB) resulting from a transient exceeded the value previously documented in its SAR and SER. The SER had repeated the results of the utility analysis and had concluded, without an explicit basis, the results were acceptable. Since there was no clear acceptance basis discussed in the SER, the utility had submitted this case to the NRC as a potential USQ. The NRC responded to the utility that the change was acceptable under the criteria of 50.59 and stated:

> "However, even if all of the pins experiencing DNB were to fail, a coolable geometry would be maintained and the consequences remain a small part (less than 10 percent) of 10CFR Part 100 limits."

Thus, NRC actions demonstrated this issue was not considered an increase in consequences since the SRP acceptance limits for this event (less than 10 percent of 10CFR100 limits) were met.

5. In footnote 6 related to the NRC response to the NEI 96-07 position on consequences, the NRC states that attempting to use values from the staff's SER as acceptance limits would be difficult since SERs were not written for the purpose of establishing such limits. However, it is clear that the SERs were written to document the basis for the NRC evaluation, such that the use of SER values as limits is a conservative approach. NRC reviewers still continue their practice of using the SERs to provide practical acceptance limits related to utility submittals. Further, industry experience over the approximately 10 years since NSAC-125 came into broad use indicates that use of the SER as acceptance limits is workable and is not difficult.

6. While NRC states in Attachment 1 to SECY-98-171 that changes increasing consequences up to the limits should receive staff review, this opinion is divergent from past NRC practice. NRC has clearly focused on the SRP acceptance limits during its previous SER reviews. Cases where the NRC has imposed more restrictive acceptance criteria through its SER are believed to be relatively infrequent.

   NRC has clearly indicated its intentions to make 50.59 a risk-informed rule. Using SRP acceptance limits for does consequences is consistent with the intent of capturing risk insights in the 50.59 process. Failure to establish clear and consistent acceptance criteria would also undermine the validity and usefulness of the SRPs in the regulatory process. From a risk perspective, the difference associated with the doses reported in the SAR and the presumably higher SRP acceptance criteria are practically non-existent. It is inconsistent for the NRC to be moving in the long-term toward a risk-informed regulatory structure, including possibly the 50.59 rule as discussed in SECY-97-205 dated September 10, 1997, but failing in the short-term to accommodate this risk insight.

The NRC, in topic III.S of Attachment 1 to SECY-98-171, indicated the acceptance limit for margin of safety could be extracted from the NRC's SER vice being limited to values contained in a plant's SAR. It is inconsistent for the SER to be acceptable for defining margin of safety acceptance limits but not acceptable for dose consequence acceptance limits.

The Notice of Proposed Rulemaking (NOPR) approach inherently accepts the SRP as a true acceptance limit. This is a fundamental disagreement with the recent position promulgated by some in NRC that the SRPs are only guidance and not acceptance limits. By allowing "minimal" increases over the values documented in the SAR, NRC is in effect setting the SRP acceptance limits as the true acceptance criteria for consequences.

Thus, the proposed NRC approach in defining "minimal increases" in consequences is inherently in conflict with the NRC position that consequences are as defined in plant SARs instead of as established through clear NRC acceptance limits in the SRP or in NRC plant-specific SERs.

NRC should provide guidance regarding a change in probability class for an event analyzed in the SAR constitutes merely an increase in probability or if the change in probability class (generally with associated changes in acceptance criteria) constitutes a new accident not previously analyzed in the SAR.

II.G More than a Minimal Increase in Probability or Consequences

1. Of the three options discussed in this section, the graded approach presented in the second option offers the best approach. See the comments under Section II.F above for further discussions of increase in consequences.

2. Entergy believes using a graded approach as discussed in the second option would address the NRC's concern. Assuming several "minimal" changes are made, the calculated result approaches the acceptance limit with each change. Using a graded approach, each change would be evaluated to determine acceptability without NRC approval. This approach inherently addresses the concern of cumulative effect.

3. Regarding what constitutes a "minimal" increase in consequences based on dose information documented in the SAR, NRC should address the case of plants that have lowered dose due to one change and subsequently increased dose due to a later change. For example, consider a plant licensed with an original LOCA thyroid dose of 290 Rem thyroid. The plant later finds an over-conservatism in its analysis and reduces the dose to 225 Rem thyroid. A subsequent change to the plant then increases the dose to 275 Rem. This increase from 225 to 275 Rem should not be considered an "increase in consequences" since the plant was originally licensed to 290 Rem. NRC should clarify its proposed guidance on this subject to explicitly recognize this situation; otherwise, there is a disincentive for plants to remove known over-conservatisms from their analyses. This is another reason why an increase in consequences should be determined against the clear acceptance limits of the NRC SRP and/or SER.

4. NRC provides a specific example in the second paragraph under "Consequences of accident or malfunction" in Section II.G. Not only is this change "no more than a minimal increase" in consequences as stated by the NRC, it is simply no increase since the new analysis result remains bounded by the previous analysis result, provided the change in input assumptions are technically justifiable, consistent with acceptable methodology, and remain conservative.

II.H Possibility of an Accident of a Different Type from any Previously Evaluated in the Safety Analysis Report may be Created

1. Entergy recommends the second approach discussed above. "Accidents" should be limited to the bounding "design basis accidents".

2. In considering the definition of "accident", note that SAR Chapter 15 "accidents" must meet different acceptance criteria than "accidents" used to determine core damage frequency within Probabilistic Risk Assessments (PRA). PRAs generally focus on severe accidents rather than Chapter 15 limited fault events. For example, a design basis Loss-of-Coolant Accident (LOCA), evaluated from a best-estimate perspective consistent with PRA methodology would not be a severe accident since peak clad temperature acceptance criterion would not be exceeded and clad oxidation would be minimal. The differences in the level of acceptance criteria used for Chapter 15-type safety analyses and plant PRAs should be fully understood and considered in determining acceptance criteria or the definition of "accident" in any future risk-informed 50.59 rule.

II.I Possibility of a Malfunction of a Different Type from any Previously Evaluated in the Safety Analysis Report may be Created

Entergy agrees with the proposed changes presented in this section.

II.J Margin of Safety as Defined in the Basis for any Technical Specification is Reduced

1. Entergy finds Option 1 unacceptable for the reason stated in the proposed rulemaking; that is, this approach would have the effect of elevating input values and assumptions to the same level as TS. As the NRC recognizes, this position is inconsistent with §50.36.

2. Entergy fully supports Option 2. Any reduction in a true "margin of safety," however defined, would conceivably correspond also to potential increases in consequences or probability of accidents or malfunctions of equipment important to safety.

   In her comments, Chairman Jackson noted, "...it is not clear what type of changes would successfully pass the 10CFR50.59 test for allowed 'minimal increases in consequences' without failing the test for 'no reduction in the margin of safety.'" Therefore, due to this interaction between evaluation criteria, Option 2 appears to offer the greatest benefit.

3. Entergy finds Option 3 and its variants unacceptable. Each option basically makes the SAR value the acceptance limit. Therefore, no change could be made in the

event the SAR value changed. This approach continues the current inconsistency of licensing plants to different limits.

4. If the "margin of safety" concept is to be retained within 50.59, it is clearly desirable to focus the on the safety analyses directly related to fission product barrier performance (e.g., fuel clad, reactor coolant pressure boundary, primary containment). This is similar to the approach presented by NEI at the NEI Licensing Issues Workshop on October 19, 1998.

   The concept of "margin of safety" should be consistent with that of NEI 96-07. Margin of safety should be defined as:

   > "Margin of Safety: the difference between a clear acceptance limit (i.e., safety limits as defined per Technical Specifications and other high level design limits which protect against fission product release, e.g., containment pressure design limit) and the ultimate failure point for the barrier under consideration."

   Thus, the margin of safety would be negatively impacted by changes in methodology that would reduce the difference between the acceptance limit and the ultimate failure point. Margin of safety should be considered only for where there are clearly defined acceptance limits: Safety Limits which are defined in Technical Specifications, 2200°F for PCT, the containment design pressure, calorie/gram limits on fuel centerline melt, kW/ft limits on fuel linear heat rate, etc.

5. Revising analyses to incorporate changes in methodology that have been generically endorsed or approved by the NRC should not be regarded as having any impact on margin of safety, and thus acceptable under 50.59. For example, NRC revised SRP Section 6.5.2 in 1988 to allow revised models for crediting containment spray for fission product removal. This change clearly indicates NRC approval or endorsement of new methodology. Any plant should be able to revise its radiological analyses to credit fission product removal according to the methodology outlined in the SRP without NRC approval. To demand NRC approval in such cases is to ignore risk insights and to add regulatory burden on licensees to adopt the best known and available methodology without any commensurate increase in safety associated with such burden.

II.K Safety Evaluation

Entergy agrees with the NRC's proposal to delete the term "safety" for the reasons given in the proposed rulemaking.

II.L Reporting and Recordkeeping Requirements

1. The proposed changes to §50.71(e) would require the net effect of all changes made since the last update of the SAR, including changes to probabilities, consequences, calculated values, system or component performance, be documented in the SAR. It is not clear that this is any difference from current SAR update requirements or current utility practice; all changes in consequences, calculated values, and system or component performance are captured in SAR

changes. Changes in probability class are also captured. Generally, in using the NEI-96-07 guidance, changes in the probability of equipment malfunction or accident probability are not quantifiable, such that 50.59 evaluation criteria is met only if there is no discernible change in probability. In the vast majority of cases, there would be nothing to report in this area. Thus, it is not clear that any changes are required to 50.71(e).

There should be no change in the requirements for summarizing individual 50.59 Evaluations associated with the rule change.

2. NRC proposes to change 50.71(e) to discuss the effects of plant changes upon calculated doses and other information. The current 50.71(e) requires the SAR update to "**contain** [emphasis added] all the changes necessary to reflect information and analyses submitted to the Commission by the licensee ..." The wording of the proposed revision for the update to "**describe the effects of** [emphasis added]..." changes can be interpreted as requiring each SAR update to include a an analysis of each change included in the update, separate from the revised wording in the SAR and in addition to the summaries of the analysis included 50.59 report. This interpretation would cause a significant increase in burden associated with SAR updates over that currently performed. This increased burden is inappropriately discounted in the backfit analysis for the proposed rule and in the paperwork reduction act statement.

3. Entergy concurs with the proposed change to 50.59(b)(3), which will require licensees to maintain records of changes to the facility until the termination of the license.

II.M Part 72 Changes

1. Accident consequences (potential offsite dose) for casks licensed per Part 72 are a very small percentage of that possible for reactors, yet many requirements in Part 72 for evaluations, reporting requirements, and SAR updates are more restrictive. As a minimum, these requirements, as discussed below, should be made equivalent to their Part 50 counterparts. The current and planned requirements that are more restrictive do not conform to a policy of placing emphasis in areas with higher safety significance.

2. NRC proposes to change 50.71(e) to discuss the effects of changes upon calculated doses and other information. The current 50.71(e) requires the SAR update to "**contain** [emphasis added] all the changes necessary to reflect information and analyses submitted to the Commission by the licensee ..." The wording of the proposed revision for the update to "**describe the effects of** [emphasis added]..." changes can be interpreted as requiring each SAR update to include a an analysis of each change included in the update, separate from the revised wording in the SAR and in addition to the summaries of the analysis included 50.59 report. This interpretation would cause a significant increase in burden associated with SAR updates over that currently performed. This increased burden is inappropriately discounted in the backfit analysis for the proposed rule and in the paperwork reduction act statement.

This comment also applies to the similar changes proposed in Parts 72.70 and 72.248. If this is not the intended interpretation, it is not clear how the added requirement to discuss the net effect of all changes made since the last update would be included in the SAR update. (This added requirement even taken by itself would be a significant additional burden over those currently imposed for SAR updates).

3. A request for parameters to be considered for Part 72 licensees for margin of safety was made in the proposed rulemaking. These items should include only those with potential to increase the probability or consequence of an offsite release above the established acceptance limit. Items to be included would be containment of fuel and fission products within the cask or facility. Sub-items would include fuel and cladding temperature, cask temperature, cask internal pressure and atmosphere, and cask materials/stresses. The release/accident limits utilized for Part 50 facilities should also be used for Part 72 facilities. Utilizing more stringent requirements for Part 72 facilities does not conform to the policy to channel resources toward more safety-significant activities.

4. The NRC decision not to add an equivalent to §72.48 to Part 71 is questionable. Under the scenario proposed by the staff, a licensee or vendor could make a change to a dual purpose cask internally under 72.48 and then need to have the same change formally approved by the staff under Part 71 at a later date after the change has already been made. A licensee or vendor should be allowed the same flexibility to make changes to both storage and transportation casks. The safety considerations for a transportation cask are not of such a significant difference from a storage cask such that the NRC could not allow a process like 72.48 to exist. The lack of uniformity in regulations provides additional burden to licensees that is not commensurate with safety significance.

5. The wording for §72.70, 72.216, and 72.248 should be revised to conform entirely to 50.71(e). Current wording stresses different items for Part 72 SAR updates that are not included in Part 50 SAR updates. The underlying safety basis for SAR updates are not different, therefore the wording of the actual regulations should not differ. The differences in wording increases the burden on licensees who have to perform both Part 50 and Part 72 SAR updates by requiring different systems to be in place for the updates.

6. §72.48 contains additional burden over 50.59 because of additional criteria for review of environmental impacts and occupational exposure. In the finding of no significant environmental impact included in the proposed rulemaking, the staff states the amount of reviews required to make changes under the proposed 50.59 process is sufficient to determine that the rule will not cause a significant environmental impact. If the 72.48 review processes are revised to conform with that of 50.59, it is logical to draw the conclusion that a significant environmental impact will not occur by utilizing 72.48. However, the current and proposed 72.48 includes an additional requirement to evaluate the potential for a significant unreviewed environmental impact. If this requirement is not necessary for reviews of changes made to production and utilization facilities made under 50.59 with their higher potential environmental impacts, it should not to be necessary for changes

made to Part 72 facilities.

Similarly, the current and proposed 72.48 requires an evaluation for significant increase in occupational exposure. This requirement is not included in 50.59. No justification is given for the difference in requirements. Additionally, both Part 50 and Part 72 facilities are subject to Part 20; therefore ALARA reviews are already included in site processes.

These additional nonconforming requirements should be deleted from 72.48 due to the additional burden imposed on Part 72 licensees over Part 50 licensees without any additional safety significance.

7. The wording for the seven criteria in 72.48 has not been revised to conform to 50.59. Specifically, 72.48 and other Part 72 regulations use the term "structures, systems and components important to safety" while 50.59 uses "equipment important to safety." Absent any safety-based reason for the wording differences, the wording between 50.59 and 72.48 should not be different.

8. The new requirement for SAR updates by general licensees in 72.216(d) is a new significant reporting burden. Previously the SARs utilized by general licensees were considered to belong to the cask vendor. General licensees did not provide SAR updates to the NRC. The impact of this new requirement has not been specifically addressed in the paperwork reduction act statement, the regulatory analysis or the backfit analysis. While some merit exists in requiring general licensees to update SARs to account for plant-specific differences, no consideration has been given to an implementation schedule for the new requirement. When SAR updates were initially imposed on reactor licensees, a schedule for the first update was included in the regulation which considered the greater than normal burden associated with the first update. A similar schedule should be added to the proposed 72.216(d).

9. 10CFR72.70, proposed 72.216(d), and proposed 72.248 would require an annual SAR update. However, a reactor SAR update can be as long as 24 months. No justification is given for requiring the more frequent updates for cask or MRS SARs than for reactor SARs. Since the potential safety consequences for casks are orders of magnitude less than reactors, the updating frequency should be equivalent, if not longer than allowed for reactor SARs,

   Additionally, in 72.70 the requirement to update every six months after issuance of the license and 90 days prior to planned receipt is overly restrictive. NRC is currently in the process of deleting the requirement in 72.82(e) to perform a notification to the staff after preoperational testing and 30 days before loading. Many changes related to cask loading included in the SARs will not be identified or analyzed until preoperational testing is performed. Thus the 90-day SAR update requirement could be interpreted as another holdpoint before loading. Any changes made under 72.48 should not be considered of such a safety significance to require a SAR update three months prior to loading. Additionally, the preloading SAR update requirements should be clarified to state if applicable to site-specific licensees, general licensees, or both. It should be noted 50.71(e) does not include similar requirements for production and utilization facilities.

10. §50.71(e) states that SARs must be updated to reflect all changes made up to six months before the submittal date. The existing and proposed SAR updating requirements in Part 72 do not state a cutoff date for changes to be included in the updates. A Part 72 licensee could be considered in noncompliance if a change made two days prior to submittal is not included in the SAR update. The Part 72 SAR updating requirements should be revised to conform with those in Part 50.

11. §72.48 requires an annual report of changes made. However 50.59 allows a similar report to be submitted on a 24-month interval. Similar to the above comment, no justification is given for requiring more frequent reporting for changes made under 72.48. Since the potential safety consequences for casks are orders of magnitude less than reactors, the updating frequency should be equivalent, if not longer than allowed for changes to part 50 facilities.

12. §72.48 is being revised to make distinctions between site-specific licensees and general licensees. This regulation requires amendments to be submitted per §72.56. Cask vendors may make amendments under the proposed 72.244. However, §72.56 is not being revised to specifically define if it applies to both site-specific and general licensees. If §72.56 does not apply to general licensees, no current regulation specifies what actions a general licensee may take if its 72.48 review indicates a license amendment is required.

13. Proposed 72.216 and 72.248 include requirements for general licensees and certificate holders to provide copies of SAR updates to each other. No guidance is provided for a timetable for internal reviews and incorporation or rejection of the changes made by the other party. Additionally, site-specific licensees may utilize cask types that have also received general approval. No requirements are given for site-specific licensees to provide updates to their respective cask vendors or general licensees that utilize the same general type casks. These discrepancies should be clarified.

VI. Request for Comment

1. The Commission is seeking input on a number of options relating to the criterion of margin of safety reduction, and its definition.

   As discussed in the comments to Section II.J above, Entergy supports deleting the margin of safety criterion from the rule.

2. The Commission is interested in options for defining what constitutes a "minimal" increase in the probability of occurrence of an accident previously evaluated in the FSAR or in the probability of equipment malfunction.

   Each plant has a set of events for which it must respond. Each event is assigned to one of the following frequency classifications:

- Incidents of moderate frequency – may occur during a calendar year to once per 20 years
- Infrequent incidents – may occur once in 20 years to once in 100 years
- Limiting faults – are not expected to ever occur.

The events and their frequency classifications are identified in each facility's SAR. The NRC should recognize changes within the frequency classification do not constitute an increase in probability. An increase in probability would be realized only if the event moved into a more frequent classification (e.g., from infrequent incidents to incidents of moderate frequency). This position would not require the term "minimal increases in probability" to be defined while still maintaining assurance of public health and safety.

For each frequency classification identified above, the NRC has established acceptance criteria pertaining to dose consequences each event must meet. These criteria are typically identified and discussed in the SAR. The NRC should recognize changes in dose consequences that continue to meet these acceptance criteria do not represent an increase in consequences. This position would not require the term "minimal increase in consequences" to be defined while maintaining assurance of public health and safety.

3. The Commission is interested in comments upon the proposed definitions for such terms as "facility as described in the FSAR," "procedures as described in the FSAR," and "tests or experiments".

   Entergy believes adding definitions to the rule is not necessary and only adds confusion and additional details to the rule. NEI 96-07 contains the needed definitions and is the appropriate location for them. This is consistent with Mr. Diaz's comments.

4. As part of the present rulemaking, the Commission is seeking comment on the need for a clear definition of accident as it is used in Sec. 50.59 to reflect the Commission's intent that the "accidents" referred to are those dealt with in the safety analysis report.

   Entergy recommends the second approach discussed above. "Accidents" should be limited to the bounding "design basis accidents". In considering the definition of "accident", note that SAR Chapter 15 "accidents" must meet different acceptance criteria than "accidents" used to determine core damage frequency within PRAs. PRAs generally focus on severe accidents rather than Chapter 15 limited fault events. For example, a design basis Loss-of-Coolant Accident (LOCA), evaluated from a best-estimate perspective consistent with PRA methodology would not be a severe accident since peak clad temperature acceptance criterion would not be exceeded and clad oxidation would be minimal. The differences in the level of acceptance criteria used for Chapter 15-type safety analyses and plant PRAs should be fully understood and considered in determining acceptance criteria or the definition of "accident" in any future risk-informed 50.59 rule.

5. In addition to the NRC proposals in Sections II and III, the Commission is also interested in receiving comments on the proposals and language suggested by NEI.

   Entergy believes the best course of action, considering risk insights and the desire for regulatory stability, is for the NRC to fully endorse NEI 96-07. Specific Entergy comments related to the NEI proposals are:

   A. Negligible Increase in Probability of Occurrence:

      See Entergy's comments on "increase in probability" in Section **II.F**, Probability of Occurrence or Consequences of an Accident or Malfunction of Equipment Important to Safety Previously Evaluated in the Safety Analysis Report may be Increased, above.

   B. Negligible Increase in Consequences of an Accident or Malfunction:

      See Entergy's comments on "increase in consequences" in Section **II.F** above.

   C. Malfunction of a Different Type:

      Entergy supports NEI's position.

   D. Margin of Safety Provided by any Technical Specification:

      Entergy supports deleting the margin of safety criterion from the rule. If margin of safety is not deleted, then NRC should endorse the NEI 96-07 approach.

XII. Backfit Analysis

The Backfit Analysis is included in the Regulatory Analysis

1. The NRC states the proposed rule does not impose a new staff position because a regulatory staff position was never clearly established. This statement is misleading and incorrect. Although it is correct the NRC has not established a standard, agency-wide position on 50.59, it has established various staff positions, albeit changing, throughout the past several years. For instance, positions were established during inspections that examined licensees' 50.59 processes.

2. The NRC states the proposed rule imposes no burden on a licensee because exercising authority under §50.59 or 72.48 is optional. This statement applies faulty circular logic.

(Fortunately, despite items 1 and 2 above, the NRC performed a backfit analysis.)

3. As discussed in Section **II.M**, Part 72 Changes, above, NRC has not adequately identified and addressed additional burdens placed on Part 72 licensees by proposed rulemaking pertaining to SAR updates. These burdens must be addressed in the backfit analysis.

Additional Comments on Risk Insights:

Many consider a risk-informed 50.59 would replace the deterministic evaluation process currently codified within 50.59 with a PRA. While acceptable changes in core damage frequency (CDF) or large early release frequency (LERF) can be indicators of acceptability, NRC will need to thoroughly consider the differences between deterministic design basis approaches and those of PRA. For example, PRA is meant to use best-estimate approaches whereas deterministic design / licensing basis approaches usually use worst-case assumptions. PRA focuses on severe accidents. The events analyzed in the SAR would not constitute severe accidents and would generally not contribute to CDF. A large break LOCA, analyzed on a realistic and best-estimate basis, would generally result in peak clad temperatures less than the 1800°F at which hydrogen generation would start to occur. Thus, the large break LOCA would not be considered as a contributor to core damage if only a Chapter 15-style worst-case single active failure occurred.

A reasonable approach to risk-informed 50.59 regulations would have to consider the following aspects:

1. Some role for determining acceptability of changes based on impact on CDF or LERF

2. Risk insights for improving the deterministic evaluation criteria that would have to remain a part of 50.59 to address non-severe accident impact

PRA acceptance criteria could possibly also be modified, although this would have to be in a manner that does not require significant overhaul of the existing plant specific PRAs in use today. Care must be taken with the application of risk insights in developing risk-informed revised deterministic criteria, due to the differences in plant PRAs developed in response to NRC Generic Letter 88-20, which did not include a prescriptive or standardized approach for developing plant PRAs.

In her comments in the NOPR, Chairman Jackson' raised a concern that "the staff appears to be more reluctant to allow risk-informed approaches if the result is relinquishment of review and approval authority". This appears to be manifested in the NOPR itself, since the approach of allowing only "minimal" increases in consequences over that documented in the SAR instead of using clear and defined acceptance limits from the SER and SRP cannot be justified on a risk-informed basis.

The ACRS discusses risk-informed regulation in its September 30, 1998 memo to Chairman Jackson:

> "Many of the present regulations are based on deterministic and prescriptive requirements that cannot be quickly replaced. Therefore, the current requirements will have to be maintained while risk-informed regulations are being developed and implemented. Furthermore, we expect that a number of licensees will, for a variety of reasons, be unwilling to embrace a new regulatory system. Therefore, the NRC should be prepared to accommodate a two-tier system, i.e., a modified version of the current regulatory process and a risk-informed system. This situation will prevail for a number of years and may create circumstances that should be addressed by the Commission."

Licensees are concerned that the transition to risk-informed regulation will result in imposing a second layer of regulatory requirements (i.e., deterministic and risk-related regulations) without any reduction of the deterministic regulatory burden. Previous experiences with risk-informed approaches have not been successful in terms of having added a risk-informed element to regulatory expectations without any relaxation of the deterministic compliance mindset (e.g., the Maintenance Rule). NRC must, for the sake of regulatory stability and reducing regulatory burden, ensure that risk-informed regulation does not merely become an added regulatory layer, including future risk-informed approaches to 50.59.

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December 21, 1998

DOCKET NUMBER
PROPOSED RULE PR 50, 52 & 72
(63FR56098)

Mr. John C. Hoyle
Office of the Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Attention: Rulemakings and Adjudications Staff

Re: Comments on Proposed Rulemaking Concerning 10 CFR 50.59, Changes, Tests, and Experiments (63 Fed. Reg. 56098 – October 21, 1998)

Dear Sir:

On behalf of the Nuclear Utility Backfitting and Reform Group (NUBARG),[1/] we are submitting these comments to address the proposed rulemaking regarding "Changes, Tests, and Experiments," issued October 21, 1998 (63 Fed. Reg. 56098).

NUBARG generally supports the Commission's proposed rulemaking because, in many respects, it improves the process for reviewing changes at nuclear facilities. In this regard, NUBARG supports NEI's comprehensive comments on the proposed rule. There is, nevertheless, one area warranting additional comment on the backfitting implications of the proposed rule. Specifically, NUBARG believes that certain aspects of the proposed rule require a more robust backfitting analysis. We encourage the Staff to carefully consider the comments below.

The Backfitting Rule, 10 C.F.R. § 50.109, permits backfits to be imposed either because they meet one of the recognized exceptions to the backfitting rule, or because the backfit is

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1/ NUBARG is a consortium of sixteen utilities which was formed in the early 1980s and actively participated in the development of the NRC's backfitting rule (10 C.F.R. § 50.109) in 1985. NUBARG has subsequently monitored the NRC's implementation of the backfitting rule.

Acknowledged by card DEC 31 1998

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a cost-justified substantial safety enhancement.[2] The backfitting analysis of the proposed rule acknowledges that "the proposed definitions of 'change' in combination with the definition of 'facility as described ...' and for 'reduction in margin of safety...' might be considered backfits." In addition, "[w]hile the NRC concludes that these proposed rule changes regarding 10 CFR § 50.59 (or 10 CFR § 72.48) requirements (i.e. the definitions) clarify existing requirements, some licensees might view these as imposing requirements that are different from what is currently required." Consequently, the Staff performed a backfitting analysis against the nine factors set forth in 10 C.F.R. § 50.109(c).

NUBARG's Comments

1. The rule changes should expressly be limited to prospective application.

The changes proposed to Section 50.59 would not affect past licensee actions if the rule were applied only prospectively; however, if applied retrospectively to previous Section 50.59 evaluations, the proposed changes could have a significant impact. Retrospective application of the rule might be inferred by the NRC's position that the rule change does not alter the previous agency positions on Section 50.59.

Accordingly, the final rule should make clear that the changes are to be applied prospectively only. If applied retrospectively, the rule changes would constitute a significant backfit. Retrospective application has not been justified by the current backfitting analysis.

2. Even prospective application of the rule may require a more detailed backfitting analysis.

Even if the new rule were to be applied only prospectively, certain changes, including replacing the phrase "unreviewed safety question" (USQ) with the "need to obtain a license amendment" and the scope of what constitutes a "change," could represent a substantial increase in scope from the prior rule. For example, the proposed rule would add definitions in Section 50.59 of "change" and of "facility as described in the final safety analysis report (as updated)" to "establish that evaluation is required for changes to the analyses and bases for the facility as well as for physical or hardware changes to the facility." 63 Fed. Reg. at 56102. This increase in the scope of coverage of Section 50.59 would represent an increased burden on licensees and thus a backfit that must be justified through the backfitting analysis that specifically addresses the new burden being imposed.

The present backfitting analysis, however, is very weak in attempting to justify these new positions. First of all, the NRC's backfitting analysis does not seek to identify all new positions

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[2] See 10 C.F.R. § 50.109(a); "Backfitting Guidelines," NUREG-1409 at pp. 3-4 (July 1990).

that would broaden the coverage of Section 50.59 or otherwise represent new requirements (backfits). Moreover, it does not justify the new positions with any specificity under the cost-benefit standards of Section 50.109. The backfitting analysis is very conclusory, and in fact, appears deficient in that it does not make the requisite findings under Section 50.109 that the proposed backfits would result in a substantial increase in overall safety and that the direct and indirect costs are justified in view of this substantial safety benefit. Given the lack of specificity in the backfitting analysis as well as the proposed rule on the contemplated changes, unless the NRC adopts some of the less restrictive proposals NEI has offered, the Staff should develop a backfitting analysis that comprehensively addresses the changes proposed in this rule.

3. The new rule should include a more efficient process for approving changes that do not require a change to the license.

The proposed Section 50.59(c)(2) would require a license amendment prior to implementing a change, test or experiment if any of the conditions in subsections (i) - (vi) are met.[3/] Experience shows, however, that there are many changes that do not actually affect the terms of the license or the Technical Specifications, even if they might give rise to an unreviewed safety question under the current Section 50.59. In some cases, under the current Section 50.59, this has resulted

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[3/] The proposed Section 50.59(c)(2) currently reads, in part, as follows *(emphasis added)*:

> (2) A licensee shall obtain an *amendment to the license pursuant to Sec. 50.90* prior to implementing a change, test or experiment if it would:
> (i) Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to Sec. 50.90 after the last final safety analysis report was updated pursuant to Sec. 50.71 of this part;
> (ii) Result in more than a minimal increase in the probability of occurrence of a malfunction of equipment important to safety previously evaluated . . . ;
> (iii) Result in more than a minimal increase in the consequences of an accident previously evaluated . . . ;
> (iv) Result in more than a minimal increase in the consequences of a malfunction of equipment important to safety previously evaluated . . . ;
> (v) Create a possibility for a design basis accident of a different type than any previously evaluated . . . ;
> (vi) Create a possibility for a malfunction of equipment important to safety with a different result than any previously evaluated . . . ;
> (vii) Result in a reduction in the margin of safety associated with any Technical Specification.

in licensees adding new provisions to their Technical Specifications, such as specific footnotes for single-cycle changes, to accommodate the USQ change. This practice could result in adding unnecessary clutter to the plant Technical Specifications. The proposed Section 50.59(c)(2) would continue this practice, and therefore could result in the creation of more additions to licensees' Technical Specifications -- a result which was supposed to have been cured, in part, with issuance of Improved Technical Specifications.

NUBARG recommends that the NRC develop a review and approval process for changes, *short of a license amendment pursuant to Section 50.90*, when the proposed change does not require any amendment to the language of the license or Technical Specifications, but still meets the threshold for requiring NRC review. The Staff should be able to approve such a change through issuance of a Safety Evaluation Report (SER). The fact that a change meets the threshold requiring prior NRC review and approval under Section 50.59 does not necessarily mean that it rises to the level of requiring a license amendment. If the change does not affect the license, in the sense of necessitating a change to the terms of the license or Technical Specifications, the NRC should be able to perform its review without the need to follow the cumbersome Sholly process for license amendments.

Conclusion

NUBARG appreciates the opportunity to comment on this significant initiative. We remind you that the complexity of the proposed rule, including final resolution of the options offered by the Commission,[4/] could substantially alter the rule from that which has been proposed for public comment. Consequently, we encourage you to ensure that the final rule either is within the bounds

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[4/] For example, the Commission offered several options for the "more than minimal" increase standard, 63 Fed. Reg. at 56104; and the definition of an "accident," 63 Fed. Reg. at 56106.

of the proposed rule or provide an opportunity for public comment on any portions of the final rule that have substantially changed from the proposed rule.

Very truly yours,

Daniel F. Stenger

Daniel F. Stenger
Robert K. Temple
Counsel to the Nuclear Utility Backfitting
and Reform Group

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NG-98-2045
December 18, 1998

DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63FR56098)

Mr. John C. Hoyle
Secretary of the Commission
Attention: Rulemakings and Adjudications Staff
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Duane Arnold Energy Center
Docket No: 50-331
Op. License No: DPR-49
Comments on Proposed Rulemaking to 10 CFR 50.59, Changes, Tests, or Experiments, 63 Fed. Reg. 56098 - October 21, 1998

References: 1) Letter from S. Frantz (MLB) to Rulemakings and Adjudications Staff (NRC), "Comments on Proposed Rule on Changes, Tests, and Experiments (63 Fed. Reg. 56098)," December 21, 1998
2) Letter from A. Pietrangelo (NEI) to J. Hoyle (NRC), "Industry Comments Proposed Rulemaking to 10 CFR 50.59, Changes, Tests, or Experiments, (63 Fed. Reg. 56098 - October 21, 1998)," December 21, 1998

File: A-100, A-119

Dear Mr. Hoyle:

In a Federal Register Notice on October 21, 1998 (63 Fed. Reg. 56098), the NRC requested comments by December 21, 1998 on Proposed Rulemaking to 10 CFR 50.59 (Changes, Tests, or Experiments), and related changes to other sections of Part 50, Part 52 and Part 72. IES Utilities submits the following public comments on Proposed Rulemaking to 10 CFR 50.59.

Acknowledged by card DEC 31 1998

We would like to begin by stressing the importance of the flexibility that 50.59 affords licensees. This rule allows licensees to make improvements to their facilities in a timely, straightforward manner. It is essential that this aspect of the rule be preserved in the final rule.

In addition to Reference 1, submitted on our behalf by Morgan, Lewis & Bockius, IES Utilities endorses the Reference 2 comments submitted by the Nuclear Energy Institute (NEI). We appreciate the opportunity to comment on the proposed rule and thank you for your consideration of our comments.

Sincerely,

Kenneth E. Peveler

Kenneth E. Peveler
Manager, Regulatory Performance

KEP/LBS

cc: L. B. Swenzinski
E. Protsch
D. Wilson
R. Laufer (NRC-NRR)
J. Caldwell (Region III)
NRC Resident Office
Docu

Florida Power
CORPORATION
Crystal River Unit 3
Docket No. 50-302
Operating License No. DPR-72

(14)

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ADJUDICATIONS STAFF

DOCKET NUMBER
PROPOSED RULE PR 50, 52 & 72
(63FR56098)

December 18, 1998
3F1298-21

Mr. John C. Hoyle
Secretary of the Commission
Attention: Rulemakings and Adjudications Staff
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Comments on Proposed Rulemaking, 10 CFR Parts 50, 52, and 72, "Changes, Tests, and Experiments"

Dear Mr. Hoyle:

Florida Power Corporation (FPC) appreciates the opportunity to comment on the proposed rulemaking of 10 CFR Parts 50, 52, and 72, "Changes, Tests, and Experiments," as published in the Federal Register, October 21, 1998, Volume 63, Number 203. FPC endorses the comments to the subject proposed rulemaking to be provided by the Nuclear Energy Institute (NEI) on the industry's behalf, with one exception. Of the options being considered by the Commission regarding "margin of safety", FPC prefers and fully supports Option 2, Delete Margin of Safety as a Criterion (Section II.J of the proposed rulemaking). Evaluating changes against a "margin of safety" criterion is redundant to evaluating the impact upon probabilities or consequences (particularly if industry 10 CFR 50.59 guidance were to explicitly cover this subject). In her comments, Chairman Jackson noted, "...it is not clear what type of changes would successfully pass the 10 CFR 50.59 test for allowed 'minimal increases in consequences' without failing the test for 'no reduction in the margin of safety'." Therefore, due to this interaction between evaluation criteria, Option 2 appears to offer the greatest benefit.

Please contact me at (352) 563-4566 if you have any questions regarding FPC's comments.

Sincerely,

Sherry L Bernhoft

Sherry Bernhoft, Director
Nuclear Regulatory Affairs

SLB/twc

xc: Regional Administrator, Region II
Senior Resident Inspector
NRR Project Manager

DEC 31 1998
Acknowledged by card

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'98 DEC 21 P2:58

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RULEMAKINGS AND
ADJUDICATIONS STAFF

VIRGINIA POWER

December 17, 1998

Serial No.: GL 98-042

Secretary
Attn: Rulemakings and Adjudication's Staff
U.S. Nuclear Regulatory Commission
Washington D.C. 20555-0001

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

(13)

Gentlemen:

COMMENTS ON PROPOSED RULEMAKING, 10 CFR PARTS 50, 52, AND 72, "CHANGES, TESTS, AND EXPERIMENTS"

Virginia Power appreciates the opportunity to comment on the proposed rulemaking of 10 CFR Parts 50, 52, and 72, "Changes, Tests, and Experiments" published in the Federal Register on October 21, 1998. This rulemaking to revise the regulations governing proposed changes to nuclear facilities will result in increased regulatory stability. It is expected to clarify requirements and reduce unnecessary burden, provide licensees with reasonable latitude in implementing change, and continue to provide reasonable assurance of public health and safety as licensees implement changes at their facilities.

Comments on the proposed rulemaking have been prepared and submitted separately by NEI on behalf of the nuclear industry. We have reviewed the NEI comments and endorse them. In addition, there are a few key aspects of the proposed rulemaking for which we offer further comment for your consideration. Our additional comments are provided in the attachment.

If you have any questions, please contact Mr. Joe Hegner at (804) 273-2770 or Ms. Gwen Newman at (804) 273-4255.

Sincerely,

James P. O'Hanlon

James P. O'Hanlon

Attachment

DEC 31 1998
Acknowledged by card

cc: Mr. Ralph E. Beedle
Nuclear Energy Institute
1776 I Street, NW, Suite 400
Washington D.C. 20006-3708

Mr. Anthony R. Pietrangelo
Nuclear Energy Institute
1776 I Street, NW, Suite 400
Washington D.C. 20006-3708

Mr. Russell J. Bell
Nuclear Energy Institute
1776 I Street, NW, Suite 400
Washington D.C. 20006-3708

VIRGINIA POWER SPECIFIC COMMENTS ON PROPOSED RULEMAKING
10 CFR Parts 50, 52, and 72

Organization of Rule Requirements

The Commission proposes to combine existing paragraph 50.59(a), which refers to the need for prior Commission approval of changes, tests, and experiments under certain circumstances, with the method of receiving that approval as discussed in paragraph (c), which states that the licensee shall submit an application for amendment under §50.90. The revised regulation will state more clearly that a licensee must apply for *and obtain* a license amendment, pursuant to §50.90, before implementing such change, test, or experiment. Additionally, the Commission proposes to remove reference in the rule to the term "unreviewed safety question" to emphasize that §50.59 establishes a regulatory rather than a safety threshold. The proposed changes are appropriate and will clarify existing requirements. However, we wish to highlight a potential concern with the proposed rule language in that the change in terminology may inadvertently impact previous guidance and accepted practices that have utilized the term "unreviewed safety question."

Revision 1 to Generic Letter 91-18, published on October 8, 1997, resolved the concerns regarding the role of 10 CFR 50.59 for resolution of degraded or nonconforming conditions. We agree with the NEI-submitted industry comments that the proposed change in terminology should not alter this guidance and the accepted practices that have used the term "unreviewed safety question," particularly as used in the generic letter.

The generic letter guidance established that decisions regarding continued operation, and plant startup, should be determined on the basis of operability, conformity with the license, and safety significance, not on whether a USQ has been identified. When a degraded or nonconforming condition has been identified, and a corrective action plan developed and that plan meets the criteria in the proposed rule necessitating prior NRC approval (formerly labeled a USQ), the licensee should be able to continue to operate or restart the facility in accordance with that plan without having to obtain prior NRC approval. Generic Letter 91-18, Revision 1, Section 4.8, Final Corrective Action, states "The proposed final resolution can be under staff review and not affect the continued operation of the plant, because interim operation is being governed by the processes of the operability determination and corrective action of Appendix B." That Section also states, "...the need to obtain NRC approval for a change (e.g., because it involves a USQ) does not affect the licensee's authority to operate the plant. The licensee may make mode changes, restart from outages, etc., provided that necessary equipment is operable and the degraded condition is not in conflict with the TS or the license."

VIRGINIA POWER SPECIFIC COMMENTS ON PROPOSED RULEMAKING 10 CFR Parts 50, 52, and 72

The NEI-submitted industry comments propose the Statements of Consideration that accompany the final rule acknowledge that it is the intent of the revised rulemaking that GL 91-18 guidance remains unchanged. We agree the intent should not be changed and this position should be appropriately documented. We offer for consideration that the regulation may be a more appropriate vehicle than a generic letter to clearly distinguish between the scope of two regulations (i.e., 10 CFR 50.59 and 10 CFR 50, Appendix B, Criterion 16). We suggest that the rule language be modified to ensure that implementation of a licensees corrective action plan in accordance with 10 CFR 50, Appendix B, Criterion 16 that may involve NRC review in accordance with 10 CFR 50.59(c)(2), not be inappropriately deferred because the proposed wording in §50.59 indicates that NRC approval is required prior to implementation.

The following change to 50.59(c)(2) is proposed: "A licensee shall obtain an amendment to the license pursuant to Section 50.90, prior to implementing a change, test, or experiment unless the activity is in accordance with Section 50, Appendix B, if it would..."

