March 22, 2001

MEMORANDUM TO: Susan F. Shankman, Deputy Director
Licensing and Inspection Directorate
Spent Fuel Project Office, NMSS

THRU: Michael Tokar, Chief /RA/ original signed by /s/
Transportation and Storage Safety
and Inspection Section
Spent Fuel Project Office, NMSS

FROM: Chester Poslusny, Senior Project Manager /RA/ original signed by /s/
Transportation and Storage Safety
and Inspection Section
Spent Fuel Project Office, NMSS

SUBJECT: WORKSHOP ON IMPLEMENTING THE REVISED 10 CFR 72.48 REGULATION

On March 16, 2001, representatives from the U.S. Nuclear Regulatory Commission's Spent Fuel Project Office, the Nuclear Energy Institute (NEI), and industry conducted a workshop on implementing the new requirements of 10 CFR 72.48, which become effective April 5, 2001. Attachment 1 is a list of workshop attendees. Attachment 2 is a package provided to all workshop participants, which includes the meeting agenda, the slides presented, the draft Regulatory Guide, NEI 96-07, Appendix B, *Guidelines for 10 CFR 72.48 Implementation,* and other related references.

The purpose of the workshop was to discuss the changes to 10 CFR 72.48, the responsibilities of vendors and licensees under the new requirements, and what information needs to be reported between licensees and vendors and to NRC. The vendor and reactor licensee representatives raised a number of issues and questions during the workshop. Two of the items that require follow up by both NRC and NEI are (1) when the 24-month period for updating the Final Safety Analysis Report begins for the vendor and licensee, and (2) the development of guidance on controlling the licensing basis (FSAR as updated) for specific cask designs. NEI staff introduced the use of Frequently Asked Question input sheets and noted that in the future the inputs and responses would be posted on the NEI web site. Further, it was noted that a session on lessons learned from 10 CFR 72.48 implementation would be included in an NEI licensing workshop currently scheduled to be held in November 2001.

Attachments: 1. Attendees List
2. Workshop Package

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DATE:	3/20/01	3/22/01	3/22/01			

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

March 22, 2001

MEMORANDUM TO: Susan M. Frant, Deputy Director
Licensing and Inspection Directorate
Spent Fuel Project Office, NMSS

THRU: Michael Tokar, Chief
Transportation and Storage Safety
and Inspection Section
Spent Fuel Project Office, NMSS

Michael Tokar

FROM: Chester Poslusny, Senior Project Manager /RA/
Transportation and Storage Safety
and Inspection Section
Spent Fuel Project Office, NMSS

Chester Posly

SUBJECT: WORKSHOP ON IMPLEMENTING THE REVISED 10 CFR 72.48 REGULATION

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Attachments: 1. Attendees List
2. Workshop Package

Attachment 1
Attendance List

Workshop on 10 CFR 72.48 Implementation
March 16, 2001

Attendance List

NAME	ORGANIZATION	Phone #	E-mail
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Workshop on 10 CFR 72.48 Implementation
March 16, 2001

Attendance List

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Workshop on 10 CFR 72.48 Implementation
March 16, 2001

Attendance List

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Lynnette Hendricks	NEI	202-739-8109	lxh@nei.org

Attachment 2

NRC NEI 72.48 IMPLEMENTATION WORKSHOP MEETING MATERIALS

NRC NEI 72.48 Implementation Workshop
NRC White Flint II Auditorium
March 16, 2001

NRC NEI 72.48 Implementation Workshop
NRC White Flint II Auditorium
March 16, 2001

Contents

NRC NEI 72.48 Implementation Workshop
NRC White Flint II Auditorium
March 16, 2001

8:00 AM	Welcome and Workshop Objectives	
	NRC – Perspectives	Bill Brach
	Industry – Perspectives	L. Hendricks
8:30 AM	10CFR72.48 Rule	NRC
	Regulatory Guide	NRC
	Regulatory Issue Summary	NRC
	Inspection Guidance	NRC
9:20 AM	Break	
9:30 AM	Panel Discussion - Implementation	A.Nelson/C.Jackson
	NEI 96-07 App B	
	• Applicability	Glenn Michael
	• Screening process	Pete LeBlond
	• Evaluation process	Terry Sides
11:15 AM	Break	
11:30AM	Panel Discussion (continued)	
	• Vendor perspectives (case study)	Brian Gutherman
	• Documentation and reporting	Glenn Michael
	• Discussion and Q&A	All
1:00 PM	Closing remarks	NEI/NRC

NRC NEI 72.48 Implementation Workshop
NRC White Flint II Auditorium
March 16, 2001

8:00 AM	Welcome and Workshop Objectives	
	NRC – Perspectives	E. William Brach Dir. Spent Fuel Project Office
	Industry – Perspectives	Lynnette Hendricks Dir. Licensing, NEI
8:30 AM	10CFR72.48 Rule Regulatory Guide Regulatory Issue Summary	Christopher Jackson, SFPO
	Inspection Guidance	Chester Poslusny, SFPO
9:20 AM	Break	
9:30 AM	Panel Discussion NEI 96-07 App B Implementation	Alan Nelson, NEI
	• Applicability	Glenn Michael Arizona Public Service
	• Screening Process	Pete LeBlond LeBlond & Assoc.
	• Evaluation Process	Terry Sides Southern Nuclear Co.
11:15 AM	Break	
11:30AM	Panel Discussion (continued) • Vendor Perspectives	Brian Gutherman, Holtec International
	• Documentation and Reporting	Glenn Michael Arizona Public Service
	• Discussion and Q&A	All
1:00 PM	Closing remarks	NEI/NRC

Part 72.48 Implementation
Frequently Asked Question *

10 CFR 72.48 ____________________
(note appicable subsection)

NEI 96-07 App. B__________________
(note applicable section)

Question for Clarification:

Recommended Response:

* The effective date for "10 CFR 72.48, Changes, Tests, and Experiments," is April 5, 2001. During the course of implementation there maybe regulatory interpretations or guidance (NEI 96-07 Appendix B: Guidelines for 10 CFR 72.48 Implementations) that might need clarification. NEI will establish FAQs on the NEI Members Home Page (see key technical issues: 10 CFR 50.59 & Dry Storage). Once the FAQ has been forwarded to Alan Nelson (apn@nei.org) it will be peer reviewed by the Issue Task Force and forward to the NRC SFPO for review and comment and later posted as final.

10 CFR 72.48 RULE CHANGES

Christopher Jackson
Chet Poslusny
Spent Fuel Projects Office

INTRODUCTION

- PURPOSE OF THE RULE AND RULE CHANGE
- WHAT HAS CHANGED?
- IMPLEMENTATION ISSUES

PURPOSE OF 72.48

- PERMIT CHANGES THAT MAINTAIN AN ACCEPTABLE LEVEL OF SAFETY, AS DOCUMENTED IN THE SAR

NEED FOR NEW RULE

- IMPLEMENTATION PROBLEMS SURFACED WITH THE OLD RULE
- HOW TO INTERPRET CERTAIN OF THE OLD CRITERIA BECAME DIFFICULT
- INCONSISTENT IMPLEMENTATION THE OLD RULE BECAME A PROBLEM

GOALS FOR NEW RULE

- MAKE RULE CLEAR AND EASIER TO USE
- ALLOW MINIMAL CHANGES
- CREATE CONSISTENCEY WITH 10 CFR 50.59

WHAT HAS CHANGED?

- ELIMINATED THE TERM "UNREVIEWED SAFETY QUESTION"
- ELIMINATED THE SIGNIFICANT INCREASE IN OCCUPATIONAL EXPOSURE CRITERION
- ELIMINATED THE SIGNIFICANT ENVIRONMENTAL CONSEQUENCE CRITERION

WHAT HAS CHANGED?

CONTINUED

- ELIMINATED REDUNDANT CHANGE MECHANISMS
- ALLOW MINIMAL INCREASES IN FREQUENCY AND LIKELIHOOD
- PROVIDED DEFINITIONS FOR KEY TERMS

WHAT HAS CHANGED?

Continued

- "MARGIN OF SAFETY" CRITERION REPLACED WITH NEW CRITERIA
  - LIMITS ON FISSION PRODUCT BARRIERS
  - CHANGES TO METHODOLOGIES
- EXPANDED CHANGE AUTHORITY TO CoC HOLDERS, AND,
- EXPANDED THE REPORTING REQUIREMENTS.

REVISED RULE

- APPLICABILITY
  - CHANGES DESCRIBED IN SAR
- SCREENING
  - CHANGES THAT AFFECT DESIGN FUNCTION
- EVALUATION PROCESS
  - EIGHT CRITERIA
- DOCUMENTATION AND REPORTING

EVALUATION PROCESS

- MORE THAN MINIMAL INCREASE;
  - FREQUENCY OF ACCIDENT,
  - LIKELIHOOD OF MALFUNCTION,
  - CONSEQUENCES OF ACCIDENT,
  - CONSEQUENCES OF MALFUNCTION,
- CREATE POSSIBILITY;
  - ACCIDENT,
  - MALFUNCTION.

EVALUATION PROCESS

CONTINUED

- EXCEED OR ALTER FISSION PRODUCT LIMIT,
- DEPART FROM A METHOD OF EVALUATION.

IMPLEMENTATION ISSUES

- REGULATORY GUIDE 3.72, "GUIDANCE FOR IMPLEMENTATION OF 10 CFR 72.48, CHANGES, TESTS, AND EXPERIMENTS," WILL BE ISSUED PRIOR TO RULE EFFECTIVE DATE.
- RG 3.72 WILL ENDORSE NEI 96-07 APPENDIX B DATED MARCH 5, 2001.

IMPLEMENTATION ISSUES

Continued

- REGULATORY ISSUE SUMMARY 2001-03, "CHANGES, TESTS, AND EXPERIMENTS," WAS ISSUED IN JANUARY OF 2001, DESCRIBING SCHEDULER EXEMPTIONS.
- LICENSE HOLDERS HAVE PROPOSED ALTERNATIVES.

INSPECTION GUIDANCE

- IP 60857, "REVIEW OF 10 CFR 72.48 EVALUATIONS"
- TO BE ISSUED IN APRIL 2001.
- MODELED AFER IP 71111.02 USED FOR 50.59 EVALUATIONS.
- USED IN SUPPORT OF IP 60851 THROUGH 60856.

INSPECTION GUIDANCE

IP 60857 INSPECTION REQUIREMENTS

- Select sample of evaluations and screenings
  - Guidance provided on obtaining a "smart" sample
- Review and assess adequacy of evaluations and screenings
  - Inspectors referred to RG 3.72 and NEI 96-07 for guidance and examples in assessing whether evaluations are appropriate
- If needed, perform programmatic review using IP 37001
  - As appropriate, substitute Part 72 ISFSI-related terms for Part 50 reactor-related terms

POTENTIAL FUTURE WORK

- FSAR UPDATING GUIDANCE
- EVALUATION METHODOLOGY GUIDANCE
- REVISED GUIDANCE DUE TO LESSONS LEARNED

Text of 10 CFR 72.48

§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 (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 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 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 §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.

Comparison Between 50.59 and 72.48

Comments	50.59	72.48
	(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.	(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.	(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).

Comparison Between 50.59 and 72.48

	(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) 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.
	(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) *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**.
	(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) *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).

	(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).	(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) 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.	(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.**

Comparison Between 50.59 and 72.48

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

Comparison Between 50.59 and 72.48

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

Comparison Between 50.59 and 72.48

	(c)(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.	(c)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.
	(c)(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.	(c) (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.	(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.
	(d)(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.	(d)(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.

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

Comparison Between Old 72.48 and New 72.48

Comments	Old 72.48	New 72.48
		(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.

Comparison Between Old 72.48 and New 72.48

Comments	Old 72.48	New 72.48
		(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).
	(a)(1) The holder of a license issued under this part:	(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.

Comparison Between Old 72.48 and New 72.48

Comments	Old 72.48	New 72.48
The restrictions for changes that involve "a significant increase in occupational exposure or a significant unreviewed enviromental impact" have not been carried over to the new rule.	May: (i) Make changes in the ISFSI or MRS described in the Safety Analysis Report, (ii) Make changes in the procedures described in the Safety Analysis Report, or (iii) 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 in the license conditions incorporated in the license, an unreviewed safety question, a significant increase in occupational exposure or a significant unreviewed enviromental impact.	(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 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;	(c)(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)

Comparison Between Old 72.48 and New 72.48

Comments	Old 72.48	New 72.48
		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 (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 FSAR (as updated);
	(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;	(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);
	(iii) If the margin of safety as defined in the basis for any technical specification is reduced.	(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.
		(c)(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. .
		(c) (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

Comparison Between Old 72.48 and New 72.48

Comments	Old 72.48	New 72.48
	(b)(1) The licensee shall maintain records of changes in the ISFSI or MRS and of changes in procedures made pursuant to this section if these changes constitute changes in the ISFSI or MRS or procedures described in the Safety Analysis Report. The licensee shall also maintain records of tests and experiments carried out pursuant to paragraph (a) of this section. These records 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. The records of changes in the ISFSI or MRS and of changes in procedures and records of tests must be maintained until the Commission terminates the license.	(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) Annually, or at such shorter interval as may be specified in the license, the licensee shall furnish to the appropriate regional office, specified in appendix A of part 73 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, a report containing a brief description of changes, tests, and experiments made under paragraph (a) of the section, including a summary of the safety evaluation of each. Any report submitted by a licensee pursuant to this paragraph will be made a part of the public record pertaining to this license.	(d)(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.
	(d)(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	(d)(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

Comparison Between Old 72.48 and New 72.48

Comments	Old 72.48	New 72.48
	period of 5 years.	CoC issued pursuant to this part. (d)(4) The records of changes in procedures and of tests and experiments shall be maintained for a period of 5 years.
		(d)(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).
		(d)(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.
	(c) The holder of a license issued under this part who desires -- (1) To make changes in the ISFSI or MRS or the procedures as described in the Safety Analysis Report, or to conduct tests or experiments not described in the Safety Analysis Report, that involve an unreviewed safety question, a significant increase in occupational exposure, or significant unreviewed environmental impact, or (2) To change the license conditions shall	

Comparison Between Old 72.48 and New 72.48

Comments	Old 72.48	New 72.48
	submit an application for amendment of the license, pursuant to §72.56.	

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

January 23, 2001

NRC REGULATORY ISSUE SUMMARY 2001-03
CHANGES, TESTS, AND EXPERIMENTS

ADDRESSEES

All U.S. NRC Part 50 and Part 72 licensees and Part 72 Certificate of Compliance holders.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) as guidance to addressees in making the transition to the requirements of recently amended regulations in Title 10 of the *Code of Federal Regulations*, namely, Sections 50.59 and 72.48 (10 CFR 50.59 and 10 CFR 72.48). Both sections are titled "Changes, tests, and experiments." This RIS requires no action or written response on the part of an addressee.