Minimal Increase in Probability or Consequences

The Commission has provided three options by which licensees could implement changes involving minimal increases in probability or consequences. Consistent with the industry position described in the NEI submittal on this issue, Virginia Power supports implementation of the third option. However, we note that the third option, as described in the proposed rulemaking, may inadvertently limit the ability of certain licensees to make minimal changes. We do not believe that the Commission intended to limit this ability to only a certain subset of licensees.

The third option proposes to limit the fraction of remaining margin that may be consumed by a particular change to 10 percent of the remaining margin between current conditions and acceptance guidelines. The focus on acceptance guidelines makes this option limiting for certain licensees whose original licensing basis may not have been in accordance with the acceptance guidelines, although still deemed acceptable to the NRC for reasons set forth in plant-specific Safety Evaluation Reports. Virginia Power proposes adopting the third option with the remaining margin defined as the difference between current conditions and the regulatory limits. As proposed, the Commission's approach results in licensees whose current conditions have already exceeded the acceptance guidelines from making even a minimal change without prior NRC approval.

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Illinois Power Company
Clinton Power Station
P.O. Box 678
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ILLINOIS POWER

'98 DEC 21 P2:57

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U-603134
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December 18, 1998

DOCKET NUMBER
PROPOSED RULE PR 50, 52+72
(63FR56098)

U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Attention: Rulemaking and Adjudication Staff

Subject: Illinois Power Comments on Proposed Rule Changes to 10CFR50.59

Dear Madam or Sir:

The purpose of this letter is to provide Illinois Power's (IP's) comments on the proposed rule changes for 10 CFR Parts 50, 52, and 72 published in the Federal Register on October 21, 1998.

IP believes that the following provisions in the proposed rule represent improvements in the existing rule and should be adopted:

- Allowing minimal increases in probabilities and consequences.
- Providing a definition of tests or experiments which excludes from the scope of 10CFR50.59 those tests and experiments that are not inconsistent with the USAR.
- Requiring prior NRC approval for a different type of malfunction only if it creates a different result.
- Excluding from the scope of 10CFR50.59 changes to programs that are governed by other regulations, such as 10 CFR § 50.54.
- Providing a definition of procedures which excludes administrative procedures from the scope of 10CFR50.59.

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IP endorses the industry comments provided by the Nuclear Energy Institute by letter dated December 21, 1998, signed by Anthony R. Pietrangelo, with one exception. With regard to Section II, part J, "Margin of Safety as Defined in the Basis for any Technical Specification is Reduced," IP supports Option 2, that is, deleting the criterion on margin of safety. Proposed and existing 10CFR50.59 questions regarding equipment failures and malfunctions adequately address issues that would be addressed in margin of safety determinations. Additionally, numerous restrictions on the ability of licensees to make changes without prior NRC approval currently exist. For example:

- Changes must comply with NRC regulations. Licensees must seek prior NRC approval for exemptions from the regulations.

- Changes must comply with the Technical Specifications, which govern all of the important structures, systems, and components in the plant. Licensees must seek NRC approval of license amendments to the Technical Specifications.

- Changes must satisfy the other criteria in 10CFR50.59 pertaining accidents and malfunctions. If not, the licensee must seek NRC approval of license amendments for the changes that do not meet these criteria.

In total, these restrictions ensure that a licensee cannot make a change that is unsafe or that would result in a significant reduction in the level of safety provided by the license basis.

IP would like to emphasize NEI's comments regarding proposed changes to 10CFR50.71(e). IP strongly opposes the proposed expansion of 10CFR50.71(e). Because implementation of changes that have only a negligible impact on the probability of accidents or malfunctions would be allowed under the proposed rules, it is unnecessary to add new NRC requirements for tracking the cumulative effects of such changes. Additionally, since the majority of determinations concerning the impact of a change on the probability of accidents or malfunctions will continue to be largely qualitative (versus quantitative) in nature, determining the additive effects of such changes is not possible.

In addition to the comments provided above, IP is also submitting comments on SECY-98-171, which provided the NRC's resolution of comments on draft guidance on 10CFR50.59 contained in NUREG-1606, "Proposed Regulatory Guidance Related to Implementation of 10CFR50.59 (Changes, Tests, or Experiments)." SECY-98-171 states that a licensee may not install and test a modification under 10CFR50.59 prior to issuance of the amendment that approves operation of the modification. This resolution is not consistent with the language in 10CFR50.59 or with industry practice.

Many modifications require license amendments because of the operational issue posed by the modification, not the installation and testing issues associated with the modification. If installation and testing of the modification does not require a license amendment under 10CFR50.59, these activities should be permitted even though operation with the modification is the subject of a pending license amendment request.

Supplementary information for the final rule should clarify that licensees may design, plan, install, and test a modification prior to NRC approval of the license amendment provided the appropriate evaluation in accordance with 10CFR50.59 is performed and these activities are consistent with the applicable Technical Specifications.

Sincerely yours,

Richard F. Phares
Manager - Nuclear Safety and
Performance Improvement

MAR/krk

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'98 DEC 21 P2:56

Steven P. Frantz
202-467-7460

OFFICE OF SECRETARY RULEMAKINGS AND ADJUDICATIONS STAFF

December 21, 1998

DOCKET NUMBER
PROPOSED RULE PR 50, 52 & 72
(63FR56098)

Office of the Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

RE: Comments on Proposed Rule on Changes, Tests, and Experiments (63 Fed. Reg. 56098)

Dear Sir:

On October 21, 1998, the NRC published a notice in the Federal Register of a proposed change to 10 CFR § 50.59 and related sections dealing with changes, tests, and experiments. The notice requested comments by December 21, 1998. In response to that notice, we are hereby providing the following comments on behalf of Alliant Utilities/IES Utilities Inc., Illinois Power Company, and Pennsylvania Power & Light Company .

Our comments on the proposed rule are provided in Attachment 1. In summary, we support the intent of the proposed changes to Section 50.59. These proposed changes are essential to overcome NRC's recent, overly-legalistic interpretation of Section 50.59 and to restore the original purpose of Section 50.59 - - namely, to provide a licensee with the flexibility to make changes which do not adversely affect the level of safety provided in the safety analysis report. Additionally, the proposed rule is beneficial in providing a step toward a more risk-informed approach to regulation of plant changes.

However, we do have some concern with the language of some of the proposed changes. As described in more detail in Attachment 1, we are particularly concerned with the proposed provision on "reduction in the margin of safety." This provision would render Section 50.59 more restrictive than the current provisions in Section 50.59. Such a change is not necessary to maintain the level of safety described in the safety analysis report, and would result in the diversion of licensee and staff resources to process amendment requests on inconsequential changes. In this regard, we support the views of the individual Commissioners - - in particular, this provision should either be deleted entirely from the rule, replaced with a provision that focuses on preservation of barriers to fission product release, or replaced with a provision that allows minor reductions in the margin of safety.

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In summary, we commend the proposal of the NRC to restore the original intent of Section 50.59 and make the rule more risk-informed. NRC should issue the proposed rule in final form, with the changes recommended in Attachment 1.

Sincerely,

Steven P. Frantz

Steven P. Frantz

Attachment

ATTACHMENT 1

COMMENTS ON PROPOSED RULE ON
<u>CHANGES, TESTS, AND EXPERIMENTS</u>

1.0 <u>Introduction</u>

Section 50.59 has been a part of the Commission's regulations for more than thirty years. The purpose of this section is to provide a licensee with the flexibility to make changes which do not adversely affect the level of safety provided in the final safety analysis report (FSAR).

Until recently, Section 50.59 worked well in practice, and had a stable and predictable application. The industry was able to use the section to make inconsequential changes without prior NRC approval, and in general the NRC found that the industry was properly implementing the rule.

During the last several years, NRC has developed and applied an overly-legalistic interpretation of Section 50.59. This new interpretation has contributed to a several-fold increase in escalated enforcement actions related to Section 50.59, has restricted the types of changes that licensees can make without prior NRC approval, and has increased the number of license amendments needed by licensees. In turn, this has forced both licensees and the NRC to divert their resources to resolve issues that, by all accounts, do not have a significant impact on safety.

On October 21, 1998, the NRC published a notice in the Federal Register of a proposed change to Section 50.59. These proposed changes would restore the original purpose of Section 50.59 and provide a step toward a more risk-informed approach to regulation of plant changes. We support the intent of the proposed changes to Section 50.59. In particular, we believe that the following provisions in the proposed rule represent improvements in the existing rule and should be adopted:

- Allowing minimal increases in probabilities and consequences
- Providing a definition of tests or experiments which excludes from the scope of Section 50.59 those tests and experiments that are not inconsistent with the FSAR
- Requiring prior NRC approval for a different type of malfunction only if it creates a different result
- Excluding from the scope of Section 50.59 changes to programs that are governed by other regulations, such as 10 CFR § 50.54
- Providing a definition of procedures which excludes administrative procedures from the scope of Section 50.59

However, we have some concerns with the language of some on the proposed changes. Section 2 below provides our comments on the language in the proposed rule and responses to some of the NRC's questions and proposed options.

In addition to our comments on the proposed rule, we are also submitting comments on SECY-98-171, which provided the NRC's resolution of comments on draft guidance on Section 50.59 contained in NUREG-1606. Many of these "resolutions" are applicable to proposed Section 50.59 as well as the existing rule. Therefore, we believe that it is appropriate to bring to the attention of the Commission our concerns with respect to these resolutions. Our comments on SECY-98-171 are provided in Section 3 below.

2.0 <u>Comments on Proposed Rule</u>

We endorse the comments of the Nuclear Energy Institute (NEI). In addition, we have specific comments on the proposed rule, which are provided below.

In general, the comments in Sections 2.1 to 2.8 below refer to the proposed provisions in Part 50. However, these comments are equally applicable to the corresponding sections in Part 52 and Part 72.

2.1 <u>Reduction in Margin of Safety</u>

<u>NRC Option 1</u>

This option would designate non-conservative changes in input assumptions and analytical methods as a reduction in margin of safety. We strongly oppose this option. This option is more restrictive than current NRC and NEI guidance, is not necessary for safety, and would impose undue burdens.

Currently, NRC and NEI guidance each define margin of safety as the difference between the acceptance limit in the licensing basis and the regulatory limit (or failure point) for the parameter in question. Both NRC and NEI guidance explicitly state that the calculated accident value for the parameter in the FSAR should *not* be considered in determining the margin (unless it happens to be the same as the acceptance limit). *See, e.g.,* draft NUREG-1606, pp. 32-33. In contrast, Option 1 would classify non-conservative changes in input assumptions and analytical methods as a reduction in margin of safety, even if such changes did not affect the acceptance limit for the parameter. Thus, Option 1 would be substantially more restrictive than current guidance and practice.

Such a change is not necessary to preserve the level of safety in the licensing basis for a plant. As long as the acceptance limit in the licensing basis is unaffected, the level of safety provided by the plant is unaffected. Therefore, there is no benefit to safety from Option 1.

Furthermore, because Option 1 is more restrictive than the current regulation, it will result in the need for more license amendments. This will impose a burden on licensees to prepare amendment applications, and a burden on the NRC to process such applications. This additional burden will divert both NRC and licensee resources from matters that are more important to safety.

In summary, Option 1 is more restrictive than the current rule, has no safety benefits, and would impose undue burdens on the NRC and licensees. Therefore, the Commission should reject this option.

Option 2

This option would delete the criterion on margin of safety. We support this option. Even without this criterion, there are numerous restrictions on the ability of a licensee to make changes without prior NRC approval. In particular:

- Changes must comply with NRC regulations. Licensees must seek NRC approval exemptions from the regulations.

- Changes must comply with the Technical Specifications, which govern all of the important structures, systems, and components in the plant. Licensees must seek NRC approval of license amendments to the Technical Specifications.

- Changes must satisfy the other criteria in Section 50.59 pertaining to accidents and malfunctions. If not, the licensee must seek NRC approval of license amendments for the changes that do not meet these criteria.

In total, these restrictions ensure that a licensee cannot make a change that is unsafe or that would result in a significant reduction in the level of safety provided by the licensee basis. As a result, we believe that the criterion on margin of safety is unnecessary and should be deleted.

Option 3

This option actually consists of a series of options, some of which are more restrictive than current NRC and NEI guidance, and others which appear to be improvements in the current regulations and guidance. Our detailed analysis of these various options is provided in Attachment 2.

In summary, as an alternative to deleting the criterion on margin of safety in its entirety, we would support a criterion along the lines proposed by NEI - - namely, that a licensee could make changes that did not adversely affect the design basis limits for fission product barriers.[1/]

1/ If NRC decides to retain a criterion related to margin of safety, the criterion should allow (continued...)

2.2 Minimal Increases

We strongly support the proposal to allow licensees to make changes which involve "minimal" increases in probabilities or consequences of malfunctions or accidents previously evaluated in the FSAR. However, we do have a number of comments on the definition of "minimal" as provided in the proposed guidance in the Federal Register notice (63 Fed. Reg. at 56104-5).

First, the proposed guidance states that several provisions in NEI 96-07 satisfy the proposed standard on minimal. We agree with these statements. However, we also note that NEI 96-07 was developed to implement the current rule, which is more restrictive than the proposed rule. Therefore, the Commission should clarify that NEI 96-07 does not represent the outer bounds of what is acceptable under the proposed rule.

Second, the proposed guidance states that "the probability of malfunction is more than minimally increased if a new failure mode as likely as existing modes is introduced." We do not believe that this guidance is appropriate in all cases. For example, under NRC's deterministic regulations, licensees are required to postulate certain malfunctions and failures (e.g., double guillotine pipe breaks) which are not always credible. Introduction of a new malfunction or failure mode that is equally incredible should not trigger the need for a license amendment. The Commission should clarify its guidance accordingly.

Finally, the Federal Register notice identifies three quantitative options for defining minimal increase in consequences: 1) 0.5 rem[2/]; 2) a "graduated approach" based upon the distance of the calculated value from the limit; and 3) 10% of the difference between the calculated value and the limit. We believe that the third option, as modified per NEI's comments, should be adopted by the Commission, because it would allow for greater increases the further the licensee is from the limit, and it is simpler than the second option. We believe that the first option is too restrictive in

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1/(...continued)

a licensee to make changes that result in a "minimal" reduction in the margin of safety. Such a provision would be consistent with the proposed changes in the other criteria which would allow minimal increases in probability and consequences of accident and malfunctions.

2/ The proposed guidance states that a change in design basis assumptions or analytical methods would not qualify as minimal, if such a change was needed to demonstrate that the change in consequences is less than 0.5 rem. This language could be misleading, since there may be cases in which a change in the design basis or analytical methods is beneficial or neutral to safety and should be allowed without seeking prior NRC approval. Therefore, we recommend that the guidance be revised to state that prior NRC approval would be required if the licensee cannot demonstrate that the change in consequences is less than 0.5 rem using the existing design basis assumptions and analytical methodologies.

cases where the calculated value is very small relative to the limit - - in essence, this option would penalize licensees who provided substantial margins in their initial designs.

2.3 Additions to a Facility

Proposed Section 50.59(a)(1) states, without qualification, that a change includes an "addition." We agree that it is appropriate for a licensee to perform a 50.59 evaluation for an addition that has the potential for changing the operation or response of the plant as described in the FSAR, or for introducing a new hazard not previously described in the FSAR. However, many additions are truly trivial (or are improvements in safety) - - such as adding identification tags, or adding battery-operated lights. There are other additions that are fully consistent with the requirements in the FSAR; e.g., adding new cable or adding a new radiation monitor that meets all of the codes, standards, and other criteria listed in the FSAR. A licensee should be allowed to screen these additions, and should not be required to perform a full 50.59 evaluation for those additions that do not have the potential for affecting the safety of the plant as described in the FSAR.

The Federal Register notice (63 Fed. Reg. at 56102) implies that the term "addition" only pertains to changes in the facility. However, as written, the definition of "change" in proposed Section 50.59 does not discriminate between changes in the facility and changes in procedures. Therefore, if read literally, proposed Section 50.59 would appear to require a 50.59 evaluation any time a licensee adds a new procedure. We assume that such a result was not the intent of the Commission, and obviously such a result would impose an unwarranted burden on licensees.

Accordingly, we recommend that the Commission clarify that the term "addition" means an addition to *the facility* that either (1) introduces a new hazard that potentially could affect a safety function described in the FSAR, (2) changes the operation or response of the facility as described in the FSAR, or (3) is otherwise inconsistent with the FSAR or outside the controlling parameters of the design basis as described in the FSAR. The Commission should also clarify that an addition does not require a 50.59 evaluation if it meets all of the applicable criteria in the FSAR.

In this regard, we are recommending that the Commission treat "additions" in the same manner that it is proposing to treat "tests or experiments" not described in the FSAR. In particular, the proposed definition of "tests or experiments" does not require a 50.59 evaluation for all new tests or experiments, but only those that are inconsistent with the FSAR or outside the design basis of the FSAR. The Commission should treat "additions" in the same manner.

2.4 Procedures

In general, we support the proposed definition of procedures in Section 50.59(a)(4). We believe that this definition is appropriately focussed on procedures that could affect the manner in which components are operated or controlled.

However, the proposed definition also refers to procedures describing the "conduct of operations." This could be construed as encompassing the types of administrative procedures typically found in Chapter 13 of the FSAR. Since administrative procedures are not relevant to the criteria in Section 50.59 for determining whether prior NRC approval is needed, the Commission should clarify that such procedures are not within the scope of the definition of procedures.

2.5 Facility as Described in the FSAR

The proposed definition of facility as described in the FSAR includes design, performance requirements, methods of operation, evaluations, and methods of evaluation described in the FSAR or "required to be included" in the FSAR. The phrase "required to be included" could be interpreted as requiring licensees to conduct 50.59 evaluations for changes in information not actually in the FSAR, but that should have been included in the FSAR.

We believe that this phrase will lead to confusion and unwarranted reviews by licensees. A licensee should only be required to conduct 50.59 evaluations for changes to information actually contained in the FSAR, as updated. In evaluating changes, a licensee should not be required to search for information that is not in the FSAR but which the NRC believes should have been included in the FSAR. In other words, Section 50.59 should not be used as an enforcement mechanism for ensuring that the content of the FSAR is appropriate. The NRC has other, more appropriate mechanisms for accomplishing this purpose, such as 10 CFR § 50.71(e). Therefore, the Commission should delete the phrase "required to be included."

2.6 Combination of Changes

The Federal Register notice (63 Fed. Reg. at 56102) states that the Commission endorses the staff's position in draft NUREG-1606 about packaging of several changes with offsetting effects -- namely, that interdependent changes can be treated as single changes, but that "treating as one change the combination of changes . . . to offset one that would otherwise require prior approval is not an appropriate application of § 50.59." This statement in the notice, and the corresponding provision in draft NUREG-1606 which states that changes must be "linked" to be treated as a single change, are confusing and should be clarified.

It appears to be the NRC's position that changes may be combined only if the initial change "causes" or "requires" a subsequent change in another system or component. Such a definition is too narrow. We agree that a subsequent change that decreases the probability of an accident should not be used to compensate for a change that increases the consequences of an accident, or vice versa. We also agree that changes should not be combined if they do not pertain to the same accident sequence. However, if one change offsets an increase in a particular accident probability (or consequence) attributable to another change, a licensee should be allowed to combine the changes even if one of the changes is not "caused" or "required" by the other change. For example, the probability of any particular accident scenario is typically the product of the probabilities of several independent events (P_1 x P_2 x P_N). As long as any increase in P_1 is offset by a decrease in P_2, there is no increase in probability of the accident, even if P_1 and P_2 correspond to independent events. Thus, licensees should be allowed to group several changes into a single 50.59 safety evaluation, as long as the changes pertain to the same accident analysis in the updated FSAR.

2.7 FSAR Updates

Proposed Section 50.71(e) would require FSAR updates to describe the net effects of "all changes," including probabilities, consequences, calculated values and system or component performance. As discussed below, it is not practical or necessary for FSAR updates to describe the effects of "all changes."

- In many cases, the existing FSAR may not include some of the types of information identified in proposed Section 50.71(e). In particular, it is not typical for FSARs to describe the probabilities of accidents and malfunctions. The final rule should clearly state that the FSAR update need not include the requested information, if the existing FSAR did not have such information. For example, if the existing FSAR does not describe the probability of a particular accident associated with a change, the FSAR update need not provide a discussion of the probability of the accident. In summary, FSAR updates for 50.59 changes should only be required to update existing information, not expand the type of information included in the FSAR.

- Both NRC and industry guidance recognize that 50.59 evaluations may be qualitative and need not be quantitative. *See, e.g.*, 63 Fed. Reg. at 56104. Furthermore, even quantitative 50.59 evaluations may consist of simplified calculations or calculations using assumptions that are more conservative than the original calculation, rather than a revision of the original calculations. As a result, many 50.59 evaluations will not generate numerical information suitable for inclusion in the FSAR, and Section 50.71(e) should not be used to require licensees to generate numerical information that is not needed to satisfy Section 50.59.

Since it is not practical to require FSAR updates to include the effects of "all changes,"[3/] we recommend that this proposed provision on Section 50.71(e) not be included in the final rule.

3/ There may be occasions in which a 50.59 evaluation does result in the calculation of a new licensing basis value (e.g., as a result of a new dose calculation using the licensing basis analytical methodology). In such cases, the licensee is already required by Section 50.71(e) to include this new value in the updated FSAR, and the proposed rule is unnecessary for this purpose.

2.8 Definition of Accidents

The Federal Register notice (63 Fed. Reg. at 56106) requests comments on two proposals for defining the term "accident." The first proposal is a somewhat lengthy and complex definition. In light of the long history of the use of the term "accident" in Section 50.59 and the lack of any confusion regarding its meaning, we do not believe that there is any benefit in providing a new, complex definition.

The second proposal would substitute "design basis accident" in place of the term "accident." We agree that use of the term "design basis accident" is appropriate, since it has a standard and long-accepted definition. We believe that use of this term is especially beneficial with respect to the fifth criterion on "possibility of a design basis accident of a different type." Use of design basis accident in this criterion would provide a beneficial confirmation of existing practice - - namely, it would clarify that low probability, severe accidents are not encompassed within the scope of this criterion. In this regard, we endorse the definition of "accident" provided by NEI.

2.9 Dual-Purpose Spent Fuel Casks

The Federal Register notice (63 Fed. Reg. at 56110) contains the following provision with respect to changes involving dual-purpose spent fuel storage/transportation casks: 1) a change in the cask can be made without prior NRC approval under 10 CFR § 72.48 as it pertains to storage; but 2) a change in the cask *cannot* be made without prior NRC approval with respect to transportation, because there is no provision in Part 71 that is equivalent to Section 72.48. As discussed below, this provision is not necessary to safety and is contrary to sound administration.

In general, most if not all safety aspects of the design of a dual-purpose cask can be subject to a single analysis to satisfy both the transportation requirements in Part 71 and the storage requirements in Part 72. Thus, in most if not all cases, a 72.48 evaluation of a change in a dual-purpose cask with respect to storage will also demonstrate that the change does not adversely impact the level of safety in the certification basis for transportation issues associated with the cask.

Therefore, a licensee or a certificate holder should be able to make changes in a dual-purpose cask without prior NRC approval under both Part 71 and Part 72, provided that the scope of the 72.48 evaluation covers both transportation and storage issues. To accomplish this purpose, we recommend that the following provision be added to Section 72.48 to allow such changes:

> (d) A licensee or certificate holder of a dual-purpose spent fuel cask approved for storage under this part and approved for transportation under part 71 may make changes as permitted under paragraph (b)(2) of this section without obtaining a certificate amendment under part 71, provided that the scope of the FSAR (as updated) includes analyses that address the applicable requirements in part 71, and provided that the scope

of the written evaluation required by paragraph (c)(1) of this section includes such analyses.

2.10 Parallelism between Part 50 and Other Parts

In a number of cases, the proposed changes in Part 52 and Part 72 are different from the proposed changes in Part 50. For example:

- The proposed revisions to the change process in the design certification rules in Part 52 do not include the definitions that are provided in proposed Section 50.59. Since these definitions have substantive effect, the design certification rules should either include these definitions or reference back to Section 50.59 for the definitions.

- Proposed Sections 50.59(d)(2) and 50.71(e)(4) would allow reports of changes and FSAR updates to be submitted within 6 months after each refueling outage, not to exceed 24 months between updates. In contrast, proposed Sections 72.48(c)(2) and 72.216(d) would require reports of changes and FSAR updates to be submitted annually.

- Proposed Section 72.48(b) includes two criteria (i.e., Criteria (viii) and (ix)) which exceed those provided in proposed Section 50.59(c).

- Proposed Sections 72.70(b), 72.216(d), and 72.248(b) would require FSAR updates to include several types of information that are not required to be submitted as part of FSAR updates under proposed Section 50.71(e).

- Section 50.71(e)(4) states that FSAR updates need only reflect changes made prior to six months of the update. No comparable provision is contained in proposed Sections 72.70, 72.216, and 72.248.

In each case, the provisions in Part 72 are more restrictive than those in Part 50. There is no compelling reason to treat Part 72 licensees and certificate holders more stringently than Part 50 licensees. Therefore, we recommend that the provisions in Part 72 be made consistent with those in Part 50.

We recognize that, in several cases identified above, the Part 72 provisions in question are not new, are currently contained in a similar form in Part 72, and have been inconsistent with the provisions in Part 50 for years. However, we believe that now is an appropriate time to correct this anomaly in the Commission's regulations. Providing consistency in the regulations will result in benefits to licensees without impacting safety. In particular, the inconsistent provisions impose burdens upon facilities which hold licenses under both Part 50 and Part 72, since they require licensees to establish and implement two sets of administrative requirements. Making the provisions consistent will enable licensees to establish and implement a single set of administrative requirements, with corresponding cost savings.

2.11 Provisions Unique to Part 72 Requirements

As discussed above, we believe in general that the requirements related to changes and FSAR updates should be consistent throughout Parts 50, 52, and 72. However, there are some unique aspects of Part 72 licenses and certificates that necessitate somewhat different treatment.

First, as discussed in Section 2.1 above, we recommend that the criterion on margin of safety be deleted. If the Commission nevertheless believes that such a criterion is warranted, we recommend that the Commission adopt NEI's proposal related to preservation of design basis limits for barriers to fission product releases. Obviously, for Part 72 facilities, such barriers are different than for Part 50 facilities, and therefore the criterion or its associated guidance will also have to be different. For example, for Part 72 facilities that utilize storage casks, the barriers would consist of the fuel cladding and casks, and a licensee or certificate holder would be required to evaluate whether a change impacted the design basis limits for these barriers.

Second, the proposed Part 72 provisions would require holders of certificates for storage casks to submit FSAR updates for changes to the cask design. However, certificate holders are vendors, not users of casks. Due to design changes permitted by Part 72, a certificate holder may have sold a number of casks with somewhat different designs (or at any particular time may be offering for sale casks with somewhat different designs). Therefore, the FSAR (as updated) should not just reflect the most recent design changes, but should also reflect other versions of the design that are extant. Thus, the Commission should revise Section 72.248 to clarify that the updated FSAR need not be limited to the most current design but may also identify previous designs that have been (or could be) produced.

3.0 Comments on SECY-98-171

As mentioned above, Attachment 1 to SECY-98-171 provided the NRC's resolution of comments on draft guidance on Section 50.59 contained in NUREG-1606. Many of these "resolutions" are applicable to proposed Section 50.59 as well as the existing rule. Our concerns with respect to these resolutions are provided below.[4/]

3.1 Replacement with an Equivalent Component

SECY-98-171 states that 50.59 evaluation must be performed for a replacement of a component with a different component that has equivalent design requirements. This resolution should be clarified to indicate that such an evaluation is required only if the replacement component has characteristics that are different from those described in the FSAR.

4/ In addition to the concerns stated herein, we believe that other "resolutions" are incorrect or inappropriate. However, our concerns with these other resolutions are cured by provisions in the proposed rule or are addressed as part of our comments on the proposed rule.

3.2 Partial Implementation of Changes Prior to Issue of a License Amendment

SECY-98-171 states that a licensee may not install and test a modification under Section 50.59 prior to issuance of the amendment that approves operation of the amendment. This resolution is not consistent with the language in Section 50.59 or with industry practice.

Many modifications require license amendments because of the operational issues posed by the amendment, not the installation and testing issues associated with the amendment. If installation and testing of the modification does not require a license amendment under Section 50.59, these activities should be permitted even though operation with the modification is the subject of a pending license amendment request.

For example, installation and use of high density spent fuel storage racks typically requires a license amendment in order to change the limits in the technical specifications on spacing of spent fuel assemblies. However, procurement and installation of high density racks, with appropriate controls in place to prevent their use prior to receipt of the license amendment, would not be inconsistent with the technical specifications. As long as the licensee can perform a 50.59 evaluation which demonstrates that installation with such controls (and other controls to ensure safe storage of existing fuel) does not require a license amendment under Section 50.59, a licensee should be permitted to install but not use the racks prior to receipt of the amendment because the amendment is needed for operation but not installation.

Therefore, the Commission should allow installation and testing of all or part of a modification prior to receipt of a license amendment for the modification, provided that 1) the amendment is needed for operation but not installation; and 2) the licensee performs a 50.59 evaluation for the installation and testing.

ATTACHMENT 2

COMMENTS ON OPTION 3
ON MARGIN OF SAFETY

The Federal Register notice (63 Fed. Reg. at 56108-9) requested comments on three aspects of margin of safety. Under each aspect, the NRC identified several options for consideration. Our comments on each of these are provided below.

a. "Which parameters should be controlled?"

The Federal Register notice identifies a number of options for defining the parameters to be considered in determining whether there is a reduction in margin. Our comments on each of these options are provided below.

Option 3(A)(1)

This option would define the margin of safety as the difference between the calculated values in the FSAR and the safety or regulatory limits. We strongly oppose this definition.

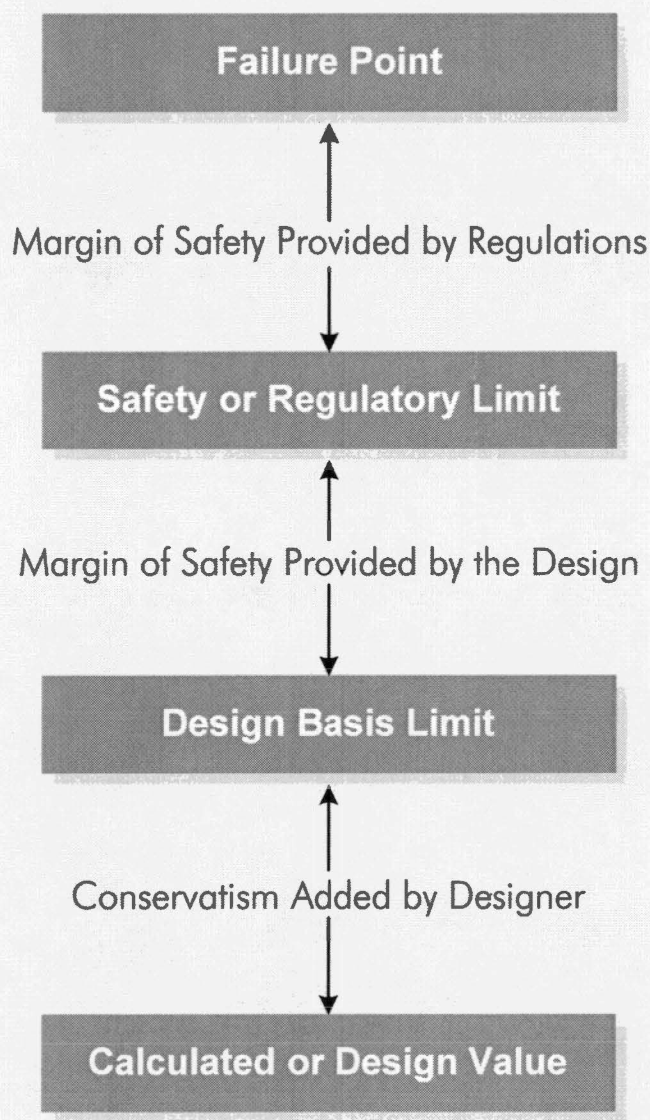
In general, plant designs are conservative relative to calculated values. Designers and licensees intentionally build such conservatisms into their designs to be able to accommodate the effects of future changes and nonconforming and degraded conditions. These conservatisms are distinct from the margin of safety provided in NRC requirements and guidance. Option 3(A)(1) would have the effect of taking conservatisms, built into the design for prudential considerations, and transforming them into regulatory margins. We believe that such a result is inappropriate and unnecessary to preserve the level of safety in the licensing basis.

The NRC should define the margin of safety as the difference between the design basis limit and the safety or regulatory limits, and should allow licensees to make unlimited changes between the calculated values and the design basis limit. Specifically, margin of safety should be defined as shown on Figure 1.

As an example with respect to peak containment pressure during an accident, if the calculated pressure identified in the FSAR is 50 psig, but the licensee conservatively specified a containment design pressure of 55 psig, the margin of safety should be defined as the difference between the design pressure of 55 psig and the safety limit, and the difference between 50 and 55 psig should not be construed as part of the margin of safety. Any other result would penalize those licensees who conservatively established their design values.

Figure 1

Margin of Safety



Options 3(A)(2) and 3(A)(3)

These options would explicitly define margin of safety in terms of the barriers to release of fission products. We support such a concept, but are concerned with the specific language chosen by the NRC to implement this concept.

We endorse the comments of the Nuclear Energy Institute (NEI) on this matter. As explained by NEI, it is appropriate and consistent with the original intent of Section 50.59 for this criterion to focus protection of fission product barriers. As long as changes are consistent with the design basis limits for these barriers, the change should be permitted without prior NRC approval.

Unfortunately, the language in the proposed rule does not satisfactorily implement NEI's proposal. In particular, the proposed rule would define the margin of safety for fission product barriers as the "difference between the *calculated value* and its associated acceptance criteria" (emphasis added). As explained above with respect to Option 3(A)(1), it is not appropriate to define margin of safety relative to calculated values. Instead, at the very least, margin of safety should be defined relative to the design basis limit.

Option 3(A)(4)

This option would be similar to Options 3(A)(2) and (3), but would be expanded to include other parameters, such as parameters associated with mitigation systems such as the emergency core cooling system (ECCS). We do not believe that such an expansion of the scope of this criterion is necessary or appropriate.

Other criteria in Section 50.59 already address mitigation systems In particular, changes that impact mitigation systems would have to meet the criterion related to minimal increases in consequences. This criterion provides sufficient protection to ensure that mitigation systems will be able to perform their design basis functions in the event of an accident.

Prior NRC approval should not be required for changes in mitigation systems which do not affect the ability of the systems to perform their design basis functions. For example, if an ECCS pump has a rated flow of 600 gpm but only requires a flow of 500 gpm to perform its design basis function, a licensee should be able to replace the pump with another pump with a rated flow of 550 gpm without the need to seek prior NRC approval.

Similarly, we do not believe that it is appropriate to include other parameters within the definition of margin of safety. In one way or other, essentially all parameters important to safety relate either to prevention (i.e., probability) of accidents, or to mitigation (i.e., consequences) of accidents. Since both probability and consequences of accidents are addressed by other criteria, there is no need to include a criterion on the margin of safety associated with such parameters.

b. "Determination of reduction in margin requiring review."

The Federal Register notice states that NRC is considering options ranging from a "no reduction" standard to a "minimal" reduction standard. We support a "minimal reduction" standard.

As the NRC has stated with respect to increases in probabilities and consequences of accident and malfunctions (63 Fed. Reg. at 56103-4), it is acceptable to permit minimal changes because there are conservatisms in NRC design and analysis requirements and acceptance criteria, and often parameters calculated and reported in FSARs do not have a high level of precision. These statements apply equally as well to margins of safety. Given the conservatisms and lack of precision in calculations, minimal changes in the margin of safety will not adversely affect either the level of safety provided by the FSAR or NRC's conclusions regarding the safety of the plant. Therefore, NRC should permit minimal reductions in margins.

The definition of the term "minimal" should be the same for reduction of margin of safety as it is for increases in probability and consequences. Different treatments of the term "minimal" would generate unnecessary confusion and should be avoided. As discussed in Attachment 1, we favor an approach to defining minimal that would allow a greater reduction in margin the further the plant is from the acceptance criteria.

c. "Evaluation of effect of the change upon analysis results."

The Federal Register notice states that the conclusions of safety analyses are subject to variance depending upon the assumptions, analysis methods or analytical techniques used, and that the Commission wants licensees to demonstrate that its evaluation techniques and analyses for changes do not invalidate the conclusions reviewed and approved by the NRC. As a result, the proposed rule would require licensees to use methodology and analytical techniques for assessing changes which either have been reviewed and approved by NRC or meet applicable guidance and standards for such analyses.

We believe that such a requirement is inconsistent with existing guidance, unnecessarily restrictive, and not necessary for safety. In essence, the NRC's proposed language would have the effect of requiring licensees to rerun calculations for each change using the original methodologies. Such a requirement would be extremely costly for licensees. Additionally, such a requirement is not necessary to preserve the level of safety provided by the FSAR.

Licensees often use simplified calculations or sensitivity analyses to evaluate proposed changes. Additionally, as the Federal Register notice itself states (63 Fed. Reg. at 56104), evaluations of changes need not be quantitative and may be qualitative. By their nature, such simplified calculations and qualitative evaluations use different analytical techniques than the methodologies identified in the FSAR. Therefore, under the literal language of the NRC's proposed rule, use of simplified calculations and qualitative evaluations would not be permissible, even though they have been standard practice in the industry for more than 30 years.

We believe that a licensee should be allowed to evaluate a proposed change using any analytical techniques or methodologies, provided that they

1) produce results that are consistent with the results that would have been obtained if the licensing basis analytical techniques and methodologies had been used; or

2) have been approved by NRC or meet applicable guidance and standards for such analyses; or

3) have been the subject of a separate 50.59 evaluation - - i e., the use of the different analytical technique or methodology is treated as a separate change requiring evaluation under Section 50.59.

(10)

DOCKETED
USNRC

DOCKET NUMBER
PROPOSED RULE PR 50,52&72
(63FR56098)

'98 DEC 21 P2:55

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

December 18, 1998
NRC:98:085

Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
ATTN: Rulemakings and Adjudications Staff

Subject: Proposed Rulemaking Concerning 10CFR50.59

Siemens Power Corporation (SPC) offers a few comments on the proposed rulemaking concerning 10CFR50.59. SPC generally endorses the language proposed by the Nuclear Energy Institute for section 50.59 (a)(2) except for provision (iv) regarding margin of safety. We believe Option 2 (on page 56107), in which "margin of safety" is deleted, should be implemented. This phrase has continually caused unnecessary confusion, especially during the past few years.

SPC understands that the requirements of 50.59 are intended to address changes in analysis methods to the extent they affect the licensing basis and the SAR in particular. However, we believe the proposed definition of Facility, which includes "(iii) evaluations or methods of evaluation required to be included in the FSAR . . . that their design bases can be met," does not appear to be necessary or appropriate (page 56102). For example, licensees who use COLRs automatically reference approved methodologies.

Whatever changes are made to 10CFR50.59, SPC believes it is necessary to adhere to the principle stated in Section II of the Notice (page 56100) in the first paragraph: "Too stringent an interpretation . . . could result in diversion of licensee and staff resources for review of inconsequential changes."

A clarification appears to be needed in Option 3 at the end of the third paragraph (page 56108): "with NRC review" should read "without NRC review."

SPC appreciates this opportunity to provide comments on this rulemaking.

Very truly yours,

James F. Mallay

James F. Mallay, Director
Regulatory Affairs

/alm

Acknowledged by card DEC 31 1998

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BY OVERNIGHT MAIL

December 17, 1998

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Attention: Rulemakings and Adjudications Staff

Subject: Proposed Rulemaking to 10CFR50.59, Changes, Tests, and Experiments (63 Fed. Reg. 56098 – October 21, 1998)

Reference: Holtec Project 5014

Holtec International endorses the comments provided to the NRC by the Nuclear Energy Institute (NEI) regarding the subject rulemaking as it pertains to 10 CFR Part 72. As a designer and near term certificate holder for two spent fuel storage cask designs, we are particularly concerned with the additional burden and cost imposed upon cask certificate holders by the new reporting requirements in Part 72. The annual frequency for proposed reporting requirements is not commensurate with the passive design features and minimal changes expected for dry spent fuel storage cask design over its service life.

Additionally, we support the complete elimination of the margin of safety criterion for determining whether a proposed change, test, or experiment evaluated under §72.48 requires NRC approval prior to implementation. There are sufficient restrictions currently in place on the ability of licensees and, in the future, certificate holders, to make changes without prior NRC approval. These include the regulations themselves, the technical specifications appended to the Certificate of Compliance, and the other criteria in Section 72.48 against which changes need to be reviewed.

Should the NRC decide the margin of safety criterion is to remain, the revised wording for the definition of margin of safety proposed by the industry (through NEI) for Section 50.59 is not applicable to Part 72 since it refers to the reactor coolant system pressure boundary. Different words, applicable to dry spent fuel storage need to be created for the Part 72 regulations.

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Please contact me at (609) 797-0900, extension 668 if you have any questions or require additional information

Sincerely,

Brian Gutherman
Licensing Manager

Document I.D. 5014248

Approval

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SOUTHERN COMPANY
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December 18, 1998

DOCKET NUMBER
PROPOSED RULE PR 50, 52 & 72
(63FR56098)

Docket Nos.	50-348	50-321	50-424	HL-5717
	50-364	50-366	50-425	LCV-1288

Mr. John C. Hoyle, Secretary
U. S. Nuclear Regulatory Commission
ATTN: Rulemakings and Adjudication's Staff
Washington, D. C. 20555-0001

Comments on the Proposed Rule,
"Changes, Tests, and Experiments"
(63 Federal Register 56098 dated October 21, 1998)

Dear Ladies and Gentlemen:

Southern Nuclear Operating Company (Southern Nuclear) has reviewed the proposed rule, " Changes, Tests, and Experiments," published in the Federal Register on October 21, 1998. In accordance with request for comments, Southern Nuclear is in total agreement with the NEI comments which are to be provided to the NRC.