BACKGROUND INFORMATION

On October 4, 1999, the NRC published final rules (64 FR 53582) amending 10 CFR 50.59 and 10 CFR 72.48. These regulations address licensee requirements for making changes to a facility (reactor facility, independent spent fuel storage installation, or monitored retrievable storage installation) without prior NRC approval. The effective date of 10 CFR 50.59, as amended, is 90 days after the issuance of applicable regulatory guidance. On November 14, 2000, the Commission approved for publication Regulatory Guide (RG) 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments." The NRC noticed the availability of RG 1.187 in the *Federal Register* on December 13, 2000 (65 FR 77773). Therefore, the effective date of 10 CFR 50.59, as amended, is March 13, 2001. RG 1.187 endorses the industry guidance document developed by the Nuclear Energy Institute (NEI), NEI 96-07, Revision 1, "Guidelines for 10 CFR 50.59 Implementation," dated November 2000. A separate RG is being prepared to address the implementation of 10 CFR 72.48, as amended.

During the public comment process on the draft RG, the concern was expressed that it would be difficult for licensees to schedule and complete necessary procedure revisions and training within 90 days of the publication of the RG because of planned outage schedules and other activities. It was further noted that the effective date for 10 CFR 72.48, as amended, is a different date (April 5, 2001). This raised questions about how licensees could effectively transition from the existing rule to the amended rule.

ML010040446

SUMMARY OF ISSUE

The issue addressed in this RIS is how the NRC will view licensee compliance with 10 CFR 50.59 or 10 CFR 72.48, as amended, when it finds a licensee observing the original requirements of either rule, as appropriate, after the effective date of the revision to each regulation. It is the NRC's view that since the amended 10 CFR 50.59 is a relaxation of the existing requirements, as a general matter, if a licensee is in compliance with the old rule, the licensee also satisfies the requirements of the amended rule. With regard to 10 CFR 72.48, the revisions to the rule were more extensive than those made to 10 CFR 50.59, particularly with regard to the reporting requirements. As a result, it is not possible to conclude that compliance with old rule also demonstrates compliance with the revised rule. However, it is the NRC's view that both the old rule and the new rule provide an acceptable level of safety. As a result, the NRC will consider scheduler exemptions to the effective date of 10 CFR 72.48 on a case-by-case basis for power reactor licensees that want to implement the revised 10 CFR 50.59 and 10 CFR 72.48 together. The NRC endorses the orderly transition to the requirements of the amended rules, even if a licensee implements them after their effective dates. More information on this matter is given in Attachment 1.

BACKFIT DISCUSSION

This RIS requires no action or written response. Consequently, the staff did not perform a backfit analysis.

FEDERAL REGISTER NOTIFICATION

The staff did not publish a notice of opportunity for public comment in the *Federal Register* because the RIS is informational and pertains to a staff position that does not represent a departure from current regulatory requirements and practice.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not request any information collection.

If you have any questions about this issue, please call or e-mail one of the technical contacts listed below.

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Office of Nuclear Reactor Regulation

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Attachments:
1. Guidance on the Transition From the Original to the Amended Requirements of 10 CFR 50.59 and 10 CFR 72.48
2. List of Recently Issued NRC Regulatory Issue Summaries

PAPERWORK REDUCTION ACT STATEMENT

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Accession No.: ML010040446 Template No.: NRR-052

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GUIDANCE ON THE TRANSITION FROM THE ORIGINAL TO THE AMENDED REQUIREMENTS OF 10 CFR 50.59 and 10 CFR 72.48

BACKGROUND

On October 4, 1999 (64 FR 53582), the NRC published a final rule revising 10 CFR 50.59 (and related requirements in 10 CFR Part 50 and 10 CFR Part 72). The Part 50 requirements were to become effective 90 days after issuance of applicable regulatory guidance. The effective date for the revised 10 CFR 50.59 is March 13, 2001, the amendments to 10 CFR 72.48 will become effective April 5, 2001. During the development of an industry guidance document on the implementation of 10 CFR 50.59 (endorsed by RG 1.187), certain issues arose concerning the transition from the old rule to the new rule. This attachment addresses these issues.

DISCUSSION OF ISSUES

Issue 1: Licensees have planned refueling outages and other activities for the period between December and March 2001 and will find it difficult to complete necessary procedure revisions and train affected personnel before the rules become effective. To ease the transition to the new rules, may a licensee continue using the old rule after the effective date of either 10 CFR 50.59 or 10 CFR 72.48 until procedure revisions and training can be completed? Alternatively, could a licensee implement the revised Section 50.59 on the same date as the revised Section 72.48 (i.e., April 5, 2001)? What licensee actions are needed to do this?

Response: In promulgating the revisions to Sections 50.59 and 72.48, the Commission noted that the revised rules allow licensees greater flexibility than the existing rules to make changes without prior NRC approval. With regard to 50.59, if a licensee is appropriately implementing the old rule, it is complying with the amended rule. Some delay in implementation beyond the effective dates of the revised rules (a few months) is reasonable and acceptable. To make an orderly transition, licensees must have sufficient time to prepare procedures and train personnel. Although no formal notification of the NRC or NRC approval is needed to delay implementation, a licensee is encouraged to communicate its plans and implementation schedule to the NRC resident inspector and regional staff. A licensee may use the sample letter at the end of this attachment to communicate its plans to NRC staff. With regard to 10 CFR 72.48, because there are additional reporting requirements associated with the new rule, implementation of the revised 10 CFR 72.48 beyond April 5, 2001 date will require a scheduler exemption.

Issue 2: Which version of 10 CFR 50.59 or 10 CFR 72.48 applies when the evaluation of a change is begun before the effective date of the amended rule but not completed until after the amended rule becomes effective?

Response: The 10 CFR 50.59 or 10 CFR 72.48 requirements in effect when a licensee completes its evaluation of a change (i.e., when the safety review committee approves the change) will apply. Evaluations started after the effective date, should follow the revised rule.

Since the revised rule is a relaxation of the old rule, the NRC staff will consider an evaluation begun under the old rule and based on the procedures for the old rule but completed after the effective date of the revised rule to comply with the revised rule during the transition period. However, without a scheduler exemption, the reporting requirements associated with the revised 10 CFR 72.48 are applicable to all changes completed following the April 5, 2001 rule implementation date.

Issue 3: If a licensee completes an evaluation under the old rule but discovers new information after the revised rule takes effect and must revise the 10 CFR 50.59 or 10 CFR 72.48 evaluation, should the licensee use the new rule or the old rule to revise the evaluation?

Response: The licensee would need to comply with the rule that is in effect at the time the evaluation is revised. However, for 10 CFR 50.59 as previously noted, since the new rule is effectively a relaxation of the old rule, using the old rule to revise the evaluation is also acceptable. Only the parts of the evaluation affected by the new information need to be revised.

Issue 4: The effective date of the revised maintenance rule (10 CFR 50.65), including the new paragraph 50.65(a)(4), is November 28, 2000, which is before the effective date of the amended 10 CFR 50.59. During the time before 10 CFR 50.59 becomes effective, are licensees required to perform both paragraph 50.65(a)(4) assessments and 10 CFR 50.59 reviews for temporary alterations in support of maintenance?

Response: The guidance in RG 1.182 is that maintenance activities, including associated temporary alterations, are to be evaluated in accordance with paragraph 50.65(a)(4) of the maintenance rule. A 10 CFR 50.59 evaluation is not required (provided the temporary alteration will be in effect for less than 90 days at power). This same guidance is given in RG 1.187 for the implementation of 10 CFR 50.59. The revised rule explicitly states that a 10 CFR 50.59 evaluation is not needed when another regulation establishes the control process for such activities. However, the Commission, in approving RG 1.182, allowed licensees to use the guidance in RG 1.182 before the effective date of the amended 10 CFR 50.59. Therefore, if a licensee evaluates temporary alterations in accordance with paragraph 50.65(a)(4) of the maintenance rule, a 10 CFR 50.59 review is not needed.

Issue 5: If an evaluation has been completed before the effective date of either 10 CFR 50.59 or 10 CFR 72.48, as amended, but the change has not yet been implemented, what action (if any) is required?

Response: The new rule requires no action for changes evaluated but not implemented before the effective date of the rule. The licensee has the option of doing a new evaluation under the revised rule for changes that might have required prior approval under the old rule but do not require prior approval under the new rule. Such an evaluation would provide the basis for not seeking NRC approval for the change.

Issue 6: May a licensee continue to reference 10 CFR 50.59 or 10 CFR 72.48 evaluations performed under the old rule and guidance when making a similar change in the future?

Response: Past evaluations will continue to be a valuable resource to licensees for 10 CFR 50.59 or 10 CFR 72.48 screening and evaluations of similar changes. However, a licensee should use the definitions and criteria of the new rule and approved guidance for evaluations of proposed changes that are begun after the revised rule becomes effective (except as noted in Issue 1, above).

Issue 7: Some previous NRC documents that discuss 10 CFR 50.59 or 10 CFR 72.48 may be inconsistent with the revised rule or the new regulatory guidance, for example, Generic Letter (GL) 95-02 (regarding analog-to-digital upgrades under 10 CFR 50.59) and Bulletin (BL) 96-02 (regarding the movement of heavy loads). How should these documents be viewed now?

Response: NRC documents such as those noted were written to be used with the old rule. To the extent that the rule requirements that led to particular statements or conclusions have been revised, the impact of the rule revisions on those statements must be taken into account. For example, GL 95-02 discusses the evaluation criterion "malfunction of a different type." This criterion will no longer apply, having been revised to "malfunction with a different result." However, other aspects of the guidance (for example, the effect of the digital instrumentation on the system in which it is used) will remain applicable.

With respect to BL 96-02, if a heavy load movement is part of a maintenance activity, there is no 10 CFR 50.59 evaluation needed. The fact that the load is larger or is moving in a different load path than previously evaluated would enter into the risk assessment required by 10 CFR 50.65 (a)(4) and determine under what plant conditions the load lift should occur. If the heavy load lift is not maintenance related, and so requires a 10 CFR 50.59 evaluation, the licensee should follow the requirements of the revised rule to determine whether prior NRC approval is needed. For example, the licensee should consider whether the change would increase the consequences of an accident previously evaluated or creates an accident of a different type.

Issue 8: The implementation guidance endorsed in RG 1.187 appears to be written with power reactors in mind. How does implementation of the revised 10 CFR 50.59 apply to non-power reactors?

Response: The effective date of the revised 10 CFR 50.59 requirements, as established by publication of the *Federal Register* notice (65 FR 77773) announcing the availability of RG 1.187, applies to non-power reactors. As noted above, flexibility is allowed in the implementation period to accommodate training and procedural updating needs, and a properly executed program for complying with the old rule requirements will likely satisfy the new rule requirements during the implementation period. Non-power reactor licensees should note that some concepts in the revised rule such as a "method of evaluation described in the FSAR" may not have an equivalent in programs based on the old rule. The NRC staff will accept and reply to questions from non-power reactor licensees that my arise during implementation of the new rule.

ISSUE 1 — SAMPLE LETTER

TO: NRC, Document Control Desk, Washington DC 20555

FROM: Appropriate Licensee Point of Contact

SUBJECT: IMPLEMENTATION OF REVISED 10 CFR 50.59

The effective date for the revised 10 CFR 50.59, was established in a December 13, 2000, *Federal Register* notice (65 FR 77773), as March 13, 2001. As discussed in Regulatory Issue Summary (RIS) 2001-03, dated January 23, 2001, the NRC has stated that to permit an orderly transition to the revised rule, licensees may implement the rule later than this date. Although an exemption is not necessary, the RIS suggested that a licensee may want to communicate its implementation plan to the NRC. It is our intention to implement the revised requirements of 10 CFR 50.59 on [date]. [Here the licensee may add any information about its plans to phase in 10 CFR 50.59 implementation; for example, the licensee will follow the new rule requirements for evaluations begun after the date provided, but will finish other evaluations under the old process]. Until that time, we will continue to implement our existing 10 CFR 50.59 review processes.

[The licensee may discuss its reasons for delaying implementation. For example, the plant will be in a refueling outage shortly after the effective date, and there is insufficient time to train personnel in the revised process; or the licensee does not want to transition during a refueling outage since this activity already places demands on staff and would not be in the best interests of safety; or the licensee wants to implement the revised section 50.59 at the same time as the revised section 72.48, to minimize confusion.]

cc: NRC Regional Office
NRC Resident Inspection Office(s) [as applicable]
NRR Project Managers (for affected facilities)
E. McKenna, NRR/RGEB

LIST OF RECENTLY ISSUED
NRC REGULATORY ISSUE SUMMARIES

Regulatory Issue Summary No.	Subject	Date of Issuance	Issued to
2001-02	Guidance on Risk-Informed Decisionmaking in License Amendment Reviews	01/18/01	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2001-01	Eligibility of Operator License Applicants	01/18/01	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2000-25	Potential Deficiency in Qualification of Okonite Single-Conductor Electrical Control Cables	12/26/00	All holders of OLs for pressurized-water reactors (PWRs), except those who have permanently ceased operations and have certified that fuel have been permanently removed from the reactor vessel
2000-24	Concerns about Offsite Power Voltage Inadequacies and Grid Reliability Challenges Due to Industry Deregulation	12/21/00	All holders of OLs for pressurized-water reactors (PWRs), except those who have permanently ceased operations and have certified that fuel have been permanently removed from the reactor vessel
2000-23	Recent Changes to Uranium Recovery Policy	11/30/00	All holders of materials licenses for uranium and thorium recovery facilities

OL = Operating License
CP = Construction Permit

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

March 2, 2001

MEMORANDUM TO: E. William Brach, Director
Spent Fuel Project Office, NMSS

FROM: Susan F. Shankman, Deputy Director */RA/ (M.W. Hodges for*
Spent Fuel Project Office, NMSS *S.F. Shankman)*

SUBJECT: PUBLIC COMMENTS AND PROPOSED FINAL REGULATORY GUIDE, "GUIDANCE FOR IMPLEMENTATION OF 10 CFR 72.48, CHANGES, TESTS, EXPERIMENTS"

BACKGROUND

The Nuclear Regulatory Commission (NRC) issued Draft Regulatory Guide DG-3020, "GUIDANCE FOR IMPLEMENTATION OF 10 CFR 72.48, CHANGES, TESTS, AND EXPERIMENTS," for public comment in December 2000. A notice was published in the Federal Register making the documents available for public comment with the public comment period ending on January 22, 2001. The NRC Draft Regulatory Guide DG-3020 endorsed, with a few clarifications, draft Nuclear Energy Institute (NEI) guidance document NEI 97-06, Appendix B entitled, "GUIDELINES FOR 10 CFR 72.48 IMPLEMENTATION." The NEI guidance document closely follows the guidance document used to implement the requirements of the revised 10 CFR 50.59 because the requirements of 10 CFR 50.59 and 10 CFR 72.48 are virtually identical. The NRC endorsed the NEI guidance on 10 CFR 50.59 in Regulatory Guide 1.187 in November of 2000. The Commission approved publication of the Regulatory Guide in Staff Requirements Memorandum, "SECY-00-0203 - FINAL REGULATORY GUIDE ON IMPLEMENTATION OF 10 CFR 50.59 (CHANGES, TESTS, AND EXPERIMENTS)," on November 14, 2000.

This memorandum summarizes all of the public comments received on the DG-3020 and describes how the comments were considered in the development of the final Regulatory Guide. As a result of the public comments, modifications have been made to the proposed final 10 CFR 72.48 Regulatory Guide. Enclosed is a copy of the proposed final Regulatory Guide that provides guidance to implement the requirements of 10 CFR 72.48.

PUBLIC COMMENT SUMMARY

Four public comment letters were received by the NRC. The comments were generally supportive of the draft regulatory guide. One comment letter was received from the NEI (Ref. 4). NEI organized a 72.48 Issue Task Force that made specific regulatory guidance comments and equivalent changes to the draft NEI 97-06, Appendix B guidance document. Subsequently, in response to the NRC request for public comment, on January 30, 2001, NEI submitted a revised version of NEI 97-06, Appendix B, which was dated January 26, 2001 (Ref.

Contact: Christopher Jackson, NMSS/SFPO
(301) 415-2947

5). Two comments were received from licensees (Ref. 2 and 3), both endorsing the NEI comments. One comment letter was received from a cask certificate holder which also endorsed the NEI comments.

METHOD OF EVALUATION COMMENTS

DG-3020 Section 1.1, "Departure From a Method of Evaluation Described in the FSAR," identified three clarifications to the NEI-97-06 guidance document. The first clarification pointed out that an example associated with the use of methodology benchmarking, to demonstrate the concept of conservative versus non-conservative changes, could be confusing for spent fuel cask applications. Because the example was directed to reactor operations, the NRC suggested that the NEI guidance be expanded to illustrate the concept. In response, NEI proposed two changes that clarify the guidance. The changes make it clear that the demonstration of a methodology as being conservative must be evaluated over the entire range of the intended use of a methodology. Because the revised NEI guidance incorporates the clarifications, suggested by the NRC associated with the benchmarking, the clarification is no longer needed in the final Regulatory Guide and has been removed.

The second clarification suggested revision of an example in the guidance associated with the NRC approval of methods. The NRC maintained that the example did not accurately describe a typical NRC technical review. NEI subsequently proposed a revision to the example in the NEI guidance, as suggested in DG-3020. Because the revised NEI guidance incorporates the clarifications, suggested by the NRC associated with the NRC approval of methods, the clarification is no longer needed in the final Regulatory Guide and has been removed.

The third clarification explained how NRC reviews are typically performed and how "approved by the NRC for the intended application," should be applied. With a few minor changes, NEI incorporated the proposed clarification into the revised NEI guidance. Because the revised NEI guidance incorporates the clarifications, suggested by the NRC associated with how "approved for the intended application" should be applied, the clarification is no longer needed in the final Regulatory Guide and has been removed.

One comment was received regarding how "method of evaluation" is defined (Ref. 1). The comment stated that a better definition of "method of evaluation" is needed and that Part 72 safety analysis activities require more guidance than a Part 50 safety analysis. Specifically, the comment suggested that the term be defined at a high level. Although the staff agrees that there are differences in the specific analyses and methods used in Part 50 and Part 72, the staff does not agree that term "method of evaluation" should be defined differently or implemented differently. The term "method of evaluation" was defined in the Statements of Consideration for both of the final 10 CFR 72.48 and 10 CFR 50.59 rules (64 FR 53582). The NRC believes that this definition is appropriately implemented in NEI 96-07, Appendix B. The staff did not change the final Regulatory Guide as a result of this comment.

FISSION PRODUCT BARRIER COMMENT

DG-3020 Section 1.2, "Design Basis Limit for a Fission Product Barrier," identified a problem associated with the list, in the NEI guidance, of typical fission product barrier design basis limits. The NRC, in DG-3020, proposed revising the example. NEI subsequently revised the example

to incorporate NRC's revision. Because the revised NEI guidance incorporates the revisions, suggested by the NRC associated with fission product barrier limits, the clarification is no longer needed in the final Regulatory Guide and has been removed.

EDITORIAL COMMENTS

One comment was received indicating that the phrasing of DG-3020, Section B associated with relationship of the guidance for 10 CFR 72.48 and 10 CFR 50.59 could cause confusion (Ref. 2). Specifically, the comment recommended that the term "generally applicable" in DG-3020, associated with the 10 CFR 72.48 guidance being generally applicable to 10 CFR 59.59 evaluations, be replaced by the term "similar." The NRC already asserts that the two guidance documents are similar, as DG-3020 characterizes the two documents as being "virtually identical." However, the NRC acknowledges that the phrasing in DG-3020 may inadvertently cause confusion in the future. After reviewing the entire regulatory guide, the NRC has concluded that statement does not contribute to the guidance provided by the document and can be removed without altering the overall intent of the guidance. As a result of the public comment and to avoid the potential for confusion in the future, the sentence has been eliminated from the final Regulatory Guide.

NEI has included a number of editorial changes in the final NEI-96-07, Appendix B, and described each of the specific changes in their comment letter (Ref. 4). The editorial changes clarify previous statements and were inserted by NEI to prevent misunderstandings. The changes include replacing the term "cask designs used" with "casks deployed," removing a reference to occupational exposure when describing the requirements of 10 CFR Part 72, and explicitly restating the requirements of 10 CFR 72.212. The NRC has reviewed these editorial changes and found them to be acceptable.

CONCLUSION

The staff has reviewed the public comments on DG-3020, which were generally supportive of the draft regulatory guide and the NEI guidance. The staff has also reviewed changes incorporated into the latest version of NEI 96-07, Appendix B (Ref. 5). The staff has determined that NEI-96-07, Appendix B adequately implements the requirements of 10 CFR 72.48. As a result of the public comments, we have made revisions to the final Regulatory Guide. The proposed final Regulatory Guide will endorse NEI-96-07, Appendix B, dated January 26, 2001, without exception.

REFERENCES

1. Letter from B. Gutherman, Holtec International, "Comments on Draft NRC Regulatory Guide DG-3020," January 18, 2001.

2. Letter from M. Tuckman, Duke Power Company, "Comments on Draft Regulatory Guide DG-3020, 'Guidance for Implementation of 10 CFR 72.48, Changes, Tests and Experiments,'" January 23, 2001.

3. Letter from S. Bauer, Arizona Public Service Company, "Palo Verde Nuclear Generating

Station (PVNGS), Units 1, 2, 3, Docket Nos. STN 50-529/529/530, Comments on Draft Regulatory Guide DG-3020, 'Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments,'" January 23, 2001.

4. Letter from L. Hendricks, Nuclear Energy Institute, "Draft Regulatory Guide DG-3020, 'Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments,'" January 22, 2001.

5. Letter from L. Hendricks, Nuclear Energy Institute, "NEI-96-07 Appendix B: 'Guidelines for 10 CFR 72.48 Implementation,'", January 30, 2001.

ATTACHMENT: Proposed Final 10 CFR 72.48 Regulatory Guide

cc: L. Hendricks
Nuclear Energy Institute

S. Bauer
Arizona Public Service Company

M. Tuckman
Duke Power Company

B. Gutherman
Holtec International

March 2, 2001

Station (PVNGS), Units 1, 2, 3, Docket Nos. STN 50-529/529/530, Comments on Draft Regulatory Guide DG-3020, 'Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments,'" January 23, 2001.

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5. Letter from L. Hendricks, Nuclear Energy Institute, "NEI-96-07 Appendix B: 'Guidelines for 10 CFR 72.48 Implementation,'", January 30, 2001.

ATTACHMENT: Proposed Final 10 CFR 72.48 Regulatory Guide

cc: L. Hendricks
Nuclear Energy Institute

S. Bauer
Arizona Public Service Company

M. Tuckman
Duke Power Company

B. Gutherman
Holtec International

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DATE	2/9/2001		2/15/01		2/9/01		2/15/01		3/1/01	

OFC	SFPO		SFPO		SFPO					
NAME	MWHodges		SFShankman (MWH)		EWBrach					
DATE	3/2/01		3/2/01		3/2/01					

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Proposed Final 10 CFR 72.48 Regulatory Guide

U.S. NUCLEAR REGULATORY COMMISSION Month 2001

REGULATORYGUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 3.XXX

(Draft was issued as DG-3020)

GUIDANCE FOR IMPLEMENTATION OF 10 CFR 72.48, CHANGES, TESTS, AND EXPERIMENTS

A. INTRODUCTION

In 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste," Section 72.48, "Changes, Tests and Experiments," contains requirements for the process by which licensees and certificate holders may make changes to their independent spent fuel storage installations (ISFSIs), spent fuel storage cask designs, or monitored retrieval storage installations (MRSs) and procedures as described in the final safety analysis report (as updated), without prior NRC approval, under certain conditions. This regulation was originally promulgated in 1980 as 10 CFR 72.35, "Changes, Tests, and Experiments." It was subsequently designated as 10 CFR 72.48 and was recently revised (October 4, 1999, 64 FR 53582). The recent revision to the rule made comparable changes to 10 CFR 50.59, "Changes, Tests, and Experiments," that addresses the change process for reactor licensees.

As a result of lessons learned from operating experience and other initiatives related to control of conformance of reactor and ISFSI facilities with their final safety analysis report (FSAR) descriptions, the NRC determined that additional action was necessary to provide clarity and consistency in implementation of the rule. The NRC staff recommended specific actions in SECY-97-205, "Integration and Evaluation of Results from Recent Lessons-Learned Reviews,"[1] dated September 10, 1997. In a staff requirements memorandum dated March 24, 1998,[1] the Commission directed the staff to initiate rulemaking to revise the requirements of 10 CFR 50.59 and 10 CFR 72.48

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[1]Copies are available on the NRC's web site <WWW.NRC.GOV> in the Reference Library through Rulemaking, and for inspection or copying for a fee from the NRC Public Document at 11555 Rockville Pike, Rockville, MD 20852; the PDR's mailing address is Mail Stop 01-F-13, Washington, DC 20555; telephone (301-415-4737) or (800)397-4209; fax (301)415-3548; email <PDR@NRC.GOV>.

Regulatory guides are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the NRC staff in its review of applications for permits and licenses. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public. Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Written comments may be submitted to the Rules and Directives Branch, ADM, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Regulatory guides are issued in ten broad divisions: 1, Power Reactors; 2, Research and Test Reactors; 3, Fuels and Materials Facilities; 4, Environmental and Siting; 5, Materials and Plant Protection; 6, Products; 7, Transportation; 8, Occupational Health; 9, Antitrust and Financial Review; and 10, General.

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to clarify the requirements and to allow changes involving only "minimal increases" in probability or consequences to be made without prior NRC approval.

On October 4, 1999, the NRC issued a revision to 10 CFR 72.48 that becomes effective on April 5, 2001. The text of this revised rule is contained in Appendix A to this regulatory guide for convenience.

Regulatory guides are issued to describe to the public methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, to explain techniques used by the staff in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with regulatory guides is not required.

The information collections contained in this regulatory guide are covered by the requirements of 10 CFR Part 72, which were approved by the Office of Management and Budget, approval number 3150-0132. 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.

B. DISCUSSION

OBJECTIVE

The objectives of 10 CFR 72.48 are to ensure that licensees and holders of Certificates of Compliance (CoC) (1) evaluate proposed changes to their facilities or cask design for their effects on the licensing basis of the ISFSI, cask design, or MRS, as described in the FSAR, and (2) obtain prior NRC approval for changes that meet specified criteria as having a potential impact upon the basis for issuance of the license or certificate of compliance. This regulatory guide, through its endorsement of a guidance document for licensees and CoC holders, provides guidance on complying with the revised requirements of 10 CFR 72.48.

DEVELOPMENT OF INDUSTRY GUIDELINE, Appendix B to NEI 96-07

Following publication of the revised rule, the Nuclear Energy Institute (NEI) submitted a guidance document, NEI 96-07, "Guidelines for 10 CFR 50.59 Evaluations," for the implementation of 10 CFR 50.59 and requested NRC endorsement through a regulatory guide. The NRC endorsed Revision 1 of NEI-96-07 in Regulatory Guide 1.187, which was issued in November 2000. On June 15, 2000, NEI submitted to the NRC Appendix B, "Guidelines for 10 CFR 72.48 Implementation," to NEI 96-07. The NRC provided written comments on the document to NEI on August 18, 2000, and NEI provided to the NRC revisions dated September 28, 2000, and November 6, 2000. The letter from NEI, dated November 9, 2000, that forwarded the November 6, 2000, version of NEI 96-07, Appendix B also contained a list of the changes from the September 28, 2000, version.

In December 2000, the NRC issued for public comment Draft Regulatory Guide DG-3020, "GUIDANCE FOR IMPLEMENTATION OF 10 CFR 72.48, CHANGES, TESTS, AND EXPERIMENTS," which endorsed Appendix B to NEI 96-07 with a number of clarifications. On January 22, 2001 NEI submitted proposed changes to Appendix B to NEI 96-07 to resolve the

Draft Regulatory Guide clarifications. On January 30, 2001 NEI submitted a revised final Appendix B to NEI 96-07, which was dated January 26, 2001.[2]

NEI developed this guidance document by modifying appropriate language and sections in Revision 1 of NEI 96-07 to apply to Part 72 licensees and certificate holders. Thus, a significant portion of Appendix B includes text that is identical to that in Revision 1 of NEI 96-07, which has been endorsed by the NRC in Regulatory Guide 1.187.

C. REGULATORY POSITION

1. APPENDIX B TO NEI 96-07

Appendix B, "Guidelines for 10 CFR 72.48 Evaluations," dated January 26, 2001, to NEI 96-07 provides methods that are acceptable to the NRC staff for complying with the provisions of 10 CFR 72.48.