Respectfully submitted,

J. B. Beasley, Jr.

JBB/TMM

Acknowledged by card DEC 31 1998

U.S. NUCLEAR REGULATORY COMMISSION
RULEMAKINGS & ADJUDICATIONS STAFF
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HL-5717
LCV-1288

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(7)

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LOCKHEED MARTIN

'98 DEC 18 P3:55

Lockheed Martin Idaho Technologies Company
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December 17, 1998

DOCKET NUMBER PROPOSED RULE PR 50, 52 + 72 (63FR56098)

Secretary, U.S. Nuclear Regulatory Commission
ATTN: Rulemakings and Adjudications Staff
Washington, DC 20555-0001

COMMENTS ON PROPOSED RULE CHANGE AT 10 CFR 50.59 AND 72.48 - **MLC-01-98**

Dear Sir:

Lockheed Martin Idaho Technologies Company (LMITCO) is the Department of Energy's (DOE) Management & Operating Contractor for the Idaho National Engineering & Environmental Laboratory (INEEL). The DOE is the license applicant for two licenses pursuant to 10 CFR Part 72; and LMITCO is assigned several responsibilities relating to these license applications and the expected licensed operations. Provided below are LMITCO's comments to the proposed rule change published on October 21, 1998 in the Federal Register at Vol. 63, Pages 56098-56125. The opportunity to comment on such a significant effort to improve the regulations and the consideration of such comments is appreciated.

COMMENT 1. The term "FSAR" should not be used in Part 72.

Basis for Comment 1.
Because the approval of Part 72 SARs is not a two-step process, the addition of the term "FSAR" to Part 72 could be confusing (specifically, there is no Part 72 use of the term PSAR). It is our understanding that once a site-specific ISFSI SAR is approved, changes made during design, construction, and operation require 72.48 evaluations; and the SAR must be periodically updated Discussion of an FSAR in Part 72 associated with the submittal after design and construction might imply an NRC re-review or an additional licensing action (rather than a reporting requirement to insure that an updated SAR is provided). The discussion of an FSAR could also imply that the 72.48 process is not required to evaluate changes until the licensee has an FSAR.

Spent fuel storage in an ISFSI represents a significantly lower amount of risk compared to operating a power reactor (the operations and design are far simpler and there are relatively few controversial issues). Therefore, a one step licensing procedure requiring only one application and one SAR should be retained in Part 72. If 72.48 does not apply to an approved SAR before submittal of the FSAR and if the final SAR must be submitted for approval as an FSAR, then there is less incentive to request approval of an ISFSI SAR before ISFSI construction.

Acknowledged by card DEC 22 1998

The proposed rulemaking at Section 72.70 could be interpreted as indicating the Commission intends to adopt the Part 50 two-part license application or safety analysis report expectations. Our understanding of the current rules at Part 72 are:

- Initial submittal and all updates of the SAR consider both (1) ISFSI (design and) construction and (2) ISFSI operation.

- The submittal at least 90 days before loading is not for the purposes of additional Commission review and approval but is meant to assure the Commission that the changes made during design and construction have been completely identified at least 90 days before loading.

- The license applicant may proceed with construction by assuming the risks that the Commission may not approve the originally submitted design.

Clarification is also requested concerning the format requirements in the proposed 72.70(c). It appears that by specifying replacement-page basis for FSAR updates, replacement-page basis is not expected during the semiannual SAR updates provided before preoperational testing.

COMMENT 2. Limit the scope of the SAR subject to 72.48/50.59 changes. It is important that existing licensee screening processes be provided a regulatory basis. One option would be to modify the definition of facility at 72.48(a)(3) and 50.59(a)(2) to limit ourselves to SSCs "important to safety" instead of all the SSCs required to be described in the FSAR. Another option would be to require licensees to identify those sections of the SAR subject to 72.48 controls.

<u>Basis for Comment 2.</u>
While the proposed rule does improve the thresholds used for objective safety and regulatory thresholds for determining when a license amendment is required, it fails to establish or even allow licensee-establishment of thresholds for the scope of the SAR subject to these evaluations. These evaluations are expensive; therefore, scope threshold is an important issue. What is recommended for consideration is a 72.48/50.59 program which allows each licensee to define the scope of the SAR subject to the 72.48/50.59 change controls. Scope definition could be included in existing licensee programs which already include implementing procedures, training, and defined roles and responsibilities. Scope definition could be implemented by establishing a process such as existing (and effective and risk-informed) licensee screening processes. Scope definition could also be implemented by defining the SAR sections which form the Bases for the Technical Specifications (in other words, by defining the SAR sections "associated with the Technical Specifications").

The willingness of NRC staff to discuss exclusion/removal of certain types of material from the SAR appears related to the concept that some information in the SAR shouldn't be covered by 72.48 or 50.59. Yet there are advantages to having the SAR as a single place for more facility information. Would it be reasonable for a licensee to define (in the SAR) (1) the licensee's 72.48 program describing the administrative controls over 72.48 and (2) which parts of the SAR are covered by 72.48? Such a program could even be made subject to "change in effectiveness evaluations" used to implement 72.44(e) and (f).

In conjunction with specifying which parts of the SAR are subject to 72.48, the licensees could specify which programs (described in the SAR or incorporated into the SAR by reference) are subject to controls comparable to 72.44(e) and (f), instead of using the 72.48 change control. Some plants do 50.59s when they change management assignments, organizational structure, or changes to programs described in the SAR. Using 72.48/50.59 to evaluate changes in programs is the least appropriate regulatory screen available: on the one hand, how could any programmatic or administrative or personnel change directly affect the configuration of the facility? So a reasonable 72.48 analysis applied to program changes should always result in the "no license amendment required" conclusion. How effective is that? Nothing in the 72.48/50.59 criteria lends itself to consideration of the contribution by programs to the "assurance" of nuclear safety because 72.48/50.59 is geared towards consideration of configuration rather than the assurance of configuration. Yet, a change in a program described in the SAR leading to an obvious decrease in effectiveness would have to be questioned by the regulator. But the basis for the regulator's complaint (in the form of a 72.48/50.59 violation) would be a stretch of the regulations and would inevitably lead to less consistent interpretation of the regulations by the several licensees and the regulator personnel.

COMMENT 3. Switch the order of 72.48(a)(2) and 72.48(a)(3).

Basis for Comment 3.
This change would result in the definitions for "SAR" and "facility" being in the same order in both Parts and would ease the comparison of the regulations at Part 50 and Part 72 (which could be important during discussions among licensing/compliance staff with backgrounds in Part 50 activities working on Part 72 projects, for example).

COMMENT 4. Upon resolution of comments and update of the statements of consideration in the publishing of the final rule change, it is requested that the information in Section II of SUPPLEMENTARY INFORMATION be used to update draft NUREG-1606. Alternatively, the Commission should expedite the resolution of comments with NEI and endorse the Institute's guidance.

Basis for Comment 4.

It is noted from a review of SECY-98-171 that draft NUREG-1606 will not be made final. In light of the number of comments on the draft NUREG (and the implied interest in a consensus on the issues in the draft NUREG) it is requested that, if appropriate, the Commission reconsider maintaining this guidance document instead of beginning a new process. It is noted that much of the information in Section II of SUPPLEMENTARY INFORMATION in the proposed rule was provided in an outline similar to the draft NUREG-1606.

COMMENT 5. All discussion of "interdependent" changes be should deleted from the proposed rule changes. Instead, all licensees should be encouraged to link multiple changes having a net increase in safety margins for a facility; and licensees with adequate margins of safety should be allowed to link multiple changes having a net minimal increase in risk.

Basis for Comment 5.

After studying the discussions provided in the SUPPLEMENTARY INFORMATION in the proposed rule and in SECY-98-171, it appears the definition of "interdependent" could be the subject of considerable confusion (considerable regulatory expense) without a corresponding safety benefit.

What is the regulatory or safety basis for restricting linkage of changes to those changes meeting the poorly defined interdependency criterion. A review of the SUPPLEMENTARY INFORMATION in the proposed rule and in SECY-98-171 did not yield the basis for such a restriction and did not yield a clear definition with which a licensee could develop implementing procedures.

With respect to linking changes and limiting the linkage of multiple changes to those considered "interdependent," consider the potential benefit of reducing total plant or facility risk. This potential benefit is less likely to be realized if a licensee is required to pursue a license amendment unless the potential benefit (cost savings) is very large. The Commission could use linking as an economic driver to accelerate improvements in higher risk facilities. Facilities meeting a low total risk threshold could link any changes while meeting a "minimal increase in risk" standard while facilities characterized by a relatively high total risk would be allowed to link changes only if there was at least a "minimal decrease in risk." Such a regulation could provide a licensee of a relatively high risk facility a real incentive to invest in the facility changes needed to achieve the Commission's risk reduction objectives.

Because ISFSIs have very low risk thresholds (compared to power reactors), ISFSIs should be permitted to link changes without restriction.

COMMENT 6. Resolve the issue of Cumulative Effect of several changes with minimal increase (bottom of Issue G) by requiring the linkage of changes.

Basis for Comment 6.
The phrase "and safety analyses performed pursuant to Secs. 72.56 or Sec. 72.244" [corresponding Part wording is "and safety analyses performed pursuant to Sec. 50.90"] used in six of the license amendment criteria makes it appear that a licensee could prepare a license amendment pursuant to 72.56 or 72.244 [50.90] and use the associated safety analysis for subsequent changes permitted by 72.48 [50.59] before the license amendment is approved.

COMMENT 7. Adopt Option 2 for Issue J (margin of safety associated with technical specification). If Option 2 is not selected, the Commission's concept of "minimal increase" should be applied to this license amendment criterion.

Basis for Comment 7.
Margins serve two purposes: (1) to simplify the analysis (reduce the cost of analysis) used to demonstrate process safety and (2) to reduce the probability or consequence of a hazard. (To clarify what is meant by the first purpose, consider that many analyses use simplifying assumptions which significantly "bound" certain conditions as a means for simplifying an analysis. This significant bounding appears to be considered by the Commission as part of the margin which the Commission appears determined to maintain.)

Where margins have been applied to the design of a process to simplify the demonstration of process safety, and a subsequent process change uses a more rigorous analysis, then this margin should be considered a reduction in safety only if this margin has also been used in the calculation of process risk. However, if this margin has not been used in the calculation of process risk, then the licensee should be allowed to spend more on additional analysis in exchange for process savings; especially if the new analysis meets published expectations in a SRP or other guidance document.

"Margin of safety" as a criterion can be safely deleted because the risk considerations implied by "margin of safety" are adequately embodied in the three risk considerations: hazard ("failure or accident of a different result or type"), probability, and consequence.

COMMENT 8. Much of the wording in the proposed 72.48 could be eliminated by defining "SAR" as the "current SAR maintained in accordance with 72.70." Also, repeated use of the phrases "last Final Safety Analysis Report" and the "FSAR as updated" does not appear to be needed for Part 72 licensees and might not be needed for Part 50 licensees after a phase in period (after all SARs are expected to be updated).

Basis for Comment 8.
Editorial.

COMMENT 9. Add "significant" to the license amendment criteria at 72.48(b)(2)(v) and (vi) [corresponding changes requested to 50.59(c)(2)(v)and (vi)].

Alternatively, provide wording to allow "minimal increase in risk" associated with these license amendment criteria.

Please consider the following wording for 72.48(b)(2) [50.59(c)(2)] as a means of incorporating this comment: "A licensee shall obtain an amendment to the license pursuant to Sec. 72.56 [50.90] prior to implementing a change, test or experiment if it would result in more than a minimal increase in facility risk." Risk could be defined as the sum (for all design basis accidents and malfunctions of SSCs important to safety) of probability of occurrence times consequence. The first six license amendment criteria of this paragraph would be addressed by this suggestion.

Basis for Comment 9.
It is understood that there are three aspects to risk: type of hazard (identified in license amendment criteria 72.48(b)(2)(v) and (vi)) [or 50.59(c)(2)(v) and (vi)], probability of hazard (identified in license amendment criteria 72.48(b)(2)(i) and (ii)) [or 50.59(c)(2)(i) and (ii)], and consequence of hazard (identified in license amendment criteria 72.48(b)(2)(iii) and (iv)) [or 50.59(c)(2)(iii) and (iv)]. Minimal increases in risk due to probability and consequence would be allowed in the proposed rule, but new hazards (accidents of a different type or malfunctions of a different result) with insignificant probability or consequence would require a license amendment given the wording of the proposed rule. In order to improve the risk-informed nature of the proposed rule, hazards should be deemed significant only if the risk is comparable (e.g., the same order of magnitude or greater) than the other hazards already approved.

When evaluating "minimal increase," all three aspects of risk should be considered together. Instead of specifying the "more than minimal" criterion for probability (criteria 72.48(b)(2)(i) and (ii)) and again for consequence (criteria 72.48(b)(2)(iii) and (iv)), probability times consequence should the criterion for evaluating changes requiring the burden of the license amendment. For example, an unapproved change resulting in more than a minimal increase in probability should be allowed if the change also results in a reduction in consequence such that the increase in risk would be "minimal."

COMMENT 10. The third part of the definition for ISFSI (72.48(a)(3)(iii)) or facility (50.59(a)(2)(iii)) should be deleted.

Basis for Comment 10.
The licensee should be encouraged to make facility improvements, to improve analytical methods, and to improve measurements and other inputs to analyses. The inclusion of evaluations in the definition of "facility" is a hindrance to improvement without adding to safety. The appropriate licensee controls for changes to the subject evaluations are more related to design control: (1) is the analytical method valid or reasonable, (2) are the inputs to the analysis accurate or conservative, and (3) does the facility still meet the limits agreed upon (perhaps with a "minimal" increase)? The Commission has adequate regulations and guidance to inspect and enforce concerns related to design control. The inclusion of evaluations in the definition of facility also appears to be inconsistent with encouraging the transition of the regulatory environment away from an overly prescriptive environment to a risk-informed performance-based environment.

The example provided by the Commission in the second paragraph of Section II, Issue B ("consider a change being made to the basis (documented in the SAR) for demonstrating adequacy of the facility without a physical change to the facility") certainly describes information which must be included in the SAR, but should changes to this information be subject to license amendment? Perhaps this issue is related to the issue of defining the scope (in other words, which parts of the SAR are subject to the 72.48/50.59 change control).

Consider the improvements in analytical methods and capabilities we've seen in the last ten years. Why should the licensee of an older facility be hindered (by the cost of license amendment) from improving the facility analysis? Why should such a licensee be hindered from making economic improvements in a facility which could be justified by the more accurate or rigorous calculation of facility risk? Why should licensee's of older nuclear facility's be hindered from using improvements in analytical methods available to other industries? The Commission should be concerned more with the hindrance of licensees' update of analytical methods. The Commission surely recognizes that the expense of the Commission's review of new analytical methods is occasionally prohibitively expensive.

The statement by the Commission at the beginning of the third paragraph of Issue B [*If changes to methods and assumptions were not controlled, a licensee might revise its analyses and then subsequently conclude that a later facility change did not require NRC approval because the results of the (new) analysis with this change were bounded by the previous analysis.*] illustrates a significant hurdle for licensees' desire to improve their facilities. The Commission's basis for license approval or license change should be compliance with regulations (72.40). It is additionally burdensome to require the licensee's de facto site-specific regulations to include the margins (between analyzed facility risk and regulatory limits), but the above quoted statement by the Commission illustrates that the licensee's de facto site-specific regulations include the methods which the licensee used to demonstrate to the Commission that the analyzed facility risk falls within regulatory limits. It should be enough that the licensee's method of assurance of nuclear safety be covered by nuclear quality assurance without also requiring the burden of license amendment.

Sincerely,

Michael L. Croson

Michael L. Croson, Licensing Engineer

/idh

cc: F. J. Borst, FSV
J. Hagers, DOE-ID
A. P. Hoskins
S. E. LeRoy
C. L. Maggart, DOE-ID
W. B. McNaught
R. A. Schiffern
S. M. Thraen

6

USEC
A Global Energy Company

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USNRC

'98 DEC 18 P3:53

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

December 17, 1998
GDP 98-0274

The Secretary of the Commission
U. S. Nuclear Regulatory Commission
Attention: Rulemakings and Adjudications Staff
Washington, D.C. 20555-0001

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

Paducah Gaseous Diffusion Plant (PGDP)
Portsmouth Gaseous Diffusion Plant (PORTS)
Docket Nos. 70-7001 & 70-7002
USEC Comments on NRC's Proposed Amendment of 10 CFR Parts 50, 52, and 72, "Changes, Tests, and Experiments"

Dear Sir:

The United States Enrichment Corporation (USEC) is pleased to submit the following comment on the NRC's proposed amendment of 10 CFR Parts 50, 52, and 72, "Changes, Tests, and Experiments," for your consideration.

Given the similarity between the subject regulations and 10 CFR Part 76.68 governing changes to the Gaseous Diffusion Plants (GDPs), it is USEC's position that revisions being proposed for §50.59 should be appropriately and concurrently considered for §76.68, as well. The NRC has argued that the degree of design detail that is currently available in the GDP safety analysis reports (SAR) makes adopting similar changes to §76.68 inappropriate. USEC disagrees with that assertion and suggests that the process by which changes are made to the plant or to the plant's operations as described in the SAR does not, and should not, vary based on the detail of the description being changed.

USEC recommends that Part 76 be revised concurrently with the ongoing proposed §50.59 revision. USEC will follow developments concerning this rulemaking closely and continue to press for similar consideration with respect to §76.68 as appropriate.

Acknowledged by card DEC 22 1998

6903 Rockledge Drive, Bethesda, MD 20817-1818
Telephone 301-564-3200 Fax 301-564-3201 http://www.usec.com
Offices in Livermore, CA Paducah, KY Portsmouth, OH Washington, DC

USEC appreciates the opportunity to provide input to the Commission's rulemaking process. Should you have any questions related to this subject or wish to discuss these comments, please contact Lisamarie Jarriel at (301) 564-3247. There are no new commitments contained in this submittal.

Sincerely,

S. A. Toelle

Steven A. Toelle
Nuclear Regulatory Assurance and Policy Manager

cc: Mr. Robert C. Pierson - NRC HQ
NRC Region III Office
NRC Resident Inspector - PGDP
NRC Resident Inspector - PORTS

(5)

ABB
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'98 DEC 18 P3:29

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RULEMAKINGS AND
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December 18, 1998
LD-98-039

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Subject: **ABB-CE Comments in Response to Notice of Proposed Rulemaking to Amend 10 CFR 50.59**

Reference: 1. 56098 Federal Register, Vol. 63, No. 203, Wednesday October 23 1998.

ABB Combustion Engineering (ABB-CE) provides the following comments in response to the notice of proposed rulemaking to amend 10 CFR 50.59, changes, tests and experiments:

1. ABB-CE fully endorses the comments on the proposed changes to 10 CFR 50.59 that have been developed by the Nuclear Energy Institute (NEI). In particular, ABB-CE endorses the industry proposal to focus the margin of safety evaluations on the Design Basis Limits which ensure the continued integrity of the three fission product barriers. ABB-CE recommends that the NRC adopt the proposed wording changes submitted by NEI for assessment of changes to the margin of safety.

2. ABB-CE believes it is necessary to return to this issue in a subsequent rulemaking to determine the appropriate scope of 10 CFR 50.59. The follow-on rulemaking should occur as soon as possible and should be done independently of the 50.71(e) rulemaking.

3. ABB-CE recommends that industry (via NEI) and the NRC develop a mutually acceptable Regulatory Guide similar to the guidance developed in NEI 96-07 which can be adopted for use by the industry. ABB-CE recommends that this guidance be in place prior to the effective date of the amended rule. The proposed rule is complex and contains terms that are potentially subject to misinterpretation. ABB-CE believes that it is crucial that the NRC and industry adopt a well written and comprehensive guidance document that contains a large number of examples aimed at clarifying the implementation of the amended 10 CFR 59. In order for the revised rule to perform one of its intended functions there needs to be uniformity of understanding and implementation across the industry. No purpose will be served if individual licensees continue to utilize their own

Acknowledged by card DEC 22 1998

ABB Combustion Engineering Nuclear Power

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U.S. NUCLEAR REGULATORY COMMISSION
RULEMAKINGS & ADJUDICATIONS STAFF
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interpretations for ambiguous phraseology. It is essential that the industry standard obtain the endorsement of the NRC.

4. For a future rulemaking, ABB-CE recommends that the staff consider extending the applicability of 10 CFR 50.59, or an equivalent rule, to activities licensed under 10 CFR Part 71 (Packaging and Transportation of Radioactive Material). ABB-CE believes that significant paperwork cost and NRC review time could be saved if a process similar to 10 CFR 50.59 were available to licensees of shipping containers to handle small changes which have a minimal effect upon the container's safe performance. Since the risk associated with shipping casks is lower than for reactors, it makes sense that certificate holders should have the same change capability.

If you have any questions concerning ABB-CE's comments on the proposed changes to 10 CFR 50.59, please contact Mr. C. B. Brinkman at (301) 881-7040, or me at (860) 285-9678.

Sincerely,

I. C. Rickard

Ian C. Rickard
Director of Licensing

cc: Anthony R. Pietrangelo
Director of Licensing
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OPPD
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Omaha, Nebraska 68102-2247

DOCKET NUMBER PR 50, 52 & 72
PROPOSED RULE (63FR56098)

DOCKETED
USNRC

'98 DEC 16 P4:16

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

December 11, 1998
LIC-98-0174

The Secretary of the Commission
Attention: Rulemakings and Adjudications Staff
U.S. Nuclear Regulatory Commission
Washington D. C. 20555-0001

Reference: Docket No. 50-285

Subject: Comments on Proposed Rulemaking for 10 CFR Parts 50, 52 and 72- Requirements for Changes, Tests and Experiments (63 Fed. Reg. 56098 - October 21, 1998)

In general, Omaha Public Power District endorses the Nuclear Energy Institute (NEI) industry comments on the subject proposed rulemaking to amend various regulations including 10 CFR 50.59. However, we have the following two concerns that are somewhat interrelated.

1. The wording of the NRC-proposed paragraphs 10 CFR 50.59(c)(2)(i) through (c)(2)(vi) and the NEI-proposed revision to the definition of "FSAR (as updated)" (Industry Recommendation 3.a-c) states that any proposed change must be reviewed against evaluations performed pursuant to 50.59 and safety analyses performed pursuant to 50.90 after the last final safety analysis report was updated pursuant to 50.71.

A 50.59 (or 50.90) evaluation could be performed (or may have been performed in the past) indicating insignificantly lower probability or consequences than described in the FSAR; in this case, the FSAR normally would not be updated to reflect this, in that "it is bounded by existing evaluation." However, literal compliance with the proposed wording would make this evaluation now become the new acceptance criteria for all future 50.59 evaluations with regard to the evaluated accident, consequences, or malfunction. Assuring compliance with this would require that all previous 50.59 and 50.90 evaluations be reviewed and the FSAR updated to reflect the most conservative of the accident/malfunction or consequences analyses performed. Additionally, any subsequent evaluation that shows even an insignificant decrease in these parameters must be reflected in the FSAR. Thus, an analysis that indicates a proposed change is acceptable also requires that the FSAR be revised to reflect this new lower threshold.

The end result is that any gains to the industry by allowing minimal increases in the "probability of occurrence" and "consequences" criteria would be negated by making the FSAR more and more conservative. Although this result was probably unintended, the sections noted above need clarification and/or the issue should be addressed in the final rule.

DEC 21 1998
Acknowledged by card

2. We strongly agree with the NEI comments concerning cumulative effects of minimal increases. However, the proposed language in 50.71(e)(4) includes "the net effect of all changes made since the last update on the safety analyses, including probabilities, consequences, calculated values, system or component performance, that are in the FSAR (as updated)." This seems to force licensees into describing in the FSAR minor or insignificant (conservative) decreases in these parameters, as noted in Comment 1. above, and somehow producing descriptions of the net effects.

This requirement is exacerbated by a lack of NRC-sanctioned guidance. A licensee could reasonably conclude that all 50.59 evaluations would require probabilistic risk assessment in order to determine cumulative net effects at the end of the reporting period. This is an unreasonable and additional burden on licensees.

If you have any questions on these comments, please contact Mr. Richard Lentz of my staff at 402-533-6918.

Sincerely,

S. K. Gambhir
Division Manager
Nuclear Operations

RRL/tcm

c: E.W. Merschoff, NRC Regional Administrator, Region IV
L.R. Wharton, NRC Project Manager
W.C. Walker, NRC Senior Resident Inspector
Document Control Desk
Winston and Strawn

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

OFFICE OF THE SECRETARY

December 2, 1998

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'98 DEC -2 A9:31

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

Mr. Brendan C. Ryan
Department of Mechanical and
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Kansas State University
302 Rathbone Hall
Manhattan, KS 66506-5205

Dear Mr. Ryan:

Thank you for your letter of November 23, 1998. Your letter of November 3, 1998 has been placed on the correct docket: Changes, Tests, and Experiments (PR- 50, 52 &72, 63FR56098). When your November 3rd letter arrived, it was mixed with a number of letters on a highly active rulemaking and was coded for that rulemaking. Recently, the error was discovered and the letter was properly coded. We have sent you the correct acknowledgment card for your comment which has been designated as comment number two on the Changes, Tests, and Experiments rulemaking.

Although we discovered the coding error prior to your letter of November 23rd, your letter is appreciated.

Sincerely,

Emile L. Julian

Emile L. Julian
Assistant for Rulemakings
And Adjudications

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR56098)

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'98 NOV 30 P4:17

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23 November, 1998

U.S. Nuclear Regulatory Commission
Attn: Rulemakings and Adjudications Staff
Washington, D.C. 20555-0001

RE: 10CFR50.59 Revisions Published 63FR56098

Gentlefolk:

On 3 November 1998, I sent you my comments on your proposed revisions to 10CFR50.59. However, the correspondence card that I received back showed that my comment had been applied to 63FR43516, not 63FR56098. Please investigate this matter and apply my comments to the appropriate regulation. An extra copy of my comments is attached as well as a copy of your comment card.

Sincerely,

Brendan C. Ryan

Brendan C. Ryan, Manager
KSU Nuclear Reactor Facility

Phone: (785) 532-6657 Fax: (785) 532-6952 E-Mail: ibryan@mne.ksu.edu
Facility Address: 112 Ward Hall, Manhattan, KS 66506-2503

We have received your recent correspondence regarding the subject referred to below. Please be advised that your correspondence has been forwarded for consideration by the Commission. Thank you for your interest.

MEDICAL USE OF BYPRODUCT MATERIAL; PROPOS
REVISION

PR-020, 032 & 035
FEDERAL REGISTER CITE: 63FR43516
COMMENT DATE: 11/03/98
COMMENT NUMBER: 418

Rulemakings and Adjudications Staff
Office of the Secretary
of the Commission

NRC FORM 532B
(7-1998)

3 November, 1998

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U.S. Nuclear Regulatory Commission
Attn: Rulemakings and Adjudications Staff
Washington, D.C. 20555-0001

RE: 10CFR50.59 Revisions Published 21 Oct. 1998, 63FR56098

Gentlefolk:

Although the proposed changes to 10CFR were constructed with best intentions, these objectives could be better accomplished through regulatory guidance. Despite increased wording, there is not a substantive change in intent of the regulation. When detached from the comment section, the proposed regulation offers little more than the existing wording. Unfortunately, the proposed complex regulatory framework eliminates the simple concept of an "Unreviewed Safety Question," which forms a cornerstone of safety consciousness. This serves to destroy the inculcation of safety culture at the operational level, where it is needed the most. I applaud the NRC for their dedication in clarifying regulations; however, the added complexity leads only to legalistic arguments. If it takes a lawyer to tell a nuclear engineer that a nuclear device is safe, then we should let them design and run our plants. Common sense is an integral part of safety, and therefore it should be the basis of regulatory change.

The first objection to the proposed wording concerns the concept of minimal increase. The word "minimal" is itself an arbitrary expression. The previous wording allowed for no increase, and was extremely clear. In fact, licensees may use this concept justify nearly any change to be minimal as long as they stay within ultimate safety limits. In trying to define "minimal increase," the NRC uses an oversimplified depiction of safety analysis. Safety limits rarely consist of a single parameter. Instead of simple linear relationships, these limits form a complex multi-dimensional envelope. Limited safety system settings and limiting conditions for operation lie within this envelope, with the boundary representing the safety margin. Projection of an operation change onto a single parameter neglects other impacts, which may dominate the response. Therefore, what is perceived as a minimal change may have a significant effect on overall safety. Contrary to the published opinion, NRC review of such changes is inescapable.

The second objection concerns the differentiation between accident probability and the failure rate of safety-related equipment. This distinction is unnecessary, since it is generally understood that safety-related equipment is directly related to prevention of, mitigation of, or recovery from accidents. Therefore safety-related equipment is necessarily included in the analysis of design basis accidents, and already explicitly covered by the existing wording. Further clarification of this subject seems unnecessary.

It is clear that a principal objective is to achieve a continuing process of safety review. On a plant scale, this can be accomplished by maintaining current safety analysis reports.

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However in daily operations, there should exist a simple metric by which individuals can make decisions, especially the realization of which decisions should be submitted to oversight committees or the NRC for review. For many years, the concept of an unreviewed safety question has served this role. The entire nuclear industry from engineers to reactor operators knows and understands this simple definition. It is a simple concept to be kept in mind and to be used everyday when approached by a new problem. In this sense, it is part of our safety culture. By expanding this concept in a complex framework, decision making is relegated to those involved in regulatory compliance. However, regulatory compliance only provides an indicator of safety. For safety to become an integral part of operations, every decision-making individual must have a general understanding of the concepts involved. Therefore, the definition of an unreviewed safety question is a tenet of safety consciousness.

If the goal of these changes is to increase awareness of safety analysis and to promote the upkeep of final safety analysis reports, then the added complexity can only make this a more arduous process. Arduous processes breed complacency, which is counterproductive to safety. Perhaps regulation should follow the "KISS" principle in engineering, namely "Keep It Simple Stupid!" Nuclear engineers took many years to realize that simple designs have fewer failure modes, unfortunately regulators seem to be taking the reverse perspective.

Personally, I feel that the biggest problem with facility changes concerns the adversarial role that industry takes with the NRC. Although we stress teamwork within our respective organizations, we fail to work as a team between regulator and licensee. At my facility, I have taken a different approach. I feel very comfortable calling the NRC to discuss everything from daily problems to facility modifications. The NRC staff has a wealth of experience that many licensees fail to utilize. However, the system must work both ways. As a simple example, I keep a separate file of all safety evaluations that I provide to the NRC during inspections. Consequently, inspectors rarely have to inquire for additional information and can spend more time on discussing ways to improve operations.

Sincerely,

Brendan C. Ryan

Brendan C. Ryan, Manager
KSU Nuclear Reactor Facility

(3)

A&K Nuclear Licensing

38845 Godfrey Pl., Fremont, CA 94536

November 18, 1998

cc: NEI
GE Nuclear Energy

Ltr2NRC9801

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attn: Rulemakings and Adjudications Staff, and Eileen McKenna

Subject: **Comments To The 10/21/98 FR Vol. 63, No 203 Proposed Rule, "Changes, Tests, and Experiments," Related Changes To 10 CFR 50.59**

Reference(s)

1. A&K Nuclear Licensing, (Licensing Training Manual) *Detailed Instructions For Performing BWR Licensing Evaluations*, (Proprietary Information) A&KRpt-9802, August 1998
2. NRC Memorandum and Order, CLI-84-9, June 6, 1984
3. Nuclear Energy Institute, "Guidelines for 10CFR50.59 Safety Evaluations," NEI 96-07.
4. Letter to T. E. Tipton, Director OMSS Division, NUMARC, from C. E. Rossi, Director Division of Operational Events Assessment, NRR, USNRC, May 12, 1988.
5. USNRC Inspection and Enforcement Manual, "10CFR 50.59", "Part 9800 (9900) CFR Discussions", "Changes to Facilities, Procedures and Tests (or Experiments)", January 1, 1984.

Dear Ms. Eileen McKenna

This letter is to introduce myself, provide comments on the NRC's 10/21/98 proposed version of 10 CFR 50.59, and supply some useful information to help the NRC develop positions on 10 CFR 50.59 that are consistent with the safety bases of the BWR. I have 25 years of criticality safety, BWR core design, and BWR safety and licensing experience. I have produced the GE portions of two BWR FSARs, and wrote and taught all of GE's operating plant licensing courses

for ten years. I am currently providing licensing services and training as a contractor, and make it my business to keep current on all issues with respect to 10 CFR 50.59. Accordingly, I'd like the future changes to 50.59 to be conservative, allow 50.59 interpreted consistently, and continue to maintain the licensed safety bases of the BWR.

Suggested changes to the 10/21/98 proposed version of 50.59 are provided in Attachment 1. An explanation of each of the suggested changes, and comments on other 10 CFR 50.59 related statements from the 10/21/98 Federal Register (Vol. 63, No. 203) are provided below.

1. Accidents and Malfunctions of a Different Type

When evaluating a potential accident or malfunction, it is important to answer the question, "If the FSAR was being written today, would this accident or malfunction be included?" If the answer is "yes", then a license amendment should be required. Subsection 5.3.5 of Reference 1 provides the guidance to answer this question.

Accidents always result in a radiological consequence greater than a 10CFR 20 allowable release limit. Therefore, for a change to create an accident of a different type, the change must allow for a new failure with resulting radiological release of such safety significance (>0.5 rem whole body dose or 1.5 rem thyroid dose) that, if the plant was being licensed for the first time, the failure would be included in the plant FSAR accident chapter. That is, *the change must allow for a new fission product release path, result in a new fission product barrier failure mode, or create a new sequence of events that results in significant fuel cladding failures.*

For a change to create a malfunction of a different type, the change must allow for a new failure with of such safety significance that, if the plant was being licensed for the first time, the failure would be included in the plant FSAR. That is, *the change must allow for a new failure mode with a different result on an item important to safety* **or** *a safety-related item* **(NRC to define important to safety or only use safety-related)**, *create the possibility of a new limiting AOO (transient), or create a new sequence of events that can result in a radiological release (via a normal release pathway) above a current operating, 10CFR 50 App. I or 10CFR 20 limit.* Equipment malfunctions should usually be considered for a malfunction of a different type based on the effects of the malfunction. A new failure mechanism is usually not a malfunction of a different type if the result or effect is the same as that previously analyzed in the FSAR (i.e., bounded by a FSAR evaluation/analysis). For example, if a pump is replaced with a new design, there may a new failure mechanism introduced that would cause a failure of the pump to run. But if this effect (failure of the pump to run) was previously analyzed or bounded by a system level failure in the FSAR, then a malfunction of a different type has not been created. Most failures and malfunctions assumed in the BWR safety analyses are on general (no specific failure mode) component or system level basis, and thus, individual component failure modes are usually not within the licensing basis. Conversely, if the FSAR does describe a detailed FMEA for a SSC important to safety, and the change proposal introduces a new failure mode, then the change proposal would create a malfunction of a different type.

Certain accidents or malfunctions are not treated in the FSAR, because their effects are bounded by other related events, which are analyzed in the FSAR. For example, a postulated pipe break in a small line may not be evaluated in the FSAR, because it less limiting than an analyzed pipe break of a larger line in the same area. Therefore, if a proposed design change would introduce a small high energy line break into an area that already had a pipe break from a larger high energy line analyzed for energy release, pipe whip, etc., postulated breaks in the smaller line should not be considered an accident or malfunction of a different type.

The generator load rejection is a malfunction of equipment **<u>NOT</u>** important to safety. This event usually is the **most limiting** BWR AOO/transient (not an accident), and determines the operating CPR limit(s). If a change would create a new event equivalent to the generator load rejection (a malfunction of equipment not important to safety that results in a limiting transient) the 10/21/98 proposed criteria (c)(2)(vi) would not catch it. However, the suggested (Attachment 1) definition for a malfunction of a different type with answering the question "If the FSAR was being written today, would this accident or malfunction be included?" does cover this and all other possible scenarios.

Related Suggested Changes To The 10/21/98 Proposed Version of 50.59:

(a) The proposed accident definition in FR 56106 is too verbose and convoluted to be interpreted and applied consistently. A more "straight forward" definition is provided in Attachment 1, and the term "*Accident*" should be defined in the regulation. Accidents are addressed in Chapter 15 of a Reg Guide 1.70 FSAR, and have radiological doses for consequences. Doses should exceed 10 CFR 20 to be categorized as resulting from an accident.

This definition is needed to clarify the differences in the safety analyses. A major example is the ECCS-LOCA analysis vs. the LOCA Radiological analysis. The ECCS-LOCA analysis is **not** an *accident* analysis, but is performance evaluation to demonstrate that a plant's ECCS meets the ECCS performance acceptance criteria in 10 CFR 50.46. The ECCS-LOCA analysis results do not include radiological doses, and it is not documented in Chapter 15. LOCA Radiological analysis is an *accident* analysis, is documented in Chapter 15, and it does have radiological doses for results.

(b) As shown in Attachment 1, the phrase "*design basis accident of a different type*" should be defined in the regulation. For an event to be categorized as an *accident*, the event must have a calculated radiological dose for a consequence. For a new *accident* to be classified as a *design basis accident*, the *accident* must result in plant design change(s) with corresponding change(s) to the plant's 10 CFR 50.2 design bases. No industry or NRC guidance provides the distinct criteria needed to consistently and properly determine what constitutes an *accident of a different type*. These criteria and the qualifications for determining a *design basis accident* are provided in the suggested definitions provided in the attachment.

(c) Similarly to needing a definition for an *design basis accident of a different type*, the phase "*malfunction of a different type*" should be defined in the regulation, as shown in Attachment 1. Again, no industry or NRC guidance provides the distinct criteria needed to consistently and properly determine what constitutes a *malfunction of a different type*. These criteria are provided in the suggested definitions provided in the attachment. However, the lack of definition of the term "*important to safety*" still can lead to misinterpretations, as discussed below.

(d) Replace license amendment criteria (c)(2)(vi) with the version in Attachment 1.

2. Important To Safety

The NRC has yet to define what nonsafety-related items are *important to safety*. The definition of *important to safety* is an unresolved licensing issue that the NRC stated in Reference 2 that it will resolve by rulemaking, which has never happened. Any definition should provide a clear set of criteria, or the definition will never lead to a consistent interpretation of *important to safety*. Subsection 2.6.3 of Reference 1 provides an practical interpretation and some examples.

A practical interpretation of equipment *important to safety* can be derived from the abnormal event categories. The abnormal event categories are accidents, transients (AOOs) and special events (e.g., ATWS and Station Blackout). Equipment important to safety always includes safety-related equipment, as this equipment is used to prevent accidents or mitigate the consequences of accidents. Nonsafety-related equipment that should be considered as important to safety with respect to 10CFR 50.59 is that equipment:

- assumed or used to prevent or mitigate the special events described in a FSAR;
- assumed or used to mitigate the transients described in a FSAR;
- whose failure or malfunction could lead to an accident, or impair the ability of other equipment to perform a safety-related function; or
- requiring (for ensuring nuclear safety) elevated quality assurance or design requirements, but not to full safety-related standards.

The following are examples of nonsafety-related equipment (i.e., not required to perform a safety-related function) that are important to safety.

- The turbine bypass system does not perform any safety-related function, but is used to mitigate turbine and generator trip transient events.
- The end of cycle BWR recirculation pump trip (RPT) is not used to prevent or mitigate any accident, does not perform any safety-related function, is not used to mitigate any event (e.g.,

seismic) addressed in 10 CFR 100, App. A, and is only used to mitigate AOOs. However, most if not all BWRs classify and/or treat the RPT as safety-related.

- The Standby Liquid Control System (SLCS) does not perform any design basis or safety-related function. However, the SLCS is used to mitigate the (beyond design basis) special events of shutdown without control rods and anticipated transients without scram (ATWS). 10CFR 50 Appendix B quality assurance requirements are usually applied to the SLCS.

- A portion of a BWR main steamline outside containment is not safety-related, but its assumed failure initiates the main steamline break outside containment accident analyzed in a FSAR. As a result, this portion of the main steamline is some times designed to safety-related standards.

- If a nonsafety-related component (e.g., piping) is installed over a safety-related component, such that a seismic event could cause the nonsafety-related component to fail and damage the safety-related component, the nonsafety-related component and/or its supports will usually have to be seismically qualified.

Conversely, the following provides guidance on determining which equipment is not important to safety.

> If a system or component that was operating prior to the event (during planned operations) does not need to be operated or is to be employed in the same manner following the event, and if the system or component is not necessary to accomplish a required safety function, then the system or component should **not** be classified as important to safety.

Related Suggested Changes To The 10/21/98 Proposed Version of 50.59:

(a) The attached suggested changes provides two options. The most straight forward option is to simply replace the term *important to safety* with the term *safety-related*, as *safety-related* was synonymous with *important to safety* (consistent with 10 CFR 100) when 50.59 was updated in 1968, and *safety-related* is already defined in 10 CFR 50.2. The other option is to maintain the term *important to safety,* and to add its definition to the regulation, as shown in Attachment 1.