2. OTHER DOCUMENTS REFERENCED IN APPENDIX B TO NEI 96-07

Appendix B to NEI 96-07 references other documents, but NRC's endorsement of Appendix B should not be considered an endorsement of any referenced documents.

3. USE OF EXAMPLES IN APPENDIX B TO NEI 96-07

Appendix B to NEI 96-07 includes examples to supplement the guidance. While appropriate for illustrating and reinforcing the guidance in Appendix B, NRC's endorsement of Appendix B should not be considered a determination that the examples are applicable for all licensees and CoC holders. A licensee or certificate holder should ensure that an example is applicable to its particular circumstances before implementing the guidance as described in an example.

4. GUIDANCE FOR SITE-SPECIFIC ISFSI LICENSE RENEWAL

For site-specific ISFSI licensees that obtain license renewal, the guidance in Appendix B and in this regulatory guide is applicable to information added to the FSAR for summary descriptions of the programs, activities for managing the effects of aging, and evaluation of time-limited aging analyses that will support the bases for site-specific ISFSI license renewal. If necessary, the staff may provide further guidance or examples for use with respect to such programs and evaluations at a later date.

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[2]Copies of Appendix B to NEI 96-07 are available through NRC's web site, <WWW.NRC.GOV> through Rulemaking, and through NRC's Electronic Reading Room at the same site, under Accession number ML010370087. Copies are available for inspection or copying for a fee from the NRC Public Document Room, telephone (301) 415-4737 or (800) 397-4209, fax (301) 415-3548, email<PDR@NRC.GOV>.

5. USE OF OTHER METHODS

Licensees and certificate holders may use methods other than those proposed in Appendix B to NEI 96-07 to meet the requirements of 10 CFR 72.48. The NRC will determine the acceptability of other methods on a case-by-case basis.

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees, certificate holders, and applicants regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which a licensee or certificate holder proposes an acceptable alternative method for complying with the specified portions of the NRC's regulations, the methods described in this guide will be used in the evaluation of licensee or certificate holder compliance with the requirements of 10 CFR 72.48.

APPENDIX A
TEXT OF 10 CFR 72.48

§ 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 (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 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 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 §§ 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.

VALUE/IMPACT STATEMENT

A separate Value/Impact Statement was not prepared for this regulatory guide. The Value/Impact Statement that was prepared as part of the Regulatory Analysis for the rulemaking in May 1999 is still applicable. Copies of the Regulatory Analysis are available for inspection or copying for a fee in the NRC's Public Document Room at 11555 Rockville Pike, Rockville, MD, Washington, DC, as part of SECY-99-130, dated May 12, 1999. The PDR may be reached by telephone at (301)415-4737 or fax at (301)415-3548.

ADAMS Accession Number of
RG-3.XXX: MLXXXXXXX

ADAMS Accession Number of
Appendix B to NEI 96-07:
ML010370087

10 CFR 72.48 Implementation: Applicability

Glenn Michael, APS

Background

- 50.59
  - NSAC-125 (1989)
  - NRC lessons learned reviews
  - NEI 96-07 & Industry Initiative
  - Draft NUREG-1606 (SECY-97-035)
  - Generic Letter 91-18, Revision 1
  - Rulemaking ending with SRM/SECY-99-130
  - NEI 96-07, Revision 1; NRC RG 1.187
- 72.48
  - NEI 96-07, Appendix B; NRC RG DG-3020

The Final Rules 50.59 and 72.48

- Accomplishments
  - Eliminated "zero standard"
  - Established key definitions
  - Refocused context on safety analyses and fission product integrity
  - Affirmed purpose as a regulatory threshold
  - Clarified role of overlapping requirements
  - Consistency between Part 50 and Part 72
  - Allowed CoC holders to utilize 72.48

NEI 96-07, Appendix B 72.48 Guidance

- NEI 72.48 Industry Task Force established
- NEI 96-07, Revision 1 used as the source
- Changes made as needed for Part 72
- Changes identified in bold font
- Several draft iterations issued for industry and NRC comment
- Draft RG DG-3020 issued Dec 2000
- Latest draft Appendix B issued March 5, 2001, incorporates DG-3020 clarifications

NEI 96-07, Appendix B

- Major differences from NEI 96-07, R1
  - Potential Part 71 impacts
  - MR and FP guidance not applicable
  - Part 50 NRC and NEI guidance documents may be useful to Part 72 licensees
  - Definition of UFSAR
  - Important-to-safety vs safety-related
  - Dose limits in 72.104 and 72.106 vs SRP

NEI 96-07, Appendix B (cont)

- Major differences from NEI 96-07, R1 (cont)
  - Design event categories vs accident categories
  - Fission product barriers
  - "Approved" methodologies
  - Process to obtain NRC approval
  - Reporting

Referenced Guidance Documents

- Part 50 NRC and NEI guidance documents referenced in Appendix B
  - NRC GL 83-11, Supplement 1 - Licensee qualification for performing safety analyses.
  - NEI 99-04/NRC RIS 2000-17 - Commitment management
  - NEI 98-03, Rev 1/NRC RG 1.181 - UFSAR update guidance
  - NEI 97-04, App B/NRC RG 1.186 - Design bases guidance
  - NRC GL 91-18, Rev 1 - Resolution of degraded and nonconforming conditions

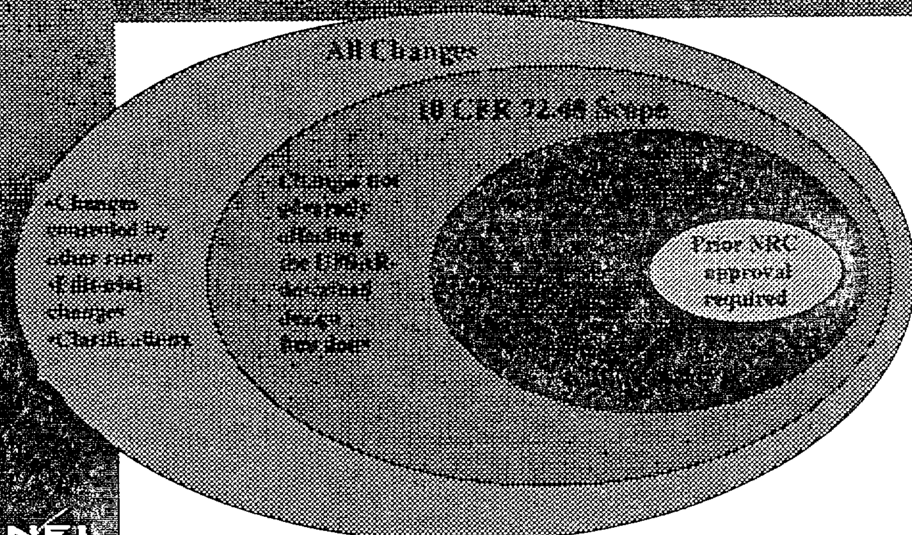
Obtaining NRC Approval When Required by 72.48

- Site Specific Licensee: Request license amendment per 10 CFR 72.56.
- CoC Holder: Request CoC amendment per 10 CFR 72.244.
- General Licensee:
  - Request CoC holder to request a CoC amendment per 10 CFR 72.244; or
  - Request a 72.7 exemption from 10 CFR 72.48(c)(2).
    - justify why exemption is needed vs. CoC amendment; and
    - justify the change itself

10 CFR 72.48 Process

- Applicability
  - Does 10 CFR 72.48 apply to the proposed activity?
- Screening
  - Must the proposed activity be evaluated against the eight criteria of 10 CFR 72.48(c)(2)?
- Evaluation
  - Does the proposed activity require prior NRC approval?

Changes Under 10 CFR 72.48



10 CFR 72.48 Applicability

- 10 CFR 72.48 generally* need not be applied to activities controlled by more specific requirements
  - Technical specifications
  - Regulation
    - e.g., 10 CFR 50.54(a), (p), (q), 72.44(e), (f), 73.55(a)

* Sometimes both 10 CFR 72.48 and another process must be applied

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72.48 Applicability Determination

- Typical actions that would not result in need for NRC approval under 72.48
  - Editorial or administrative changes.
  - Existing 72.48 screening/evaluation covers scope of change.
  - Change brings facility or cask into conformance with licensing documents.
  - Changes previously approved by NRC.
  - Correct inconsistencies where documentation supports one position or another.
  - Minor corrections to configuration documents which do not involve a change to a design function.

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72.48 Applicability Determination (cont.)

- Applicability determinations should be justified and documented in the change package.
- Applicability determination documentation is not subject to 10 CFR 72.48(d) documentation and reporting requirements.

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Compensatory Actions for D/NC Conditions

- Familiar guidance from NEI 96-07, R0, and GL 91-18, R1 (for reactors)
- Three alternative courses of corrective action to address D/NC conditions
  - Restore to UFSAR-described condition
    - Timely corrective action commensurate w/significance
  - Temporary procedure or facility change implemented pending ultimate corrective action
    - apply 10 CFR 72.48 to compensatory measure
  - Accept condition "as-is" or redesign
    - Apply 10 CFR 72.48 to the change from the UFSAR-described design

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Facility, Cask, and Procedure Changes

- For each proposed change:
  - 1. Specifically identify the change.
  - 2. Identify which specific cask(s) or facility the change applies to (e.g., specific cask numbers, etc.),
  - 3. Identify where the cask or facility feature being changed is documented (e.g., cask FSAR Rev 1).
  - 3. CoC holders should identify if the change affects casks already shipped to users .
  - 4. ISFSI licensees should identify if the change requires technical assistance from the CoC holder.
  - 5. Identify if the change is to the cask design (for 60-day reporting requirements).

NEI

NEI

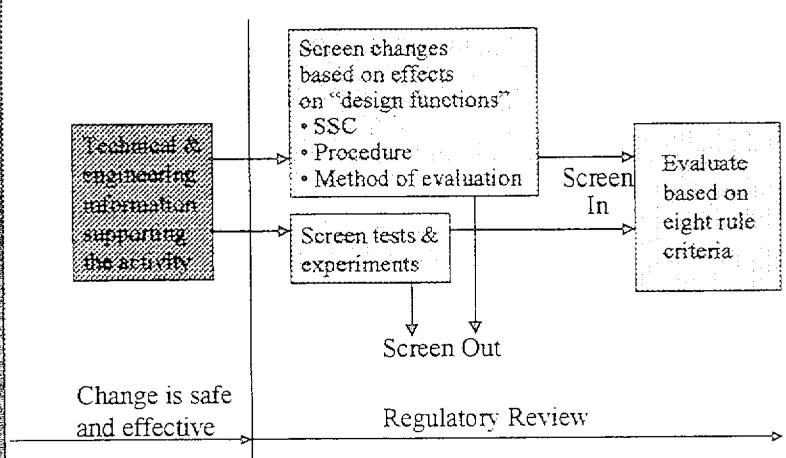
Screening Process

Pete LeBlond

President

LeBlond and Associates

Screening Process



Screening Process Background

- Screening is the process for identifying activities that require evaluation under 10 CFR 72.48
- Has always been part of industry guidance for 10 CFR 50.59
- Now supported and enhanced by rule definitions and guidance

[illegible]ing Basis

- A 10 CFR 72.48 evaluation is required if the activity is:
  - A *change* to the *facility or spent fuel storage cask design as described in the UFSAR*,
  - A *change* to a *procedure as described in the UFSAR*, or
  - A *test or experiment not described in the UFSAR*

Definition of "Change"

A modification, addition to, or removal from, the *facility or spent fuel storage cask design* or *procedures* that affects:

1) a *design function*,

2) *method of performing or controlling the function*, or

3) *an evaluation that demonstrates that intended functions will be accomplished*

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Definition of "Facility"

- *Facility or spent fuel storage cask design as described in the UFSAR*
  - The SSCs that are described in the UFSAR
  - The design and performance requirements for these SSCs
  - The evaluations or methods of evaluation included in the UFSAR which demonstrate that the intended functions of the SSCs will be accomplished
- *Facility means either an ISFSI or a MRS*

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Definition of "Procedures"

- *Procedures as described in the UFSAR* are documents that contain information that describe
  - How actions related to system operation are to be performed
  - Controls over the performance of design functions

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Definition of "Design Fuction"

- Design bases functions

  and

- Other SSC functions described in the UFSAR that support or impact design bases functions.

- Includes the conditions under which intended functions are required to be performed (e.g., equipment response times, environmental conditions, single failure)

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"Change" (cont.)

- *Design Function*
- *Method of performing or controlling a function*
  - How a design function is accomplished as credited in the safety analyses
  - E.g., specific operator actions, procedure sequence, manual vs. automatic action
- *Evaluation that demonstrates that intended functions will be accomplished*
  - *Methods of evaluation* as defined in 3.10 that are used to show that the design function will be accomplished

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Definition [illegible]

- *Methods of evaluation* means the calculational framework used for evaluating behavior or response of the facility or SSC
- Methods of interest are those that demonstrate
  - Design basis limits of fission product barriers are met
  - Consequences of accidents do not exceed regulatory limits
  - Intended design functions will be accomplished under design basis conditions

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Elements of Methodology

Elements of Methodology	Example
Data correlations	Tipover and end drop analysis
Means of data reduction	ASME III methods for evaluating cask parameters
Physical constants or coefficients	Heat transfer coefficients
Mathematical models	Decay heat models
specific limitations of a computer program	Benchmarking and correlation ranges
Statistical treatment of results	Criticality calculations; fuel characterization
Dose conversion factors and assumed source term(s)	Vendor-specific thermal design procedure
	ICRP factors

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Method vs. Input

- *Input parameters* are those values derived directly from the physical characteristics of SSCs or plant processes, including flow rates, temperatures, pressures, dimensions, measurements (e.g., volume, weight, size, etc.) and system response times.

- Input values specified in a methodology are considered an element of the method

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"Test or Experiments"

- *Tests of experiments not described in the UFSAR* means any activity where any SSC is utilized or controlled in a manner which is either:
  - Outside the reference bounds of the design bases, or
  - Inconsistent with the analyses or descriptions in the UFSAR

Screening Documentation

- Screening records are not subject to 72.48(d) record keeping requirements
- Typically retained with change packages; guidance says you should
- Not necessary for changes that require evaluation or are not implemented
- Changes that screen out may, nonetheless affect the UFSAR, and require update

Basic Screening Questions

- Will implementation of the proposed activity:
  - Affect a design function of an SSC, as described in the UFSAR?
  - Affect the performance or method of control of a design function described in the UFSAR?
  - Affect an evaluation methodology described in the UFSAR used in establishing the design bases or in the safety analyses?
- "Affect" is defined and requires an adverse impact

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Basic Screening Questions (cont.)

- Will implementation of the proposed activity:
  - Result in a test or experiment, not described in the UFSAR, which is outside the reference bounds of the design bases as described in the UFSAR or is inconsistent with the analyses or descriptions in the UFSAR?

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Change to the Facility Example 1

- Replacement of cask lid retaining bolts
  - Technical evaluation determines the replacement bolts will not affect UFSAR-described sealing function
  - "Affects" for Design Functions means "adverse"
  - If overall strength remains unchanged or is improved, then the activity screens out
  - Screening decision is independent of the need to update the UFSAR

NEI

Change to the Facility Example 2

- Replace a globe valve with a ball valve in a vent/drain line solely used during the loading process
  - The venting and draining function of the valve does not qualify as a Design Function
    - Not a Design Basis Function
    - Does not "support or impact" a Design Basis Function
  - Change screens out because there is no adverse affect on a Design Function

NEI

Change to the Facility Example 3

- Alter the brand of coating used on the cask from the brand identified in the UFSAR
  - Technical evaluation shows coatings are equivalent
  - No adverse affect on a Design Function
  - Change screens out as an equivalent change

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Change to the Facility Example 4

- Placement of a fuel oil storage tank on-site
  - Technical evaluation determines if a fire or explosion could have any impact on the cask's integrity
  - The cask's ability to withstand fires and explosions are Design Functions
  - <u>Any</u> adverse affect would screen in

NEI

Change to the Procedures Example 1

- Alteration to procedures for the maintenance of the transport equipment
  - Maintenance activities are subject to 10 CFR 72.48
  - Screening will determine if the performance or control of Design Functions are adversely affected
  - "Affects" means "adverse" or any alteration/replacement for "method of ..."
  - Maintenance of transport equipment does not involve any Design Functions
  - Procedure alteration would screen out

NEI

Change to the Procedures Example 2

- Alteration to the method of sequence of cask loading procedure
  - Cask loading would involve Design Functions
  - Sequence alteration would adversely affect (alter) the method of performing or controlling the Design Functions
  - Procedure change would screen in

NEI

Change to the Methods Example 1

- NRC-approved computer code used for cask containment analysis is altered
  - UFSAR identifies code by name but no specifics
  - Method is considered "described in the UFSAR"
  - "Affects" is defined as being outside the constraints and limitations of the NRC SER and the associated Topical Report
  - Change screens out because code is being used as intended
  - If use of the code is beyond the bounds of approval, then it screens in

NEI

10 CFR 72.48 Evaluations

Terry Sides

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NEI

10 CFR 72.48 Evaluations

- Familiar guidance with 2 major changes:
  - Allowing "minimal" increases eliminates the "zero standard" on:
    - accident frequency
    - malfunction likelihood
    - dose consequences
  - "Margin of Safety" replaced by two new criteria regarding:
    - Integrity of fission product barriers
    - Methods of evaluation
- Accident and malfunction criteria also clarified

NEI

The "Minimal" Principle

- Fundamental rationale: "Minimal" increases do not:
  - Affect basis for previous NRC licensing decisions
  - Impact acceptability of facility designs
- Allowing "minimal" changes is consistent with intent of 10 CFR 50.59 and 72.48
  - Regulatory review threshold

NEI

Possible Impacts

- Improvement
- No increase
- "Negligible" increase
  - Not discernible
  - No clear trend
- "Minimal" increase
  - Per guidance in NEI 96-07, Appendix B
- More than minimal
  - Requires license amendment

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Determining "Minimal"

- Accident frequency & malfunction likelihood
  - Qualitative evaluation
  - Optional quantitative guidance provided
- Dose consequences
  - Quantitative evaluation

NEI

"Minimal" Accident Frequency

- Higher frequency category = More than minimal
- An increase is minimal if evaluation demonstrates any of the following:
  - Negligible/no increase, or improvement
  - The following are met, as applicable *
    - NRC requirements
    - Design, material and construction standards
  - Not more than 10% increase in accident frequency; or resultant frequency is ≤ 1E-6

* Prerequisite for applying the "more than minimal" criterion

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"Minimal" Malfunction Likelihood

- An increase is minimal if evaluation demonstrates any of the following:
  - Negligible/no increase, or improvement
  - All design bases requirements are met *
  - Not more than a factor of two increase in malfunction likelihood

* Prerequisite for applying the "more than minimal" criterion

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"Minimal" Malfunction Likelihood

- "Minimal"
  - Adding devices such that all applicable requirements, codes & standards met
  - Substitution w/similar component
- More than "minimal:"
  - A change causes design stresses to exceed code allowables
  - System redundancy, diversity, independence, separation is reduced

NEI

"Minimal" Consequences

- Quantitatively determined
- Consequences = dose
- 10 CFR 72.48 does not apply to activities governed by Part 20
- Analyses or record are those by licensees or CoC holder in UFSAR, not NRC confirmatory analyses
- Accident limits based on 10 CFR 72.106
  - 10% of delta between value in UFSAR and 72.106 limit
- Off-normal limits based on 10 CFR 72.104
  - 10 CFR 72.104 limit = minimal increase

NEI

Important Clarifications

- Accidents
  - Focus is on new accident sequences
    - Similar frequency and significance to those addressed in UFSAR
    - Not bounded by previously analyzed accidents
    - Previously not considered credible that become credible
  - Natural phenomena handled under malfunction criteria
    - Earthquakes are "accidents" that challenge SSCs
    - Licensee changes don't affect frequencies

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Important Clarifications

- Malfunctions
  - Increases in likelihood of malfunction (c(2)(ii))
    - Focus on cause/mode
  - Malfunctions with a different result (c(2)(vi))
    - Focus is on effect/result
    - New malfunctions that are as likely as those previously evaluated
    - Malfunctions not bounded by previous evaluation

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Design Basis Limits for Fission Product Barriers

- "Margin of Safety" criterion being replaced by two new criteria
  - Better focused scope of review
  - Less subjective
  - No reliance on NRC SERs
- Resolves long-standing MoS problems:
  - Too vague and broad
  - "Margin of Safety" is undefined
  - Undefined scope of "basis for any technical specification"

NEI

Design Basis Limits for Fission Product Barriers

- New criterion c(2)(vii) features
  - Well-defined terms
  - Focus on design bases limits found in UFSAR
- Review guidance is separated into:
  - Identification of affected DBLFPB
  - Will the DBLFPB be "exceeded or altered?"

Identification of DBLFPBs

- "Controlling values used to determine the integrity of the fission product barrier"
- DBLFPBs have three main attributes
  - Fundamental
  - Numerical
  - Located in UFSAR
- Examples from NEI 96-07, Appendix B
  - Intended to be complete, but site-specific differences may exist

Typical Fission Product Barrier Design Basis Limits

Barrier	***Design Bases Parameter***	***Typical Design Basis Limit***
Fuel Cladding	Protection against gross rupture	Clad Temperature: consistent with model
		Criticality K [illegible] 0.95 fresh fuel assumed 95/95 probability confidence with appropriate consideration of uncertainties biases
		Decay Heat Each fuel assembly must meet the specified limit, consistent with heat transfer calculations (e.g., 1 kW max. for each assembly)
Confinement Boundary	Preservation of confinement boundary	Pressure Canister design pressure Stresses Code compliance as described in FSAR
		Leak Rate Specified leak rate to be verified by helium leak testing after closure

NEI

Exceeded or Altered

- After the change, will the DBLFPB be:
  - Exceeded - Predicted response less conservative than the numerical design basis limit
  - Altered - The design basis limit itself is changed

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Criterion 7 Example

Removal of heat conduction elements could result in:

- PCT > UFSAR analyzed limit → *DBLFPB Exceeded*
- Cask contents administratively controlled to maintain PCT ≤ UFSAR analyzed limit → *DBLFPB Altered*

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Criterion 7 Summary

- If the proposed activity does not affect a barrier design bases parameter, C.7 is N/A
- Prior NRC approval required if a barrier design bases limit is exceeded or altered

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Controlling Methods of Evaluation

Criterion c(2)(viii):

Would the change result in a departure from a method of evaluation described in the UFSAR used in establishing the design bases or in the safety analyses?

NEI

Background

- Genesis of New Criterion
  - Methods have been part of margin of safety reviews
  - NSAC-125 and NEI 96-07 controlled methods as "implicit margins"
  - Necessitated by elimination of the "margin of safety" criterion
- Why Elevated to Rule?
  - Provide regulatory basis for current practice
  - Like facility and procedures, evaluation methods are an important part of the UFSAR/licensing basis

NEI

Key Definitions

- Definition of "change:"
  - Change means a modification or addition to, or removal from, the facility or procedures that affects: (1) a design function, (2) method of performing or controlling the (design) function, or *(3) an evaluation that demonstrates that intended (design) functions will be accomplished*
- Third element of change definition pertains solely to criterion c(2)(viii) methods of evaluation

NEI

What is a "Method of Evaluation?"

Method of evaluation = Calculational framework

- Methods of interest are those that demonstrate
  - Design basis limits of fission product barriers are met
  - Consequences of accidents do not exceed regulatory limits
  - Intended design functions will be accomplished under design basis conditions

NEI

Method vs. Input

Inputs = free volume,
burnup,
cooldown, etc.

- Input values are derived directly from the physical characteristics of the spent fuel or the spent fuel cask
- Input values specified in a methodology are considered an element of the method

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What is a "Departure"

- **Departure from a method of evaluation described in the UFSAR means:**
  - (i) changing any of the elements of the method described in the UFSAR unless the results of the analysis are conservative or essentially the same; or
  - (ii) changing from a method described in the UFSAR to another method unless that method has been approved by NRC for the intended application.

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Revising a Method

- Conservative vs. Non-Conservative Results
  - Conservative is closer to the relevant acceptance criterion
  - Focus is on Results
  - Can't create margin

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Revising a Method (cont.)

- Essentially the Same
  - Results can be non-conservative if the results are essentially the same, e.g.,
    - Different computing platforms or
    - "Typical" analysis variability
    - Within analysis margin of error

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Replacing a Method

When is a new method "*approved by the NRC for the intended application*?"

- When approved for a specific ISFSI/application
- When approved for use at another ISFSI, provided:
  - Technically appropriate for intended application
  - Within bounds previously found acceptable by NRC
  - Consistent with ISFSI's design/licensing basis
  - Licensees have demonstrated capability to perform safety analyses
    - GL 83-11, Supp. 1, provides framework
    - Increases flexibility to make changes to methods

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Criterion 8 Example

No "Cherry Picking"

- FSAR states that a damping factor of 0.5% is used in a seismic analysis performed with a given methodology that meets specified limits
- Another methodology uses a 2% damping factor to demonstrate compliance with specified limits
- Must be consistent - cannot pick up the 2% damping factor without picking up all the elements of the other methodology, including specified limits

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Control of Methods Summary

- Evaluation
  - Is the change a revision to an existing method?
    - Are the results conservative or essentially the same?
  - Is one method of evaluation being replaced with another?
    - Is the new methodology approved by the NRC?
      - Is the NRC's approval directly applicable to the ISFSI/cask design and intended application?
      - Is the change technically appropriate, and has licensee or CoC holder, as applicable, demonstrated capability to perform safety analyses per GL 83-11, S1?

NEI

Vendor Perspective

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Licensing Manager

Holtec International

Vendor Perspective (cont'd)

- Background
  - Certificate holders never had 72.48 authority
  - HI-STAR Part 72 CoC approved 10/99
  - Fabrication of first HI-STAR production unit begun earlier under exemption
  - First time fabrication – changes were expected
  - Vendor not having 72.48 authority created logistics issues
    - Vendor understands basis for change
    - Licensees have 72.48 authority
    - Fabrication schedule commitments

Vendor Perspective (cont'd)

- Large majority of changes (approx. 95%) are minor changes to design drawings
  - Dimensions and tolerances
  - Interferences
  - Material types
  - Weld size, type, configuration
- Other changes affect only the SAR text
  - Test and inspection implementation
  - Sequencing of fabrication activities
  - Changes to operating procedures

Vendor Perspective (cont'd)

- Each production unit has its share of minor manufacturing deviations
  - Raw material dimensions
  - Gouges and dings occurring during handling
  - Normal supplier deviation process used
  - Rework not in conflict with licensing basis
  - Use-as-is or repair evaluated against licensing basis for one-time deviation
    - 72.48 process used for one-time deviation
    - No change to generic design drawings

Vendor Perspective (cont'd)

- Each general licensee loading casks affected by generic design changes has had to approve the same set of changes under their 72.48 program
  - Holtec provided technical justification
  - In some cases, Holtec provided draft 72.48 evaluations
  - Majority of changes not adverse
  - Requires only screening under 96-07 guidance
- CoC holder 72.48 authority eliminates duplicate 72.48 screening/evaluation by all affected licensees
  - Licensees are still responsible for site reconciliation (e.g., effect on implementing procedures)

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Vendor Perspective (cont'd)

- Current Status
  - Holtec 72.48 Procedure In Place
  - Training of Staff Completed
  - 72.48 Backlog Being Reviewed
  - Expect to Work off Backlog Through June
- Open Issues
  - SAR Maintenance for General Licensees
  - Control of Part 71 SAR for Dual Purpose Systems
  - Generic change management
    - User group role
    - Communication between CoC holder and licensees
  - FSAR control guidance for CoC holders and general licensees

NEI

Document Reporting

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NEI

Documentation and Reporting

- 10 CFR 72.48(d) requirements
  - Retain written evaluations of changes made under 10 CFR 72.48
    - Procedure changes, tests, experiments - Five years
    - Facility and cask design changes - until fuel no longer stored, cask design no longer used, or license/CoC terminated by NRC
  - Provide summary reports to NRC every 24M, max
  - Provide records of evaluations for cask design changes to required parties within 60 days

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Documentation and Reporting (con't)

- Written evaluations (72.48(d)(1))
  - Detail commensurate with safety significance
  - Goal is completeness so that another knowledgeable reviewer can draw the same conclusion
- Screening records are not subject to 72.48(d) documentation and reporting requirements
- Note: 72.48(c)(3) requires screeners/evaluators to consider FSAR changes since last update, therefore, communication between CoC holders and cask users is necessary

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Update UFSAR to Reflect Changes

Change → Change Process(es) → UFSAR Update (as appropriate)

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NEI 96-07, Appendix B

Nuclear Energy Institute

GUIDELINES FOR 10 CFR 72.48 IMPLEMENTATION

March 5, 2001

FOREWORD

In 1999, the NRC revised 10 CFR 72.48 to be consistent with the changes being made to 10 CFR 50.59. NEI 97-06, Revision 1 was developed to provide guidance for the revised 10 CFR 50.59 regulation. Because of the intended consistency between 10 CFR 50.59 and 10 CFR 72.48, this Appendix B to NEI 96-07 was developed by utilizing the NEI 96-07, Revision 1 guidance to the maximum extent possible.