3. Facility and Procedures

The plant-specific input variables and calculated results from the analyses in the FSAR can help to describe a plant, plant function or plant response, but the actual analytical models are manual actions, are administratively controlled, are often offsite functions, and usually are generic. Procedures are always related to manual actions/operations that are administratively controlled. Therefore, the analytical models are procedural.

Example 1: The development, detailed modeling, qualification and use of ECCS-LOCA models are all administratively controlled by procedures. The water level, initial reactor pressure, ECCS response times, and ECCS flow rate capabilities are all plant-specific input variables used in the ECCS-LOCA analysis, and the calculated peak cladding temperatures are all plant-specific results.

Example 2: Switching a BWR RHR loop from coolant injection mode to suppression pool cooling mode is a manual action controlled by procedure, while high pressure ECCS injection on low water level is a fully automatic design feature which is not procedural.

Related Suggested Changes To The 10/21/98 Proposed Version of 50.59:

(a) As shown in Attachment 1, limit *facility* criteria (iii) to plant-specific input variables and results from the evaluations included in the FSAR.

(b) As shown in Attachment 1, the definition of *procedures* should include two criteria. The first criteria is the 10/21/98 proposed definition qualified to state that procedures are manual actions and/or administratively controlled. The second criteria adds analytical methods to the definition of a procedure.

4. Tests and Experiments

Both the current and 10/21/98 proposed 50.59 texts fail to recognize that all later plants have detailed test descriptions in their FSARs. Both texts would allow changes to the existing tests and experiments in the FSAR without a 50.59 evaluation. For completeness, making changes to tests and experiments in the FSAR should require a 50.59 evaluation.

(a) As shown in Attachment 1, add "make changes in the tests or experiments as described in the final safety analysis report (as updated)" to paragraph (c)(1).

5. Quantitative Minimal Increase In Consequences

To maintain the original NRC acceptance bases, the plants should be categorized as pre-SRP or post-SRP plants. The earlier plants (pre-SRP) were licensed without having their NRC reviews based on the SRPs, and thus, SRP acceptance criteria do not apply to these plants. The later plants (post-SRP) were licensed with having their NRC reviews based on the SRPs, and thus, SRP acceptance criteria do apply to these plants. For the pre-SRP plants, the graduated percentage table is FR 56105 should be acceptable as long as the limits are based on the full 10 CFR 100 guideline values. For the post-SRP plants, the SRP acceptance dose criteria (10%, 25% or 100% of the 10 CFR 100 guideline values) per accident type, used as the basis for their original NRC acceptance, should be used as threshold values for determining a minimal increase in consequences.

6. Licensed Acceptance Limit and Margin of Safety

As acceptance limit(s) can be used to determine margin of safety, acceptance limits will be addressed first, followed by a discussion on margin of safety.

Acceptance Limit:

There has been much discussion and confusion on the term "acceptance limit." The term, as written, can have a broad range of interpretations. As the term is to be used in licensing evaluations, the term should be "licensed acceptance limit" (LAL).

Based on Section 2.9 of Reference 1, a Licensed Acceptance Limits (LAL) is a plant-specific value, design/regulatory criterion, plant operating condition or range of parameters within which the plant is designed or operated, and which the NRC may or may not have specified (in its Bases to the Technical Specifications or Safety Evaluation Reports), it used as the basis for its acceptance of an item. If the NRC did not specify a value or criterion, the acceptance value or criterion specified or assumed in the FSAR, which was reviewed and approved by the NRC, becomes the LAL.

For example, if the NRC explicitly stated in their SER that a plant's response to a particular event was acceptable because the dose was less than the Standard Review Plant (SRP) guidelines (without further qualification), then the NRC implicitly accepted the SRP guideline as the LAL for the plant and the particular event. If the NRC cited some value other than the SRP guideline in its SER as its criteria for licensing the plant, then that value is considered the LAL. However, if the NRC did not specifically cite any acceptance criterion, then acceptance should be based on specific criteria in regulation.

Margin of Safety:

Of all the options in the 10/21/98 FR, the FR 56107 Option 1 definition of a reduction in margin of safety is the most accurate and practical. However, the phrase "without compensating change(s)" should be added to the end of the last sentence. A SSC may have a number of aspects that determine its overall performance. If the performance of Aspect X is nonconservatively changed, but the performance of Aspect Y is conservatively changed such that the overall performance of the SSC is not changed or is improved, then there is no reduction in margin of safety.

FR 56107 Option 2 is not acceptable. The "margin of safety" criterion should remain within 50.59, and be states as shown in the 10/21/98 proposed version of 50.59. The deletion of the use of margin of safety is non-conservative, while use of the term beyond the basis of a Technical Specification is not needed.

Deleting the term is non-conservative, because non-accident events involving malfunctions of equipment not important to safety may not be adequately covered by 50.59. For, example, the limiting transient for most BWRs is the generator load rejection. This event is a malfunction of equipment **not** important to safety, and does not result in a radiological consequence. Therefore, 50.59 criteria that address equipment important to safety, accidents and consequences do not cover all types of abnormal events. However, the BWR transient analyses form the bases for a number of Technical Specifications, and are properly covered by the criterion addressing a reduction of margin of safety in the basis for any Technical Specification.

Consistent with Commissioner Diaz's statements on the staff's proposed changes to 50.59, margin of safety issues beyond the bases of the Technical Specifications are already adequately covered by the other 50.59 criteria.

10/21/98 FR 56106&7 Option 3 discussion is useful but some of the characterizations are technically incorrect. The definition in Option 3(A)(1) is not consistent with the text of Option 3 with respect to radiological releases, addresses a subject not within the scope or 50.59, has technical errors, and thus, should be deleted. For example, peak cladding temperature (PCT) calculation results are not governed by 50.59. PCT results (including their reportability requirements to the NRC) are governed by 10 CFR 50.46. PCTs are not addressed in the Technical Specifications. The margin of safety related to PCT is based on the LOCA Radiological accident analysis and not the ECCS performance analysis. The radiation source terms used in the LOCA Radiological accident analysis are based in-part on a plant's ECCS performance meeting the 10 CFR 50.46 2200°F acceptance criterion. No credit in LOCA Radiological accident analysis is given for calculated PCTs less than the 10 CFR 50.46 2200°F acceptance criterion. Therefore, the PCT margin of safety in the LOCA accident analysis is based on not exceeding the 10 CFR 50.46 2200°F acceptance criterion, and thus, the difference between the calculated PCT and the 10 CFR 50.46 2200°F acceptance criterion is design margin and not margin of safety.

Similar to Option 3(A)(1), the definition of a reduction in margin of safety of a fission product barrier in Option 3(A)(2) is in error, and the Option 3(A)(3) clarification is in error. An example of an error applicable Option 3(A)(1) and Option 3(A)(2) is in their definitions relating to the calculated peak RCS pressure. The Technical Specification RCS pressure safety limit for the BWR has always been based on the calculated peak RCS pressure being less than the (1375 psig) ASME code limit. If either of these definitions are implemented by the NRC, the licensing basis for every BWR will be invalided.

The margin of safety always starts from the regulatory acceptance or design (code) limit. An actual calculated value demonstrates that the plant design will remain within an applicable acceptance limit. Therefore, the difference between the calculated value and its acceptance limit is, by definition, design margin. If this position is changed by the NRC, the concept and use of regulatory acceptance and design (code) limits become meaningless, and the NRC will be flooded with license amendment requests generated by the 50.59 process, relating to changes that do not affect basis of the NRC acceptance of plant designs. It is recommended that all for the 3(A) options be dropped.

The approaches and definitions provided in Option 3(B)(1), (2) & (3) would be best provided in a guidance document.

Section 2.10 of Reference 1, provides the following practical definition of margin of safety for 50.59 evaluations.

The "margin of safety" (in the basis for any Technical Specification) of an item is the difference between the assumed, analyzed or design basis failure point (as available) and the item's Licensed Acceptance Limit (if specified) or the FSAR acceptance criteria (if specified).

Detailed Guidance: (From Reference 1, and primarily based on References 3-5.)

There are eight primary sources of information that may be needed to determine the effects on the Tech Specs Margin of Safety. These sources are: (1) the licensing conditions documented in the plant's license; (2) the Tech Specs functional and instrumentation sections; (3) the Tech Specs Bases (contained in Tech Specs); the design code and/or regulatory allowable values, (5) the FSAR; (6) the Technical/Operational Requirements Manual, (7) the COLR, and (8) the NRC SERs for the plant. These sources of information will usually be adequate to answer the margin of safety question. The Tech Spec Bases, SERs and FSAR are the sources for the Licensed Acceptance Limits (LALs), which provide the bases for determining margin of safety. However, for some changes that may affect a transient or ECCS analysis based Tech Spec limit or requirement, the vendor who performed the analysis may have to be contacted.

If a change is to a safety-related component, then a determination for a change in margin of safety is required. If (1) the subject component(s) will remain (as applicable) within its regulatory acceptance criteria and/or design code(s) allowable(s), (2) the associated system(s) will function as assumed in the safety analyses, and (3) no Tech Spec basis is changed in a less conservative manner, then the change will not result in a reduction of safety.

If a change is to a nonsafety-related component, but whose failure could adversely affect a safety-related SSC or a function assumed in the basis of a Tech Spec, a FMEA and a determination for a change in margin of safety are required. If the component will remain (as applicable) within its regulatory acceptance criteria and/or design code(s) allowables, its associated system will function as assumed in the FSAR, a safety-related SSC will not be adversely affected (will function as assumed in the safety analyses), and no Tech Spec basis is changed, then the change will not result in a reduction of safety.

A Tech Spec's bases may or may not explicitly define the margin of safety. The bases may only be described qualitatively. If the margin of safety is not addressed in the Tech Spec's bases, then reviews of the FSAR, SERs, and any other applicable licensing or design basis documents should be performed. Because the margin of safety may not be explicitly addressed as a numerical value, a numerical determination of the margin of safety is not always required. It may be sufficient to determine only the direction of margin change (i.e., increasing or decreasing). The judgment of change in margin of safety should be based on physical parameters or conditions, which can be observed or calculated. Where a change in margin is so small or the uncertainties in determining whether a change in margin has occurred are such that it cannot be concluded reasonably that the margin actually has changed (i.e., there is no clear trend toward reducing the margin), the change need not be considered a reduction in margin.

If the margin of safety is based on a FSAR analysis, the difference in margin before and after the change can only be determined by using the same models to perform both analyses. For example, it is not valid to compare the results of an older, simpler and more conservative analysis to a new best-estimate analysis, even if both methods have NRC approval. An exception is if the NRC has specified/required that the newer model is to be used to replace the older model. However, if the post-change analysis results are within a NRC specified LAL, the change is not a reduction in margin of safety regardless of the final result.

When examining a FSAR safety analysis, it must be determined how the results can impact the Tech Specs. An analysis result may be within the LAL for the FSAR event, but invalidate the bases showing compliance with a Tech Spec surveillance.

7. 10 CFR 50.59 Applicability Determination Criteria

For any set of criteria to able to provide consistent and accurate results, the criteria must be able to be written in a straight forward "yes" or "no" question basis. NEI 97-06 (Reference 3) provides useful guidance, but does not supply specific applicability criteria. In Reference 5, the NRC provided the following general criteria:

1. Does the proposal change the facility or procedures from their description in the FSAR?

2. Does the proposal involve a test or experiment not described in the FSAR?

3. Could the proposal affect nuclear safety in a way not previously evaluated in the FSAR?

4. Is a change in the Technical Specifications involve?

The general contexts of the first three criteria have led to numerous interpretations. The statement "affect nuclear safety in a way not previously evaluated in the FSAR" is not defined, and thus, could lead to non-conservative misinterpretations. Plus, the criteria do not address when a change proposal may already be bounded by an existing valid and approved licensing evaluation, nor contain a "catch all" criterion for completeness.

Based Appendix 4A of Reference 1 and the new definitions provided in the proposed 50.59, I suggest the use of the following more detailed applicability review criteria.

Does the procedure/analysis change, design change, modification, discovered condition, test or experiment, to which this review is applicable, represent:

1. Yes___ No___ A change to the facility (plant) from its description in the FSAR (as updated)?

2. Yes___ No___ A change to equipment/plant operations or a procedure from its description in the FSAR (as updated)?
(e.g., manual/administratively controlled action/process/function, or analysis model)

3. Yes___ No___ A change to a test or experiment as described in the FSAR (as updated)?

4. Yes___ No___ A change to a structure, system or component (SSC) not described in the FSAR (as updated), but whose operation or failure could affect a SSC, a function or an equipment/system operation (implicitly or explicitly) described or assumed in the FSAR (as updated)?

5. Yes___ No___ A new SSC, procedure, process, test or experiment, which could impact the safety of operations or affect nuclear safety in a way not previously evaluated in the FSAR (as updated)?*

6. Yes___ No___ A change to the existing situation, but is not covered by Questions 1 - 5, which could impact the safety of operations or affect nuclear safety in a way not previously evaluated in the FSAR (as updated)?*

7. Yes___ No___ A change that is already bounded by a valid and approved licensing evaluation?

8. Yes___ No___ A change to the Technical Specifications?

* Could (1) affect a safety-related function, (2) result in a new plant (primary/secondary loop) operating condition, (3) introduce a new failure mode/scenario potentially adverse to nuclear safety, (4) result in a new radioactive material release, or (5) increase the amount of a radioactive material release or release rate.

I hope the above information proves useful to you. If you have any questions, please call me.

Best Regards

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Suggested Changes To 10/21/98 Proposed 10CFR 50.59

§ 50.59 Changes, tests and experiments

(a) Definitions for the purposes of this section:

(1) *Accident* means a design basis (abnormal) event that is not expected to occur during the life of a plant, and results in an offsite radiological consequence greater than § 20 limits (>0.5 rem whole body dose or 1.5 rem thyroid dose).

(2) *Change* means a modification, addition, or removal.

(3) *Design basis accident of a different type* means an accident that results in a new fission product release path, results in a new fission product barrier failure mode, or creates a new sequence of events that results in significant fuel cladding failures, <u>and</u> requires a change to the plant's design with a corresponding change to the plant's § 50.2 design bases.

(4) *Facility as described in the final safety analysis report (as updated)* means:

(i) The systems, structures, and components that are described in the final safety analysis report (as updated),

(ii) The design, performance requirements and methods of operation for such systems, structures and components required to be included or described in the final safety analysis report (as updated), and

(iii) The **plant-specific input variables and results from the** evaluations included in the FSAR (as updated) for such SSC and which demonstrate that their intended function(s) will be accomplished.

(5) *Final safety analysis report (as updated)* means the Final Safety Analysis Report (or Final Hazards Summary Report) submitted in accordance with § 50.34, as amended and supplemented, and as modified as a result of changes made pursuant to § 50.59 and § 50.90, and, as applicable, § 50.71 (e) and (f).

(6) *Malfunction of a different type* means a new design basis event that allows for a new failure mode with a different result on <u>an item important to safety</u> or <u>a safety-related item</u> [see important to safety vs. safety-related discussion], **creates the possibility of a new limiting AOO (transient), or creates a new sequence of events that can result in a radiological release (via a normal release pathway) above a current operating, § 50 App. I or § 20 limit.**

Suggested Changes To 10/21/98 Proposed 10CFR 50.59

(7) *Procedures as described in the final safety analysis report (as updated)* means:

(i) information in the final safety analysis report (as updated) regarding how structures, systems, and components are **manually** operated and/or administratively controlled (including assumed operator actions and response times) and information describing the conduct of operations, **and**

(ii) The analytical methods of the evaluations required to be included in the FSAR (as updated) for such SSC and which demonstrate that their intended function(s) will be accomplished.

(8) *Reduction in margin of safety associated with any Technical Specification* means that the input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the final safety analysis report (as updated), that established any Technical Specification requirement, are altered in a nonconservative manner, **without compensating changes that maintain the validity of the subject Technical Specification Safety Limit or Limiting Condition for Operation.**

(9) *Tests or experiments not described in the final safety analysis report (as updated)* means any condition where the reactor or any of its systems, structures or components are utilized or controlled in a manner which is either:

(i) Outside the controlling parameters of the design bases as described in the final safety analysis report (as updated); or

(ii) Inconsistent with the analyses in the final safety analysis report (as updated).

Optional new definition

(?) Equipment important to safety means:

(i) Safety-related SSC as defined in § 50.2;

(ii) Equipment assumed or used to prevent or mitigate the special events (e.g., ATWS) described in a FSAR (as updated);

(iii) Equipment assumed or used to mitigate the anticipated operational occurrences (AOOs) described in a FSAR (as updated);

(iv) **Equipment whose failure or malfunction could lead to an accident, or impair the ability of other equipment to perform a safety-related function; or**

(v) **Equipment requiring (for ensuring nuclear safety) elevated quality assurance or design requirements, but not to full safety-related standards.**

(b) Applicability. The provisions of this section apply to each holder of a license authorizing operation of a production or utilization facility, including the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required under § 50.82(a)(1) or a reactor licensee whose license has been permanently modified to allow possession but not operation of the facility.

(c) (1) A licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), **make changes in the tests or experiments as described in the final safety analysis report (as updated),** and conduct tests or experiments not described in the final safety analysis report (as updated) without obtaining a license amendment pursuant to § 50.90 only if:

(i) A change to the technical specifications incorporated in the license is not required, and

(ii) The change, test or experiment does not meet any of the criteria in paragraph (c)(2) of this section. The provisions in this section do not apply to changes in procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(2) A licensee shall obtain an amendment to the license pursuant to § 50.90 prior to implementing a change, test or experiment if it would:

(i) Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to § 50.90 after the last final safety analysis report was updated pursuant to § 50.71 of this part;

[Note: Regardless of the NRC's current position, an examination of 10 CFR 100, App. A Sections I and III.(c) clearly demonstrates that structures, systems and components

(SSC) considered important to safety are those SSC necessary to assure the safety-related functions. Thus in the past, important to safety and safety-related were considered to be synonymous. Safety-related is defined in regulation, while important to safety is not defined in regulation. Therefore, to avoid future misinterpretation, either important to safety should be fully defined (as provided above) and 10CFR 100, App. A be clarified, or the term safety-related should be substituted for important to safety as shown below.]

(ii) Result in more than a minimal increase in the probability of occurrence of a malfunction of **safety-related** equipment previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to § 50.90 after the last final safety analysis report was updated pursuant to § 50.71 of this part;

(iii) Result in more than a minimal increase in the **(radiological)** consequences of an accident previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to § 50.90 after the last final safety analysis report was updated pursuant to § 50.71 of this part;

(iv) Result in more than a minimal increase in the **(radiological)** consequences of a malfunction of **safety-related** equipment previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to § 50.90 after the last final safety analysis report was updated pursuant to § 50.71 of this part;

(v) Create a possibility for a design basis accident of a different type than any previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to § 50.90 with respect to design basis accidents after the last final safety analysis report was updated pursuant to § 50.71 of this part;

(vi) Create a possibility for a malfunction of **safety-related** equipment with a different result than any previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to § 50.90 after the last final safety analysis report was updated pursuant to § 50.71 of this part;

or

(vi) **Create a possibility for a new malfunction of a different type and with a different result, that should be added to final safety analysis report;**

(vii) Result in a reduction in the margin of safety associated with any Technical Specification.

(d) (1) The licensee shall maintain records of changes in the facility and of changes in procedures made pursuant to this section, to the extent that these changes constitute changes in the facility as described in the final safety analysis report (as updated) or to the extent that they constitute changes in procedures as described in the final safety analysis report (as updated). The licensee shall also maintain records of tests and experiments carried out pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test or experiment does not require a license amendment pursuant to paragraph (c)(2) of this section.

(2) The licensee shall submit, as specified in § 50.4, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. The report may be submitted annually or along with the FSAR updates as specified by § 50.71(e), or at such shorter intervals as may be specified in the license.

(3) The records of changes in the facility must be maintained until the termination of a license issued pursuant to this part or the termination of a license issued pursuant to 10 CFR part 54, whichever is later. Records of changes in procedures and records of tests and experiments must be maintained for a period of five years.

DOCKET NUMBER PROPOSED RULE PR 50, 52 + 72
(63FR56098)

DOCKETED USNRC

(2)

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3 November, 1998

'98 NOV -9 P2:30

U.S. Nuclear Regulatory Commission
Attn: Rulemakings and Adjudications Staff
Washington, D.C. 20555-0001

RE: 10CFR50.59 Revisions Published 21 Oct. 1998, 63FR56098

Gentlefolk:

Although the proposed changes to 10CFR were constructed with best intentions, these objectives could be better accomplished through regulatory guidance. Despite increased wording, there is not a substantive change in intent of the regulation. When detached from the comment section, the proposed regulation offers little more than the existing wording. Unfortunately, the proposed complex regulatory framework eliminates the simple concept of an "Unreviewed Safety Question," which forms a cornerstone of safety consciousness. This serves to destroy the inculcation of safety culture at the operational level, where it is needed the most. I applaud the NRC for their dedication in clarifying regulations; however, the added complexity leads only to legalistic arguments. If it takes a lawyer to tell a nuclear engineer that a nuclear device is safe, then we should let them design and run our plants. Common sense is an integral part of safety, and therefore it should be the basis of regulatory change.

The first objection to the proposed wording concerns the concept of minimal increase. The word "minimal" is itself an arbitrary expression. The previous wording allowed for no increase, and was extremely clear. In fact, licensees may use this concept justify nearly any change to be minimal as long as they stay within ultimate safety limits. In trying to define "minimal increase," the NRC uses an oversimplified depiction of safety analysis. Safety limits rarely consist of a single parameter. Instead of simple linear relationships, these limits form a complex multi-dimensional envelope. Limited safety system settings and limiting conditions for operation lie within this envelope, with the boundary representing the safety margin. Projection of an operation change onto a single parameter neglects other impacts, which may dominate the response. Therefore, what is perceived as a minimal change may have a significant effect on overall safety. Contrary to the published opinion, NRC review of such changes is inescapable.

The second objection concerns the differentiation between accident probability and the failure rate of safety-related equipment. This distinction is unnecessary, since it is generally understood that safety-related equipment is directly related to prevention of, mitigation of, or recovery from accidents. Therefore safety-related equipment is necessarily included in the analysis of design basis accidents, and already explicitly covered by the existing wording. Further clarification of this subject seems unnecessary.

It is clear that a principal objective is to achieve a continuing process of safety review. On a plant scale, this can be accomplished by maintaining current safety analysis reports.

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Acknowledged by card NOV 30 1998

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However in daily operations, there should exist a simple metric by which individuals can make decisions, especially the realization of which decisions should be submitted to oversight committees or the NRC for review. For many years, the concept of an unreviewed safety question has served this role. The entire nuclear industry from engineers to reactor operators knows and understands this simple definition. It is a simple concept to be kept in mind and to be used everyday when approached by a new problem. In this sense, it is part of our safety culture. By expanding this concept in a complex framework, decision making is relegated to those involved in regulatory compliance. However, regulatory compliance only provides an indicator of safety. For safety to become an integral part of operations, every decision-making individual must have a general understanding of the concepts involved. Therefore, the definition of an unreviewed safety question is a tenet of safety consciousness.

If the goal of these changes is to increase awareness of safety analysis and to promote the upkeep of final safety analysis reports, then the added complexity can only make this a more arduous process. Arduous processes breed complacency, which is counterproductive to safety. Perhaps regulation should follow the "KISS" principle in engineering, namely "Keep It Simple Stupid!" Nuclear engineers took many years to realize that simple designs have fewer failure modes, unfortunately regulators seem to be taking the reverse perspective.

Personally, I feel that the biggest problem with facility changes concerns the adversarial role that industry takes with the NRC. Although we stress teamwork within our respective organizations, we fail to work as a team between regulator and licensee. At my facility, I have taken a different approach. I feel very comfortable calling the NRC to discuss everything from daily problems to facility modifications. The NRC staff has a wealth of experience that many licensees fail to utilize. However, the system must work both ways. As a simple example, I keep a separate file of all safety evaluations that I provide to the NRC during inspections. Consequently, inspectors rarely have to inquire for additional information and can spend more time on discussing ways to improve operations.

Sincerely,

Brendan C. Ryan

Brendan C. Ryan, Manager
KSU Nuclear Reactor Facility

DOCKETED
USNRC

DOCKET NUMBER
PROPOSED RULE PR 50, 52 & 72
(63 FR 56098)

'98 NOV -9 P3:25

(1)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

3 November 1998

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTN: Rulemakings and Adjudications Staff.

Enclosed are comments being submitted on the Notice of Proposed Rulemaking affecting 10 CFR Parts 50, 52 and 72 published in the Federal Register on 21 October 1998, and based in large part on the previously published memo SECY-98-171. I am submitting these comments as a private individual who is employed in the nuclear industry. These comments reflect my personal opinions and do not necessarily reflect the opinion of my employer or other nuclear industry organizations.

Paul Sicard

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Comments on SECY-98-171:

Comments being provided on the NOPR are being grouped as general comments and as related to specific topics, including the various topics under Section II, "Proposed Rule Topics and Issues."

General Comments:

1. Revision of the 10CFR50.59 rule is not required. The 50.59 rule has been in effect and being applied by utilities for over 30 years. Improvements have continued to be made by utilities in the 50.59 process, including in 50.59 related training. NSAC-125 has been a valuable tool for utilities in developing their 50.59 processes and in providing practical assistance in the performance of utility 50.59 reviews. With the NEI initiative to ensure that all sites adopt the guidance of NEI 96-07 (which was based on NSAC-125), the industry had further enhanced a stable and consistent utility approach to 50.59. The concerns raised out of issues at Millstone and Maine Yankee were associated more with failure to perform required 50.59 reviews, not with the failure of the 50.59 evaluation and review process.

   There has been an immense level of effort expended by both the NRC and the utilities in the last two years on attempting to achieve agreement on the implementation of the 50.59 rule. This effort is not warranted based on the lack of safety or risk significance associated with the issues upon which agreement has not been achieved. As stated in Chairman Jackson's comments on the proposed rulemaking in the October 21, 1998, Federal Register notice regarding margin of safety: "I am concerned that the result may be the addition of yet another layer of regulatory process rather than the elimination of any unnecessary layers." This concern also applies to other proposed changes in the rule which depart from the currently established industry guidance. Further, some opportunities for improvements in nuclear safety have possibly been delayed due to the diversion of both NRC and utility effort in the effort to refine the 50.59 rule and regulatory guidance.

   In her November 30, 1995, memo to the EDO and the General Counsel, Chairman Jackson noted that her 50.59 concerns were on ensuring that facility changes undergo 50.59 review and on ensuring that there is a consistent interpretation of the 50.59 process. The latter issue has been addressed by NEI through the mandatory industry initiative to adopt the NEI 96-07 guidance. The former issue relates to entry into the 50.59 process (i.e., the same as the issues at Millstone and Maine Yankee), and thus does not take issue with the NEI 96-07 or previous NSAC-125 guidance how to perform 50.59 reviews.

   Even though never endorsed by the NRC, NSAC-125 guidance was generally found acceptable for industry use by the NRC and Regional inspection acceptability was often based on NSAC-125. If the NRC would have found substantial fault with NSAC-125 the NRC would have developed their own guidance earlier. With 10CFR50.59, it provides a process that, when followed, works. As stated in the Dec. 16, 1995, memo from the EDO to Chairman Jackson, "the staff concludes that there is currently no indication that implementation of 10CFR50.59, as it is carried out today, has led to decreased safety, based on its inspection experience. ...the current process as it is being implemented provides reasonable assurance that plant safety has not been decreased."

As discussed in SECY-97-035, the NRC staff "has identified implementation concerns with only a small subset of the total situations that licensees evaluate under 10CFR50.59." Also, "while the NRC and industry do not fully agree on all issues associated with NSAC-125, based on inspections and reviews since its issuance, the NRC staff has seen an overall improvement in the conduct of 10CFR50.59 safety evaluations. Moreover, the guidance in NSAC-125 go beyond what is required by 10CFR50.59 in certain respects." Also, in a June 25, 1993, letter to NEI, NRC stated that "industry use of NSAC-125 has been one of the significant contributors to [the] improved quality [of 50.59 reviews]. However, because some of the guidelines in NSAC-125 go beyond the requirements of 10CFR50.59, we do not believe the guidelines are appropriate for endorsement as regulatory guidance.

Further, legal analysis produced by Winston & Strawn in July 1997 on behalf of NEI demonstrates that the guidance of NEI 96-07 (and NSAC-125 before it) complies fully with the legal requirements of 50.59.

Therefore, the optimal course of action is to not pursue the proposed rulemaking. Instead, the NRC should instead endorse NEI 96-07, which has been endorsed by the industry despite going beyond the requirements of 50.59, as an appropriate guidance document for the 50.59 process. Alternatively, NRC should propose rule changes which make the rule consistent with the existing guidance of NEI 96-07.

2. Much of the NRC approach in the rulemaking is to establish controls to ensure the NRC remains aware of changes in operating and design margins which are within established acceptance limits. This is true for both "margin of safety" and for consequences.

   It would seem that the primary NRC interest would be satisfied, with minimal increase in regulatory burden upon utilities, to change the focus of the proposed regulation. Instead of requiring licensees to obtain NRC approval through the license amendment process for non-risk and non-safety significant changes to margins within established acceptance limits, the NRC could consider revising 50.59 to accept the NEI 96-07 guidance as the basis for determining acceptability under the 50.59 evaluation criteria but to increase reporting requirements. 10CFR50.46 would be an appropriate model for such a process. Clear acceptance criteria, from the SRP or SER, would exist to determine if 50.59 evaluation criteria are met. A change in margin, within acceptance limits, of a certain amount would trigger the need to notify the NRC, similar to the 50.46 provision that the NRC be notified of a cumulative change in PCT of 50°F.

   This approach would provide the regulatory stability desired by both NRC and licensees. Because the NRC would be notified of changes in design margins, NRC would have the information it needs to determine where plants may be approaching the acceptance limits and therefore where NRC may choose to focus inspection resources to ensure nuclear safety and regulatory compliance are indeed maintained.

3. As part of issuing any revision to 10CFR50.59, the NRC should define a period over which utilities are to revise their 50.59 processes to implement changes to the 50.59 rule (as well as implementing any changes required in the industry guidance of NEI 96-07).

4. It is clear that much of the difficulty involved in 50.59 is in the detailed application of the regulatory philosophy to specific cases. NRC and NEI should work together on defining examples, including those from actual precedents at plants, that do and do not meet the 50.59 Evaluation criteria which will result from any rulemaking. This would greatly enhance regulatory stability and reduce burden by making the expectations for 50.59 Evaluation criteria clear.

II.A: Rule Organization:

1. In section 1.1.b, the NRC proposes to require that a licensee must apply for and obtain a license amendment, pursuant to Section 50.90, before implementing changes which do not meet the requirements of 50.59. This appears to be an overly restrictive process to apply in combination with the increasing restrictions being proposed by the NRC for the 50.59 process. A more streamlined process should be provided than license amendments for changes which do not meet the 50.59 criteria but which would not otherwise require NRC approval.

   Also, the proposed process to require an Operating License change under 50.90 for all changes that do not meet the 50.59 Evaluation criteria would unnecessarily clutter the plant Operating License with some information that could be relatively trivial. The Operating License should be a high level document vice a means of capturing low-level detail that should instead be handled through a licensee's commitment management system or through incorporation into the SAR. This argues for the creation of a streamlined NRC review and approval process for changes which do not meet the 50.59 Evaluation criteria, similar to that invoked under 10CFR50.46, where NRC approval is not required for every change in the LOCA analysis results of a utility.

2. It clearly is an improvement to move away from the term "Unreviewed Safety Question."

II.B: Change to the Facility as Described in the SAR:

1. It should be clearly stated and understood that a change to a "analysis method or parameter" is a change to the facility only if that "analysis method or parameter" is described, explicitly or implicitly, in the SAR.

   Consider a containment pressurization analysis which conservatively assumed a 2 psig initial containment pressure, where Technical Specifications allow only a 0.5 psig initial pressure (including accounting for instrument uncertainty, etc...). It would be clearly acceptable for a utility to relax this overconservatism from 2 psig to a 1.0 psig assumption under 50.59 without requiring a submittal to the NRC.

2. Relating to the discussions under topic III.V, "Compensating Effects," in Attachment I of SECY-97-171, the NRC should, for the sake of regulatory stability, define specific examples of changes for which it is appropriate or inappropriate to consider as integrated changes, i.e., for linking elements of the proposed change.

3. As discussed at the 19 October 1998 NEI Licensing Issues Workshop, NRC should provide specific examples of cases where activities normally viewed as maintenance (and thus outside the scope of 50.59) do involve a change to the plant (or to plant procedures) as described in the SAR.

4. The NRC should provide detailed guidance, or endorse detailed industry guidance, on the treatment of nominal values contained in the SAR under 50.59. If the SAR mentions a nominal value, there is inherently some control band associated with that value. For example, if the SAR specifies that a turbine oil pressure is maintained at 8 psig, would a procedure change to specify that the oil is to be maintained at 8 +/- 2 psig be considered a change to the plant as described in the SAR? Would it be considered a change to the plant as described in the SAR (thus requiring a 50.59 evaluation) if the control band in plant procedures were to be set at "8 to 10 psig" such that an argument could be made that 8 psig is no longer a nominal value.

5. NRC should endorse the treatment of information "incorporated by reference" in the SAR which is contained in NEI 98-03.

6. Much information incorporated by reference in the SAR consists of fuel vendor topical reports or standardized analyses, such as the GE GESTAR document for BWR's (and similar documents for other reload vendors). Documents such as GESTAR are under fuel vendor control, vice direct utility control. Since much information in such documents is referred to in licensee SAR's to provide methodology information required in the SAR (e.g., for Sections 4 or 15, amongst others), it would be beneficial to both utilities and to the NRC if the 50.59 process could be expanded (or a parallel process developed) via which the reload vendors could make changes to their high level documentation to determine whether or not such changes require NRC review or can be instituted without requiring NRC approval.

7. If a change is made in direct response to issues raised in generic communications from the NRC, such as Information Notices or Generic Letters, should this be a change that requires a 50.59 evaluation? Some within the NRC have wondered if such changes, provided acceptance limits from the SRP are not exceeded, cannot be construed as having been previously approved by the NRC because they are in response to NRC regulatory correspondence.

II.C: Change to Procedures as described in the SAR:

1. The proposed definition of procedures is welcome and will reduce utility burden by not requiring 50.59 reviews of support procedures.

II.D Tests and Experiments not described in the SAR:

1. The proposed definition is acceptable.

II.E: Safety Analysis Report (scope of 50.59):

1. It is understood that the proposed scope of 50.59 is not being changed, and it is agreed that this is reasonable for the purposes of short-term 50.59 rulemaking. NEI efforts to change the scope from the SAR to "safety analyses" are a concern as this could allow reduction of some of the

defense-in-depth requirements described in the SAR and in Technical Specification bases. Reliance solely on analytical bases is not a robust or resilient approach. Rather, the most beneficial tactic would be for the NRC to carefully decide which sections of the SAR are indeed properly subject to 50.59 and which sections are outside the bounds of 50.59 (i.e., such SAR changes would clearly not be changes to the plant or to plant procedures as described in the SAR).

II.F: Probability of Occurrence or Consequences of an Accident or Malfunction of Equipment Important to Safety Previously Evaluated in the SAR ("Minimal Increase")

Probability:

1. For Probability, the proposed rule change to allow a minimal increase standard is reasonable and corresponds to previously existing NSAC-125 and NEI 96-07 guidance.

2. Many questions are raised concerning use of risk insights within the 50.59 framework. Consider the replacement of a valve with a valve of a different design. Postulate that the failure probabilities of both valves are well known, including the variability in the failure rates. Consider that the failure rates for the two valves, including a 95% confidence (2σ) bound on the variability of the failure rates:

Existing Valve:	0.2% +/- 0.01% per year
Replacement Valve:	0.15% +/- 0.10% per year

Given these failure rates, should it be a USQ (or require a submittal to NRC on failing to meet 50.59 Evaluation Criteria) to replace a valve with an average failure rate of 0.2% with one with a lower average failure rate of 0.15%, even though the maximum 2σ failure rate increases from 0.21% to 0.25%? Should it be a USQ to replace the Replacement valve with the Existing valve design? Chairman Jackson refers to the regulatory guidance on PRA and risk-informed regulations of Regulatory Guide 1.174 in her comments on the proposed revisions to 50.59. However, RG 1.174 does not contain sufficient specifics for addressing questions of the type posed above. This is the type of question for which the NRC needs to provide additional guidance for determining, using risk insights, if there is an increase in probability of undesired outcomes.

3. NRC should provide guidance on if a change in probability class for an event analyzed in the SAR constitutes merely an increase in probability or if the change in probability class (generally with associated changes in acceptance criteria) constitutes a new accident not previously analyzed in the SAR.

Consequences:

1. For consequences, the NRC should endorse the existing guidance of NEI-96-07 (and consistent with its predecessor document NSAC-125) which sets the limit as the value accepted by the NRC in the SER, which are generally tied to the acceptance limits in the NRC Standard Review Plan (SRP), NUREG-0800.

The NRC's interest in regulatory stability is best served by having clearly established acceptance limits for the consequences of the various analyses which are presented in a licensee's SAR, where these acceptance limits can be the NUREG-0800 Standard Review Plan (SRP) acceptance limits or any plant-specific acceptance limits used by the NRC and documented in the NRC Safety Evaluation Report (SER) for the specific plant. Clearly, the NEI 96-07 position, as NRC states in section II.G, would ensure that the probability and consequences associated with any plant changes remain substantially less than a "significant increase," as referred to in 10CFR50.92.

There are many reasons, including the regulatory stability provided by having clear and established limits as discussed above, and precedents from NRC correspondence that demonstrate why it is more preferable to determine increases in consequences based upon the SRP and/or SER acceptance limits instead of the values documented in the SAR:

* The NRC attempt to tie 'increase in consequences' to the values reported in the SAR rather than to the acceptance limits quoted in the SER (usually from the SRP) will clearly penalize those plants which maintain a greater level of detail in the SAR, and would be counterproductive to NRC's interest in SAR integrity. Plants who have provided accurate and detailed information in their SAR would be penalized under the draft guidance, as any use of the design margin between what is reported in the SAR and the SRP/SER acceptance limits would result in failing 50.59 Evaluation Criteria. For example, one plant may have reported consequences in a less specific manner than others, reporting that the consequences of a certain accident (e.g., Reactor Coolant Pump Shaft Seizure) is less than a small fraction of 10CFR100 limits (e.g., 30 Rem thyroid). In contrast, a plant which maintained a higher level of fidelity and accuracy in its SAR would have placed actual numerical results for the event in its SAR. Thus, if there was a change which resulted in a slight change in the calculated dose for this event, the plant which put more effort into maintaining the accuracy of its SAR would have to make a submittal to the NRC, whereas the plant with less detail and/or completeness in its SAR would be able to make the change without NRC approval. Thus, paradoxically, the NRC approach on 'increase in consequences' would penalize those plants which attempt to maintain a greater level of detail and fidelity to the actual plant in their SAR's. Thus, the NRC statements in Attachment I to SECY-98-171 that there is no 'penalty' for plants that do a better job of maintaining their SAR is simply wrong.

* NRC has clearly indicated its intentions to make 50.59 a risk-informed rule. It would be extremely consistent with the intent of capturing risk insights in the 50.59 process to clearly have the acceptance limits for consequences to be the SRP acceptance limit instead of plant specific values for dose consequences documented in the SAR of each individual licensee. From a risk perspective, the difference associated with the doses reported in the SAR and the presumably higher SRP acceptance criteria are practically non-existing. It is inconsistent for the NRC to be moving in the long-term toward a risk-informed 50.59 rule but failing in the short-term to accommodate this very obvious risk insight, with the resulting increase in burden upon licensees.

It would be reasonable for the NRC to require licensees to notify NRC of more than "minimal" increases in consequences, similar to the notification requirements of 10CFR50.46 for LOCA acceptance criteria, and to expect that licensees would revise their SAR to reflect such changes. 50.46 works because there is a clear and established regulatory limit (2200F for Peak

Clad Temperature); the clear analogy is the use of SER and/or SRP NUREG-0800 acceptance limits (generally related to 10CFR100 siting limits) as a clear and distinct acceptance limit for the consequences of accidents. A failure by the NRC to establish clear and distinct acceptance limits will lead to inconsistencies and instability in the regulatory structure and, through distraction of licensee and regulatory engineering resources, prevent those resources from being applied in areas of true safety and/or risk significance. It would add regulatory burden without any safety benefit to the public to require submittal of such changes for NRC approval.

* NRC is improperly treating use of design margin as an increase in Consequences in the NOPR. Any increase in consequences must be with respect to NRC imposed acceptance limits, specifically those in the Standard Review Plan or in a plant SER. As written, there is ambiguity in this phrase as to the exact nature of the qualifier "previously evaluated in the SAR." Past industry and regulatory practice and precedent has clearly established that the term does not refer to an increase in the values documented in the SAR. For example, the May 10, 1989, letter from NRC (C.E.Rossi) to NUMARC (T.E.Tipton) clearly ties an increase in consequences to an increase in dose to above the acceptance limit, vice to the value reported in the SAR. While utilities have taken the restrictive approach of NSAC-125 and NEI 96-07 that this acceptance limit is that discussed in the SER, the NRC has taken the approach that this is the SRP acceptance limit.

Specifically, focusing on consequences solely, the rule asks, for an accident or malfunction of equipment important to safety previously evaluated in the SAR, if there is an increase in consequences. The rule does not establish the SAR as the baseline for such an increase. This is clearly demonstrated in the NRC SER's for numerous plants, which have stated the results submitted by licensees are acceptable because they are less than 10CFR100 limits, or less than some specific limit calculated by the NRC for the specific plant and event. The NRC promulgation of acceptance criteria in accident analyses different from the values submitted by licensees in the SAR is *de facto* acceptance that the SAR is not the baseline upon which to judge if changes to dose consequences are acceptable.