Please see the Foreword to NEI 96-07, Revision 1, "Guidelines for 10 CFR 50.59 Implementation," for background information regarding the development of NEI 96-07, Revision 1.

References in this document to "site specific licensee" include both ISFSI site specific licensees and applicants for an ISFSI site specific license. References to "CoC holder" include both spent fuel storage cask Certificate of Compliance holders and applicants for a Certificate of Compliance.

The NRC documents referenced in this document can be found on the NRC Internet Web site (www.nrc.gov) or may be obtained directly from the NRC. The NEI documents referenced in this document may be found on the NRC Internet Web site (linked from the NRC document that endorses the NEI document), or may be obtained directly from NEI.

TABLE OF CONTENTS

NEI 96-07, APPENDIX B:

Guidelines for 10 CFR 72.48 Evaluations

B1 INTRODUCTION

B1.1 PURPOSE

10 CFR **72.48** establishes the conditions under which **an independent spent fuel storage installation (ISFSI) licensee, a monitored retrievable storage installation (MRS) licensee, or a spent fuel storage cask certificate holder** may make changes in the **ISFSI** facility**, spent fuel storage cask design,** or procedures, and conduct tests or experiments without prior NRC approval. Proposed changes, tests and experiments (hereafter referred to collectively as activities) that satisfy the definitions and one or more of the criteria in the rule must be reviewed and approved by the NRC before implementation. Thus 10 CFR **72.48** provides a threshold for regulatory review—not the final determination of safety—for proposed activities.

The purpose of this **Appendix B to NEI 96-07** is to provide guidance for developing effective and consistent 10 CFR **72.48** implementation processes. **This guidance document addresses the implementation of 10 CFR 72.48 by ISFSI licensees and CoC holders for spent fuel dry cask storage. Guidance for implementation of 10 CFR 72.48 by a wet ISFSI licensee is not specifically included in this document.**

10 CFR 72.48 was revised by the NRC to conform with the revised 10 CFR 50.59 to provide for consistent implementation of these two analogous regulations. Therefore, as stated in the foreword and in Section 1.4 of NEI 96-07, the guidance of NEI 96-07 may be applied to support the implementation of 10 CFR 72.48. This Appendix was developed by starting with the guidance of NEI 96-07 for 50.59 and modifying wording only as needed to apply to 72.48. The modifications from NEI 96-07 are identified in bold lettering.

B1.2 RELATIONSHIP OF 10 CFR **72.48** TO OTHER REGULATORY REQUIREMENTS AND CONTROLS

As the process for controlling most **changes to ISFSI and spent fuel storage cask design** activities, implementation of 10 CFR **72.48** interfaces with many other regulatory requirements and controls. To optimize the use of 10 CFR **72.48**, the rule and this guidance should be understood in the context of the proper relationship with these other regulatory processes. These relationships are described below:

B1.2.1 Relationship of 10 CFR **72.48** to Other Processes that Control Licensing Basis Activities

10 CFR **72.48** focuses on the effects of proposed activities on the safety analyses that are contained in the updated FSAR (UFSAR) **for the ISFSI or spent fuel storage cask** and are a cornerstone of each **ISFSI's or spent fuel storage cask's** licensing basis. In addition to 10 CFR **72.48** control of changes affecting the safety analyses, there are several other complementary processes for controlling activities that affect other aspects of the licensing basis:

- Amendments to **a specific ISFSI** License (including the technical specifications) are sought and obtained under 10 CFR **72.56**.

- **Amendments to a cask certificate of compliance (CoC) (including terms, conditions, and specifications) are sought and obtained by the certificate holder under 72.244 (for the certificate holder and for general licensees).**

- Where changes to the **ISFSI** facility, **cask design,** or procedures are controlled by more specific regulations (e.g., quality assurance, security and emergency preparedness program changes controlled under **other applicable regulations**), 10 CFR **72.48(c)(4)** states that the more specific regulation applies.

- Changes that require an exemption from a **10 CFR Part 72** regulation are processed in accordance with 10 CFR **72.7**.

- Guidance for controlling changes to licensee commitments is provided by NEI 99-04, *Guideline for Managing NRC Commitment Changes*. **(Note: Although this guidance was developed for power reactor licensees, and endorsed for**

those licensees by the NRC in SECY-00-045 and Office Letter 900, Revision 0, it may also provide useful guidance to Part 72 licensees and CoC holders.

- The Maintenance Rule, 10 CFR 50.65, **does not apply to an ISFSI or spent fuel storage cask licensed or certified under 10 CFR Part 72. Therefore, the guidance in NEI 96-07 concerning the application of the maintenance rule for temporary changes associated with maintenance does not apply to the ISFSI or spent fuel storage cask activities under Part 72.**

- **Guidance for licensee qualification to use generically approved analysis methods is provided in NRC Generic Letter (GL) 83-11, Supplement 1. For 10 CFR 50.59 guidance, Section 4.3.8.2 of NEI 96-07 refers licensees to GL 83-11, Supplement 1, to demonstrate they are generally qualified to perform safety analyses in order to change from one method of evaluation to another. The guidance of GL 83-11, Supplement 1, should also be utilized by ISFSI licensees and cask certificate holders when evaluating proposed changes to methods of evaluation. See Section B4.3.8.2 for more detail.**

Together with 10 CFR **72.48**, these processes form a framework of complementary regulatory controls over the **ISFSI or spent fuel storage cask** licensing basis. To optimize the effectiveness of these controls and minimize duplication and undue burden, it is important to understand the scope of each process within the regulatory framework. This guideline discusses the scope of 10 CFR **72.48** in relation to other processes, including circumstances under which different processes, e.g., 10 CFR **72.48** and 10 CFR **72.56/72.244**, should be applied to different aspects of an activity.

In addition to controlling changes to the **ISFSI** facility**, spent fuel storage cask design,** and procedures described in the UFSAR under 10 CFR **72.48** as required by the rule, **general** licensees **must** also control changes to **their 10 CFR 72.212 evaluations** using the 10 CFR **72.48** process **in accordance with 10 CFR 72.212(b)(2)(ii).**

B1.2.2 Relationship of 10 CFR **72.48** to 10 CFR Part **72, Subpart G**

Prior NRC issuing an ISFSI license **or spent fuel storage cask CoC**, 10 CFR Part **72, Subpart G**, ensures that the **ISFSI** facility **and**

spent fuel storage cask design and construction meet applicable requirements, codes and standards in accordance with the safety classification of systems, structures and components (SSCs). **Subpart G** design control provisions ensure that all changes continue to meet applicable design and quality requirements. The design and licensing bases evolve in accordance with **Subpart G** requirements up to the time that an **ISFSI** license **or spent fuel storage cask CoC** is received, and 10 CFR **72.48** is not applicable until after that time. Both **Subpart G** and 10 CFR **72.48** apply following receipt of an **ISFSI** license**, or issuance of a spent fuel storage cask CoC, or implementation of 10 CFR 72.212 evaluations**.

Subpart G also addresses corrective action. The application of 10 CFR **72.48** to compensatory measures that address degraded and non-conforming conditions is described in Section **B**4.4.

B1.2.3 **Relationship of 10 CFR** 72.48 **to the UFSAR**

10 CFR **72.48** is the process that identifies when a license **or CoC** amendment is required prior to implementing changes to the **ISFSI** facility**, spent fuel storage cask design,** or procedures described in the UFSAR or tests and experiments not described in the UFSAR. As such, it is important that the UFSAR be properly maintained and updated in accordance with 10 CFR **72.70 (specific licensees) or 10 CFR 72.248 (cask certificate holders)**. **For Part 50 power reactor licensees,** guidance for updating **reactor** UFSARs to reflect activities implemented under 10 CFR 50.59 is provided by Regulatory Guide 1.181, which endorses NEI 98-03, Revision 1**, Guidelines for Updating Final Safety Analysis Reports**. **NEI 98-03, Revision 1 may also provide useful guidance to ISFSI licensees and cask CoC holders for updating the ISFSI and cask FSARs as required by 10 CFR 72.70 and 72.248. The requirements in 10 CFR 72.70 and 72.248 to update the ISFSI and cask FSARs were written by the NRC to closely conform to the reactor FSAR update requirements in 10 CFR 50.71(e).**

Changes made to the UFSAR by a specific licensee would be incorporated into the site-specific ISFSI UFSAR as required by 10 CFR 72.70.

Changes made to the cask UFSAR by the certificate holder would be incorporated into the cask UFSAR as required by 10 CFR 72.248.

General licensees should adopt and keep up-to-date the UFSAR for the casks deployed at their ISFSI. Changes made from the applicable cask FSAR by the general licensee would be identified in the required 72.48 screening/evaluation records. Although not required, the general licensee changes from the cask FSAR may be compiled in the on-site 72.212 evaluations document, or may be incorporated in a separate on-site document to assist 72.48 screeners/evaluators. Changes made by the general licensee to the ISFSI 10 CFR 72.212 evaluation would be maintained on site as required by 10 CFR 72.212(b)(2)(ii).

B1.2.4 Relationship of 10 CFR **72.48** to 10 CFR **72.3** Design Bases

10 CFR **72.48** controls changes to both 10 CFR **72.3** design bases and supporting design information contained in the UFSAR. In support of 10 CFR **72.48** implementation, Section **B**4.3.7 of this guideline defines the design basis limits for fission product barriers that are subject to control under 10 CFR **72.48**(c)(2)(vii), and Section **B**4.3.8 provides guidance on the scope of methods of evaluation used in establishing design bases or in the safety analyses that are subject to control under 10 CFR **72.48**(c)(2)(viii). Additional guidance for identifying 10 CFR 50.2 design bases is provided in NEI 97-04, Appendix B. **Since the NRC authored 10 CFR 72.48 to conform to 10 CFR 50.59, and the definition of design bases in 10 CFR 72.3 is very similar to that in 10 CFR 50.2, the guidance of Appendix B of NEI 97-04, Revision 1, for Part 50 design bases may also be useful for 10 CFR 72.48. See Section B3.5 for more details.**

As discussed in Section **B**3.3, "design bases functions" (defined in NEI 97-04, Appendix B) are a subset of "design functions" for purposes of 10 CFR **72.48** screening.

B1.2.5 Relationship of 10 CFR 72.48 to 10 CFR Part 71

Some spent fuel dry cask storage systems are designed as "multipurpose" cask systems, which are issued a CoC under 10 CFR Part 72 for storage and a CoC under 10 CFR Part 71 for transportation. These systems also have separate UFSARs for the Part 72 certification and the Part 71 certification. 10 CFR 72.48 controls activities only with respect to the design and licensing bases of the cask storage system certified under Part 72. When activities are proposed for a multipurpose cask

system that is certified under both Part 72 and Part 71, the activities may affect the Part 71 transportation design and licensing bases. Activities that affect Part 71 design and licensing bases need to be assessed and controlled under Part 71 requirements, and are outside the scope of this document.

B1.3 10 CFR 72.48 PROCESS SUMMARY:

After determining that a proposed activity is safe and effective through appropriate engineering and technical evaluations, the 10 CFR **72.48** process is applied. This process involves the following basic steps as depicted in Figure **B1**:

- Applicability and Screening: Determine if a 10 CFR **72.48** evaluation is required.
- Evaluation: Apply the eight evaluation criteria of 10 CFR **72.48**(c)(2) to determine if a license amendment **(for specific licensees) or CoC amendment (for general licensees and certificate holders)** must be obtained from the NRC.
- Documentation and Reporting: Document and report to the NRC, **and to appropriate licensees or certificate holders,** activities implemented under 10 CFR **72.48**.

Later sections of this appendix discuss key definitions, provide guidance for determining applicability, screening, and performing 10 CFR **72.48** evaluations, and present examples to illustrate the application of the process.

B1.4 APPLICABILITY TO 10 CFR **50.59**

Concurrent with the rulemaking to amend 10 CFR 50.59, the NRC made conforming changes to the analogous provisions in 10 CFR 72.48 controlling licensee changes, tests and experiments to independent spent fuel storage installations (ISFSIs). The provisions of 10 CFR 72.48 were also extended to holders of Part 72 Certificates of Compliance. As a result, 10 CFR 72.48 establishes criteria identical to those in 10 CFR 50.59 under which both an ISFSI license holder and a certificate holder may make changes to the **ISFSI** facility or cask design, changes to procedures and conduct tests or experiments without prior NRC approval.

The intent of conforming 10 CFR 72.48 to the terms of 10 CFR 50.59 was to provide for consistent implementation of these two analogous regulations.

B1.5 CONTENT OF THIS GUIDANCE DOCUMENT

The NRC has established requirements for **ISFSIs and spent fuel storage cask** systems, structures and components to provide reasonable assurance of adequate protection of the public health and safety. Many of these requirements, and descriptions of how they are met, are documented in the **ISFSI or spent fuel storage cask** updated FSAR (UFSAR). 10 CFR **72.48** allows a**n ISFSI** licensee **or spent fuel storage cask certificate holder** to make changes in the **ISFSI** facility**, spent fuel storage cask design,** or procedures as described in the UFSAR, and to conduct tests or experiments not described in the UFSAR, unless the changes require a change in the technical specifications **or spent fuel storage cask CoC** or otherwise require prior NRC approval. In order to perform 10 CFR **72.48** screenings and evaluations, an understanding of the design and licensing basis of the **ISFSI facility and spent fuel storage cask design** and of the specific requirements of the regulations is necessary. Individuals performing 10 CFR **72.48** screenings and evaluations should also understand the rule and concepts discussed in this guidance document.

In Section **B**2, the relationship between the design criteria established in 10 CFR **72, Subpart F**, and 10 CFR **72.48** is discussed as background for applying the rule.

Section **B**3 presents definitions and discussion of key terms used in 10 CFR **72.48** and this guideline.

Section **B**4 discusses the application of the definitions and criteria presented in 10 CFR **72.48** to the process of changing the **ISFSI facility, spent fuel storage cask design,** or procedures and the conduct of tests or experiments. This section includes guidance on the applicability requirements for the rule, the screening process for determining when a 10 CFR **72.48** evaluation must be performed, and the eight evaluation criteria for determining if prior NRC approval is required. Examples are provided to reinforce the guidance. Guidance is also provided on addressing degraded and nonconforming conditions and on dispositioning 10 CFR **72.48** evaluations.

Section **B5** provides guidance on documenting 10 CFR **72.48** evaluations and reporting to NRC **and to the other spent fuel storage cask users or certificate holders**.

B2 DEFENSE IN DEPTH DESIGN PHILOSOPHY AND 10 CFR 72.48

One objective of Title 10 of the Code of Federal Regulations is to establish requirements directed toward protecting the health and safety of the public from the uncontrolled release of radioactivity. At the design stage **for a spent fuel storage cask**, protection of public health and safety is ensured through the **robust** design of the physical barriers to guard against the uncontrolled release of radioactivity **and through the use of shielding to minimize radiation dose to the public from both normal and off-normal conditions of operation**. The defense-in-depth philosophy includes reliable design provisions to **(1) prevent criticality, (2) withstand postulated accidents and natural phenomena, (3) ensure fuel retrievability, and (4) provide heat removal capability**. The **two** physical barriers that **typically** provide defense-in-depth are:

- Fuel Clad
- **Spent Fuel Cask Confinement Boundary**

These barriers perform a health and safety protection function. **For storage of failed fuel, alternative barriers may be utilized to provide functions that would normally be served by the fuel clad, such as retrievabilty and criticality prevention (configuration of the fuel).** The **barriers** are designed to reliably fulfill their operational function by meeting all criteria and standards applicable to mechanical components **and** pressure components. The public health and safety protection functions are analytically demonstrated and documented in the UFSAR. Analyses summarized in the UFSAR demonstrate that under the assumed accident conditions, the consequences of accidents challenging the integrity of the barriers will not exceed limits established in 10 CFR **72.106**. **Analyses in the UFSAR also demonstrate that offsite doses during normal operations and anticipated occurrences will not exceed the limits of 10 CFR 72.104. In addition, the confinement barriers and systems must meet the criteria established in 10 CFR 72.122(h) for specific and general licensees, and 10 CFR 72.236 for CoC holders.** Thus, the UFSAR analyses provide the final verification of the nuclear safety design phase by documenting **ISFSI facility and/or spent fuel storage**

cask performance in terms of public protection from uncontrolled releases of radiation. 10 CFR **72.48** addresses this aspect of design by requiring prior NRC approval of proposed activities which, although safe, require a technical specification **or CoC** change or meet specific threshold criteria for NRC review.

This protection philosophy pervades the UFSAR accident analyses and Title 10 of the CFR. To understand and apply 10 CFR **72.48**, it is necessary to understand this perspective of maintaining the integrity of the physical barriers designed to contain radioactivity **and minimize doses to the public**. This is because:

- UFSAR accidents and malfunctions are analyzed in terms of their effect on the physical barriers. There is a relationship between barrier integrity and dose.
- The principal "consequences" that the physical barriers are designed to preclude is the uncontrolled release of radioactivity. Thus for purposes of 10 CFR **72.48**, the term "consequences" means dose.

For many **ISFSI** licensees **and spent fuel storage cask CoC holders, NRC Standard Review Plan (SRP, including NUREG-1536 or NUREG-1567) guidelines identify** the accidents or malfunctions **to be evaluated in the UFSAR**. **Accident events are considered to occur infrequently, if ever, during the lifetime of the facility/cask.** Consequences resulting from accidents and malfunctions are analyzed and documented in the UFSAR and are evaluated against dose acceptance limits of **10 CFR 72.106. In addition, the SRP identifies anticipated occurrences (also known as off-normal events) to be evaluated in the UFSAR that are expected to occur with moderate frequency or once per calendar year. Doses from anticipated occurrences and normal operations must be within the limits of 10 CFR 72.104.**

The design effort and the operational controls necessary to ensure the required performance of the physical barriers during **normal operations, anticipated occurrences, and accident conditions** are extensive. Because 10 CFR **72.48** provides a mechanism for determining if NRC approval is needed for activities affecting **ISFSI facility and spent fuel storage cask** design and operation, it is helpful to review briefly the requirements and the objectives imposed by the CFR on **ISFSI facility and spent fuel storage cask design,** construction and operation. The review will define more clearly the extent of applicability of 10 CFR **72.48**.

Subpart F to 10 CFR Part **72** provides General Design Criteria for **ISFSI and spent fuel storage cask designs**. **10 CFR 72.122(h) of Subpart F** includes criteria for protection by **the confinement barriers and systems**. The criteria establish requirements for inherent protection, instrumentation and control, **confinement barriers and systems**, control rooms **(if present)**, electric power systems, and related inspection and testing. All of these requirements concentrate on protecting fission product barriers either through inherent or mitigative means.

The following are considered the basic nuclear safety criteria for the design of an ISFSI installation:

> **(1) maintain subcriticality;**
>
> **(2) prevent the release of radioactive material above acceptable amounts;**
>
> **(3) ensure radiation rates and doses do not exceed acceptable levels; and**
>
> **(4) maintain retrievability of the stored radioactive materials.**

10 CFR 72.124 of Subpart F establishes extensive requirements on **ISFSI and spent fuel storage cask criticality safety**, the objectives again being the protection of fission product barriers **and the maintenance of long-term integrity**. With similar intent, **other** Sections **of Subpart F to Part 72** provide extensive design, inspection, testing, and operational requirements for the quality of the **ISFSI and spent fuel storage cask**. These requirements ensure inherent and engineered protection of the fission product barriers. **10 CFR 72.122(a) of Subpart F** imposes requirements on the quality of implemented protection and the conditions under which these systems must function without loss of capability to perform their safety functions. These conditions include natural phenomena, fire, operational and accident-generated environmental conditions.

The implementation of this design philosophy requires extensive accident analyses to define the correct relationship among nominal operating conditions, **functional and operating limits, and** limiting conditions for operations in order to **protect the integrity of the stored fuel or waste container, and to guard against the uncontrolled release of radioactive materials**. The **specific license** UFSAR, **the spent fuel storage cask UFSAR, and the general license 10 CFR 72.212 evaluations** present the set of

limiting analyses required by NRC. The limiting analyses are utilized to confirm the systems and equipment design, to identify critical setpoints and operator actions, and to support the establishment of technical specifications. Therefore, the results of the UFSAR accident analyses reflect performance of equipment under the conditions specified by NRC regulations or requirements. Changes to **an ISFSI facility, spent fuel storage cask** design and operation **or general license 10 CFR 72.212 evaluation,** and **to** conduct of new tests and experiments have the potential to affect the probability and consequences of accidents, to create new accidents and to impact the integrity of fission product barriers. Therefore, these activities are subject to 10 CFR **72.48**.

B3 DEFINITIONS AND APPLICABILITY OF TERMS

The following definitions and terms are discussed in this section:

B 3.1 10 CFR **72.48** Evaluation

B 3.2 Accident Previously Evaluated in the FSAR (as updated)

B 3.3 Change

B 3.4 Departure from a Method of Evaluation Described in the FSAR (as updated) **Used in Establishing the Design Bases or in the Safety Analyses**

B 3.5 Design Bases (Design Basis)

B 3.6A Facility

B 3.6**B** Facility **or Spent Fuel Storage Cask Design** as Described in the FSAR (as updated)

B 3.7 Final Safety Analysis Report (as updated)

B 3.8 Input Parameters

B 3.9 Malfunction of an SSC Important to Safety

B 3.10 Methods of Evaluation

B 3.11 Procedures as described in the FSAR (as updated)

B 3.12 Safety Analyses

B 3.13	Screening
B 3.14	Tests or experiments not described in the FSAR (as updated)

B3.1 10 CFR **72.48** EVALUATION

Definition:

A 10 CFR **72.48** evaluation is the documented evaluation against the eight criteria in 10 CFR **72.48**(c)(2) to determine if a proposed change, test or experiment requires prior NRC approval via license amendment under 10 CFR **72.56 (specific licensee) or CoC amendment under 72.244 (cask certificate holder, for itself or for a general licensee).**

Discussion:

It is important to establish common terminology for use relative to the 10 CFR **72.48** process. The definitions of *10 CFR **72.48** Evaluation* and *Screening* are intended to clearly distinguish between the process and documentation of licensee screenings and the further evaluation that may be required of proposed activities against the eight criteria in 10 CFR **72.48**(c)(2). Section **B**4.3 provides guidance for performing 10 CFR **72.48** evaluations The screening process is discussed in Section **B**4.2

The phrase "change made under 10 CFR **72.48**" (or equivalent) refers to changes subject to the rule (see Section B4.1) that either screened out of the 10 CFR **72.48** process or did not require prior NRC approval based on the results of a 10 CFR **72.48** evaluation. Similarly, the phrases "10 CFR **72.48** applies [to an activity]" or "[an activity] is subject to 10 CFR **72.48**" mean that screening, and if necessary, evaluation is required for the activity. The "10 CFR **72.48** process" includes screening, evaluation, documentation and reporting to NRC of activities subject to the rule.

B3.2 ACCIDENT PREVIOUSLY EVALUATED IN THE FSAR (AS UPDATED)

Definition:

Accident previously evaluated in the FSAR (as updated) means a design basis accident or event described in the **ISFSI or spent fuel storage cask** UFSAR including accidents, such as those typically

analyzed in **the accident analyses section(s)** of the UFSAR, and events the **ISFSI** facility **or cask design** is required to withstand such as floods, fires, earthquakes, and other external hazards.

Discussion:

The term "accidents" refers to the postulated design basis accidents that are analyzed to demonstrate that the **ISFSI** facility **and spent fuel storage casks** can be operated without undue risk to the health and safety of the public. For purposes of 10 CFR **72.48**, the term "accidents" encompasses other events for which the **ISFSI facility or cask design** is required to cope and which are described in the UFSAR (e.g., tornado missiles, fire, earthquakes and flooding).

Accidents also include new transients or postulated events added to the licensing basis based on new NRC requirements and reflected in the UFSAR pursuant to 10 CFR **72.70 (specific licensee) or 72.248 (certificate holder and general licensee)**.

B3.3 CHANGE

Definition:

Change means a modification or addition to, or removal from, the **ISFSI** facility **or spent fuel storage cask design** or procedures that affects: (1) a design function, (2) method of performing or controlling the function, or (3) an evaluation that demonstrates that intended functions will be accomplished.

Discussion:

Additions and removals to the **ISFSI** facility **or spent fuel storage cask design** or procedures can adversely impact the performance of SSCs and the bases for the acceptability of their design and operation. Thus the definition of change includes modifications of an existing provision (e.g., SSC design requirement, analysis method or parameter), additions or removals (physical removals, abandonment, or non-reliance on a system to meet a requirement) to the **ISFSI** facility **or spent fuel storage cask design** or procedures.

The definitions of "change…," "facility **or spent fuel storage cask design** …" (see Section **B**3.6 **b**), and "procedures…" (see Section **B**3.11) make clear that 10 CFR **72.48** applies to changes to underlying analytical bases for the **ISFSI** facility **or cask design** and operation as well as for changes to SSCs and procedures. Thus 10 CFR **72.48**

should be applied to a change being made to an evaluation for demonstrating adequacy of the **ISFSI** facility **or cask design** even if no physical change to the **ISFSI** facility **or cask design** is involved. Further discussion of the terms in this definition is provided as follows:

Design functions are UFSAR-described design bases functions and other SSC functions described in the UFSAR that support or impact design bases functions. Implicitly included within the meaning of design function are the conditions under which intended functions are required to be performed, such as equipment response times, process conditions, equipment qualification and single failure.

Design bases functions are functions performed by systems, structures and components (SSCs) that are (1) required by, or otherwise necessary to comply with, regulations, license conditions, **CoC conditions,** orders or technical specifications, or (2) credited in licensee **or CoC holder** safety analyses to meet NRC requirements.[1]

UFSAR description of design functions may identify what SSCs are intended to do, when and how design functions are to be performed, and under what conditions. Design functions may be performed by **important-to-safety** SSCs or non-**important-to-safety** SSCs and include functions that, if not performed, would initiate an accident that the **ISFSI or cask design** is required to withstand.

As used above, "credited in the safety analyses" means that, if the SSC were not to perform its design bases function in the manner described, the assumed initial conditions, mitigative actions or other information in the analyses would no longer be within the range evaluated (i.e., the analysis results would be called into question). The phrase "support or impact design bases functions" refers both to those SSCs needed to support design bases functions (cooling, power, environmental control, etc.) and to SSCs whose operation or malfunction could adversely affect the performance of design bases functions (for instance, control systems and physical arrangements). Thus, both **important-to-safety** and non-**important-to-safety** SSCs may perform design functions.

Method of performing or controlling a function means how a design function is accomplished as credited in the safety analyses,

[1] Definition of *design bases function* from revised Appendix B to NEI 97-04 (endorsed by Regulatory Guide **DG 1093**).

including specific operator actions, procedural step or sequence, or whether a specific function is to be initiated by manual versus automatic means. For example, substituting a manual actuation for automatic would constitute a change to the method of performing or controlling the function.

Evaluation that demonstrates that intended functions will be accomplished means the method(s) used to perform the evaluation (as discussed in Section **B**3.10). For example, a thermodynamic calculation that demonstrates **the storage cask design** has sufficient heat removal capacity for responding to a postulated accident.

Temporary Changes

Temporary changes to the **ISFSI** facility **or spent fuel storage cask design** or procedures, such as placing temporary lead shielding on equipment, removal of barriers and use of temporary scaffolding and supports, are made to facilitate a range of **ISFSI or cask** activities and are subject to 10 CFR **72.48** as follows:

- 10 CFR **72.48** should be applied to temporary changes proposed as compensatory measures to address degraded or non-conforming conditions as discussed in Section **B**4.4.
- Other temporary changes to the **ISFSI** facility **or spent fuel storage cask design** or procedures are subject to 10 CFR **72.48** in the same manner as permanent changes, to determine if prior NRC approval is required. Screening and, as necessary, evaluation of such temporary changes may be considered as part of the screening/evaluation of the proposed permanent change.

The Maintenance Rule, 10 CFR 50.65, does not apply to an ISFSI or to a spent fuel storage cask licensed or certified under 10 CFR Part 72. The guidance of NEI 96-07 in the context of 10 CFR 50.59 for assessing and managing temporary changes associated with maintenance activities in accordance with 10 CFR 50.65(a)(4) would not apply to ISFSI/cask changes.

B3.4 DEPARTURE FROM A METHOD OF EVALUATION DESCRIBED IN THE FSAR (AS UPDATED) **USED IN ESTABLISHING THE DESIGN BASES OR IN THE SAFETY ANALYSES**

Definition:

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.