* The NOPR approach inherently accepts the SRP as a true acceptance limit. By allowing "minimal" increases over the values documented in the SAR, NRC is in effect setting the SRP acceptance limits as the true acceptance criteria for consequences. While utilities would be unlikely to use this approach, it does allow in theory for a licensee to have multiple "minimal increases" in dose consequences as documented in the SAR which would gradually approach the SRP acceptance limits. This is in many ways a more burdensome approach that applies ultimate acceptance criteria on consequences which are exceed those allowed by the industry guidance of NEI-96-07. The industry guidance clearly recognizes limits established by the NRC review process, which are documented in NRC SER's. The proposed NRC revision would inherently set the SRP as the acceptance limit, without addressing if the SER set a more conservative and/or restrictive limit.

Thus, in many ways, this proposed NRC approach provides for a theoretical agreement with the basis for the existing industry guidance of NEI-96-07 (and NSAC-125 before it), except that the industry guidance would establish potentially more conservative (lower) limits on consequences by also considering the basis of acceptance as documented in the NRC SER's.

Thus, the proposed NRC approach in defining "minimal increases" in consequences is inherently in conflict with the NRC position that consequences are as defined in plant SAR's instead of as established through clear NRC acceptance limits in the SRP or in NRC plant-specific SER's.

* Note that NRC, in topic III.S of Attachment 1 to SECY-98-171, indicated that the acceptance limit for margin of safety can be extracted from the NRC SER vice being limited to values contained in a plant's SAR. It is inconsistent for the SER to be an acceptable location for defining margin of safety while the NRC contends that the acceptance limit for consequences are not those outlined in the plant-specific SER's.

* In discussing the 50.59 evaluation process, the NRC notes that "the intent of the 50.59 process is to permit licensees to make changes to the facility, provided the changes maintain the level of safety documented in the original licensing basis, such as in the safety analysis report." Since the NRC documents its review of the original licensing basis, including the regulatory acceptability of that basis, in its Safety Evaluation Reports (SER's), the SER is thus clearly an important source for defining the level of safety of the original licensing basis.

Thus, the NRC should endorse the approach of NEI 96-07 on defining what constitutes an Increase in Consequences.

2. In footnote 6 related to the NRC response to the NEI 96-07 position on Consequences, the NRC states that attempting to use values from the staff's SER as acceptance limits would be difficult since SER's were not written for the purpose of establishing such limits. However, it is clear that the SER's were written to document the basis for the NRC evaluation, such that the use of SER values as limits is a conservative approach. NRC reviewers still continue their practice of using the SER's to provide practical acceptance limits related to utility submittals. Further, industry experience over the approximately 10 years since NSAC-125 came into broad use indicates that use of the SER as acceptance limits is workable and is not difficult. Thus, the NRC contentions concerning use of the SER are not correct.

3. As the NRC states under Topic IV.B in SECY-98-171 ("USQ Threshold"), one option for rulemaking would be that no "USQ" (or submittal to NRC) would exist if the change remains within the acceptance guidelines specified by the NRC staff.

   To enforce use of a specific limits, each licensee can submit a proposed commitment to NRC to establish plant specific acceptance limits on dose consequences based upon NUREG-0800 SRP limits and considering the NRC discussion in the plant specific SER related to the acceptance logic for the utility analysis.

   For example, consider a plant that submitted a LOCA dose analysis with a 290 Rem EAB thyroid dose for its original SAR. The NRC SER accepted the utility analysis on the basis of imposing a change in an input criteria (e.g., containment unfiltered bypass leak rate), such that the resulting dose was accepted by the NRC on the basis of being "well within" the NUREG-0800 acceptance criteria (i.e., 300 Rem thyroid per 10CFR100 for LOCA); the NRC calculated a dose of 260 Rem with their mandated change in input criteria, whereas the utility analysis with the same change in inputs would result in a calculated dose of 255 Rem thyroid. In this case, the utility would submit a commitment to maintain a dose acceptance limit of 255 Rem and to provide this information within its SAR.

While this approach would not be as simple as direct use of the NRC SRP and/or SER acceptance criteria as the measure of increases in consequences, this approach would have the advantage to the NRC of documenting the acceptance limit for consequences in the SAR. This would also address the issues raised by NRC lawyers concerning the role of the SER in determining acceptance criteria, in that the NRC lawyers could then view the acceptance criteria as being the committed value which is being added to the SAR. The objective of regulatory stability would be achieved by having a clear established acceptance limit, which would be established consistent with the established industry approach of using the SRP and/or SER as the conceptual limits; this concept has been part of a clearly successful industry approach to 50.59 since NSAC-125 was adopted in the late 1980's.

4. Generally, the proposed regulations are inconsistent with the established regulatory oversight process involved in 10CFR50.46. 50.46 works because there is a clear and established regulatory limit (2200F for Peak Clad Temperature); the clear analogy is the use of SER and/or SRP NUREG-0800 acceptance limits (generally related to 10CFR100 siting limits) as a clear and distinct acceptance limit for the consequences of accidents. A failure by the NRC to establish clear and distinct acceptance limits will lead to inconsistencies in the regulatory structure and, through distraction of licensee and regulatory engineering resources, prevent those resources from being applied in areas of true safety and/or risk significance.

5. While NRC states in Attachment 1 to SECY-98-171 that changes increasing consequences up to the limits should receive staff review, this opinion is divergent from past NRC practice. NRC has clearly focused on the NUREG-0800 acceptance limits during its previous SER reviews. Cases where the NRC has imposed a more restrictive acceptance criteria through its SER are believed to be relatively infrequent.

6. To tie any increase in consequences to values in the SAR would be counterproductive to NRC's interest in SAR integrity. Plants who have provided accurate and detailed information in their SAR would be penalized under the draft guidance, as any use of the design margin between what is reported in the SAR and the SRP/SER acceptance limits would result in a USQ. However, plants who have maintained useless non-detailed information in their SAR which, for example, merely repeated that dose consequences met the appropriate requirement (e.g., < 10CFR100, less than a small fraction of 10CFR100, less than GDC 19 limits) would be allowed to continue to use design margin between their actual calculated values and the values reported in the SAR without having to go through NRC review and without the burden of the additional processing required for changes involving USQ's.

NRC agreement with the fact that the SAR is not the baseline for determining if there is an increase in consequences is documented in the May 10, 1989, NRC letter from C.E.Rossi to T.E.Tipton of NUMARC. In this letter, the NRC states that

> "If a proposed change, test, or experiment, would result in an increase in dose from an accident or equipment malfunction above that previously reviewed and approved by the

> staff as part of the licensing basis for the plant (i.e., the acceptance limit), then the proposed change, test or experiment involves an unreviewed safety question and would require prior NRC approval."

The NRC also states in this letter:

> "...if in licensing the plant the staff explicitly found that the plant's response to a particular event was acceptable because the dose was less than the SRP guidelines (without further qualification) then the staff implicitly accepted the SRP guideline as the licensing basis for the plant and the particular event, and the licensee may make changes that increase the consequences for the particular event, up to this value without NRC approval. However, if the staff cited some value other than the SRP guideline as its criteria for licensing the plant then that value is considered the licensing basis for the plant."

Thus, the NRC has clearly established that the acceptance basis in the SER, which is often that of the SRP, is the proper licensing basis for the plant. Thus, any value for the dose consequences which remains less than that acceptance basis has been reviewed by the NRC as within the plant licensing basis, hence is not a Unreviewed Safety Question.

NOTE that the NRC references this same May 10, 1989, letter to NUMARC as providing the current NRC thinking on the meaning of 'licensing basis' in addressing comments received on draft NUREG-1606 in Attachment 1 to SECY-98-171. Since NRC recognizes the continued validity of this letter in SECY-98-171, this continued validity must also extend to the subject of consequences.

7. An example exists where NRC has explicitly used the SRP alone as the basis for limits on a plants licensing basis. In 1992, a PWR submitted to the NRC, as a potential Unreviewed Safety Question, a case where the calculated percent of fuel rods experiencing DNB as the result of a transient analysis exceeded the value previously documented in its SAR and SER. The SER had repeated the results of the utility analysis and had concluded, without an explicit basis, that the results were acceptable. Since there was no clear acceptance basis discussed in the SER, the utility had submitted this case to the NRC as a potential USQ. The NRC responded to the utility that the change was acceptable under the criteria of 50.59 and stated that:

> "However, even if all of the pins experiencing DNB were to fail, a coolable geometry would be maintained and the consequences remain a small part (less than 10 percent) of 10CFR Part 100 limits."

Thus, NRC actions demonstrated that it was not considered an increase in consequences since the SRP acceptance limits for this event (less than 10 percent of 10CFR100 limits) were met.

II.G: More than a Minimal Increase in Probability or Consequences:

1. While it would be preferable for the NRC to endorse the approach of NEI 96-07 Revision 0 on the topic of increases in consequences, the concept of allowing "minimal increases" in consequences does provide a workable approach to resolving the philosophical differences between the NRC and the industry on the legal requirements of 50.59. However, a much better approach would be to use the NRC approach on defining "minimal increases" as triggers for reporting changes to the NRC, as under 50.46, instead of for requiring submittals for NRC approval.

   Clearly, the NEI 96-07 position, as NRC desires, would ensure that the probability and consequences associated with any plant changes remain substantially less than a "significant increase," as referred to in 10CFR50.92. Thus, it would be reasonable and provide improved regulatory stability if the acceptance criteria for consequences were clearly tied to the basis for NRC approval as described in the SRP or in the plant-specific SER.

   The fact that the NOPR ties its definition of "minimal increases" in consequences to the SRP is itself an obvious inherent endorsement of the NEI 96-07 position that the acceptance limits should be per the SER and/or SRP.

2. In determining what constitutes a "minimal" increase in consequences based on dose information documented in the SAR, NRC needs to address the case of plants which have lowered their doses due to one change and subsequently increase the dose due to a later change. For example, consider a plant with an original LOCA thyroid dose of 290 Rem thyroid. The plant subsequently finds an overconservatism in its analysis and reduces the dose to 225 Rem thyroid. A subsequent change to the plant then increases the dose to 275 Rem. This should not be considered as an increase in consequences, since the plant was originally licensed to a value to 290 Rem. NRC needs to clarify its proposed guidance on this subject to explicitly recognize this; otherwise, there is a disincentive for plants to remove known overconservatisms from their analyses. This is another reason why an increase in consequences should be determined against the clear acceptance limits of the NRC SRP and/or SER.

3. NRC provides a specific example in the second paragraph under "Consequences of accident or malfunction" in section II.G. Note that not only is this change "no more than a minimal increase" in consequences as stated by the NRC, this change is simply no increase since the new analysis result remains bounded by the previous analysis result, provided the change in input assumptions are technically justifiable, consistent with acceptable methodology, and remain conservative.

4. NRC discusses three options for approaching the definition of "minimal" increase in consequences under section II.G. The first option, of allowing a 0.5 Rem increase, would result in increases in regulatory burden with no commensurate safety benefit. The concept of the second and third options are workable; clearly, the third option is the simpler of the two and therefore would be the most preferable.

   Furthermore, it would be desirable to define "minimal" as a larger fraction of the remaining margin than the 10% suggested under Option 3 in Section II.G. Defining "minimal" as 25% or

50% of the remaining margin between current conditions and acceptance guidelines would meet the NRC intent that the consequences associated with any plant changes remain substantially less than a "significant increase," as referred to in 10CFR50.92, and would still ensure that the regulatory limits would not be exceeded. Therefore, it be a risk-informed improvement to define "minimal" as 25% or 50% of the remaining margin vice the originally suggested 10% and still accomplish all of the discussed NRC purposes.

5. The NRC is proposing to require licensees to report the effects of changes in a different manner to evaluate cumulative effects on probability or consequences associated with changes evaluated under the proposed 50.59 "minimal increase" criteria. It is not clear what benefit is derived from the addition of this requirement that is not already fulfilled through existing SAR update requirements and through the existing requirements to report changes to the plant implemented under 50.59.

II.H: Possibility of an Accident of a different type from any Previously Evaluated in the SAR may be created:

1. The definition of 'design basis event' in Section I, "Background," presents a reasonable approach. This can be improved by being more specific, that is, to refer to AOO's and accidents analyzed in the "Safety Analysis" chapter of the SAR (usually Chapter 15), containment performance analyses (usually in SAR Chapter 6), and other specific events (e.g., Station Blackout, ATWS) which should have their high level analysis acceptance criteria discussed in the SAR. It would be acceptable to treat external phenomena (e.g., tornadoes, seismic events, fire) either as an accident or as a precursors for the malfunction of equipment important to safety; the impacts of such phenomena upon the probability or consequences of accidents and/or equipment malfunctions would be adequately addressed under 50.59 by either approach.

*. In considering the definition of "accident" note for the future that a definition of accident, tied to SAR Chapter 15 events, is a very different acceptance criteria than that of Core Damage Frequency, as used within PRA. This is an important consideration in the development of a risk-informed approach to 50.59. PRA's are generally focused on severe accidents rather than Chapter 15 type Limiting Fault events. A design basis LOCA, evaluated from a best estimate perspective consistent with PRA methodology, would not be a severe accident since PCT acceptance criteria would not be exceeded, and clad oxidation (and thus hydrogen production) would be minimal. The differences in the level of acceptance criteria used for Chapter 15 type safety analyses and plant PRA's would need to be fully understood and considered in determining acceptance criteria or the definition of accident in any future risk-informed 50.59 rule.

II.I: Possibility of a Malfunction of a Different Type from any Previously Evaluated in the SAR may be created:

1. Adoption of the proposed NEI rule wording is reasonable and puts the proper safety focus on this criteria.

II.J: <u>Margin of Safety as defined in the Basis for any Technical Specification is reduced:</u>

1. The NRC Commissioners are correct in directing that the original staff proposal of SECY-98-171 that a reduction in margin of safety occurs when the input assumptions, analytical methods, or acceptance conditions/criteria/limits change in a nonconservative direction should not be adopted. This was an overly restrictive approach which will not contribute to increases in safety or risk reduction. This is almost tantamount to requiring that NRC approval be requested for all changes to the Technical Specification BASES, which is clearly not the intent in the creation of the BASES.

   The original staff proposal is presented as Option 1 in the NOPR. This approach does not acknowledge that many Technical Specifications are not directly related to safety analyses, but represent defense-in-depth mechanisms to add robustness to plant operations. An example of this would be the flow-biased scram setpoints for BWR's, as well as the scram setpoints associated with the adoption of Enhanced Option 1-A BWR stability solutions. These setpoints are not related to or the products of safety analyses. Thus, it would be a less than optimal approach to focus on both "margin of safety" and "safety analyses" in the proposed rule.

   Because of the inherent conservatisms and disconnects between analyses, the NRC statement of SECY-98-171 that "Whether an increase or a decrease in a value is nonconservative is of course dependent on the nature of the parameter, but is generally self-evident" is not necessarily true. For example, various aspects of PWR ECCS analyses for Peak Clad Temperature (PCT) use both the maximum and the minimum safety injection flows within the same PCT analysis. Thus, the true sensitivity of the results to input assumptions is clouded in such cases.

2. If the "margin of safety" concept is to be retained within 50.59, it is clearly desirable to focus the on the safety analyses directly related to fission product barrier performance (e.g., fuel clad, reactor coolant pressure boundary, primary containment). This is similar to the approach presented by NEI at the NEI Licensing Issues Workshop on October 19, and has some similarity to Option 3 of the NOPR.

   The specific suboptions in the NOPR on controlling parameters do not appear reasonable in that they will focus on the difference between the calculated parameter values (e.g., peak clad temperature, maximum RCS pressure, etc.) and the associated safety limit. This would be an approach which adds to the regulatory burden without any commensurate increase in safety or reduction in risk.

   This would also be inconsistent with the established approach of 10CFR50.46, which sets a clear acceptance limit for Peak Clad Temperature and provides for reporting requirements. Under the proposed Options 3A(1), 3A(2), and 3A(3), increases in calculated PCT which would not even require being reported under 50.46 would require submittal for NRC approval under 50.59. This approach would be highly inconsistent and add much regulatory burden without any commensurate increase in safety or decrease in risk.

   The suboption 3A(1), 3A(2), and 3A(3) definitions approaches all appear to require NRC approval for changes which would meet clearly established acceptance limits on parameters important to fission product barrier performance. This would produce <u>regulatory instability</u>, and therefore not meet a basic aim of the current exercise to refine 50.59. The proposed definitions would introduce potential conflicts with NRC approved methodologies used by reload fuel vendors for reload licensing analyses and would introduce potential conflicts with NRC approved approaches for the relocation of certain limits from the Technical Specifications to licensee controlled Core Operating Limit Reports (COLR's). For example, reload analyses for both PWR's and BWR's involve calculating the peak vessel pressure for the reload core to ensure that ASME overpressure acceptance limits are met. Currently, there is no reduction in margin of safety and no increase in consequences provided the acceptance limits are met. The proposed suboptions all could be interpreted as requiring NRC approval for increases in calculated peak vessel pressures which remain less than the acceptance limit. However, these analyses are being performed using NRC approved methodologies which may be specifically referenced within the plant's COLR and/or Technical Specifications. Similarly, limits on MAPLHGR (Maximum Average Planar Linear Heat Generation Rate) as a function of fuel exposure are provided as part of BWR core reloads and are incorporated into the COLR; the proposed suboptions would all imply that a change in MAPLHGR value, even within defined acceptance criteria, could be construed as failing the 50.59 Evaluation criteria and thus requiring NRC approval.

The concept of "margin of safety" should be consistent with that of NEI 96-07. Margin of safety should be defined as:

> "Margin of Safety: the difference between a clear acceptance limit (i.e., safety limits as defined per Technical Specifications and other high level design limits which protect against fission product release, e.g., containment pressure design limit) and the ultimate failure point for the barrier under consideration."

7

Thus, the margin of safety would be negatively impacted by changes in methodology which would reduce the difference between the acceptance limit and the ultimate failure point.

Margin of safety should be considered only for where there are clearly defined acceptance limits: Safety Limits which are defined in Technical Specifications, 2200F for PCT, the containment design pressure, calorie/gram limits on fuel centerline melt, Kw/Ft limits on fuel linear heat rate, etc.

If 'margin of safety' is to be confined to the 'safety analyses,' for purposes of regulatory stability the NRC must also carefully and explicitly define the scope of safety analyses that are to be considered in evaluation of barrier performance. Are such analyses only to be the ECCS analyses and/or containment performance analyses? (i.e., the analyses that directly impact the fission product barriers?) Or are the analyses done to ensure that plant support systems meet analytical assumptions in the ECCS analyses and containment performance analyses also considered safety analyses? For example, if a service water temperature of 105F maximum is assumed, are the service water system analyses to determine that this maximum temperature is not exceeded also considered as safety analyses? The concern for considering lower tier analyses is that having to consider such analyses results in a very broad scope of plant analyses being potentially construed as potentially impacting Margin of Safety. This would undesirably dilute the improved safety focus which would otherwise be associated with a "margin of safety" definition tied to the safety analyses for fission product barrier performance.

3. Option 2, to delete "margin of safety" as a 50.59 Evaluation criteria, is the best of the options presented in the NOPR.

   Given that any reduction in a true "margin of safety," however defined, would conceivably correspond also to potential increases in consequences or potential increases in the probability of accidents or of malfunctions of equipment important to safety, the additional safety benefits that arise due to consideration of "margin of safety" are not quantified. Thus, evaluating changes against a "margin of safety" criteria could be construed as a redundant evaluation to the evaluation of impact upon probabilities or consequences (particularly if industry 50.59 guidance were to explicitly cover this subject). In her comments, even Chairman Jackson noted "...it is not clear what type of changes would successfully pass the 10CFR50.59 test for allowed 'minimal increases in consequences' without failing the test for 'no reduction in the margin of safety.'" Thus, due to this interaction between evaluation criteria, it would not be unreasonable for the NRC to delete consideration of "margin of safety" from the 50.59 rule.

   "Margin of safety" would still have to be addressed in No Significant Hazards considerations submitted to the NRC to support requested Technical Specification changes. Therefore, the thoughts that have gone into defining "margin of safety" for the other options in the NOPR could be used as a basis for defining clear expectations on what needs to be addressed in the 50.90 No Significant Hazards evaluations.

   If the NRC would desire NRC approval to change a particular parameter, then NRC could require that such parameters be explicitly included in Technical Specifications rather than allowing such parameters to be controlled under licensee controlled documents such as the Technical Requirements Manual (TRM), COLR, or SAR.

4. It has been established that the legal requirement of 50.59 concerning "margin of safety" is to address the impact within the Bases section of Technical Specifications and that it is not legally required to go beyond this. This is clearly consistent with the original intent of the NRC in the history of the formulation of 50.59.

5. Regardless of the final approach on the "margin of safety" issue, if it is to remain part of the 50.59 Evaluation criteria NRC should provide clear and specific examples of plant changes that are believed to meet and to not meet the criteria.

6. NRC should clarify the acceptance limits of 51.55 concerning burnup assumptions for the transportation of spent fuel for BWR's, as well as clarifying if this is subject to 50.59 evaluation criteria.

Analytical Methods:

1. The NRC statement in Attachment 1 (Topic III.U) to SECY-98-171 that a comparison between two different methodologies is not valid is not necessarily correct and does not have a technical basis. The difference between the two methodologies may be improvements in numerics or may reflect increases in basic technical knowledge over the time between when the two different

methodologies were developed. For example, ICRP 2 dose conversions factors, based on a 1950's publication, were the usual basis for calculated doses in the original SAR submittals for most plants. However, since then, ICRP 30 dose conversion factors were published in 1979 and were adopted by the NRC as the basis for 10CFR20 in the early 1990's. Thus, while calculations based upon ICRP 30 result in lower doses than those using ICRP 2 dose conversion factors, the basis is clearly understood to be the increased technical knowledge developed over the approximately 20 year interval between when ICRP2 and ICRP30 were published.

Because of this, NRC should explicitly allow licensees to fully utilize ICRP30 dose conversion factors in determining dose consequences of SAR Chapter 15 events. There is no safety or risk benefit to requiring plants to go through the effort of submittal to the NRC to justify the use of improved radiological data of ICRP 2 instead of the outdated data of ICRP 30, since use of ICRP 2 has been explicitly and implicitly accepted by the NRC through its use as the basis for 10CFR20. This should not be viewed as a change in methodology, but as the adoption of the most improved and up-to-date basis for determining the acceptability of utility radiological analyses.

Failure to accommodate realistic physical information can result in overconservatisms that result in challenges that would not otherwise exist to plant equipment and thus can undercut the desired robustness in plant operational safety. NRC must ensure that it does not impose regulatory expectations for compliance which provide a disincentive for licensees to use modern methods to assess risk and safety of their plants.

2. It should not be regarded as having any impact on margin of safety when licensees revise analyses to incorporate changes in methodology which have been generically endorsed or approved by the NRC. For example, NRC revised the Standard Review Plan section 6.5.2 in 1988 to allow revised models for crediting containment spray for fission product removal. This clearly indicates NRC approval or endorsement of this methodology. Any plant should be able today to revise its radiological analyses to credit fission product removal according to the methodology outlined in the SRP without requiring submittal to the NRC.

   To otherwise demand NRC approval in such cases is to ignore risk insights and to add regulatory burden on licensees to adopt the best known and available methodology without any commensurate increase in safety associated with such burden.

3. Consider the case of a plant which determines that there is a small nonconservatism (on order of 1%) in its suppression pool volume, as documented in the Bases of Technical Specification. Correcting this would result in a very small increase in offsite doses (due to slightly higher ESF leakage activity concentrations) and slight increases in containment pressures and temperatures post-accident. Provided the resulting increases in doses or pressures are within acceptance limits, this is a case where a reasonable 50.59 process would conclude that NRC approval is not required to accept such a nonconformance.

II.K: Safety Evaluation:

It is agreed that the 50.59 Evaluation is best not referred to as a "safety evaluation." As stated, this evaluation serves a regulatory purpose, not a safety purpose. While in an optimal regulatory structure, there would be an extremely strong correlation between safety and every regulation that must be met, due to the history of development of current regulations, the strength of this correlation varies amongst regulations. Also, the 50.59 process does not recognize that changes can affect consequences and probabilities in differing directions, such that there can be increases in one which are offset by decreases in the other, such that there is a net risk reduction. This is one of the arguments for risk-informing the 50.59 rule as a means of increasing focus on safety. Because such changes would result in a net increase in safety yet fail the 50.59 criteria, it is agreed that the term "safety evaluation" should no longer be used.

II.L: Reporting and Recordkeeping:

1. The proposed changes to 50.71(e) would require the net effect of all changes made since the last update of the SAR, including changes to probabilities, consequences, calculated values, system or component performance, that are in the SAR. It is not clear that this is any difference from current SAR update requirements or current utility practice; all changes in consequences, calculated values, and system or component performance are captured in SAR changes. Changes in probability class are also captured. Generally, in using the NEI-96-07 guidance, changes in the probability of equipment malfunction or accident probability are not quantifiable, such that 50.59 evaluation criteria is met only if there is no discernible change in probability. Thus, there would in the vast preponderance of cases be nothing to report in this area. Thus, it is not clear that any changes are required to 50.71(e).

   There should be no change in the requirements for summarizing individual 50.59 Evaluations associated with the rule change.

2. The proposed rule changes should be revamped to focus on providing clear and discrete acceptance criteria for dose consequences and limits associated with fission product barrier performance (e.g., safety limits, containment design pressure, etc.), with enhanced reporting of changes that would otherwise reduce the operational margin between calculated parameter values and the acceptance limits. NRC approval should not be required for changes in such operational margins, be this for a dose, pressure, temperature, stress, post-LOCA hydrogen concentrations, etc., as long as acceptance limits are met.

   Thus, the proposed rule change should be totally revamped to accept the NEI 96-07 guidance on acceptance limits for consequences and the NEI 96-07 approach on "margin of safety" (preferably focused on fission product barrier performance), rather than to provide vague and imprecise approaches on consequences and margin of safety where what would be acceptable could vary drastically from plant to plant and be strongly influenced by how the utility deals with the underlying tension between the two objectives of maintaining an accurate SAR and treatment of the SAR as codifying much of the plant licensing basis.

VIII: Finding of No Significant Environmental Impact:

1. NRC needs to recognize that regulatory burden plays a role in the viability of commercial nuclear power plants. While it is clear to the industry that there is a correlation between strong regulatory performance and successful operating and commercial (i.e., production cost) performance, an increased regulatory burden without commensurate increases in nuclear safety or reduction in accident risk can impact plant production cost performance. The impact on the environment of replacing nuclear power from nuclear plants which have been or may be shutdown due to increased regulatory burden needs to be considered, especially in light of the reduction in greenhouse gas generation provided through the clean generation of nuclear energy. Nuclear energy has been the single most important factor in preventing the emission of greenhouse gasses in the United States, according to the Department of Energy's Climate Challenge Program. According to the Nuclear Energy Institute (NEI), the global atmosphere would have gained another 466 million metric tons of carbon in 1994 alone. In 1996 alone, nuclear plants offset the emission of 5.3 million tons of sulfur dioxide and 2.5 million tons of nitrogen oxide.

   Thus, the negative impact of burdensome regulations which do not increase safety or decrease risk can have a clear impact on the environment if such regulations result in the shutdown of nuclear power plants.

Risk Insights:

1. Many consider that a risk-informed 50.59 would substitute a PRA evaluation in place of the deterministic evaluation process currently codified within 50.59. While acceptable changes in Core Damage Frequency (CDF) or Large Early Release Frequency (LERF) can be indicators of the acceptability of changes, In attempting to formulate a risk-informed 50.59 rule, NRC will need to thoroughly consider the differences between deterministic design basis approaches and those of Probabilistic Risk Assessment (PRA). For example, PRA is meant to use best estimate approaches whereas deterministic design / licensing basis approaches usually use worst case assumptions. PRA focuses on severe accidents; the events analyzed within the SAR would not constitute severe accidents and would generally not contribute to core damage frequency (CDF). A Large Break LOCA, analyzed on a realistic and best estimate basis, would generally result in Peak Clad Temperatures less than the 1800F at which hydrogen generation would start to occur, and would thus not be considered as a contributor to core damage if only a Chapter 15 style worst case single active failure occurred.

   A reasonable approach to risk-informed 50.59 regulations would have to consider some role for determining acceptability of changes based on impact on CDF or LERF, as well as using risk insights for improving the deterministic evaluation criteria that would have to remain a part of 50.59 to address non-severe accident impact. PRA acceptance criteria could possibly also be modified, although this would have to be in a manner that does not require significant overhaul of the existing plant specific PRA's in use today. Care must be taken with the application of risk insights in developing risk-informed revised deterministic criteria, due to the differences in plant PRA's developed in response to GL 88-20, which did not include a prescriptive or standardized approach for developing plant PRA's.

Chairman Jackson's concern, in her comments in the NOPR, that "the staff appears to be more reluctant to allow risk-informed approaches if the result is relinquishment of review and approval authority" is true. This is clearly manifested in the NOPR itself, since the approach of allowing only "minimal" increases in consequences over that documented in the SAR instead of using clear and defined acceptance limits from the SER and SRP cannot be justified on a risk-informed basis.

The Advisory Committee on Reactor Safety discusses risk-informed regulation in its 30 September 1998 memo to Chairman Jackson.

> "Many of the present regulations are based on deterministic and prescriptive requirements that cannot be quickly replaced. Therefore, the current requirements will have to be maintained while risk-informed regulations are being developed and implemented. Furthermore, we expect that a number of licensees will, for a variety of reasons, be unwilling to embrace a new regulatory system. Therefore, the NRC should be prepared to accommodate a two-tier system, i.e., a modified version of the current regulatory process and a risk-informed system. This situation will prevail for a number of years and may create circumstances that should be addressed by the Commission."

Licensees are concerned that the transition to risk-informed regulation will result in the imposition of second layer of regulatory requirements, i.e., both deterministic and risk-related regulations, without any reduction of the deterministic regulatory burden. Previous experiences with risk-informed approaches have not been successful in terms of the efforts and time required by both NRC and utilities and in terms of having added a risk-informed element to regulatory expectations without any relaxation of the deterministic compliance mindset (the Maintenance Rule is a prime example of this). NRC must, for the sake of regulatory stability and reducing regulatory burden, ensure that risk-informed regulation does not merely become an added regulatory layer, including future risk-informed approaches to 50.59.

Comments on Regulatory Analysis (Backfit):

1. The Regulatory Analysis is incorrect in stating that the rule changes reduce regulatory burden since it makes the incorrect assumption that the current burden is based upon the NRC's view of the existing regulations rather than the actual legal requirements, which are met fully and completely by NEI-96-07, as demonstrated in the Regulatory Analysis produced for NEI in July 1997.

   NRC states that there is a difference in interpretation between recent NRC correspondence on the subject and NEI 96-07. Thus, it is clear that there will be a real change in the burden associated with the proposed rule change. This burden is exacerbated by the lack of NRC resources and the increasing time required to obtain license amendment approvals from the NRC. Thus, the statement under item (7) that "The resources needed for oversight of licensee activities following completion of this rule change is not expected to change from the current level" ignores the impact the NOPR will have upon NRC review resources.

2. The statement in the regulatory burden discussion that:

> "The Commission notes that exercise of the authority under 10CFR50.59 or 10CFR72.48 is at the licensee's option so no burden is imposed unless a licensee wishes to make facility or procedure changes without NRC approval."

is a false statement, as has been demonstrated in proceedings earlier concerning Maine Yankee. This neglects the realities confronted by licensees in evaluating nonconformances under 50.59.

3. The continuing costs of this backfit neglect in section (5) the cost to utilities of the increased overhead and reviews associated with submittals to the NRC of work that can otherwise be approved internally. The costs associated with the increase in decision cycle time, due to the delays required when NRC approval is required, are also ignored.

4. Based on Entergy experience, the NRC estimate in section (5) of 100 persons/site trained on 50.59 is low. Recent numbers of qualified individuals for the four Entergy sites totaled 1593, or an average of nearly 400 per site.

DOCKET NUMBER
PROPOSED RULE PR 50, 52 + 72
(63FR 56098)

DOCKETED
USNRC

'98 OCT 19 P3:07

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

10 CFR Parts 50, 52 and 72

RIN 3150-AF94

Changes, Tests, and Experiments

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations concerning the authority for licensees of production or utilization facilities, such as nuclear reactors, and independent spent fuel storage facilities, to make changes to the facility or procedures, or to conduct tests or experiments, without prior NRC approval. The proposed rule would clarify which changes, tests and experiments conducted at a licensed facility require evaluation, and the criteria that determine when NRC approval is needed before such changes to a licensed facility can be implemented. The proposed rule would also add definitions for terms that have been subject to differing interpretations, reorganize the rule language for clarity, and revise the criteria for when prior NRC approval is needed. The Commission is also seeking comment on several specific issues as discussed below.

DATES: Submit comments by December 21, ~~(60 days from publication),~~ 1998. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

Pub. on 10/21/98

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001. ATTN: Rulemakings and Adjudications Staff.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. Federal workdays.

FOR FURTHER INFORMATION CONTACT: Eileen McKenna, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-2189. (emm@nrc.gov) or Naiem Tanious, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001, telephone (301) 415-6103 (nst@nrc.gov).

SUPPLEMENTARY INFORMATION:

I. Background

II. Proposed Rule Topics and Issues

A. Organization of the rule requirements

B. Change to the facility as described in the Safety Analysis Report

C. Change to the procedures as described in the Safety Analysis Report

D. Tests and experiments not described in the Safety Analysis Report

E. Safety Analysis Report

F. Probability of occurrence or consequences of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report may be increased

G. More than a minimal increase in probability or consequences

H. Possibility of an accident of a different type from any previously evaluated in the

Safety Analysis Report may be created

I. Possibility of a malfunction of a different type from any previously evaluated in the Safety Analysis Report may be created

J. Margin of safety as defined in the basis for any technical specification is Reduced

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L. Reporting and record keeping requirements

M. Part 72 changes

III. Section by Section Analysis

IV. Commission Voting Record on SECY-98-171

V. Rule Language Proposed by the Nuclear Energy Institute

VI. Request for Public Comments

VII. Availability of Documents and Electronic Access

VIII Finding of No Significant Environmental Impact

IX. Paperwork Reduction Act Statement

X. Regulatory Analysis

XI. Regulatory Flexibility Certification

XII. Backfit Analysis

XIII. Criminal Penalties

XIV. Agreement State Compatibility

I. Background

The existing requirements governing the authority of production and utilization facility licensees to make changes to their facilities and procedures, or to conduct tests or experiments, without prior NRC approval are contained in 10 CFR 50.59. (Comparable provisions exist in 10 CFR 72.48 for licensees of facilities for the independent storage of spent nuclear fuel and high-level radioactive waste. This proposed rulemaking affects the requirements for 10 CFR Parts 50, 52 and 72; for simplicity, the discussion will focus primarily on the language in 10 CFR 50.59). These regulations provide that licensees may make changes to the facility or procedures as described in the safety analysis report, or conduct tests or experiments not described in the safety analysis report, without prior Commission approval, unless the proposed change, test or experiment involves a change to the Technical Specifications incorporated in the license or an unreviewed safety question. Section 50.59(a)(2), as currently codified, states:

> "A proposed change, test or experiment shall be deemed to involve an unreviewed safety question (i) if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report may be increased; or (ii) if a possibility for an accident or malfunction of a different type than any evaluated previously in the safety analysis report may be created; or (iii) if the margin of safety as defined in the basis for any technical specification is reduced".

The rule also specifies record keeping and reporting requirements associated with such changes, tests or experiments.

In order to understand the reasons for the provisions of the current rule, and how the Commission proposes to revise it, it is helpful to understand how this process fits within the overall requirements undergirding licensing and oversight of nuclear reactors.

Overview of Licensing Process

The application for an operating license includes the final safety analysis report (FSAR) which is to contain: a description of the facility; the design bases and limits on operation; and the safety analysis for the structures, systems, and components (SSC) and of the facility as a whole. The safety analysis emphasizes performance requirements, analytical bases and technical justifications, and evaluations that show how safety functions will be accomplished. Design bases include the specific functions that the SSC need to perform, the parameters that need to be controlled to assure the function, and the range of values for these parameters. As part of the FSAR, the applicant is required to propose, for NRC approval, Technical Specifications(TS) that will become part of the license.

The NRC issues a license after finding, among other things, that the plant has been built according to its design and can be operated within its design limits. The NRC prepares a safety evaluation report that documents the basis for its findings, including its review of the design information provided in the FSAR (and supporting documents) and the applicable acceptance criteria (established either in regulations, standards or guidance documents). In some cases, the NRC staff performs independent analyses to confirm the adequacy of the facility design to meet regulatory requirements. One example of this practice is the staff calculation of radiological consequences (doses) for design basis accidents.

The licensee is required to operate the facility in accordance with NRC regulations and with requirements contained in the license. The license describes the facility in general terms, and includes specific conditions imposed on the facility and the licensee, as well as incorporates the TS. Section 50.36 of the regulations defines for inclusion in the TS, those limits and parameters of most immediate significance for protection of public health and safety: safety limits, limiting safety system settings, limiting conditions for operation, surveillance requirements, and design features to which changes would have a significant effect on safety, and administrative controls. The TS are derived from the safety analysis, evaluations, and design bases described in the FSAR. Any changes to the TS must receive NRC review and approval before they are made.

Engineering evaluations demonstrate that the fundamental safety principles of the plant design are met. Design basis events play a central role in plant design. These are a combination of postulated challenges and failure events against which plants are designed to ensure adequate and safe plant response. Design basis events are defined as conditions of normal operation, anticipated operational occurrences and design basis accidents, external events and natural phenomena for which the plant has been designed to ensure the integrity of the pressure boundary, the capability to shutdown safely, and the capability to prevent or mitigate the consequences of accidents. For events with high frequency, NRC requires that consequences be low (such as by preventing fuel damage). For more severe, but less probable accidents, the allowable consequences are higher, but must still meet the regulatory guidelines established in 10 CFR Part 100. Adequacy of the reactor design is evaluated by consideration of postulated design basis events viewed as sufficiently credible that the facility should be designed to prevent or mitigate their effects.

During the design process, plant response is evaluated using assumptions that are intended to be conservative to account for uncertainties in analysis or data. In the Final Safety Analysis Report (FSAR), analyses are done conservatively to account for uncertainties in the design, construction, and operation of nuclear power plants. These conservatisms are introduced into FSAR analyses in numerous ways. For example, some computer codes model systems and processes in a simplified but bounding fashion. Analysis input assumptions are typically worst case values (consistent with the design and operating limits) of instrument drift or error, temperature, pressure, fluid volume and enthalpy, flow rate, system response time, heat transfer rate and heat capacity, reactivity coefficients, power history and decay heat. An FSAR analysis also typically assumes the worst-case single-active failure of equipment.

National standards and other regulatory policies, such as defense-in-depth, constitute additional engineering considerations that influence plant design and operation. Commensurate with expected frequency and consequences of challenges to the system, defense-in-depth could require: (1) multiple means to accomplish safety functions and prevent release of radioactive material (multiple barriers); (2) reasonable balance among prevention of core damage, prevention of containment failure and consequence mitigation; (3) system redundancy; (4) independence; and (5) diversity.

Various margins exist in a facility design. These margins are based on, for example, assumptions of initial conditions, conservatisms in computer modeling and codes, allowance for instrument drift and system response time, redundancy and independence of components in safety trains, and plant response during operating transient and accident conditions. Margin is provided by meeting codes and standards or alternatives approved for use by NRC, including the safety analysis acceptance criteria in the FSAR and in supporting analyses. Not all margin that exists falls within the purview of "reduction in margin of safety[1] as defined in the basis for

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[1]Margin of safety is not defined in the regulations, although it is mentioned in §50.34(a) ["the margins of safety during normal operations and transient conditions anticipated during the

any technical specification."

When a plant is licensed, the NRC states in its Safety Evaluation Report (SER) why it found each FSAR analysis acceptable. An FSAR analysis may be accepted because it was considered to be adequately conservative and because the NRC's acceptance criteria for that analysis are met. Frequently, the SER states specific conditions the NRC relied upon for concluding that the analysis was conservative. Examples of such conditions may be the use of an NRC-approved computer code, correlation, or setpoint methodology, specific limitations on one or more input assumptions, or penalties put into a calculation to account for uncertainties. In addition to being stated in a plant-specific SER, these conditions may be found in other safety evaluations such as for an analysis method proposed by a topical report.

Changes to the basis for licensing occur over the life of the plant through promulgation of new rules, plant-specific license amendments and other analyses and reviews that may be conducted, such as in response to NRC bulletins and generic letters. The NRC prepares a safety evaluation for many of these issues based upon either licensee requests for changes or licensee responses to NRC requests for information. The licensee is required to periodically update the final safety analysis report to reflect effects of these changes so that the safety analysis report (as updated) remains a complete and accurate description and analysis of the facility such that it can serve as the reference document for evaluation of changes made under 10 CFR 50.59.

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life of the facility"]; §50.92(c) ["No significant hazards considerations if the proposed amendment would not involve a significant reduction in a margin of safety"] as well as §50.59.

10 CFR 50.59 Evaluation Process

Section 50.59 was promulgated in 1962 to allow licensees to make certain changes that affect systems, structures, components, or procedures described in the SAR without prior approval provided certain conditions were met. In 1968, the rule was revised to modify some of the criteria for when approval was required. The intent of the § 50.59 process is to permit licensees to make changes to the facility, provided the changes maintain the level of safety documented in the original licensing basis, such as in the safety analysis report. The process is thus structured around the licensing approach of design basis events (anticipated operational occurrences and accidents); safety-related mitigation systems, and consequence calculations for the design basis accidents. Margins and equipment functionality, reliability and availability also may be impacted by facility changes. Therefore, the criteria for requiring NRC approval were directly related to: (1) preserving licensing assumptions concerning initiation of design basis events by not allowing a different type of initiating event or probability of occurrence larger than previously considered; (2) preserving effectiveness (reliability) of the mitigation systems by not allowing introduction of different equipment malfunctions and by limiting increases in probability of malfunction, or reductions in the margin of safety (which reflects the capability of the system); and (3) preserving acceptability of consequences by limiting increases in consequences of the postulated design basis events.

Implementation Guidance

In 1989, an industry guidance document, NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations" was published to assist licensees in the conduct of the evaluations required under §50.59. The NRC neither endorsed nor disapproved this document. While the staff concluded that the evaluation process established in NSAC-125 was generally sound, the staff was unable to endorse the document because of some inconsistencies between the implementation guidance and the language of § 50.59.

On October 31, 1997, the Nuclear Energy Institute (NEI) submitted for staff review a revised guidance document, NEI 96-07, "Guidelines for 10 CFR 50.59 Safety Evaluations." This document is an updated version of NSAC-125 that NEI modified in response to some of the staff positions, and other implementation issues arising from licensee use of the NSAC-125 guidance. Along with the submittal of the guidance document, NEI included an industry-wide initiative that would require industry adoption and implementation of the revised guidance by June 1998. The NRC provided comments to NEI concerning this guidance in a letter dated January 9, 1998. This letter noted that certain aspects of this guidance were unacceptable for implementation of § 50.59 as presently written.

Staff efforts to develop guidance on implementation of § 50.59 were prompted by a reassessment of the 10 CFR 50.59 evaluation process, conducted in 1995, that examined existing guidance and practice, with the goal of identifying how the process could be improved, or where additional guidance was needed. The staff provided an action plan to the Commission on April 15, 1996, outlining the actions the staff proposed to complete with respect to guidance and oversight of implementation of § 50.59. The staff review identified a number of areas in which the meaning of the rule language is not clear, or where staff and industry interpretations (such as those in NSAC-125) are different. In SECY-97-035, dated February 12, 1997, the staff forwarded to the Commission proposed regulatory guidance on implementation of § 50.59. In this SECY, the staff presented positions on a number of topic areas. These positions in some cases reaffirmed existing regulatory practice or clarified staff expectations, and in other areas, established positions where guidance did not previously exist. In its proposed guidance, the staff compared its proposed regulatory guidance to industry guidance contained in NSAC-125. In accordance with a Commission Staff Requirements Memorandum dated April 25, 1997, the staff guidance was published in the Federal Register as draft NUREG-1606 (Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59), for public comment on May 7, 1997 (62 FR 24947).

In response to the *Federal Register* notice, many comments were submitted that voiced strong opposition to a number of the positions proposed by the staff. These comments were summarized in Attachment 1 to SECY-97-205, Integration and Evaluation of Results from Recent Lessons-Learned Reviews, dated September 10, 1997. Since that time, the NRC has conducted a more detailed review of the comments and concludes that some issues can be resolved through guidance, while in other areas, rulemaking is necessary to clarify the implementation issues. A copy of this analysis of comments is available for review in the NRC Public Document Room. As noted, the staff concluded that rulemaking was necessary to resolve some of the issues associated with implementation of the rule.

II. Proposed Rule Topics and Issues

The NRC is proposing rulemaking on § 50.59 (and § 72.48) to address a number of issues concerning implementation of the current rule, and suitability of the criteria that determine when an unreviewed safety question exists. The implementation issues primarily relate to cases involving judgment as to whether a proposed change requires NRC approval before it can be implemented. The differing interpretations of the rule as it relates to an increase in probability of an accident, or an increase in consequences have contributed to disputed inspection and enforcement findings. Too stringent an interpretation of the meaning of the requirements could result in diversion of licensee and staff resources for review of inconsequential changes. Too high a threshold for NRC review could lead to erosion of safety margins without NRC review, particularly from the cumulative effect of more than one change. In developing the proposed rule, the Commission has carefully weighed these matters in trying to establish an appropriate threshold for NRC review.

Conforming changes are proposed in other portions of the rules, including § 50.66, § 50.71(e) for production and utilization facilities licensed under Part 50. Conforming changes are also required in § 72.212(b)(4) and Appendices A and B to Part 52 (Design Certification Rules for ABWR and System 80+ respectively).

In addition, the Commission is proposing to make parallel changes applicable to facilities for independent spent fuel storage facilities licensed in accordance with Part 72. These changes are included in the sections below (in some cases, the discussion of the issue focuses on § 50.59 for simplicity; except where noted, the discussion is also applicable to the changes for § 72.48). As part of the proposed changes to Part 72, the Commission is also proposing to extend the change control process authority granted to ISFSI or MRS license holders (in § 72.48) to holders of NRC Certificates of Compliance (CoC) for a spent fuel storage cask design.

In addition to changes to the requirements within sections 50.59 and 72.48, the

Commission is also proposing to rearrange certain provisions of these rules to provide a more logical structure. These changes do not affect the substance of the requirements, but rather affect only where they are located and how they are stated. These organizational changes are discussed first, followed by discussion of each of the issues where revisions to requirements are proposed by this rulemaking. The proposed rule revisions are presented in the order that the issues currently arise in the regulations.

A. Organization of the Rule Requirements

The organizational changes being proposed include the following:

(1) Applicability

In the existing rule, language concerning applicability to different facilities is contained in three different paragraphs. These facilities are: production and utilization facilities (including power and non-power reactors) that are authorized to operate, and reactors (both power and non-power) that have permanently ceased operations. The Commission proposes to place all of these provisions in one paragraph that is clearly labeled "Applicability."[2]

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[2] Section 50.59(a) refers to holders of a license authorizing operation of a production or utilization facility. Section 50.59(d) explicitly refers to power reactor licensees who have submitted certification of permanent cessation of operation required under § 50.82(a)(1)(i). As noted in § 50.82(a)(iii), for power reactors whose licenses were modified to allow possession but not operation, before the effective date of this rule [that is of §50.82], the certification of § 50.82(a)(1)(i) shall be deemed to have been submitted. Section 50.59(e) refers to non-power reactors whose license no longer authorizes operation. The net effect is that § 50.59 applies to both power and nonpower reactors, whether authorized to operate or no longer authorized to operate (and to other production or utilization facilities).

(2) Form of prior Commission approval

Existing paragraph 50.59(a) refers to the need for prior Commission approval of changes, tests, and experiments under certain conditions, but the method of receiving that approval is not discussed until paragraph (c), which states that the licensee shall submit an application for amendment under § 50.90. The Commission proposes to combine these two paragraphs and to revise the regulation to state more clearly that a licensee must apply for *and obtain* a license amendment, pursuant to § 50.90, before implementing such changes, tests, or experiments. This organizational change to the rule of combining (existing) paragraphs (a) and (c) will also facilitate some of the other proposed changes, such as the criteria for when approval is needed.

(3) Criteria for needing Commission approval of changes, tests and experiments and Unreviewed Safety Question (USQ) designation

The Commission proposes to remove the reference in the rule to the term "unreviewed safety question" and instead to refer to the need to obtain a license amendment. The Commission believes that the terminology of "USQ" has sometimes led to confusion about the purpose of the evaluation required by § 50.59. Some licensees have concluded that if they determined a change was safe, there could be no need for NRC approval.

The Commission notes that the purpose of performing evaluations against the criteria specified in § 50.59 is to identify possible changes that might affect the basis for licensing of the facility so that any changes that might pose a safety concern are either reviewed by the NRC or not implemented by the licensee. This evaluation process will thus distinguish those changes which by their nature do not raise safety concerns and therefore do not require prior NRC approval to confirm their safety, from those that must be reviewed by the NRC to independently confirm their safety before implementation. To avoid confusion between a determination of safety and a determination of the need for NRC approval, the Commission proposes to revise § 50.59 to delete use of the term "unreviewed safety question" and instead to list the criteria (in new § 50.59(c)(2)) that require prior Commission approval, in the form of a license amendment. It is also noted that many facility technical specifications refer to unreviewed safety question determinations and such TS should ultimately be revised in accordance with the final wording of § 50.59. The deletion of reference to USQ also requires a number of conforming changes to other parts of the regulations, including Part 52 (Appendices A and B), in which the term is presently used.

This proposed rule would revise the existing compound statements contained with the evaluation criteria to state each specific criterion individually. This will make the regulation more consistent with how it is generally implemented by licensees. Changes to the criteria are discussed in the sections below.

Finally, the Commission would simplify existing § 50.59(c) by removing the following statement: "The holder of a license...who desires (1) a change to its technical specifications... shall submit an application for amendment of his license pursuant to § 50.90." This statement refers to changes to the TS not associated with a change, test or experiment. The Commission concludes that a more suitable place for this provision is within § 50.90, and therefore as part of this rulemaking, proposes to modify § 50.90 to state that if a licensee wishes to amend its license (including the TS incorporated into it), the licensee must file an application as specified in § 50.90. Revised § 50.59(c)(i) would be revised to state that if a proposed change, test, or experiment would involve a TS change, the § 50.90 process must be followed in order to change the technical specification such that the proposed change, test or experiment may be implemented.

B. Change to the Facility as Described in the Safety Analysis Report

Section 50.59 states that "changes to the facility as described in the safety analysis report" must be evaluated to determine whether prior approval is needed before implementation. As discussed in NUREG-1606 and in the comment discussions, a common understanding between the NRC and the industry on what constitutes a "change to the facility as described in the safety analysis report" is necessary for effective functioning of the review process. Guidance on preparation of § 50.59 evaluations provides the means for review of the effects of changes, but these reviews are not conducted if the activity is not considered to be a "change..." The Commission concludes that modification of an existing provision (e.g., SSC, design requirement, analysis method or parameter), additions, and removals (physical removals or non-reliance on a system to meet a requirement) are all changes to the facility as described in the final safety analysis. The Commission believes that additions to the facility which were not previously evaluated, could adversely impact facility performance and the bases upon which the NRC previously determined the acceptability of the design as described in the SAR. Accordingly, the Commission concludes that additions should be considered "changes to the facility as described in the SAR" in order to assure that such changes are subject to evaluation using the § 50.59 criteria for determining whether prior NRC review and approval are necessary.

Differences in interpretation have occurred about whether changes that do not actually change the physical plant (the "hardware") require a §50.59 evaluation. As an example, consider a change being made to the basis (documented in the SAR) for demonstrating adequacy of the facility without a physical change to the facility. Such changes might include changes to evaluative methods, acceptance standards, procurement specifications, or other information for SSC described in the FSAR. The Commission believes that § 50.59 does apply to the requirements for design, construction and operation, and the safety analyses for the facility that are documented in the FSAR. Section 50.34(b), "Final safety analysis report," requires the FSAR to contain a presentation of the design bases and the limits on its operation, a description and analysis of the SSC of the facility, with emphasis upon performance requirements, the bases, with technical justifications therefore, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished. The original licensing decision was based in part upon the margins provided by performance requirements, analysis methods and assumptions described in the SAR, and reviewed by the staff in the SER. Therefore, the Commission concludes that changes to such information (e.g., performance requirements, methods of operation, the bases upon which the requirements have been established, and the evaluations) should be considered to constitute a change to the "facility as described in the SAR" in order to assure that such changes are subject to evaluation using the § 50.59 criteria for determining whether prior NRC review and approval are necessary.

If changes to methods and assumptions were not controlled, a licensee might revise its analyses and then subsequently conclude that a later facility change did not require NRC approval because the results of the (new) analysis with this change were bounded by the previous analysis. This proposed rulemaking would add definitions in § 50.59 of "change" and of "facility as described in the final safety analysis report(as updated)" to more explicitly establish that evaluation is required for changes to the analyses and bases for the facility as well as for physical or hardware changes to the facility.

Accordingly, the Commission proposes to add the following as definitions in section 50.59:

Change means a modification, addition, or removal.

Facility as described in the final safety analysis report (as updated) means (i) the structures, systems, and components (SSC) that are described in the final safety analysis report (as updated), (ii) design or performance requirements or methods of operation for such SSC required to be included or described in the final safety analysis report (as updated), and (iii) evaluations or methods of evaluation required to be included in the FSAR (as updated) for such SSC that demonstrate that their intended functions will be accomplished or that their design bases can be met.

The Commission endorses the staff's previously stated position (in draft NUREG-1606) about what constitutes a single change, as compared to packaging of several changes with offsetting effects. Interdependent changes (i.e., where a second change is caused by the first, with respect to function or performance), can be treated as a single change, whereas treating as one change the combination of changes (whether to the facility directly or to the safety analysis) to offset one that would otherwise require prior approval is not an appropriate application of §50.59.

C. Change to the Procedures as Described in the Safety Analysis Report

The Commission proposes to provide a definition of "procedures as described in the safety analysis report" in order to have definitions in the rule for all the major terms and criteria. This definition would include the evaluations demonstrating that requirements are met, such as assumed operator actions and response times.

The Commission also notes that § 50.34(b) states that the final SAR is to contain the managerial and administrative controls to be used to meet Appendix B (Quality Assurance), and plans for coping with emergencies, per Appendix E. Section 50.59 applies to changes to procedures as described in the SAR. Quality assurance and emergency planning program requirements are subject to the change control provisions of § § 50.54(a) and 50.54(q) respectively. Based on this set of rule provisions, it could be inferred that changes to quality assurance or emergency plans would require both a § 50.59 evaluation and a § 50.54 [either (a) or (q)] evaluation. The § 50.54[3] regulations provide criteria and reporting requirements specific to the plans and which were promulgated after § 50.59. To reduce duplication of effort, the Commission proposes that changes to these programs be governed by § 50.54 requirements, and that a § 50.59 evaluation would not be required unless other information described in the FSAR is also being changed. The proposed rule would add language to specifically exclude from the scope of § 50.59 changes to procedures where other more specific requirements and criteria have been established by regulation for controlling these

[3] Section 50.54(p) establishes change control requirements for safeguards contingency plans. While these plans are part of the application submitted pursuant to §50.34, they are not part of the FSAR, and thus §50.59 would not apply to these plans.

changes (e.g.,for information required by § 50.34(b)(6)(ii) and (v)), through a provision in the §50.59(c)(1) of the proposed rule.

The proposed definition for "procedures as described in the final safety analysis report (as updated)" is as follows:

Procedures as described in the final safety analysis report (as updated) means information in the final safety analysis report (as updated) regarding how systems, structures and components are operated and controlled (including assumed operator actions and response times), including assumed operator actions and response times, and information on conduct of operations.

D. Tests and Experiments not Described in the Safety Analysis Report

Section 50.59 also discusses the conduct of tests or experiments not described in the safety analysis report. "Test" is, of course, subject to many meanings including both routine verifications of function, and also more unusual evolutions. In the former category, there are many tests that are conducted that are not explicitly described in the SAR. For example, a licensee conducts tests of component and system performance that verify the SSCs perform the functions as described or required. (Performance of tests is typically controlled by procedure.) However, there also may be tests of new materials or means of plant operation that may put the plant in a situation that has not been previously evaluated and that could affect the capability of SSC to perform their required functions. The existing rule was designed to ensure that the latter type of tests would be reviewed before they were conducted. Therefore, to assure that there is clear definition with respect to the tests that are subject to prior NRC review and approval before they are conducted, the Commission proposes that a definition of "tests and experiments not described in the safety analysis report" be provided in §50.59 as follows:

> *Tests or experiments not described in the final safety analysis report (as updated)* means any activity where the reactor or any of its systems, structures, or components are used or controlled in a manner which cannot be shown to be within (i) the controlling parameters of their design bases as described in the final safety analysis report (as updated) or (ii) consistent with the analyses in the final safety analysis report (as updated).

E. Safety Analysis Report

In developing the proposed rule changes, the Commission noted the varying references to the safety analysis report within related sections of Part 50. For example, in §50.59, the phrase used is "safety analysis report," in §50.66, the reference is to the "updated final safety analysis report;" and § 50.71(e) refers to the updated FSAR. (Other sections and parts generally refer to the final safety analysis report (e.g. Part 55), but this is not universally true (e.g. §50.54(a)). For purposes of §50.59, "safety analysis report" refers to the current revision of the FSAR, so that the changes are evaluated against the most complete and accurate description of the facility. When performing evaluations, a licensee needs to consider changes already made for which the FSAR update has not yet been submitted to the NRC. The Commission emphasizes the need for as current a reference base as possible for §50.59 evaluations, in order that the evaluations appropriately consider other changes already made that may have impacted the facility or procedures. However, a licensee is not required to submit an update to its FSAR in the form specified by § 50.71(e) except at the required frequency. To enhance consistency, the Commission is proposing to revise the rule language in these sections to add a definition of the final safety analysis report (as updated) and to clarify in the evaluation criteria that evaluations need to account for changes made through other processes that have not yet been included in an update to the FSAR. The Commission did not use "Updated FSAR" for this purpose in order to take into account two special circumstances: (1) nonpower reactors, who are not required to submit updates to the FSAR, although they still need to consider other changes previously made when performing § 50.59 evaluations, and (2) a plant licensed to operate, during the period between initial licensing and the first update. This revision is reflected in the definitions in the earlier sections and in the following sections. The definition also refers to "Final Hazards Summary Report," which is the applicable document for some early plants whose application was submitted before the regulatory term "safety analysis report" was adopted.

The proposed definition is as follows:

Final safety analysis report (as updated) means the final safety analysis report (or Final Hazards Summary Report) submitted in accordance with § 50.34, as amended and supplemented, and as modified as a result of changes made pursuant to § 50.59 and § 50.90, and, as applicable, § 50.71(e) and (f).

F. Probability of Occurrence or Consequences of an Accident or Malfunction of Equipment Important to Safety Previously Evaluated in the Safety Analysis Report may be Increased

The current language of the rule states that an unreviewed safety question exists when the probability of occurrence or consequences of an accident or malfunction of equipment important to safety previously evaluated *may be* increased [emphasis added]. Many of the concerns with current implementation relate to the appropriate interpretation of the words "probability of occurrence... or consequences... may be increased." In the draft NUREG-1606, the NRC staff stated that the plain reading of the words would mean that uncertainty about whether there has been an increase must lead to the conclusion that the criterion is met. As a result of trying to deal with the question of uncertainty, licensees were placed in the position of having to prove there could not be an increase, even when there was no reason to believe that the proposed change, test or experiment would have that effect. A similar problem was experienced in considering whether the possibility of an accident or malfunction of a different type *may be* created.

Many of the commenters on the staff's proposed positions viewed this as overly restrictive and stated that it would result in many changes requiring prior NRC approval that are below the level of significance warranting such review. The position espoused in the revised industry guidance document (NEI 96-07) is that an increase in probability or consequences must be discernable in order for approval to be needed. The Commission concludes that the plain reading of the existing rule language is not consistent with this interpretation.

Although the current rule language would not permit discernable increases in probability or consequences, the Commission has concluded that at minimum, this would be a reasonable standard for requiring prior approval of changes, tests or experiment for increases in probability of occurrence of an accident or malfunction. The existing rule language dates from early in the development of reactor regulation, whère with the knowledge base at the time, the then-AEC found it appropriate to set a very low threshold for changes. Over the last thirty years, the Commission has garnered experience with implementation of § 50.59 and insights from probabilistic risk assessments, both of which indicate that this threshold can be adjusted without adversely impacting safety. Further, the analytical capabilities to calculate probabilities have greatly advanced, such that the effect of even minor changes on probabilities can be evaluated. Therefore, the Commission proposes to revise existing paragraph § 50.59(a)(2)(i) of the rule by replacing "may be increased" with "would result in more than a minimal increase," in order to provide that there must be a clearly discernable change to require approval, the "minimal increase" concept is described in the next section. As noted above, the (a)(2) paragraph would be broken into four statements and renumbered as (c)(2)(i) through (iv).

G. More than a Minimal Increase in Probability or Consequences

The Commission notes that § 50.59 permits changes that do not otherwise require approval (such as would be the case if the provisions being changed are in TS or license, quality assurance or emergency plans, or inservice inspection and testing programs). Because the information being revised is of less immediate importance to public health and safety, and in consideration of the conservatisms in NRC design and analysis requirements, acceptance criteria, and the precision with which safety analyses are performed, "minimal" variations in probability of occurrence or consequences of accidents and malfunctions should not affect the basis for the licensing decision. This conclusion is based upon the qualitative consideration of probability during plant licensing; accident probabilities were assessed in relative frequencies; equipment failures were generally postulated to gauge the robustness of the design, without estimating their likelihood of occurrence. Therefore, minimal increases in probability could not even have been identifiable, and could not impact the conclusions reached about acceptability of the facility design. Radiological consequences for accidents are calculated and reported at a level of precision such that minimal increases also would not impact the safety determination. The Commission therefore concludes that the proposed criteria would provide reasonable assurance that those changes that would affect the NRC's basis for licensing would be identified as requiring NRC approval before implementation. The revised criteria would also provide some degree of flexibility for licensees to make changes with smaller impacts without the need to obtain a license amendment.

On the other hand, the Commission intends to limit the amount of increase in probability or consequences of accidents such that it remains substantially less than a "significant increase" as referred to in § 50.92 (in accordance with § 50.92, a license amendment involving a significant increase in the probability or consequences of an accident previously evaluated involves a "significant hazards considerations;" any hearing for an amendment constituting a "significant hazards consideration" must be completed prior to the grant of the amendment.) The standard in the proposed rule is qualitative (probability or consequences no more than minimally increased). The intent of this proposed rule is to allow changes that are small enough that they would not affect the facility's licensing basis, or adversely affect safety performance. While the proposed rule would allow minimal increases, licensee still must meet applicable regulatory limits and other acceptance criteria to which they are committed (such as contained in Regulatory Guides, etc.) Because the "more than minimal" standard allows for there to be a discernable increase, NRC needs to establish a point beyond which one would conclude that the increase is not minimal. The following guidance is offered, including values as to when the Commission would conclude that the revised criteria are not met. Quantitative calculations are not required except for those instances in which a licensee offers other than qualitative arguments as part of its evaluation.

Probability of occurrence of an accident

The current guidance in NEI 96-07 states: "Where a change in probability is so small or the uncertainties in determining whether a change in probability has occurred are such that it cannot be reasonably concluded that the probability has actually changed (i.e. there is no clear trend towards increasing the probability), the change need not be considered an increase in probability." The Commission believes this satisfies the proposed NRC standard.

In order to be considered as a minimal increase, the resulting probability (considering the change, test or experiment) must still satisfy the event frequency classification provided in the licensee's FSAR (as updated), e.g., for an anticipated operational occurrence (expected once a year) or for a design basis accident (not expected during life of plant, but sufficiently credible to require mitigation).

Probability of equipment malfunction

The Commission believes that the probability of malfunction is more than minimally increased if a new failure mode as likely as existing modes is introduced. The determination should be made either at the component level, or consistent with the failure modes and effects analyses, taking into account single failure assumptions, and the level of the change being made.

Guidance in NEI 96-07 states: "Where a change in probability is so small or the uncertainties in determining whether a change in probability has occurred are such that it cannot be reasonably concluded that the probability has actually changed (i.e. there is no clear trend towards increasing the probability), the change need not be considered an increase in probability." The Commission believes this satisfies this criterion.

The probability of malfunction of equipment important to safety previously evaluated in the FSAR (as updated) is no more than minimally increased if "design bases" assumptions and requirements are still satisfied [i.e., the seismic or wind loadings, qualification specifications, procurement requirements]. As part of this guidance, note that NRC concludes that licensees can treat changes in external hazard design requirements as potentially affecting equipment malfunction probability rather than as "accident probability."

<u>Consequences of accident or malfunction</u>

Guidance in NEI 96-07 states: "Where a change in consequences is so small or the uncertainties in determining whether a change in consequences has occurred are such that it cannot be reasonably concluded that the consequences have actually changed (i.e. there is no clear trend towards increasing the consequences), the change need not be considered an increase in consequences." The NRC believes this satisfies the revised NRC standard.

If a licensee has performed an analysis with certain bounding assumptions, and the change would increase a specific parameter from its present value to a different value that is still bounded by the value assumed in the analysis, NRC concludes that such a change satisfies the criteria of no more than a minimal increase in consequences.

As a quantitative measure, the Commission is considering some options. One would be to establish that a 0.5 rem increase in calculated dose as a result of the change be used to assess whether a minimal increase has occurred. This range of change would generally be in the decimal place for accident analyses where doses are reported in rem. The facility must still satisfy applicable acceptance values (e.g., the SRP) or regulatory requirements (e.g., Part 100) for the particular accident. If a licensee would need to change its design basis assumptions or analytical methods, or both, to demonstrate that the change in consequences is less than 0.5 rem, then the NRC does not view the change as minimal and would expect the licensee to submit a license amendment for such a change.

In addition, the Commission is considering a graduated approach, consistent with the concept of "minimal" being small enough so as not to impact the basis for acceptability. When the facility is far from the limit, a larger increase can be accommodated without concern about impact on the basis for acceptability. The values proposed take into account such factors as differences between licensee calculated values and staff estimation of existing performance, potential for a single change with a large increase, or for several "minimal" increases to approach the regulatory limits. The specific proposal offered for comment is:

Example using 300 rem thyroid dose as the limit

Existing calculated dose	"minimal" change	pre-change	after the change
<50% of limit	≤10% increase	140 rem	170 rem
≤80% of limit	≤5% increase	205 rem	220 rem
more than 80%	≤1% increase (NTE limit)	245 rem	248 rem

A third option under consideration, similar to option 2, would limit the fraction of remaining margin that can be consumed by a particular change. By defining "minimal" as being 10% of the remaining margin between current conditions and acceptance guidelines, the amount of change would decrease as the limit is approached, and the limit could not be exceeded.

Cumulative Effect

The Commission is concerned about the cumulative effect of minimal increases. Since some increases are allowed, the Commission believes that the proposed process would place greater importance on: (1) complete and accurate SAR updating; (2) the licensee's evaluation process taking into account other changes made since last update; (3) the licensee's screening process examining plant changes to determine whether they are indeed changes requiring evaluation; and (4) reporting requirements so that staff can assess the ongoing nature of cumulative impact.

The issue then becomes how the NRC can best oversee the process such that several "minimal" changes do not result in unacceptable results. The Commission has decided to require licensees to report effects of changes in a different manner to facilitate evaluation of cumulative effect, as discussed in a later section on reporting requirements, in which the Commission proposes to require that the SAR update in accordance with § 50.71(e) discuss the effects of the changes upon calculated doses and other information.

H. Possibility of an Accident of a Different Type from any Previously Evaluated in the Safety Analysis Report may be Created

As noted in Section F above, the uncertainty connected with demonstrating that no accident or malfunction may have been created is a major source of confusion and difficulty in implementing the existing rule; and is unnecessary for purposes of identifying when NRC review of a change is needed. Accordingly, the Commission proposes that the language in existing § 50.59(a)(2)(ii) be revised as discussed below in this section and the following one. As noted earlier, the Commission is proposing to separate the requirements into distinct criteria for clarity. This criterion would now read "if a possibility for an accident of a different type from any previously evaluated in the final safety analysis report (as updated) is created." Under the proposed rule, a license amendment would be needed only if the licensee reasonably concluded that the possibility of an accident of a different type is created. This contrasts with the current rule, which would require a license amendment if the licensee is uncertain or unable to reasonably conclude that a new accident of a different type is not created. The Commission concludes that this proposed rule change will still identify those proposed changes, tests, or experiments that the NRC should review, without also including other changes of lesser significance that may be viewed as meeting the existing criteria.

Need for Definition of Accident

In determining whether a proposed change requires prior NRC approval under section 50.59, the rule refers to whether "accidents" previously evaluated in the SAR are impacted, or whether an accident of a different type may be created (see also section 50.92 criteria for "no significant hazards consideration)". Those accidents evaluated in the SAR, that is, those events that a plant must show that it can withstand, are derived from a number of regulatory requirements, and the safety analyses are included in the FSAR.

The regulations and NRC guidance documents, refer to "a design basis accident" (section 50.36), to design basis events (section 50.49), to loss-of-coolant accidents (Appendix A), to anticipated operational occurrences (Appendix A) and to accidents that could result in release of significant quantities of radioactive fission products (Part 100). The PSAR, and by extension the FSAR, pursuant to section 50.34, is to contain "analysis and evaluation of the design and performance of SSC of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of (i) the margins of safety during normal operations and transient conditions anticipated during the life of the facility and (ii) the adequacy of SSC provided for the prevention of accidents and the mitigation of the consequences of accidents.." RG 1.70 states that the FSAR is to include postulated anticipated operational occurrences; postulated off-design transients that induce fuel failures above those expected for normal operational experience, and design basis accidents. The Standard Review Plan for Chapter 15, refers to anticipated operational occurrences and to postulated accidents, and also to "transients and accidents" (the SRP notes that other events, such as response to external phenomena, are covered in other chapters).

Design basis accident(s) has been used in regulatory practice both singularly and generally. The regulations also include the concept of a design basis accident (DBA), for purposes of evaluating siting, which is an assumed fission product release, based upon a major accident that would result in potential hazards not exceeded by those from any accident considered credible. Such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products. The set of "accidents" that a plant must postulate for purposes of FSAR design and safety analyses, including LOCA, other pipe ruptures, rod ejection, etc., are often referred to as "design basis accidents".

The terms of accidents and transients are often used in regulatory documents (as for example in Chapter 15 of the Standard Review Plan), where transients are viewed as the more likely, low consequence events and accidents as more serious. In the context of probabilistic risk assessment, transients are typically viewed as initiating events, and accidents as the sequences that result from various combinations of plant and safety system response.

However, the meaning of the term "accident" as it is used more generally in Part 50, is somewhat obscured by the use of the term "design basis event." In section 50.49, design basis event is defined as:

> normal operations including anticipated operational occurrences, design basis accidents, external events, natural phenomena (earthquakes, tornados, hurricanes, floods, tsunami and seiches), for which the plant must be designed to ensure safety-related functions.

In view of the range of language presently used to describe the types of events evaluated as part of the licensing basis, the Commission is contemplating the need to clarify its intent as to the extent of events that are within the purview of the criteria in § 50.59 and in §72.48). For purposes of stimulating discussion, the Commission offers two proposals. One would be to set forth a definition for the term "accident" as follows:

> an initiating event or combination of events and/or conditions that could occur from equipment failure, human error, natural or manmade hazards which challenges the integrity of one or more fission product barriers (fuel, reactor coolant system, release of radionuclides (confinement/containment)), required to be analyzed and/or accounted for by the Commission and addressed in the licensee's safety analysis report.

Such a definition would make it clear that the Commission's intent in referring to "accidents" in § 50.59 (and in §72.48) is to refer to the design basis accidents that are addressed in the SAR. The second approach is to add the phrase "design basis accident" into the existing criteria. This could be done for each of the three criteria that refer to "accident" or just for the one on accident of a different type. Since the criteria on probability and consequences also contain language about "previously evaluated in the SAR," there may be less need for a reference to "design basis accident" in these criteria. The proposed rule language includes use of the phrase "design basis accident" in the one criterion, for purposes of obtaining public comment.

I. Possibility of a Malfunction of a Different Type from any Previously Evaluated in the Safety Analysis Report may be Created

In a similar fashion, the Commission proposes to modify the remaining part of existing

§ 50.59(a)(2)(ii), concerning malfunctions of a different type by creating a new criterion that would read "if a possibility for a malfunction of equipment important to safety with a different result than any evaluated previously in the final safety analysis report (as updated) **Is** created." This criterion involves three revisions to the existing rule. The first change is the use of the phrase "is created" which would require a determination that the possibility has been created, rather than uncertainty as to exclusion.

The second change is to insert the words "of equipment important to safety." The existing rule does not provide this characterization within paragraph (ii), but it is included in paragraph (i). It has generally been inferred that the statement in paragraph (ii) is an abbreviated version of that in paragraph (i). A review of the history of the 1968 rulemaking adopting revisions to Section 50.59 did not disclose any discussion suggesting that the Commission intended to distinguish between the (a)(2)(i) and the (a)(2)(ii) criteria with respect to the scope of equipment covered. Therefore, the Commission concludes that the rule was intended to apply to the same scope of equipment in each cases, and therefore, proposes to include the words in this criterion to eliminate any doubt.

The final change is being proposed in response to the comments on the staff-proposed guidance (NUREG-1606) on the interpretation of malfunction (of equipment important to safety) of a different type. The commenters believe that the cause of the malfunction should be a consideration in determining whether the probability of the malfunction may have increased, and that a malfunction of a different type would only be created if the effects of the malfunction are not already bounded by the FSAR analysis. The recent industry guidance states that if a component were subject to failure from a new failure mode but the failure of the component is already considered in the safety analysis, then there would not be a failure of a different type.

The Commission does not agree that the industry interpretation is consistent with the rule as written, which refers to creation or possibility of a malfunction of a different type, not of a different result. However, the Commission recognizes that in its reviews, equipment malfunctions are generally postulated as potential single failures to evaluate plant performance; thus, the focus of the NRC review was on the result, rather than the cause/type of malfunction. Unless the equipment would fail in a way not already evaluated in the safety analysis, there is no need for NRC review of the change that led to the new type of malfunction. Therefore, as the third change in § 50.59(a)(2)(ii), the Commission is proposing to change the phrase "of a different type" to "with a different result". Therefore, this criterion would read: "if a possibility for a malfunction of equipment important to safety with a different result ...is created."

In implementing this position, attention must be given to whether the malfunction is evaluated at the component level or the overall system level. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and resulting event initiators or mitigation impacts, it also needs to consider the nature of the change. Thus for instance, if failures were previously postulated on a train level because the trains were independent, a change that introduces a cross-tie might need to be evaluated to see whether new outcomes have been introduced. The staff has provided guidance on this issue in Generic Letter (GL) 95-02, concerning replacement of analog systems with digital instrumentation. The GL states that in considering whether new types of failures are created, this must be done at the level of equipment being replaced -- not at the overall system level. Further, it is not sufficient for a licensee to state that since failure of a system or train was postulated in the SAR, any other equipment failure is bounded by this assumption, unless there is some assurance that the mode of failure can be detected and that there are no consequential effects (electrical interference, materials interactions, etc), such that it can be reasonably concluded that the SAR analysis was truly bounding and applicable. Otherwise, the Commission would conclude that there was increase in probability of malfunction or that a malfunction with a different result has been created.

J. Margin of Safety as Defined in the Basis for any Technical Specification is Reduced

Two criteria in the current regulations (§ 50.59) specifically focus upon accidents and equipment malfunction (creation, consequences and likelihood) as the measures for determining when a change requires prior NRC approval. However, the phrases "margin of safety" and "as defined in the basis for any technical specification" in the third criterion have been the subject of differing interpretations because the rule does not define what constitutes a margin of safety or a basis for any technical specification in the context of §§ 50.59 and 72.48. In addition, some have questioned the need for the third criterion on "margin of safety."

The Commission has under consideration a number of proposals on margin. In the proposed rule text specifically being offered for comment, one option has been inserted so that commenters can examine the relationship of this aspect of the proposed rule to other changes being offered. This should not be viewed as meaning that this option is preferred by the Commission. The range of options under consideration is discussed in more detail below.

Questions of margin are commonly judged in terms of the degree of confidence that the response of the facility, or of particular SSC, to postulated challenges is acceptable. Various margins exist in a facility design. These margins are based on, for example, assumptions of initial conditions, conservatisms in computer modeling and codes, allowance for instrument drift and system response time, redundancy and independence of components in safety trains, and plant response during operating transient and accident conditions. Margin to conditions that might be detrimental to safety is also determined by establishing acceptance criteria to be met for response to various accidents and transients. Acceptance criteria are established at a value that accounts for uncertainty about physical properties and other variability and thus provides margin to unacceptable plant conditions. Margins are built into the facility to account for routine plant fluctuations and transients. Margins are also built into the plant to establish the regulatory envelope within which a plant has demonstrated its ability to respond to a spectrum of design basis accidents. It is in this category termed the "regulatory envelope," that the NRC believes that regulatory oversight of changes in margin may be needed from the standpoint of § 50.59. Thus the Commission notes that not all margins fall within the purview in which changes to the margin require prior NRC approval. As part of this rulemaking, the Commission wants to clarify which margins fall within the regulatory envelope and how possible reductions in margin resulting from facility or procedure changes, or from conduct of tests and experiments should be evaluated.

In defining in the rule a standard for NRC review and approval of changes to margins in the regulatory envelope, the Commission may want to preserve the NRC's ability to review changes when there is a potentially significant reduction in a margin of safety[4], but clearly would not want to unduly affect licensee operations. Therefore, for this proposed rulemaking, the Commission is offering the public the opportunity to comment on a range of options for treating margin. Commenters are requested to present opinions about the merits, or concerns about the specific proposals, or both, and also to offer any other suggestions for wording.

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[4] In accordance with 10 CFR 50.92(c)(3), license amendments involving a significant reduction in a margin of safety do not meet the criteria for a "no significant hazards consideration" determination; thus, changes involving a significant reduction in a margin of safety are not to be performed under 10 CFR 50.59.

Option 1: Control inputs to analyses and methods that establish TS

The Commission believes it is reasonable to interpret the specific reference to "basis for any technical specification" in the 1968 rulemaking that added the "margin of safety" criterion as preserving the margins in the analyses that established the TS requirements. For instance, the minimum plant performance conditions and configurations stated in the TS are the limiting conditions for operation, limiting safety system settings, and safety limits. Margins of safety exist within the safety analyses as a result of the specific input assumptions, methods, or other limits that were used. These parameters and methods were proposed by the licensee and reviewed by NRC to account for uncertainties, instrumentation response, and ranges of possible operating conditions. Because §50.59 requires prior NRC approval for a change to the TS, a change that could invalidate the basis upon which the TS values were established should also receive prior approval. In accordance with this interpretation, changes that invalidate these specific conditions described in the FSAR for analyses that established the TS requirement (such as a limiting condition of operation, or a limiting safety system setting) would reduce the margin of safety associated with the TS.

Under this option, the Commission would conclude that the analyses and information in the FSAR establish the basis for the margins of safety for the TS. Thus, the Commission would propose to add a definition for "reduction in margin of safety associated with any technical specification" and to conform the criterion for needing a license amendment in new Section 50.59(c)(2). The existing terminology of "basis for any TS" would be replaced by "associated with any TS."

The following definition would be added:

Reduction in margin of safety associated with any technical specification means that the input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the final safety analysis report (as updated), that established any technical specification requirement, are altered in a nonconservative manner.

Although this option would maintain the safety analyses that underlie the TS, this approach would also have the effect of giving input values and assumptions the weight of TS, which is inconsistent with the philosophy in § 50.36 of establishing TS only on those values of most immediate safety importance. In many instances, changes to inputs can be accommodated by other available margins so that the licensing envelope is preserved.

Option 2: Delete "margin of safety" as a criterion.

Under this option, the Commission would delete any criterion focusing upon margins. Instead, the Commission would rely upon the other criteria in § 50.59, as well as the regulatory requirement that all changes to TS be reviewed and approved by the NRC, to assure that there are no significant adverse changes to margins in design and operation. The Commission would argue that there is no need for prior review of changes that do not satisfy any of the other evaluation criteria in view of "risk-informed" insights and greater understanding of the margins that exist through meeting the body of regulatory requirements. The Commission seeks comment on whether any of the other evaluation criteria should be revised were this approach to be adopted.

Option 3: Control margins associated with results of analyses

Instead of focusing on the inputs to safety analyses, another interpretation would be to examine the results of the safety analyses, and to determine whether changes to operational characteristics or other information described in the FSAR (as updated) would reduce the level of protection afforded by the TS (i.e., by the limiting safety system settings and limiting conditions of operation), as reflected in the results of safety analyses.

As part of the licensing review for a facility, the NRC established a level of required performance (which will be referred to in this discussion as acceptance criteria) for certain physical parameters, such as those that define the integrity of the fission product barriers (fuel cladding, reactor coolant system boundary and containment). Satisfying these acceptance criteria (or regulatory limits) produces a margin of safety to loss of barrier integrity. The safety analyses presented in the FSAR (as updated) demonstrate that the response of the barriers to the postulated accidents, transients, and malfunctions meets the acceptance criteria. For certain of these parameters, TS safety limits have been established; these safety limits are limits upon important process variables that are found necessary to reasonably protect the integrity of physical barriers that guard against the uncontrolled release of radioactivity.

However, for other parameters, a licensee must determine the licensing basis of the parameter in question by reviewing the plant-specific safety analyses. The acceptance criterion is that value approved by the NRC for a particular parameter or process variable (e.g., ASME Code stress limits, a departure from nucleate boiling ratio limit or maximum critical power ratio limit or containment design pressure). These acceptance criteria may be stated in the FSAR, may be in NRC regulations, or may be presented in the NRC Standard Review Plan.

(Note: This approach may require some licensees to revise their FSAR to accurately describe the regulatory values for the set of critical parameters. For example, licensees would need to identify the expected operating or design values and then specify the minimum performance capabilities for the related parameters, which cannot be modified with NRC review).

In constructing the requirements for controlling margin through consideration of results of analyses, there are three aspects to take into account: (a) which results/parameters are to be controlled through the § 50.59 process, (b) the degree of change to be allowed without review, and (c) how the changes should be evaluated in demonstrating that the criterion is satisfied. In the sections below, these three aspects are separately discussed in order to amplify upon the issues under consideration. However, any rule language option would need to include some provision for each of the three aspects.

(a) Which parameters should be controlled?

The margins of safety that would be controlled by the 10 CFR 50.59 process can be characterized in different ways.

<u>OPTION 3(A)(1) - Safety and regulatory limits</u>

The margin between regulatory limits and the failure of physical barriers is protected in the regulations (and also in the portion of the Technical Specifications (TSs) called "safety limits"). The margin, as reflected in approved safety and accident analyses, between the protection afforded by the TSs (e.g., the limiting safety system settings and limiting conditions of operations) and the associated regulatory limits is a possible interpretation as to "the margin of safety as defined in the basis for any TS", which would be subject to the 10 CFR 50.59 evaluation process. Thus, one proposal under consideration would be to define "margin of safety" as follows:

> The "margin of safety as defined in any technical specification" (margin of safety) is the amount (quantitative or qualitative) of margin between the operation of the facility as described in the technical specifications and the exceedance of safety limits listed in the technical specifications or other regulatory limits. In relation to accident analysis, the margin of safety is typically the difference between calculated parameters (e.g., peak fuel clad temperature, maximum RCS pressure, etc.) and the associated regulatory or safety limit. The margin of safety is a product of specific values and limits contained in the technical specifications (which cannot be changed without NRC approval) and other values, such as assumed accident or transient initial conditions or assumed safety system response times, which are not specifically contained in the technical specifications. Any change to the values not specifically contained in the technical specifications must be evaluated for impact on the margin between the calculated result of an accident or transient and the safety or regulatory limit.

With this option, before changing operational characteristics described in the UFSAR (not directly controlled by TS), a safety evaluation must be performed to determine, among other things, if the change results in a reduction in the level of protection afforded by the TS [margin of safety as defined in any TS]. Such a reduction would typically occur only if the operational characteristic had been used as a bounding condition in the analysis upon which the selection of TS was based, or in analysis where the acceptability of selected TS values was demonstrated. Licensees could make desired changes to operational characteristics without prior NRC approval, provided that the change does not result in accident analysis results that are nearer the regulatory, or safety, limits than the corresponding results that the NRC used in evaluating the acceptability of the TS during licensing of the facility.

OPTION 3(A)(2) - Fission product barriers - definition

The NRC notes that § 50.36 (requirements for Technical Specifications) has criteria for when TS are to be provided that specifically are tied to design basis accident or transient analysis that either assumes the failure of or presents a challenge to the integrity of a fission product barrier. Thus, the margin as defined in the basis for any TS can be reasonably viewed as that margin associated with preserving integrity of these barriers. Therefore, the NRC is also considering a more explicit linkage to the response of the three fission product barriers generally relied upon to provide protection from uncontrolled release of radioactive materials from a reactor facility. Under such a proposal, the text of the rule would explicitly state that it is the response of fission product barriers (fuel, reactor coolant system, and containment) to accidents, transients, and malfunctions that is being controlled.

The following could be given as a definition of margin of safety and of fission product barrier response. Regulatory guidance would explicitly list the parameters (for PWRs and BWRs) that are to be controlled.

> The margin of safety for any fission product barrier response is the difference between the calculated value and its associated acceptance criteria.

Fission product barrier response means those parameters that must be satisfied in the event of postulated design basis events to demonstrate integrity of the fuel, reactor coolant system and containment system barriers.

The following parameters would be included: Fuel and cladding performance (peak cladding temperature, or energy deposition, DNBR or MCPR, oxidation), RCS performance (pressure, flows, stress), and containment performance (peak pressure, containment leakage).

<u>OPTION 3(A)(3) - Specified parameters</u>

A variant on the previous option would be to actually list the parameters of interest directly in the criterion for prior review, as for instance, the criterion could read:

(vii) Result in a change to the FSAR (as updated) calculated value of RCS peak pressure, containment peak pressure, or fuel performance (DNBR/MCPR, others), etc.

This variant has the advantage of being more precise, but the rule language would need to be crafted to account for various reactor types.

<u>OPTION 3(A)(4) - Include mitigation capability</u>

The Commission is interested in preserving the integrity of both prevention and mitigation capabilities available in the plant, and is therefore considering an option that would include both features within the "margin" criterion if the margin criterion is maintained. If this approach were adopted, the definition or the list of parameters would be supplemented with the performance parameters for the accident mitigation capability of the plant, as for instance, ECCS performance (pressures, flows, actuation values), engineered safety feature performance (flows, pressures, spray effectiveness, system efficiencies).

Finally, in conjunction with any of these approaches, the Commission is also considering whether there are other parameters important to preservation of barriers that should be explicitly defined. For instance, for fuel stored in spent fuel pools, or for the reactor during periods of shutdown or refueling, there may be other analysis results (water level, pool temperature) in lieu of reactor coolant system pressure. Therefore, the Commission seeks input as to whether there are other parameters of interest beyond those previously offered that should be included within the "margin of safety" criterion if that criterion is maintained, and how should the rule language be revised to specify what those parameters might be.

(b) Determination of reduction in margin requiring review

Once the parameters of interest are determined, it is also necessary to define when a reduction in margin warranting NRC review and approval has occurred. The Commission is evaluating options ranging from any "nonconservative change in calculated values," to a "minimal change" standard, and ultimately an option that would allow increases up to "specified limits (acceptance criteria)" for those parameters that may be established in the regulations or NRC guidance (such approaches to the limits might be controlled in a graduated fashion as was discussed in the section of this notice relating to "minimal increases"). An option for the degree of reduction would be paired with an option (such as one of those listed in (a) above) to provide the text of the rule.

OPTION 3(B)(1) - No reduction

One approach would be require that the safety analysis, considering the effect of the change, must show that the accident analysis results are not nearer to any safety or regulatory limit, thus, a "no reduction in margin" standard. Possible rule text:

> Changes, or the net effect of multiple changes, which result in a reduction in the margin of safety require prior NRC approval. Changes, or the net effect of multiple changes, which do not cause a reduction in the margin of safety do not require prior NRC approval.

OPTION 3(B)(2) - Minimal amount - definition of margin reduction

As discussed in other sections of this notice, the Commission concludes that the revised rule should allow licensees some flexibility in making changes, through development of a "minimal increase" standard. In considering margins, the Commission is thus weighing how such a concept could be applied. One option would be that NRC approval would be required for a change, test, or experiment if the output values (calculated in the SAR) are altered by more than a minimal amount. The "margin" criterion would be modified to state that a change in calculated result of "more than a minimal amount" would require prior review and approval. Either in the rule itself, or in guidance, the Commission would define "minimal amount", modeled upon the options offered for minimal increases in consequences (see section II.G. of this notice). For example, there could be a fixed amount (percent change) in margin, as long as regulatory limits are still met. If guidance itemizes the parameters, such guidance could also customize how "minimal" should be judged for each particular parameter (allowing greater amounts for certain parameters depending on precision of calculations, sensitivity of results and other considerations).

For instance, the definition of "margin of safety reduction..." might be stated as follows:

Reduction in margin of safety means that as a result of a change, the [MARGIN] is altered in a nonconservative manner by more than a minimal amount.

<u>OPTION 3(B)(3) - Minimal determined with respect to acceptance criteria (available margin)</u>

It is also possible to achieve this result by removing the language referring to margin of safety (and to TS), and defining "minimal" in the rule itself in terms of the results or analyses for barrier response, with respect to meeting the acceptance criteria for those barriers. For example, rule language could read as follows:

License amendment needed if as a result of a change, test or experiment :

(vii) there is more than a 10% reduction in the difference between the calculated value and the acceptance criteria for fission product barrier response to accidents evaluated in the SAR.

If such an approach is followed, the Commission would propose to include a definition of acceptance criteria, such as follows:

Acceptance criteria are those values, established by NRC regulation or review guidance, to which the licensee is committed through its FSAR (as updated), as the basis for acceptability of response to the postulated accident, transient or malfunction.

(c) Evaluation of effect of the change upon analysis results

The Commission also notes that the results of safety analyses are subject to variance depending upon the assumptions, analysis methods or analytical techniques used. In many instances, these factors were reviewed by the NRC during its licensing deliberations, and their use may have formed part of the basis for the conclusion that acceptable safety margins were demonstrated. Therefore, the Commission wishes to ensure that proposed changes by a licensee would not invalidate these conclusions by requiring a demonstration that the evaluation techniques and analyses are suitable.

To accomplish this, the Commission is considering having as part of whichever definition of "margin of safety reduction" is selected the following statement [Option 3(c)]:

> All analyses and evaluations for assessing the impacts of proposed changes must be performed using methodology and analytical techniques which are either reviewed and approved by the NRC or which are shown to meet applicable review guidance and standards for such analyses.

The alternative to this proposed language would be to rely upon a licensee's design control processes under their quality assurance requirements and program, to provide the assurance that any evaluative work has been conducted with methods and techniques commensurate with the safety significance of the analyses being performed.

IMPACTS FOR PART 72 CHANGES

Certain of the options discussed above may need to be modified for application to independent spent fuel storage facilities or spent fuel storage cask designs in Part 72. While the overall philosophy would be the same, the particular outputs or barriers that would be specified for reductions in margin would have to be defined in terms of the barriers against release of radioactivity afforded by fuel storage facilities. For instance, these might include calculated fuel temperature or cladding oxidation, and stresses (or pressures) on the cask structure. Comment is also requested on the appropriate parameters for facilities licensed under Part 72.

K. Safety Evaluation

Section 50.59(b)(1) requires licensees to maintain records that must include a written safety evaluation that provides the bases for the determination that the change, test, or experiment does not involve an unreviewed safety question. Section 50.59(b)(2) requires submittal of a report containing a brief description of any changes, tests, or experiment, including a summary of the safety evaluation of each. In the interest of emphasizing the regulatory purpose of the evaluation required under § 50.59, which led the Commission to propose deletion of the term "unreviewed safety question," the Commission proposes to delete the word "safety" in referring to the required evaluation for determining whether the change, test, or experiment requires a license amendment. For purposes of the summary report of tests and experiments submitted to NRC, the staff would propose that the rule specify that a summary of the evaluation be provided (rather than a summary of the safety evaluation).

A similar change is proposed for § 50.71(e), which presently refers to safety evaluations either in support of license amendments or of conclusions that changes did not involve USQs. The Commission proposes to change "safety evaluation in support of license amendments" to "safety analysis in support of license amendments," to reduce confusion between the information prepared by the licensee for the amendment (safety analysis) and the NRC review (safety evaluation). The second part of this phrase would be revised to refer to the "evaluation that changes did not require a license amendment in accordance with § 50.59(c)(2) of this part." (In this case, it is a licensee evaluation against the regulatory criteria in § 50.59 that is being referred to). In addition, other minor wording changes are proposed such as with respect to terminology on "final safety analysis report" and "effects of" (see reporting requirements discussion below). Conforming changes in the Appendices to Part 52 and in Part 72 to revise language to refer to "evaluation" are also proposed.

L. Reporting and Recordkeeping Requirements

In view of the "minimal increase" criteria in § 50.59, the Commission concludes that the reporting requirements for the SAR update should be enhanced to enable the NRC to better understand the potential cumulative impact of changes that might have been made since the last update. Therefore, the Commission proposes to supplement the reporting requirements on "effects" of changes to require that in the FSAR update submittal (with the replacement pages), the licensee shall include a description of each change affecting that part of the SAR that provides sufficient information to document the effect of the change upon the probability or consequences of accidents or malfunctions, or reductions in margin associated with that part of the SAR. Accordingly, the Commission proposes to revise § 50.71(e) to read as follows:

"(e) Each person licensed to operate a nuclear power reactor pursuant to the provisions of § 50.21 or § 50.22 of this part shall update periodically, as provided in paragraphs (e)(3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the operating license, to assure that the information included in the FSAR (as updated) contains the latest information developed. The submittal must describe the effects[1] of: (1) all changes made in the facility or procedures as described in the FSAR; (2) all safety analyses and evaluations performed by the licensee either in support of requested license amendments, or in support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2) of this part; (3) all analyses of new safety issues performed by or on behalf of the licensee at Commission request; and (4) the net effect of all changes made since the last update on the safety analyses, including probabilities, consequences, calculated values, system or component performance, that are in the FSAR (as updated). The updated information shall be appropriately located within the update to the FSAR.

[1] *Effects of* changes includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate."

Finally, the Commission is proposing a change to the record retention requirements in existing paragraph § 50.59 (b)(3) [renumbered by this rulemaking to (c)(3)]. The change would add to the requirement that the records of changes to the facility be maintained until the termination of the license, the statement "or until the termination of a license issued pursuant to 10 CFR Part 54, whichever is later." This change would make more clear the requirement that records must be maintained through the life of the facility so that they will remain available until such time as they are no longer needed (that is, when the license is terminated, not just at the end of the initial licensing term).

M. Part 72 Changes

In Part 72 the Commission is proposing to make conforming changes to § 72.48 with those made to § 50.59 and to expand the scope of § 72.48 so that holders of a Certificate of Compliance (CoC) are also subject to it. In addition to the proposed changes to § 72.48, the Commission proposes to make changes in other sections of Part 72. When Subpart L - Approval of Spent Fuel Storage Casks, was originally added to Part 72, no provisions were included to address potential amendments of CoCs. However, regulations in this area are necessary to provide requirements for certificate holders in instances where a proposed change does not meet the tests of § 72.48, and an amendment to the CoC is necessary. Therefore §§ 72.244 and 72.246 would be added to Subpart L, to provide regulations on applying for, and approving, amendments to CoCs. Section 72.248 would also be added to provide regulations for the certificate holder submitting an updated final safety analysis report, which would document the changes it made to procedures or structures, systems, and components under the provisions of § 72.48. The Commission notes that a general licensee is not precluded from loading spent fuel into an approved spent fuel storage cask during the 90-day period allowed for the certificate holder to submit a final safety analysis report. This approach is the same as that required for Part 72 license holders to update their final safety analysis report under § 72.70. The Commission also notes, that for dual-purpose spent fuel casks (i.e., casks which have been issued CoCs for transportation and storage under Parts 71 and 72, respectively), no regulation equivalent to § 72.48 exists in Part 71. Consequently, a certificate holder could make changes to the design of a spent fuel storage cask under the authority of § 72.48 (i.e., without prior NRC approval); however, if the change also affected the transportation aspects of the cask's design and involved a modification to the Part 71 certificate, then NRC approval and amendment of the transportation CoC would be required before the cask could be used to transport spent fuel to another site. Additionally, a transportation cask CoC has a term of 5 years, compared to the 20-year term for a storage CoC. Consequently, the Commission envisions that most of this type of change would be captured during the periodic renewal of a transportation CoC and this delay would not have a significant adverse impact on a licensee's ability to transport spent fuel in a dual purpose cask.

In § 72.3 the definition for *independent spent fuel storage installation* (ISFSI) would be revised to remove the tests for evaluation of the acceptability of sharing common utilities and services between the ISFSI and other facilities. The existing requirement in § 72.24(a) - Contents of application: Technical Information, would be revised to reference shared common utilities and services in the applicant's assessment of potential interactions between the ISFSI and another facility. The Commission would remove the existing requirement in § 72.3 for the applicant to evaluate the impact of sharing common utilities and services on the "other facility." The Commission believes that evaluation of the impact on the "other facility" should not be part of the licensing process for an ISFSI. Rather, such evaluation should be part of the license amendment process for that "other facility" and should be performed under the regulations used to license that "other facility."

Changes to § 72.56 would be conforming changes to those made to § 50.90. Changes to § 72.70 are also conforming changes to those made to § 50.71(e); additionally, requirements would be added to § 72.70 on standards for submitting revised Final Safety Analysis Report (FSAR) pages. The Commission notes that the proposed § 72.70 would retain the requirement that the site-specific licensee submit a final safety analysis report at least 90 days prior to the planned receipt of spent fuel or high-level waste. The Commission has not received any requests for exemption from this regulation and believes that this regulation does not impose an undue burden or schedule impact on licensees. The proposed rule also modifies the requirements for filing of updates (through reference to § 72.4) to be consistent with other changes being made to Part 72. Changes to § 72.216 for a general licensee are similar to the changes made to § 72.70 for a site-specific licensee and are also conforming changes to those made to § 50.71(e). The Commission also envisions that a general licensee who wishes to adopt a change to the design of a spent fuel storage cask it possesses--which was previously made to the generic design by the certificate holder under the provisions of § 72.48--would be required to perform a separate evaluation under the provisions of § 72.48 to determine the suitability of the change for itself. The changes to §§ 72.9 and 72.86 are conforming changes due to the addition of new §§ 72.244, 72.246, and 72.248.

Changes to Part 72 Record keeping requirements would include the clarification that records required by § 72.48 shall also include determinations that significant increases in occupational exposure or unreviewed environmental impacts did not exist, such that a license amendment would have been required. (The existing language linked the written evaluation only to the "unreviewed safety question" determination, and thus did not explicitly require Record keeping for the determinations of whether the change would cause a significant increase in occupational exposure or a significant unreviewed environmental impact).

Certificate holders would also be required to keep records of such changes as would be allowed under § 72.48.

Requirements in § 72.70 would be established for reporting changes to procedures. The Commission notes that § 72.70 presently requires that the update include[5] a description and analysis of changes in the structures, systems, and components with emphasis upon performance requirements; the bases, with technical justification therefor, upon which such requirements are based; and evaluations showing that safety functions will be accomplished. It also requires an analysis of the significance of any changes to codes, standards, regulations, or regulatory guides which the licensee has committed to meeting the requirements of which are applicable to the design, construction, or operation of the facility. New reporting requirements for certificate holders would be added in §§ 72.244 and 72.248, similar to existing requirements imposed on licensees in §§ 72.56 and 72.70, respectively. New reporting requirements for general licensees would be added as § 72.216(d), similar to existing reporting requirements for site-specific licensees in § 72.70 and proposed requirements for certificate holders in § 72.248. In both of these sections, the Commission is adding a requirement that the entity making a change to the cask, either the general licensee or the certificate holder, provide a copy of the submittal to the other party for their information.

[5] The similarity in the language between §§ 72.24 and 50.34(a) and between §§ 72.70 and 50.34(b)(2) is noteworthy.

III. SECTION BY SECTION ANALYSIS

10 CFR Part 50

10 CFR 50.59

As discussed in more detail above, § 50.59 would be restructured and revised to have the following components.

Paragraph (a) - This is a new paragraph that provides definitions of terms such as "change", "facility as described..," in order to specify more clearly which changes, tests and experiments require further evaluation and how reductions in margin of safety are to be determined. The references to "safety analysis report" are being revised to "final safety analysis report (as updated)" to state that the evaluations are to be performed that take into account other changes made that have affected the final safety analysis report since its original submittal.

Paragraph (b) - Relocation of existing applicability provisions.

Paragraph (c)(1) - Relocation of existing provisions establishing which changes, tests, or experiments require evaluation, using the defined terms. The terminology of "unreviewed safety question" has been replaced by referring to the need to obtain a license amendment. This paragraph also clarifies that the licensee must submit its request for license amendment, and obtain the amendment prior to implementing those changes, tests or experiments that involve TS or otherwise meet the criteria for prior NRC approval as specified in (new) paragraph (c)(2).

Paragraph (c)(2) - Reformatting of the evaluation requirements into seven distinct statements of the criteria and revision of the criteria for when prior NRC approval of a change, test or experiment is required. Specifically, language of "more than a minimal increase" was inserted in the criteria concerning increases in probability and consequences, and revisions to the rule requirements were made concerning creation of accidents of a different type and malfunctions of equipment with a different result. Clarification is also being provided that the margins of safety are those associated with TS requirements established by the FSAR analyses, and are not confined to the BASES section of the TS. These revisions clarify the criteria for when prior approval is needed and allow some flexibility for licensees to make changes that would not affect the NRC basis for licensing of the facility.

Paragraph (d)(1) - Renumbered paragraph with record keeping requirements. Also includes change from "safety evaluation" to "evaluation."

Paragraph (d)(2) - Renumbered paragraph with reporting requirements.

Paragraph (d)(3) - Renumbered and revised paragraph on retention of records, to cover the term of any renewed license.

<u>10 CFR 50.66</u>

The proposed changes for § 50.66 are to conform existing language referring to unreviewed safety questions, and references to updated final safety analysis report, to the language proposed in revised § 50.59 for consistency.

10 CFR 50.71(e)

The proposed changes to this section are to conform language with respect to unreviewed safety question, safety evaluation, and reference to final safety analysis report (as updated), with the proposed language in § 50.59, and to clarify reporting requirements relating to "effects of" changes such that cumulative effects of minimal increases in probability and consequences are included in the update to the FSAR.

10 CFR 50.90

A portion of existing § 50.59(c) would be relocated into this section. This change would place the requirements for changes to technical specifications in the rule section on amendments to licenses.

10 CFR PART 52

Appendix A and Appendix B to 10 CFR Part 52

The proposed changes to these sections are to conform references to unreviewed safety question, safety evaluation and the evaluation criteria concerning when prior NRC approval is needed, to the language in the proposed revision to § 50.59.

10 CFR PART 72

10 CFR 72.3

The definition for *independent spent fuel storage installation* would be revised to remove the tests for evaluation of the acceptability of sharing common utilities and services between the ISFSI and other facilities. (Section 72.24 is also proposed to be revised to include this evaluation).

10 CFR 72.9

Paragraph (b) would be revised as a conforming change to include in the list of information collection requirements the new reporting requirements in §§ 72.244 and 72.248 for reports of changes made by CoC holders and for updates to the safety analysis reports by CoC holders.

10 CFR 72.24

This section would be revised to reference shared common utilities and services in the applicant's assessment of potential interactions between the ISFSI and another facility (previously covered by § 72.3).

10 CFR 72.48

New definitions have been added for terms such as "change" and "facility as described in the Final Safety Analysis Report (as updated)." The specific criteria in existing paragraph (a)(2) have been revised to separate out the various statements, to insert the language of "more than a minimal increase," and to modify the criterion from "malfunction of a different type" to "malfunction of a different result." The text for Record keeping requirements was revised to refer to the need for license or certificate of compliance (CoC) amendments, rather than involving an unreviewed safety question. As part of this revision, the Commission is also clarifying that the records shall also provide a basis for why a proposed change, test, or experiment did not require a license or CoC amendment with respect to significant increases in occupational exposure or significant unreviewed environmental impacts. Additionally, the term "Final Safety Analysis Report (FSAR) (as updated)" has been used to provide greater clarity and consistency with § 50.59 and other sections of Part 72. The filing requirements for the summary reports are modified to be consistent with § 72.4 (Communications).

10 CFR 72.56

Existing § 72.48 (c)(2) is being relocated into this section. This is a parallel change to that proposed for § 50.59 and § 50.90, wherein the Commission would place the requirements for changes to license conditions in the rule section on amendments to licenses.

10 CFR 72.70

Paragraphs (a) and (b) would be revised to use the terms "Final Safety Analysis Report," "FSAR," and "as updated." Paragraph (b)(2) would be revised to add changes to procedures to the annual updates of the FSAR. New paragraph (c) would be added to provide requirements on submitting revisions to the FSAR.

10 CFR 72.86

Paragraph (b) currently includes those sections under which criminal sanctions are not issued. This paragraph would be revised by adding §§ 72.244 and 72.246 as a conforming change to reflect that certificate holders who fail to comply with these new sections would not be subject to the criminal penalty provisions of § 223 of the Atomic Energy Act (AEA). New § 72.248 has not been included in paragraph (b) to reflect that certificate holders who fail to comply with this new section would be subject to the criminal penalty provisions of § 223 of the AEA.

10 CFR 72.212(b)(4)

The change to this section is to conform the reference to 10 CFR 50.59 provisions, specifically to change from the terminology of unreviewed safety question to referring.to need for license amendment for the facility (that is, the reactor facility at whose site the independent spent fuel storage installation is located).

10 CFR 72.216

New paragraph (d) provides requirements for a general licensee to submit annual updates to a final safety analysis report (FSAR) for the cask or casks approved for spent fuel storage cask that are used by the general licensee. The general licensee is also required to provide a copy of its submittal to the certificate holder. This section is similar to the requirements in §§ 72.70 and 72.248 for submission of annual updates to the FSAR associated with a site-specific Part 72 licensee or a certificate holder, respectively.

10 CFR 72.244

This new section provides requirements for a certificate holder to submit an application to amend the certificate of compliance (CoC). This section is similar to the requirements in § 72.56 for licensees to apply for an amendment to their license.

10 CFR 72.246

This new section provides requirements for approval of an amendment to a CoC. This section is similar to the requirements in § 72.58 for approval of an amendment to a license.

10 CFR 72.248

This new section provides requirements for submittal of annual updates to a FSAR associated with the design of a spent fuel storage cask which has been issued a CoC. This new section also provides that the changes to procedures and structures, systems, and components associated with the spent fuel storage cask and which are made pursuant to § 72.48 would be included in the annual update. The proposed revisions would also require that the certificate holder provide a copy of the FSAR submittal to each general licensee using that cask. This section is similar to the requirements in § 72.70 for submission of annual updates to the FSAR associated with a site-specific Part 72 license and new section 72.216 for general licensees to provide updates to the FSAR.

IV. Commission Voting Record on SECY-98-171

The staff forwarded to the Commission a proposed rulemaking package on § 50.59 and related regulations in SECY-98-171, dated July 10, 1998. This document was placed in the Public Document Room on July 29, 1998. Subsequently, the Commission voted to approve issuance of a proposed rule for public comments with several additions and changes that are reflected in this notice. The Commission also directed that the record of their decision on SECY-98-171 be included as part of this notice to clearly inform stakeholders on preliminary positions taken by the Commission. The text of the resultant staff requirements memorandum and of the individual Commissioner vote sheets, is presented below.

COMMISSION SRM ON SECY-98-171, DATED SEPTEMBER 25, 1998

The Commission has approved publication, for a 60 day public comment period, the proposed rulemaking that would revise 10 CFR 50.59 and related provisions in Parts 50, 52 and 72 concerning the processes controlling licensee changes, tests and experiments for production and utilization facilities and for facilities for independent storage of spent nuclear fuel and high-level radioactive waste. The Voting Record, which includes the Commissioner votes and this Staff Requirements Memorandum, should be published in the Federal Register notice to clearly inform stakeholders on preliminary positions taken by the Commission [(Enclosed)].

The Commission also approves the staff's recommendations for handling violations of 10 CFR 50.59 and 72.48, including staff plans for exercise of enforcement discretion, while rulemaking is underway.

The Commission requested that the staff specifically solicit public comment in the Federal Register notice on:

1. A wide array of options for the margin of safety criterion (50.59(c)(2)(vii) in the proposed rule) and its definition including: a) deleting the criterion and definition, b) a new definition as described in Chairman Jackson's vote, and c) an option which would decouple the last criterion from technical specifications and focus instead on a new criterion relating to performance of fission product barriers (e.g., reactor coolant system pressure, containment pressure, etc), with minimal changes being allowed up to specified limits, perhaps utilizing a graduated approach similar to the approaches proposed for other criteria.

2. Options for defining "minimal" as it pertains to "probability of occurrence of an accident" or "probability of equipment malfunction."

3. The definitions of "facility," "procedures," and "tests or experiments," including

elimination of the definitions.

4. A clear definition of "accident."

(This action scheduled for completion October 9, 1998)

The Commission requests the staff to complete the revised 50.59 rule on an expedited schedule.

(This action scheduled for completion February 19, 1999).

All Commissioners approved in part and disapproved in part the proposed rulemaking on 10 CFR Parts 50, 52 and 72 requirements concerning changes, tests and experiments and staff recommendations on changes to other regulations and enforcement policy, and provided additional comments. In their vote sheets, all Commissioners approved the staff's recommendations to approve publication of the proposed rule for public comment, and use of the enforcement discretion guidance in its assessment of severity levels for violations while the rulemaking is underway, and provided some additional comments. In particular, all Commissioners disapproved the staff's proposed margin of safety criterion (50.59(c)(2)(vii) in the proposed rule) and its definition and each Commissioner provided an option for evaluation during the comment period. The Commissioners also specifically requested comments on a number of other issues. Because of the need to finalize this rule as expeditiously as possible and because SECY-98-171 has already been publicly available since July 29, 1998, the Commission agreed to a 60 day comment period, and that the staff complete the revised 50.59 rule by February 19, 1999. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on September 25, 1998.

Chairman Jackson's Comments on SECY-98-171

I approve, in part, and disapprove, in part, the staffs proposal for rulemaking. I approve the staff's proceeding with issuance of the proposed rule language for public comment in order to support the expedited finalization of a revision to these processes. I disapprove of the specific language proposed by the staff for Section 50.59(c)(2)(vii), "reductions in the margin of safety."

I agree with the recent letter from ACRS on this rulemaking, in that: 1) 10 CFR 50.59 can accommodate risk-informed decisionmaking. 2) the positions, as presented, on margin of safety may add regulatory burden without a commensurate safety benefit.

I disagree with ACRS in that I believe;

1) the rulemaking should go out for public comment to foster comment on this high priority issue, and
2) the regulatory guidance can be worked in parallel with the rulemaking.

I note that a further reason for issuing this package for public comment at this time is that the paper calls for the proper use of enforcement discretion as this rulemaking progresses, thereby providing further stability in the implementation of this rule in the industry.

Further, I propose that the SRM on this SECY, and the voting record, be placed in the FR notice to clearly inform stakeholders on preliminary positions taken by the Commission.

Giving Definition to Minimal

Attached to the recent ACRS letter was "A Proposal for the Development of a Risk-Informed Framework for 10 CFR 50.59 and Related Matters." The proposal forwarded by the ACRS parallels an existing risk-informed approach described in Regulatory Guide 1.174. Regulatory Guide 1.174 describes a method for determining the level of review, based on severe accident implications, for proposed licensing actions. The proposal forwarded by the ACRS describes methodology for creating frequency-consequence curves for Class 1-8 accidents. The proposal states that existing processes could be extended to provide appropriate context for whether the results of a change are "minimal." The proposal also notes that aspects of this type of approach are in use in the international regulatory community. The approach utilized in the proposal forwarded by the ACRS is consistent with the Commission guidance in the Staff Requirements Memorandum of March 24, 1998 on SECY-97-205.

Without commenting on the specifics of the proposal forwarded by the ACRS, I am convinced that changes to nuclear plants can be evaluated in a risk-informed context. Any such approach would benefit from paralleling existing methodology. Careful consideration would be required to ensure that the "consequence" and "frequency" standards are appropriate for a 50.59 type application. For instance, "consequences" could be evaluated at one of the following levels: fractional releases, off-site or on-site doses, or challenges to fission product release barriers. "Frequency" could be evaluated for Class 1-8 accidents or for design basis accidents using existing guidelines for risk-informed regulation. The level at which consequences and frequency of events were tracked would also impact the type of parallel, deterministic (e.g., protection of redundancy, defense in depth, etc.), considerations against which changes would have to be evaluated. For instance, evaluating consequences at the level of the loss of a single barrier, or occurrences of accident sequence initiators, might allow elimination of parallel, deterministic, considerations such as "margin."

It is of some concern to me that the while staff has pursued risk-informed approaches to issues like the review of TSs, the use of Graded Quality Assurance, and programs like In-service Inspection and Inservice Testing, the staff appears to be more reluctant to allow risk-informed approaches if the result is the relinquishment of review and approval authority. Because prior NRC review and approval impacts the cost and schedule of licensed activities, we must ensure that we require such prior review and approval only when justified or required by mandate. We should not limit the application of risk-informed regulation as a means to ensure continued NRC reviews and approvals of licensed activities. This message is complimentary to my oft repeated message to industry that the use of risk information is "double-edged," that is that relief and additional regulatory scrutiny may both result from its use.

Margin of safety

The staff proposes to provide a specific definition of "Reduction in margin of safety associated with any technical specification," and to revise the current provisions of 10 CFR 50.59(a)(2)(iii) to explicitly refer to this definition. While I commend the staff on its efforts to provide clear, definitive, requirements in this proposed rulemaking, I am concerned that the proposed rule is not consistent with policy direction established by the Commission in the SRM dated March 24, 1998. I concur that it is important that the staff has the independence to (and, I believe, has the responsibility to) inform the Commission when there are concerns with Commission guidance (as it did in COMSECY 98-013). However, I believe that when the staff proposes to take action that is inconsistent with Commission direction, it is obliged to provide a clear and complete rational for the proposed departure. I do not feel that the staff has met that obligation for the "margin of safety" aspect of this proposed rule. However, this said, I do not disagree with the staff's conclusion that we should be careful to understand, and maintain, a consistent regulatory basis on "margin of safety." We must proceed in a manner that does not call into question the existing deterministic basis for "reasonable assurance" of public safety embodied in plants' Technical Specifications (TSs).

My previous discussions with the staff have indicated that it is extremely difficult (and probably not legally defensible) to allow decreases in the "margin of safety" when the upper and lower limits between which "margin" may exist are not defined in relation to the regulatory requirements for safe operation. Based upon these discussions, I can only assume that the staff is hesitant to allow direct reductions in margin within the "basis" for TSs because some such changes could create a de-facto change in the TSs themselves. The staff may also be concerned by the lack of consistency in the "margin of safety in the basis for TSs" associated with the different generations of existing licenses (e.g., older customized TSs compared to improved standardized TSs), and associated with the different methods utilized in the technical review and approval of the TS (e.g., some TSs might be based on maintaining margin between accident analysis results and acceptance limits, while other TSs might be based on margin which was built into analytical techniques and methodologies used in the accident and safety analysis, with no "margin" between the results and the acceptance limits, etc.).

The staff's proposed method of requiring prior agency approval to changes of input assumptions, analytical methods, etc., for those parameters which affected the selection of TSs, results in the newly controlled parameters being treated essentially the same way as values in the TSs. It also appears that implementation of the staffs proposed control over a broad range of parameters used in the safety analysis would effectively prevent any change to the facility that would result in a "minimal change in consequence," a condition allowed elsewhere in the proposed rule. In other words, it is not clear what type of changes would successfully pass the 10 CFR 50.59 test for allowed "minimal increases in consequences," without failing the test for "no reductions in the margin of safety." I do not believe that the potential safety significance of all the parameters to be covered under the proposed definition of a reduction in the margin of safety always justify the requirement of prior NRC approval.

The staff should continue to work to establish a technically sound method for allowing licensees to make plant changes where there is only "minimal" impact on safety. If fundamental conflicts exist with allowing reductions in some "margins of safety," especially those on which the validity of TSs are based, then staff should provide a clear explanation of this, and should address how other changes to the structure of the regulation, which do not create fundamental conflicts, can be made in a manner which achieves the Commission's objective of removing unnecessary burdens from licensees.

Attachment "A" to this vote describes one alternate method for addressing the issue of "margin of safety." This alternative would maintain existing margins of safety (associated with TSs), while providing greater flexibility to licensees in implementing changes to their facilities. This alternative is based on methodology similar to that described in NEI 96-07. This methodology requires evaluating the effect of proposed tests and changes on the accident analysis results (rather than inputs, as proposed by the staff), in cases where TSs are based on accident analysis considerations. Prior NRC approval of changes, tests, and experiments would be limited to those cases where there was a net effect on the accident analysis results. The alternative also recognizes the significance of the analytical techniques used in the safety or accident analysis, and would require some form of prior approval for analytical methods used to support changes when the change did not have prior NRC approval. This approach could provide staff reasonable assurance that the assumptions made by the license reviews are not invalidated. The staff should evaluate this option, along with other comments in this area, during the comment period.

In considering the technical and regulatory underpinning of this clause of Section 50.59, I have become concerned that we are evaluating incremental changes to a provision which is not well suited to such changes. I am concerned that the result may be the addition of yet another layer of regulatory process rather than the elimination of any unnecessary layers. For this reason, the staff should be receptive to internal or public comments on feasible alternatives which eliminate the discussion of "the margin of safety in the basis of TSs," while maintaining the integrity of the plant's licensing basis. I envision that it may be possible to eliminate the rule language criteria on "margin of safety" if evaluations of "frequency" and "consequences" are performed at a level of significance which bounds allowable "minimal" reductions in margin.

ACCIDENT OF A DIFFERENT TYPE

In determining the effect of any proposed change to Section 50.59, it will be necessary to more clearly understand what an "accident of a different type" is. The staff should provide a more definitive definition of an accident than was included in COMSECY-98-013. The information provided by the staff should address, as a minimum, the following:

1) What is an "accident" under this Section, and is it consistent with other existing regulations (e.g., Section 50.92, Section 50.34, Appendix A of Part 50, etc.)?
2) Is an "accident of a different type" better described as an "initiating event (e.g., loss of

feedwater, loss of offsite power, new common mode failure mechanism, etc.) of a different Type?"

3) What are the bounds which limit those "accidents" which are the subject of this Section (e.g., only those initiating events which, when evaluated using approved analytical techniques, result in transients with the potential to challenge fission product barriers, etc.)?

PROCEDURES

I commend staff on inserting a definition for the term "Procedures as described in the final safety analysis report (as updated)." However, I am concerned that the definition provided may cloud the distinction between: (1) those procedures which must be screened, or evaluated, under Section 50.59, and (2) the criteria which necessitates a full safety evaluation. I believe that staff seeks to indicate that all procedures which are described as being required in the FSAR are subject to a 50.59 screening. The screening would identify the need for a full safety evaluation only if a proposed procedure change created a change to the "information in the FSAR regarding how structures, systems, and components are operated and controlled...." Staff should solicit comment on this definition and clarify the proposed definition, as required, in the final rule.

<u>MAKING THE RULE RISK INFORMED</u>

I note with interest that members of the ACRS believe that there are substantial barriers in the existing deterministic framework of 10 CFR Part 50 to the concept of allowing "minimal" changes in accident probabilities or consequences. In my previous vote on SECY-97-205, "Integration and Evaluation of Results from Recent Lessons-Learned Reviews," I approved the staff's proposal to develop the framework for risk-informed regulatory processes. In particular, I called for the staff to develop a series of milestones by which the Commission could "chart its course in its move to more risk-informed regulatory processes." Additionally, I promoted the idea of promulgating a new regulation in 10 CFR Part 50, that would make clear how the Commission uses risk information in its decision-making. In proceeding with the "short-term" changes to 10 CFR 50.59 (and related regulations; "short-term" actions from SECY-97-205), and in responding to the ACRS, the staff should re-evaluate whether the Agency should initiate action to provide for a risk-informed framework that would allow for the efficiencies to be gained through use of risk-informed, performance-based revisions to our regulatory processes.

Attachment "A" to Chairman Jackson's vote sheet on SECY-98-171

"STRAW MAN" ON MARGIN OF SAFETY

Regarding margin:

- The margin between regulatory limits and the failure of physical barriers is protected in the regulations (and also in the portion of the Technical Specifications (TSs) called "safety limits").
- The margin, as reflected in approved safety and accident analyses, between the protection afforded by the TSs (e.g., the limiting safety system settings and limiting conditions of operations) and the associated regulatory limits is "the margin of safety as defined in the basis for any TS."
- The margin between normal plant or system operation and the "bounding" assumptions used in accident analysis is below the threshold of safety significance that requires NRC prior approval for changes.
- The results of safety and accident analyses are subject to significant variance,

depending on the analytical techniques and methods used in the analysis. Where a licensee wishes to make a change in their facility without prior NRC approval, the effects of the change must be evaluated using analytical techniques and methods which are NRC approved for the application, or which are reviewed and vetted (but not subject to specific NRC approval) in a NRC approved manner.

Direct changes to technical specifications require prior NRC approval. Before changing other operational characteristics described in the UFSAR, a safety evaluation must be performed to determine, among other things, if the change results in a reduction in the level of protection afforded by the TS [margin of safety as defined in any TS]. Such a reduction would typically occur only if the operational characteristic had been used as a bounding condition in the analysis upon which the selection of TS was based, or in analysis where the acceptability of selected TS values was demonstrated. Licensees can make desired changes to operational characteristics without prior NRC approval, provided that the change does not result in accident analysis results that are nearer the regulatory, or safety, limits than the corresponding results that the NRC used in evaluating the acceptability of the TS during licensing of the facility.

This regulatory position could be codified by adding the following footnote to Section 50.59(a)(2)(iii):

The "margin of safety as defined in any technical specification" (margin of safety) is the amount (quantitative or qualitative) of margin between the operation of the facility as described in the technical specifications and the exceedance of safety limits listed in the technical specifications or other regulatory limits. In relation to accident analysis, the margin of safety is typically the difference between calculated parameters (e.g., peak fuel clad temperature, maximum RCS pressure, etc.) and the associated regulatory or safety limit. The margin of safety is a product of specific values and limits contained in the technical specifications (which cannot be changed without NRC *approval) and other values, such as assumed accident or transient initial conditions or assumed safety system* *response times, which are not specifically contained in the technical specifications. Any change to the values not specifically contained in technical specifications must be evaluated for impact on the margin between the calculated result of an accident or transient and the safety or regulatory limit. Changes, or the net effect of multiple changes, which result in a reduction in the margin of safety require prior* NRC *approval. Changes, or the net effect of multiple changes, which do not cause a reduction in margin of safety do not require prior* NRC *approval. All evaluatory work in assessing the impact of proposed changes must be performed using methodology and analytical techniques which are either reviewed and approved by the* NRC *or which are reviewed and vetted in a manner approved by the* NRC.

COMMISSIONER DIAZ'S COMMENTS ON SECY-98-171

I consider this rulemaking effort to be our short term fix for the 50.59 rule, not the longer term risk-informed rule enhancement discussed in SECY-97-205.

I approve the publication of this rulemaking package for a 90-day public comment period, contingent upon the additions described in the last paragraph of my comments. I propose that the package also include the Commissioners' votes for public consideration. The purpose of issuing the rulemaking package is to expedite rulemaking by opening the process for public comments during the Commission's continuing deliberation on this matter. It should be made very clear to all stakeholders that publication of the package is an invitation to participate in improving the rulemaking. In fact, I do not agree with several of the proposed positions in this paper, as delineated in my specific comments below.

I agree with the staff's recommendation to remove the reference to "unreviewed safety question" from 50.59 and to make conforming changes in Parts 50, 52, and 72. I also agree with staff's proposal to allow a minimal increase in the probability of occurrence or consequence of an accident or malfunction previously evaluated, and to not allow the creation of an accident of a different type or malfunction of equipment important to safety with a different result than any previously evaluated.

I agree with the ACRS comments in their June 16, 1998, letter regarding the definition of "reduction in margin of safety." Notwithstanding the staff's suggestion of a possible Commission interpretation, the language "altered in a nonconservative manner" can still be interpreted as a de facto "zero increase" standard for the 50.59 criterion on margin of safety. I believe the risk-informed 50.59 approach suggested in the ACRS letter deserves serious consideration as part of longer term improvements and should be considered in the staff's response, due in February 1999, to the SRM for SECY-97-205.

The current language in 50.59(a)(2)(iii) ("margin of safety as defined in the basis for any technical specification") is, in fact, defined and bounded by the technical specifications. Therefore, as long as the licensee proposed change, test, or experiment under 50.59 is not in violation of the technical specification requirements, the requisite margin of safety is maintained, and it is possible to eliminate "reduction of margin of safety" from the rule as a condition requiring prior staff approval. This change will eliminate the existing ambiguity in the use of 50.59 for changes with minimal safety significance. This alternative should also be published for public comment; it is consistent with the safety envelope provided by the technical specifications and is a straightforward improvement that will match with the eventual conversion to a risk-informed rule.

I support the staff's recommended changes in the reporting and record keeping requirements relating to 50.59. The enforcement policy and its corresponding implementation guidance should be changed in accordance with the revised 50.59 rule. I recommend that, during the rulemaking period, the enforcement policy be revised to grant discretion (i.e., suspend issuance of Level IV violations) under Section VII.B.6 for those 50.59 violations of little or no safety significance.

I do not agree with the recommended definitions of "facility", "procedures", "reduction in margin of safety", and "tests or experiments." These definitions appear to increase prescriptiveness at the input of the licensees' change process instead of the output, and therefore, are more broad-based than the definitions to date. I believe that these definitions will create more burden for the NRC and licensees, are not consistent with the original intent of the 50.59 rule, i.e., to evaluate whether the licensee proposed changes will result in inadequate protection of public health and safety, and therefore, are not necessary.

On the other hand, the "accident" in the proposed revisions to 50.59 should be defined. The "accident of a different type than any previously evaluated" as described in the proposed 50.59(c)(2)(v) should be of the same safety significance as the "accident" in the proposed 50.59(c)(2)(I) and (c)(2)(iii). The staff should determine if the anticipated operational transients and the postulated design basis accidents described in the FSAR form a sufficient basis for the 50.59 evaluation.

The staff should continue its interactions with NEI in resolving the differences between the NRC's position on 50.59 implementation guidance and that contained in NEI 96-07. The regulatory guide for 50.59 that endorses a revised NEI 96-07, with exceptions and clarifications, as appropriate, should be developed concurrently with the rulemaking process.

In summary, the staff should proceed with publishing the existing rulemaking package, and concurrently solicit public comment on the following alternatives: 1) eliminate "reduction of margin of safety" as a condition requiring prior staff approval, 2) eliminate the broadened definitions of "facility", "procedures", "reduction in margin of safety", and "tests or experiments," and 3) clearly define "accident" in the proposed revisions to 50.59. I urge the staff to complete the revised 50.59 rule and the associated regulatory guide by the end of March, 1999.

Commissioner McGaffigan's Comments on SECY-98-171

I approve publishing this rulemaking package for a ninety-day public comment period. However, like my colleagues, I do not agree with the staff proposal regarding "reduction in the margin of safety associated with any technical specification."

As the Chairman points out, the definition of "reduction in margin of safety ..." would extend the requirements for prior agency approval to underlying aspects (e.g., input assumptions) of parameters that affected the selection of technical specifications, and result in the newly controlled parameters being treated essentially the same way as values in the technical specifications. This is the wrong way to go.

It is clear from my colleagues' and my vote that the margin of safety criterion (50.59(c)(2)(vii) in the proposed rule) and the definition will need to be fixed in the final rule. My concern at this point is that the staff discuss a wide enough array of options in the Federal Register notice to ensure that the proposed rule will not have to be renoticed before being finalized. Commissioner Diaz has proposed to simply delete the criterion and definition as not needed. The Chairman has proposed essentially a new definition. Another option would decouple the last criterion from technical specifications and focus instead on a new criterion relating to performance of fission product barriers (e.g., RCS pressure, containment pressure. etc), with minimal changes being allowed up to specified limits, perhaps utilizing a graduated approach similar to the approaches proposed for other criteria. Comment should be solicited on this option as well.

I believe that the staff has done a good job in proposing options for defining "minimal" for consequences of an accident or malfunction. On probability, however, the staff has essentially only said that NEI 96-07 satisfies the proposed NRC standard for a "minimal" increase. That is a good step forward, and will bring regulatory stability. I believe that in choosing the word " minimal" the Commission intended to grant greater flexibility than the NEI 96-07 "so small" or negligible standard. The staff should continue to try to give better definition to "minimal" as it pertains to "probability of occurrence of an accident" or "probability of equipment malfunction" and solicit comment on this.

Finally, I endorse the use of enforcement discretion under Section VII of the Enforcement Policy as the rulemaking proceeds for those 50.59 violations of little or no safety/risk significance. The staff should treat (vice "consider treating" as proposed by staff) as minor violations cases where the violation of existing rule requirements would not constitute a violation under the rule were it revised as proposed. I do not object to documenting such minor violations in inspection reports because the rule is still in a proposed revision stage.

V. Rule Language Proposed by The Nuclear Energy Institute

In a letter dated November 14, 1997, the Nuclear Energy Institute provided to the NRC suggested language for revising 10 CFR 50.59 that they believed would enable the NRC to endorse NEI 96-07. This language is included here in this Statement of Considerations so that interested parties can offer comment on whether this language should be adopted by the NRC. The supporting information for NEI's proposal is contained in the referenced letter which is available for review in the Public Document Room.

Specifically, NEI proposed that [existing] section 50.59(a)(2) be revised to read:

(a)(2) A proposed change, test, or experiment shall be deemed to involve an unreviewed safety question: (i) if there is more than a negligible increase in the probability of occurrence of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report; or (ii) if the consequences of an accident or malfunction important to safety previously evaluated in the safety analysis report exceeds the established acceptance limit; or (iii) if a possibility for an accident of a different type or malfunction with a different result from any evaluated previously in the safety analysis report may be created; or (iv) if the margin of safety provided by any technical specification is reduced.

In this rulemaking, the Commission is proposing to adopt certain aspects of the changes offered by NEI (e.g., on malfunction with a different result). The Commission is seeking comment as to whether other aspects of this proposal should be adopted. The Commission also offers the following observations about this proposal for consideration as part of the comment process:

A. Negligible Increase in Probability of Occurrence

NEI proposes that the rule be revised to state that a change would be an USQ "if there is more than a negligible increase in the probability of occurrence of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report." As discussed above, the Commission is proposing a "more than minimally increased" criterion, which is considered comparable in overall intent to what was proposed by NEI.

B. Increase in Consequences of an Accident or Malfunction

NEI proposes that the rule be revised such that a change would be a USQ if the consequences of an accident or malfunction previously evaluated exceed the established acceptance limit. As NEI discusses further in its letter, the established acceptance limit would be the value that was previously reviewed and approved by the NRC generally as documented in the staff's safety evaluation report (SER). [6]

The current industry guidance, NEI 96-07, would permit, in some instances, increases in consequences up to the regulatory thresholds (such as Part 100), without review. As discussed in (draft) NUREG-1606, the staff typically performs independent evaluations of radiological consequences of accidents, rather than an in-depth review of the licensee's calculations, during licensing of the plant. As a result, the degree of conservatism in the licensee calculations differs from that used in the staff's assessments. As noted above, the Commission is proposing to revise the rule to allow "minimal" increases in consequences without prior approval, provided that the regulatory limits are still met. The Commission has some concerns about allowing licensee changes without review, which when evaluated with licensee assumptions and methods, result in doses at or very close to the regulatory guidelines (e.g., Part 100). This is because such changes, if reviewed with staff assumptions (or starting from the staff's previous estimation of the accident dose), might result in the regulatory guidelines not being met. Rather than allowing one change to result in an increase in consequences up

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[6] Attempting to use values from the staff's SER as acceptance limits would be difficult since SERs were not written for the purpose of establishing such limits. In a literal sense, neither the SAR nor the SER set an "acceptance limit." Rather, the SAR documents an applicant's/licensee's analytically derived conclusion that a given event has a certain consequence which is within the regulatory bounds set by NRC regulations. The SER is intended only to confirm or modify that conclusion. The SAR value as modified through the staff's review and approval then becomes the baseline for future analyses.

to the guidelines, the Commission concludes that minimal increases, along with NRC oversight of cumulative effects, is the appropriate standard for review.

C. Malfunction with a Different Result

As discussed above, the Commission is proposing to adopt this particular proposed change to the rule.

D. Margin of Safety Provided by Any Technical Specification

NEI proposes to replace the existing language of "as defined in the basis for any technical specifications," with "as provided by any technical specification" with respect to reductions in the margin of safety. The proposed change is intended to clarify that the margin of safety is not necessarily limited to information in the BASES section of the technical specification. NEI 96-07 guidance notes that the SAR, staff SERs and other licensing basis documents should be reviewed to determine if a proposed change would result in a reduction in margin of safety. NEI intended to use this rule language in conjunction with guidance that the margin of safety is the range of values between the acceptance limit reviewed by the NRC (e.g., ASME code stress limits, containment design pressure, etc.) and the failure point. The Commission is seeking comment on a range of options relating to margin of safety, including the option proposed by NEI.

VI. Request for Comment

The Commission requests comments on the proposed rule, as discussed in Section II above. In addition, the Commission is seeking comment on a number of specific issues related to this rulemaking. All commenters are encouraged to provide specific comments on the following issue areas:

1. The Commission is seeking input on a number of options relating to the criterion of margin of safety reduction, and its definition. Some possible alternatives are presented in Section II.J as being representative of the range of approaches under consideration, but the Commission is open to other proposals that commenters may wish to put forth as representing the best means to provide a clear understanding of which margins should fall within the regulatory envelope of requiring approval if they would be reduced as a result of a change, test or experiment, if the margin of safety criterion were to be retained.

2. The Commission is interested in options for defining what constitutes a "minimal" increase in the probability of occurrence of an accident previously evaluated in the FSAR or in the probability of equipment malfunction (refer to Section II.G). This might include suggested examples of changes that commenters believe represent only a "minimal increase" in probability.

3. The Commission is interested in comments upon the proposed definitions for such terms as "facility as described in the FSAR," "procedures as described in the FSAR," and "tests or experiments" (refer to Sections II.B, C, and D). The Commission is soliciting views on whether (1) definitions are necessary, (2) the proposed definitions are desirable, even if not

necessary, and (3) whether the suggested definitions are clear and focused upon the appropriate changes that should be evaluated. In this light, the Commission is also interested in comments on a broader view of the scope of changes that should be evaluated; for instance, should the scope be linked to the SAR, or should the focus of changes to the facility be linked to another set of regulatory information?

4. As part of the present rulemaking, the Commission is seeking comment on the need for a clear definition of accident as it is used in § 50.59 to reflect the Commission's intent that the "accidents" referred to are those dealt with in the safety analysis report (see Section II.H of this notice for discussion of issues related to definition of accident).

5. In addition to the NRC proposals in Sections II and III, the Commission is also interested in receiving comments on the proposals and language suggested by NEI (Section V).

VII. Availability of Documents and Electronic Access

Certain documents related to this rulemaking, including comments received and the regulatory analysis, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, D.C. NRC documents also may be viewed and downloaded electronically via the interactive rulemaking website established by NRC for this rulemaking.

You may also provide comments via the NRC's interactive rulemaking web site through the NRC home page (http://www.nrc.gov). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301) 415-5905; e-mail

CAG@nrc.gov.

VIII. Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule, if adopted, will not have a significant impact on the environment. The proposed rule changes are of two types: those that relate to the processes for evaluating and approving changes to licensed facilities and those that involve the degree of potential change in safety for which changes can proceed without NRC review. The process changes being proposed will make it more likely that planned changes are properly reviewed and approved by NRC when necessary. With respect to the criteria changes, only minimal increases in probability or consequences of accidents (still satisfying regulatory limits) would be allowed without prior NRC review. All changes to the Technical Specifications, which are the operating limits and other parameters of most immediate concern for public health and safety, will continue to require prior NRC review and approval. Changes to the facility that would involve an accident of a different type from any already analyzed, or reductions in defined margins of safety require prior approval. Further, changes which result in more than minimal increases in radiological consequences will continue to require prior NRC approval, including NRC consideration of potential impact on the environment. Therefore, the Commission concludes that there will be no significant impact on the environment from this proposed rule. This discussion constitutes the environmental assessment and finding of no significant impact for this proposed rule.

IX. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements. Existing requirements were approved by the Office of Management and Budget approval numbers 3150-0011 and 3150-0132.

The proposed rule changes would affect information collection requirements through the existing reporting requirements in § 50.59 for a summary report of changes, tests and experiments, performed under the authority of § 50.59 and in § 50.71(e) for submittal of updates to the FSAR, as well as record keeping requirements To the extent that the definitions provided in the proposed revisions would require evaluations that are not presently being performed, there may be an increase in record keeping and reporting. The Commission estimates that this is a small increment over the existing burden. On the other hand, some changes might be screened out as not needing evaluation on the basis of these definitions, and thus there would overall be at most a small increase in the record keeping required.

In addition, the requirements under § 72.48 are also being revised to explicitly require records of determinations concerning occupational dose and environmental impact (the existing rules required the evaluations but did not explicitly specify record retention requirements for these evaluations). The Commission does not believe this that this change will significantly impact record keeping burden because records of evaluations of changes are already required (as to whether they involve a USQ), and the evaluation itself is already required by the rule. The Part 72 burden associated with the definitions of when evaluations are required should be significantly less than for § 50.59 since the number of licensees is smaller and the expected number of changes is also smaller. Further, there is a recordkeeping requirement established for CoC holders who make changes to an approved storage cask design in accordance with § 72.48.

With respect to reporting requirements, the Commission is proposing to modify the FSAR update requirement to state that the updates must include specific information on the effects of changes made. This was not explicitly stated in the current rule, although it could be inferred that this was what the update rule intended, as follows. In the Statement of Considerations for § 50.71(e),(45 FR 30615), the NRC commented on the relationship between changes made under § 50.59 and FSAR updating, stating: "The 50.59(b) reporting may not be detailed sufficiently to be considered adequate to fulfill the FSAR updating requirement. The degree of detail required for updating the FSAR will be generally greater than a 'brief description' and a 'summary of the safety evaluation'." Thus, the Commission clearly expected the update submittal to include sufficient information to appropriately reflect the changes that were made. The burden associated with explicitly documenting in the update the effects of the changes on event probabilities and consequences is therefore small.

The public reporting burden for this information collection request is estimated to average 3100 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The Commission estimates that there is only a slight increase in burden associated with these proposed changes over the existing burden. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the collection of information contained in the proposed rule and on the following issues:

1. Is the proposed collection of information necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of the burden correct?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the collection of information be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed collection of information, including suggestions for reducing the burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0017, -0020, -0011, -0009, and -01320), Office of Management and Budget, Washington, D.C. 20503.

Comments to OMB on the collections of information or on the above issues should be submitted by (insert date 30 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

X. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the values and impacts of the alternatives considered by the Commission and includes the backfit analysis required by § 50.109 (and § 72.62). The alternatives considered in this analysis include no action, issuance of guidance only, or rulemaking. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, D.C. and is available through the NRC interactive rulemaking website. Single copies of the analysis may be obtained from Eileen McKenna, EMM@NRC.GOV (301) 415-2189, Mail stop O-11-F-1, U.S. Nuclear Regulatory Commission, Washington D.C. 20555.

The Commission requests public comment on the draft analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

XI. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, (5 U.S.C. 605(b)), the Commission 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 and decommissioning of nuclear power plants, nonpower reactors, and independent spent fuel storage facilities. The companies that own these facilities 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.

XII. Backfit Analysis

As required by § 50.109 and § 72.62, the Commission has completed a backfit analysis for the proposed rule, which is included within the regulatory analysis. The Commission has determined, based on this analysis, that in most respects, the proposed rule does not impose new requirements, but provides more flexibility or clarification of existing requirements. In other respects, such as the definitions of change to the facility and "reduction of margin of safety..." , some licensees may view the revised rule as imposing new requirements. Therefore, the Commission has prepared an analysis considering the factors in § 50.109(c), which is included in the Regulatory Analysis.

XIII. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act (AEA), the Commission is issuing the proposed rule to amend 10 CFR 50 : 50.59,: 50.66, and : 50.71; and 10 CFR 72: 72.48,: 72.70,: 72.212, and : 72.248, under one or more of sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

XIV. Compatibility of Agreement State Regulations

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the Federal Register (62 FR 46517, September 3, 1997), this rule is classified as compatibility Category "NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of Title 10 of the Code of Federal Regulations, and although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws, but does not confer regulatory authority on the State.

List of Subjects

10 CFR Part 50

Antitrust, Classified Information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and record keeping requirements.

10 CFR Part 52

Administrative practice and procedure, Antitrust, Backfitting, Combined license, Early site permit, Emergency planning, Fees, Inspection, Limited work authorization, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Reporting and record keeping requirements, Standard design, Standard design certification.

10 CFR Part 72

Manpower training programs, Nuclear materials, Occupational safety and health, Reporting and record keeping requirements, Security measures, Spent fuel

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 50, 52 and 72.

PART 50 - DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

AUTHORITY: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955 as amended (42 U.S.C. 2131, 2235), sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, and 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Section 50.37 also issued under E.O. 12829, 3 CFR 1993 Comp., P. 570; E.O.

12958, Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80 - 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C 2237).

2. Section 50.59 is revised to read as follows:

§ 50.59 Changes, tests and experiments

(a) Definitions for the purposes of this section:

(1) Change means a modification, addition, or removal.

(2) Facility as described in the final safety analysis report (as updated) means:

(i) The systems, structures, and components that are described in the final safety analysis report(as updated),

(ii) The design, performance requirements and methods of operation for such systems, structures and components required to be included or described in the final safety analysis report (as updated), and

(iii) The evaluations or methods of evaluation required to be included in the FSAR (as updated) for such SSC and which demonstrate that their intended function(s) will be accomplished.

(3) *Final safety analysis report (as updated)* means the Final Safety Analysis Report (or Final Hazards Summary Report) submitted in accordance with § 50.34, as amended and

supplemented, and as modified as a result of changes made pursuant to § 50.59 and § 50.90, and, as applicable, § 50.71(e) and (f).

(4) Procedures as described in the final safety analysis report (as updated) means information in the final safety analysis report (as updated) regarding how structures, systems, and components are operated and controlled (including assumed operator actions and response times) and information describing the conduct of operations.

(5) Reduction in margin of safety associated with any technical specification means that the input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the final safety analysis report (as updated), that established any technical specification requirement, are altered in a nonconservative manner.

(6) Tests or experiments not described in the final safety analysis report (as updated) means any condition where the reactor or any of its systems, structures or components are utilized or controlled in a manner which is either:

(i) Outside the controlling parameters of the design bases as described in the final safety analysis report (as updated) or

(ii) Inconsistent with the analyses in the final safety analysis report (as updated).

(b) Applicability. The provisions of this section apply to each holder of a license authorizing operation of a production or utilization facility, including the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required under § 50.82(a)(1) or a reactor licensee whose license has been permanently modified to allow possession but not operation of the facility.

(c)(1) A licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) without obtaining a license amendment pursuant to § 50.90 only if:

(i) a change to the technical specifications incorporated in the license is not required, and

(ii) the change, test or experiment does not meet any of the criteria in paragraph (c)(2) of this section. The provisions in this section do not apply to changes in procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(2) A licensee shall obtain an amendment to the license pursuant to § 50.90 prior to implementing a change, test or experiment if it would:

(i) Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to section 50.90 after the last final safety analysis report was updated pursuant to section 50.71 of this part;

(ii) Result in more than a minimal increase in the probability of occurrence of a malfunction of equipment important to safety previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to section 50.90 after the last final safety analysis report was updated pursuant to section 50.71 of this part;

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to section 50.90 after the last final safety analysis report was updated pursuant to section 50.71 of this part;

(iv) Result in more than a minimal increase in the consequences of a malfunction of equipment important to safety previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to section 50.90 after the last final safety analysis report was updated pursuant to section 50.71 of this part;

(v) Create a possibility for a design basis accident of a different type than any previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to section 50.90 with respect to design basis accidents after the last final safety analysis report was updated pursuant to section 50.71 of this part;

(vi) Create a possibility for a malfunction of equipment important to safety with a different result than any previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to section 50.90 after the last final safety analysis report was updated pursuant to section 50.71 of this part;

(vii) Result in a reduction in the margin of safety associated with any Technical Specification.

(d) (1) The licensee shall maintain records of changes in the facility and of changes in procedures made pursuant to this section, to the extent that these changes constitute changes in the facility as described in the final safety analysis report (as updated) or to the extent that they constitute changes in procedures as described in the final safety analysis report (as updated). The licensee shall also maintain records of tests and experiments carried out pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test or experiment does not require a license amendment pursuant to paragraph (c)(2) of this section.

(2) The licensee shall submit, as specified in § 50.4, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. The report may be submitted annually or along with the FSAR updates as specified by § 50.71(e), or at such shorter intervals as may be specified in the license.

(3) The records of changes in the facility must be maintained until the termination of a license issued pursuant to this part or the termination of a license issued pursuant to 10 CFR Part 54, whichever is later. Records of changes in procedures and records of tests and experiments must be maintained for a period of five years.

3. In § 50.66, introductory paragraph (b), paragraphs (b)(4), (c)(2), (c)(2)(i), (c)(2)(ii), and (c)(3)(iii) are revised to read as follows:

§ 50.66 Requirements for thermal annealing of the reactor pressure vessel.

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(b) Thermal Annealing Report. The Thermal Annealing Report must include: a Thermal Annealing Operating Plan; a Requalification Inspection and Test Program; a Fracture

Toughness Recovery and Reembrittlement Trend Assurance Program; and Identification of Changes Requiring a License Amendment

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(4) Identification of Changes Requiring a License Amendment. Any changes to the facility as described in the final safety analysis report (as updated) which requires a license amendment pursuant to § 50.59(c)(2) of this part, and any changes to the technical specifications, which are necessary to either conduct the thermal annealing or to operate the nuclear power reactor following the annealing must be identified. The section shall demonstrate that the Commission's requirements continue to be complied with, and that there is reasonable assurance of adequate protection to the public health and safety following the changes.

(c) ★ ★ ★

(2) If the thermal annealing was completed but the annealing was not performed in accordance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program, the licensee shall submit a summary of lack of compliance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program and a justification for subsequent operation to the Director, Office of Nuclear Reactor Regulation. Any changes to the facility as described in the final safety analysis report (as updated) which are attributable to the noncompliances and which require a license amendment pursuant to § 50.59(c)(2) and any changes to the technical specifications, shall also be identified.

(i) If no changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to Technical Specifications are identified, the licensee may restart its reactor after the requirements of paragraph (f)(2) of this section have been met.

(ii) If any changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to the Technical Specifications are identified, the licensee may not restart its reactor until approval is obtained from the Director, Office of Nuclear Reactor Regulation and the requirements of paragraph (f)(2) of this section have been met.

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(iii) If the partial annealing was not performed in accordance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program, the licensee shall submit a summary of lack of compliance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program and a justification for subsequent operation to the Director, Office of Nuclear Reactor Regulation. Any changes to the facility as described in the final safety analysis report (as updated) which are attributable to the noncompliances and which require a license amendment pursuant to § 50.59(c)(2) and any changes to the technical specifications which are required as a result of the noncompliances, shall also be identified.

(A) If no changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to technical specifications are identified, the licensee may restart its reactor after the requirements of paragraph (f)(2) of this section have been met.

(B) If any changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to technical specifications are identified, the licensee may not restart its reactor until approval is obtained from the Director, Office of Nuclear Reactor Regulation and the requirements of paragraph (f)(2) of this section have been met.

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4. In § 50.71 paragraph (e) is revised to read as follows:

§50.71 Maintenance of records, making of reports.

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(e) Each person licensed to operate a nuclear power reactor pursuant to the provisions of § 50.21 or § 50.22 of this part shall update periodically, as provided in paragraphs (e)(3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the operating license, to assure that the information included in the report contains the latest information developed. This submittal must contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submission of the original FSAR, or as appropriate the last update to the FSAR under this section. The submittal must include the effects[1] of:

(1) All changes made in the facility or procedures as described in the FSAR;

(2) All safety analyses and evaluations performed by the licensee either in support of requested license amendments, or in support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2) of this part;

(3) All analyses of new safety issues performed by or on behalf of the licensee at Commission request; and

(4) The net effect of all changes made since the last update on the safety analyses, including probabilities, consequences, calculated values, system or component performance, that are in the FSAR (as updated). The updated information shall be appropriately located within the update to the FSAR.

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5. Section 50.90 is revised to read as follows:

§ 50.90 Application for Amendment of license or construction permit.

Whenever a holder of a license or construction permit desires to amend the license (including the Technical Specifications incorporated into the license) or permit, application for an amendment must be filed with the Commission, as specified in § 50.4, fully describing the changes desired, and following as far as applicable, the form prescribed for original applications.

PART 52 - EARLY SITE PERMITS, STANDARD DESIGN CERTIFICATIONS; AND COMBINED LICENSES FOR NUCLEAR POWER PLANTS

6. The authority citation for Part 52 continues to read as follows:

AUTHORITY: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2133, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5546).

[1] *Effects of* changes includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate."

7. Appendix A to Part 52 is amended by revising Section VIII.B, paragraphs 5.a,b,d, and Section X.A.3 as follows:

Appendix A - Design Certification Rule for the U.S. Advanced Boiling Water Reactor

VIII. Processes for Changes and Departures

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B. Tier 2 information

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a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the technical specifications, or otherwise requires a license amendment as defined in paragraphs B.5.b and B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would---

(1) Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the probability of occurrence of a malfunction of equipment important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of equipment important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for a design basis accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of equipment important to safety with a different result than any evaluated previously in the plant-specific DCD; or

(7) Result in a reduction in the margin of safety associated with any Technical Specification for an application or license referencing this design certification.

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d. If a departure requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

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X. Records and Reporting

A. Records.

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3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

8. Appendix B to Part 52 is amended by revising Section VIII.B, paragraphs 5.a,b,d, and Section X.A.3 to read as follows:

Appendix B - Design Certification Rule for the system 80+ Design

VIII. Processes for Changes and Departures

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B. Tier 2 information.

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a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the technical specifications, or otherwise requires a license amendment as defined in paragraphs B.5.b and B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would—

(1) Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the probability of occurrence of a malfunction of equipment important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of equipment important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for a design basis accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of equipment important to safety with a different result than any evaluated previously in the plant-specific DCD; or

(7) Result in a reduction in the margin of safety associated with any Technical Specification for an application or license referencing this design certification.

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d. If a departure requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

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X. Records and Reporting

A. Records.

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3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

PART 72 - LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE

9. The authority citation for Part 72 continues to read as follows:

AUTHORITY: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); Secs. 131, 132, 133, 135, 137, 141, Pub. L. 97-425, 96

Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100-203, 101 Stat. 1330-232, 1330-236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97-425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

10. Section 72.3 is amended by revising the definition for independent spent fuel storage installation or ISFSI to read as follows:

§ 72.3 Definitions.

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Independent spent fuel storage installation or ISFSI means a complex designed and constructed for the interim storage of spent nuclear fuel and other radioactive materials associated with spent fuel storage. An ISFSI which is located on the site of another facility licensed under this part or a facility licensed under part 50 of this chapter and which shares common utilities and services with such a facility or is physically connected with such other facility may still be considered independent.

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11. In Section 72.9, paragraph (b) is revised to read as follows:

§ 72.9 Information collection requirements: OMB approval.

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(b) The approved information collection requirements contained in this part appear in §§ 72.7, 72.11, 72.16, 72.19, 72.22 through 72.34, 72.42, 72.44, 72.48 through 72.56, 72.62, 72.70 through 72.82, 72.90, 72.92, 72.94, 72.98, 72.100, 72.102, 72.104, 72.108, 72.120, 72.126, 72.140 through 72.176, 72.180 through 72.186, 72.192, 72.206, 72.212, 72.216, 72.218, 72.230, 72.232, 72.234, 72.236, 72.240, 72.244, and 72.248.

12. In § 72.24, paragraph (a) is revised as follows:

§ 72.24 Contents of application: Technical information.

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(a) A description and safety assessment of the site on which the ISFSI or MRS is to be located, with appropriate attention to the design bases for external events. Such assessment must contain an analysis and evaluation of the major structures, systems and components of the ISFSI or MRS that bear on the suitability of the site when the ISFSI or MRS is operated at its design capacity. If the proposed ISFSI or MRS is to be located on the site of a nuclear power plant or other licensed facility, the potential interactions between the ISFSI or MRS and such other facility--including shared common utilities and services--must be evaluated.

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13. Section 72.48 is revised to read as follows:

§ 72.48 Changes, Tests and Experiments.

(a) Definitions - As used in this section:

(1) Change means a modification, addition or removal.

(2) Final Safety Analysis Report (as updated) means:

(i) For site-specific licensees, the Safety Analysis Report for a ISFSI, MRS or spent fuel storage cask, submitted in accordance with § 72.24, as modified as a result of changes made pursuant to § 72.48, and as updated in accordance with § 72.70;

(ii) For general licensees, the Safety Analysis Report for a ISFSI, MRS or spent fuel storage cask, as modified as a result of changes made pursuant to § 72.48, and as updated in accordance with § 72.216; and

(iii) For certificate holders, the Safety Analysis Report for an approved cask, modified by as a result of changes made pursuant to § 72.48 and as updated in accordance with § 72.248.

(3) The ISFSI, MRS, or spent fuel storage cask as described in the Final Safety Analysis Report (as updated) means:

(i) The systems, structures, and components that are described in the Final Safety Analysis Report as updated in accordance with §§ 72.70, 72.216 or 72.248,

(ii) The design, performance requirements and methods of operation for such systems, structures, and components required to be included or described in the Final Safety Analysis Report (as updated), and

(iii) The evaluations for such systems, structures, and components required to be included in the Final Safety Analysis Report (as updated) and which demonstrate that their intended function(s) will be accomplished.

(4) Procedures as described in the Final Safety Analysis Report (as updated) means information in the Final Safety Analysis Report (as updated) regarding how structures, systems, and components are operated or controlled and information describing conduct of operations.

(5) Reduction in margin of safety associated with any technical specification means that the input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the Final Safety Analysis Report (as updated), that established any technical specification requirement, are altered in a nonconservative manner.

(6) Tests or experiments not described in the Final Safety Analysis Report (as updated) means any condition where the ISFSI, MRS or spent fuel storage cask or any of its systems, structures, or components are utilized or controlled in a manner which is either:

(i) Outside the controlling parameters of the design bases as described in the Final Safety Analysis Report (as updated) or

(ii) Inconsistent with the analyses in the Final Safety Analysis Report (as updated).

(b)(1) A licensee or certificate holder may make changes in the ISFSI, MRS, or spent fuel storage cask as described in the Final Safety Analysis Report (as updated), make changes in the procedures as described in the Final Safety Analysis Report (as updated), and conduct tests or experiments not described in the Final Safety Analysis Report (as updated), without obtaining either (A) a license amendment pursuant to § 72.56 (for licensees), if a change in the conditions incorporated in the license is not required, and the change, test, or experiment does not meet any of the criteria in paragraph (b)(2) of this section. or (B) a Certificate of Compliance (CoC) amendment pursuant to § 72.244 (for certificate holders), if a change in the terms, conditions or specifications incorporated in the CoC is not required; and the change, test, or experiment does not meet any of the criteria in paragraph (b)(2) of this section. The provisions in this section do not apply to changes in procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(2) A licensee shall obtain a license amendment pursuant to § 72.56 and a certificate holder shall obtain a CoC amendment pursuant to § 72.244, prior to implementing a change, test, or experiment if it would:

(i) Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to sections 72.56 or 72.244 after the last Final Safety Analysis Report was updated pursuant to sections 72.70, 72.216 or 72.248, of this part, as applicable;

(ii) Result in more than a minimal increase in the probability of occurrence of a malfunction of structures, systems, and components important to safety which were previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to sections 72.56 or 72.244 after the last final safety analysis report was updated pursuant to sections 72.70, 72.216 or 72.248, of this part, as applicable;

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to sections 72.56 or 72.244 after the last final safety analysis report was updated pursuant to section 72.70, 72.216 or 72.248, of this part, as applicable;

(iv) Result in more than a minimal increase in the consequences of a malfunction of structures, systems, and components important to safety which were previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to section 72.56 or 72.244 after the last final safety analysis report was updated pursuant to section 72.70, 72.216 or 72.248, of this part, as applicable;

(v) Create the possibility for a design basis accident of a different type than any evaluated previously in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to sections 72.56 or 72.244 with respect to design basis accidents after the last final safety analysis report was updated pursuant to section 72.70, 72.216 or 72.248, of this part, as applicable;

(vi) Create the possibility for a malfunction of structures, systems, and components important to safety with a different result than any evaluated previously in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to sections 72.56 or 72.244 after the last final safety analysis report was updated pursuant to section 72.70, 72.216 or 72.248, of this part, as applicable;

(vii) Result in a reduction in the margin of safety associated with any technical specification;

(viii) Result in a significant increase in occupational exposure;

(ix) Result in a significant unreviewed environmental impact.

(c)(1) Each licensee or certificate holder shall maintain records of changes in the ISFSI, MRS, or spent fuel storage cask and of changes in procedures it has made pursuant to this section if these changes constitute changes in the ISFSI, MRS, or spent fuel storage cask or procedures described in the Final Safety Analysis Report (as updated). The licensee or certificate holder shall also maintain records of test and experiments carried out pursuant to paragraph (b) of this section. These records shall include a written evaluation that provides the bases for the determination that the change, test, or experiment does not require a license or CoC amendment pursuant to paragraph (b)(2). The records of changes in the ISFSI, MRS, or spent fuel storage cask and of changes in procedures and records of tests and experiments shall be maintained until spent nuclear fuel is no longer stored in the ISFSI, MRS or spent fuel storage cask, and the Commission terminates the license or CoC. For a holder of cask Certificate of Compliance who permanently ceases operation, any such records shall be provided to the new holder of cask Certificate of Compliance or to the Commission, as appropriate, in accordance with § 72.234(d)(3).

(2) Annually, or at such shorter interval as may be specified in the license or CoC, each holder of a license or cask Certificate of Compliance shall submit a report containing a brief description of changes, tests and experiments made by the license or certificate holder under paragraph (b) of this section, including a summary of the evaluation of each. Licensee and certificate holders shall submit their reports in accordance with § 72.4. Any report submitted by a licensee or certificate holder pursuant to this paragraph will be made a part of the public record pertaining to the license or CoC.

14. Section 72.56 is revised to read as follows:

§72.56 Application for amendment of license.

Whenever a holder of a license desires to amend the license (including a change to the license conditions), an application for an amendment shall be filed with the Commission fully describing the changes desired and the reasons for such changes, and following as far as applicable the form prescribed for original applications.

15. In § 72.70, paragraphs (a), (b) and (b)(2) are revised to read and a new paragraph (c) is added to read as follows:

§ 72.70 Safety analysis report updating.

(a) The design, description of planned operations, and other information submitted in the Safety Analysis Report for an ISFSI or MRS shall be updated by the licensee and submitted to the Commission at least once every six months after issuance of the license during final design and construction, until preoperational testing is completed, with a Final Safety Analysis Report (FSAR) completed and submitted to the Commission at least 90 days prior to the planned receipt of spent fuel or high-level radioactive waste. The FSAR shall include a final analysis and evaluation of the design and performance of structures, systems, and components that are important to safety taking into account any pertinent information developed since the submittal of the license application.

(b) After the first receipt of spent fuel or high-level radioactive waste for storage, the FSAR shall be updated annually and submitted to the Commission by the licensee. This submittal shall include the following:

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(2) A description and analysis of changes in procedures or in structures, systems, and components of the ISFSI or MRS, as described in the FSAR (as updated), with emphasis upon:

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(c) The licensee shall submit revisions of the FSAR to the Commission in accordance with § 72.4, on a replacement-page basis that is accompanied by a list which identifies the current pages of the FSAR following page replacement. Each replacement page shall include both a change indicator for the area changed (e.g., a bold line vertically drawn in the margin adjacent to the portion actually changed) and a page change identification (date of change or change number or both).

16. In § 72.86, paragraph (b) is revised to read as follows:

§ 72.86 Criminal penalties.

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(b) The regulations in part 72 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 72.1, 72.2, 72.3, 72.4, 72.5, 72.7, 72.8, 72.9, 72.16, 72.18, 72.20, 72.22, 72.24, 72.26, 72.28, 72.32, 72.34, 72.40, 72.46, 72.56, 72.58, 72.60, 72.62, 72.84, 72.86, 72.90, 72.96, 72.108, 72.120, 72.122, 72.124, 72.126, 72.128, 72.130, 72.182, 72.194, 72.200, 72.202, 72.204, 72.206, 72.210, 72.214, 72.220, 72.230, 72.238, 72.240, 72.244, and 72.246.

17. In §72.212, paragraph (b)(4) is revised to read as follows:

§ 72.212 Conditions of general license issued under §72.210.

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(b) ★ ★ ★

(4) Prior to use of this general license, determine whether activities related to storage of spent fuel under this general license involve a change in the facility Technical Specifications or require a license amendment for the facility pursuant to § 50.59(c)(2) of this Chapter. Results of this determination must be documented in the evaluation made in paragraph (b)(2) of this section.

18. In § 72.216, new paragraph (d) is added to read as follows:

§ 72.216 Reports.

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(d) The final safety analysis report (FSAR) for each approved cask used by the general licensee shall be updated annually and submitted to the Commission by the general licensee. The submittal shall include the following:

(1) A description and analysis of changes in procedures or in structures, systems, and components of the spent fuel storage cask, as described in the FSAR (as updated), with emphasis upon:

(i) Performance requirements,

(ii) The bases, with technical justification therefor upon which such requirements have been established, and

(iii) Evaluations showing that safety functions will be accomplished.

(2) An analysis of the significance of any changes to codes, standards, regulations, or regulatory guides which the general licensee has committed to meeting the requirements of which are applicable to the design, construction, or fabrication of the spent fuel storage cask.

(3) The general licensee shall submit revisions containing updated information to the Commission, in accordance with § 72.4, on a replacement-page basis that is accompanied by a list which identifies the current pages of the FSAR following page replacement. The general licensee shall also provide a copy of the submittal to the holder of the certificate for the cask. Each replacement page shall include both a change indicator for the area changed (e.g., a bold line vertically drawn in the margin adjacent to the portion actually changed) and a page change identification (date of change or change number or both). Each replacement page shall also indicate the cask FSAR, including the certificate holder's revision number, upon which the general licensee's update is based.

19. Section 72.244 is added to read as follows:

§72.244 Application for amendment of a certificate of compliance.

Whenever a certificate holder desires to amend the CoC (including a change to the terms, conditions or specifications of the CoC), an application for an amendment shall be filed with the Commission fully describing the changes desired and the reasons for such changes, and following as far as applicable the form prescribed for original applications.

20. Section 72.246 is added to read as follows:

§72.246 Issuance of amendment to a certificate of compliance.

In determining whether an amendment to a CoC will be issued to the applicant, the Commission will be guided by the considerations that govern the issuance of an initial CoC.

21. Section 72.248 is added to read as follows:

§ 72.248 Safety analysis report updating.

(a) The design, description of planned operations, and other information submitted in the Safety Analysis Report for a spent fuel storage cask shall be updated by the certificate holder and submitted to the Commission after the design of the spent fuel storage cask has been approved pursuant to § 72.238. This Final Safety Analysis Report (FSAR) shall be completed and submitted to the Commission within 90 days after approval of the cask design. The FSAR shall incorporate all changes and requirements contained in the CoC and the staff's safety evaluation report (SER) associated with approval of the cask's design.

(b) The FSAR shall be updated annually and submitted to the Commission by the certificate holder. This submittal shall include the following:

(1) A description and analysis of changes in procedures or in structures, systems, and components of the spent fuel storage cask, as described in the FSAR (as updated), with emphasis upon:

(i) Performance requirements,

(ii) The bases, with technical justification therefor upon which such requirements have been established, and

(iii) Evaluations showing that safety functions will be accomplished.

(2) An analysis of the significance of any changes to codes, standards, regulations, or regulatory guides which the certificate holder has committed to meeting the requirements of which are applicable to the design, construction, or fabrication of the spent fuel storage cask.

(c) The certificate holder shall submit revisions containing updated information to the Commission, in accordance with § 72.4, on a replacement-page basis that is accompanied by a list which identifies the current pages of the FSAR following page replacement. The certificate holder shall also provide a copy of the submittal to each general licensee using the spent fuel storage cask. Each replacement page shall include both a change indicator for the area changed (e.g., a bold line vertically drawn in the margin adjacent to the portion actually changed) and a page change identification (date of change or change number or both).

Dated at Rockville, Maryland, this 14th day of October, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.