Discussion:

The 10 CFR **72.48** definition of "departure ..." provides licensees with flexibility to make changes in methods of evaluation that are "conservative" or that are not important with respect to demonstrating that SSCs can perform their intended design functions. See also the definition and discussion of "methods of evaluation" in Section **B**3.10. Guidance for evaluating changes in methods of evaluation under criterion 10 CFR **72.48**(c)(2)(viii) is provided in Section **B**4.3.8.

Conservative vs. Non-Conservative Evaluation Results

Gaining margin by revising an element of a method of evaluation is considered to be a non-conservative change and thus a departure from a method of evaluation for purposes of 10 CFR **72.48**. Such departures require prior NRC approval of the revised method. In other words, analytical results obtained by changing any element of a method are "conservative" relative to the previous results, if they are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines). For example, a change in an element of a method of evaluation that changes the result of a **cask** peak pressure analysis from 45 psig to 48 psig (with design basis limit of 50 psig) would be considered a conservative change for purposes of 10 CFR **72.48**(c)(2)(viii). This is because results closer to limiting values are considered conservative in the sense that the new analysis result provides less margin to applicable limits for making future physical or procedure changes without a license amendment.

If use of a modified method of evaluation resulted in a change in calculated **cask** peak pressure from 45 psig to 40 psig, this would be non-conservative. This is because the change would result in more margin being available (to the design basis limit of 50 psig) for a licensee to make more significant future changes to the physical **cask** or procedures.

"Essentially the Same"

Licensees may change one or more elements of a method of evaluation such that results move in the non-conservative direction without prior NRC approval, provided the results are "essentially the same" as the previous result. Results are "essentially the same" if they are within the margin of error for the type of analysis being performed. Variation in results due to routine analysis sensitivities or calculational differences (e.g., rounding errors and use of different computational platforms) would typically be within the analysis margin of error and thus considered "essentially the same."

"Approved by the NRC for the Intended Application"

Rather than make a minor change to an existing method of evaluation, a licensee may also adopt completely new methodology without prior NRC approval provided the new method is approved by the NRC for the intended application. A new method is "approved by the NRC for the intended application" if it is approved for the type of analysis being conducted and the licensee **or CoC holder** satisfies applicable terms and conditions for its use. Specific guidance for making this determination is provided in Section **B**4.3.8.2.

B3.5 DESIGN BASES (DESIGN BASIS)

Definition:

(10 CFR **72.3**) Design bases means that information that identifies the specific functions to be performed by a structure, system, or component of an **ISFSI** facility **or of a spent fuel storage cask** and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be restraints derived from generally accepted state-of-the-art practices for achieving functional goals or requirements derived from analysis (based on calculation or experiments) of the effects of a postulated **event under** which a structure, system, or component must meet its functional goals. **The values for controlling parameters for external events include:-**

- **Estimates of severe natural events to be used for deriving design bases that will be based on consideration of historical data on the associated parameters, physical data, or analysis of upper limits of the physical processes involved; and**

- **Estimates of severe external man-induced events to be used for deriving design bases that will be based on analysis of human activity in the region, taking into account the site characteristics and the risks associated with the event.**

Discussion:

The definition of design bases in 10 CFR 72.3 is analogous to the definition of design bases in 10 CFR 50.2. Guidance and examples for identifying 10 CFR 50.2 design bases are provided in Appendix B of NEI 97-04, *Design Bases Program Guidelines*, Revision 1, [Month] 2000. The NRC wrote SECY-00-0047, dated February 23, 2000, to propose a draft regulatory guide (DG-1093) to endorse Appendix B to NEI 97-04. **As described in SECY-00-0047, the NEI general guidance is as follows:**

> **10 CFR 50.2 design bases consist of the following:**
>
> - **Design bases functions: Functions performed by SSCs that are (1) required to meet regulations, license conditions, orders or technical specifications, or (2) credited in safety analyses to meet NRC requirements.**
>
> - **Design bases values: Values or ranges of values of controlling parameters established by NRC requirement, established or confirmed by safety analyses, or chosen by the licensee from an applicable code, standard or guidance document as reference bounds for design to meet design bases functional requirements.**

SECY-00-0047 discusses how the implementation of the proposed NEI guidance would affect a number of Part 50 sections. Regarding 50.59, SECY-00-0047 states that "[t]he staff believes that the clarification of the definition of design bases may help licensees determine which methods are included in the scope of the [50.59(c)(2)(viii) 'departure from a method of evaluation'] criterion. The Staff also believes that, because most methods currently described in the UFSAR establish design values that are consistent with the NEI guidance for design bases values, few UFSAR methods will be excluded by this clarification."

The requirements of 10 CFR 72.48 are analogous to the requirements of 10 CFR 50.59, and the definition of design bases in 10 CFR 72.3 is analogous to the definition of design bases in 10 CFR 50.2. Therefore, the guidance of Appendix B to NEI 97-04, Revision 1, for 10 CFR Part 50 design bases may also be used for 10 CFR Part 72 design bases.

B3.6A FACILITY

Definition:

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

Discussion:

In this guidance, references to ISFSI facility include both ISFSI facility and MRS facility.

B3.6B FACILITY **OR SPENT FUEL STORAGE CASK DESIGN** AS DESCRIBED IN THE FSAR (AS UPDATED)

Definition:

Facility **or spent fuel storage cask design** as described in the final safety analysis report (FSAR) (as updated) means:

- The structures, systems, and components (SSC) that are described in the FSAR (as updated),
- The design and performance requirements for such SSCs described in the FSAR (as updated), and
- 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.

Discussion:

For specific licensees, the scope of information that is the focus of 10 CFR **72.48** is the information presented in the original FSAR **for the ISFSI facility and spent fuel storage cask design submitted and updated per the requirements of 10 CFR 72.70. For cask certificate holders, the scope of information that is the focus of 10 CFR 72.48 is the information presented in the original FSAR for the spent fuel storage cask design submitted and updated per the requirements of 10 CFR 72.248. For general licensees, the scope of information that is the focus of 10 CFR 72.48 is the information presented in the original FSAR for the spent fuel storage cask design, as amended and supplemented. Pursuant to 10 CFR 72.212(b)(2)(ii), any changes to the written evaluations for the ISFSI facility required by 10 CFR 72.212 must be evaluated using the requirements of 10 CFR 72.48(c).**

10 CFR **72.48** screening of **ISFSI** facility **or spent fuel storage cask design** changes is discussed in Section **B**4.2.1.1.

B3.7 FINAL SAFETY ANALYSIS REPORT (AS UPDATED)

Definition:

Final Safety Analysis Report (as updated) means:

- **For specific licensees, the Safety Analysis Report for a facility submitted and updated in accordance with 10 CFR 72.70;**
- **For general licensees, the Safety Analysis Report for a spent fuel storage cask design, as amended and supplemented; and**
- **For certificate holders, the Safety Analysis Report for a spent fuel storage cask design submitted and updated in accordance with 10 CFR 72.248.**

Discussion:

As used throughout this guidance document, UFSAR is synonymous with "FSAR (as updated)." The scope of the UFSAR includes its text, tables, diagrams, etc., as well as supplemental information explicitly incorporated by reference. References that are merely listed in the

UFSAR and documents that are not explicitly incorporated by reference are not considered part of the UFSAR and therefore are not subject to control under 10 CFR **72.48**.

For general licensees, the FSAR (as updated) means the FSAR for the particular cask design used at the ISFSI, as amended (updated) by the CoC holder in accordance with 10 CFR 72.248 (including changes since the last update), and as supplemented by changes made by the general licensee from the cask FSAR under 72.48. The changes made by the general licensee from the cask FSAR would be identified in the required 72.48 screening/evaluation records. Although not required, the general licensee changes from the cask FSAR may be compiled in the on-site 72.212 evaluations document, or may be incorporated in a separate on-site document to assist 72.48 screeners/evaluators.

Per 10 CFR **72.48**(c)(4), licensees are not required to apply 10 CFR **72.48** to UFSAR information that is subject to other specific change control regulations. For example, licensee Quality Assurance Programs, Emergency Plans and Security Plans **may be** controlled by **other more specific regulations**.

Per 10 CFR **72.48**(c)(3), the "FSAR (as updated)," for purposes of 10 CFR **72.48**, also includes UFSAR update pages approved by the **specific** licensee **or certificate holder** for incorporation in the UFSAR since the last required update was submitted per 10 CFR **72.70 or 72.248**. The intent of this requirement is to ensure that decisions about proposed activities are made with the most complete and accurate information available. Pending UFSAR revisions may be relevant to a future activity that involves that part of the UFSAR. Therefore, pending UFSAR revisions to reflect completed activities that have received final approval for incorporation in the next required update should be considered as part of the UFSAR for purposes of 10 CFR **72.48** screenings and evaluations, as appropriate. Appropriate configuration management mechanisms should be in place to identify and assess interactions between concurrent changes affecting the same SSCs or the same portion of the UFSAR. **The configuration management mechanisms for general licensees (and specific licensees, as applicable) should ensure that they are notified in a timely manner of pending UFSAR changes by the certificate holders of the casks they are using, so that these pending changes will be considered in subsequent 72.48 screenings/evaluations.**

Specific guidance on the required content of **ISFSI and cask** UFSAR updates **may be provided in the future.**

B3.8 INPUT PARAMETERS

Definition:

Input parameters are those values derived directly from the physical characteristics of SSC or processes in **the ISFSI facility or cask design**, including flow rates, temperatures, pressures, dimensions or measurements (e.g., volume, weight, size, etc), and system response times.

Discussion:

The principal intent of this definition is to distinguish methods of evaluation from evaluation input parameters. Changes to methods of evaluation described in the UFSAR (see Section **B**3.10) are evaluated under criterion 10 CFR **72.48**(c)(2)(viii), whereas changes to input parameters described in the **U**FSAR are considered changes to the **ISFSI** facility **or cask design** that would be evaluated under the other seven criteria of 10 CFR **72.48**(c)(2), but not criterion (c)(2)(viii).

If a methodology permits the licensee **or cask certificate holder** to establish the value of an input parameter on the basis of **ISFSI facility- or cask design**-specific considerations, then that value is an input to the methodology, not part of the methodology. On the other hand, an input parameter is considered to be an element of the methodology if:

- The method of evaluation includes a methodology describing how to select the value of an input parameter to yield adequately conservative results. However, if a licensee **or cask certificate holder** opts to use a value more conservative than that required by the selection method, reduction in that conservatism should be evaluated as an input parameter change, not a change in methodology.
- The development or approval of a methodology was predicated on the degree of conservatism in a particular input parameter or set of input parameters. In other words, if certain elements of a methodology or model were accepted on the basis of the conservatism of a selected input value, then that input value is considered an element of the methodology.

Examples illustrating the treatment of input parameters are provided in Section **B4.2.1.3**.

Section **B**4.3.8 provides guidance and examples to describe the specific elements of evaluation methodology that would require evaluation under 10 CFR **72.48**(c)(2)(viii) and to clearly distinguish these from specific types of input parameters that are controlled by the other seven criteria of 10 CFR **72.48**(c)(2).

B3.9 MALFUNCTION OF AN SSC IMPORTANT TO SAFETY

Definition:

Malfunction of SSCs important to safety means the failure of SSCs to perform their intended design functions described in the UFSAR.

Discussion:

Guidance and examples for applying this definition is provided in Section **B**4.3.

B3.10 METHODS OF EVALUATION

Definition:

Methods of evaluation means the calculational framework used for evaluating behavior or response of the **ISFSI** facility, **cask design,** or an SSC.

Discussion:

Examples of methods of evaluation are presented below. Changes to such methods of evaluation require evaluation under 10 CFR **72.48**(c)(2)(viii) only for evaluations used either in UFSAR safety analyses or in establishing the design bases, and only if the methods are described, outlined or summarized in the UFSAR. Methodology changes that are subject to 10 CFR **72.48** include changes to elements of existing methods described in the UFSAR and to changes that involve replacement of existing methods of evaluation with alternative methodologies.

Elements of Methodology	Example
▪ Data correlations	▪ **Tipover and end drop analysis**
▪ Means of data reduction	▪ **ASME methods for evaluating cask parameters**
▪ Physical constants or coefficients	▪ Heat transfer coefficients
▪ Mathematical models	▪ Decay heat models
▪ Specific limitations of a computer program	▪ **Benchmarking and correlation ranges**
▪ Specified factors to account for uncertainty in measurements or data	▪ **Criticality calculations; fuel characterization**
▪ Statistical treatment of results	▪ Vendor-specific thermal design procedure
▪ Dose conversion factors and assumed source term(s)	▪ ICRP factors

Methods of evaluation described in the UFSAR subject to criterion 10 CFR **72.48**(c)(2)(viii) are:

- Methods of evaluation used in analyses that demonstrate that design basis limits of fission product barriers are met (i.e., for the parameters subject to criterion 10 CFR **72.48**(c)(2)(vii)).

- Methods of evaluation used in UFSAR safety analyses, including **cask** and accident analyses typically presented in **the accident analyses section(s) of the** UFSAR, to demonstrate that consequences of accidents do not exceed 10 CFR **72.106** dose limits.

- Methods of evaluation used in supporting UFSAR analyses that demonstrate intended design functions will be accomplished under design basis conditions that the **ISFSI facility and cask design are** required to withstand, including natural phenomena, environmental conditions, and dynamic effects.

- **Methods of evaluation used in UFSAR analyses that demonstrate that radioactive doses from normal**

operations and anticipated occurrences will be within the limits of 10 CFR 72.104.

B3.11 PROCEDURES AS DESCRIBED IN THE FSAR (AS UPDATED)

Definition:

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).

Discussion:

For specific licensees, the scope of information that is the focus of 10 CFR **72.48** is the information presented in the original FSAR **for the ISFSI facility submitted and updated per the requirements of 10 CFR 72.70. For cask certificate holders, the scope of information that is the focus of 10 CFR 72.48 is the information presented in the original FSAR for the spent fuel storage cask design submitted and updated per the requirements of 10 CFR 72.248. For general licensees, the scope of information that is the focus of 10 CFR 72.48 is the information presented in the original FSAR for the spent fuel storage cask design, as amended and supplemented (see section B3.7).**

For purposes of 10 CFR **72.48**, "procedures" are not limited to procedures specifically identified in the UFSAR (e.g., operating and emergency procedures). Procedures include UFSAR descriptions of how actions related to system operation are to be performed and controls over the performance of design functions. This includes UFSAR descriptions of operator action sequencing or response times, certain descriptions (text or figure) of SSC operation and operating modes, operational and radiological controls, and similar information. If changes to these activities or controls are made, such changes are considered changes to procedures described in the UFSAR, and the changes are subject to 10 CFR **72.48**.

Even if described in the UFSAR, procedures that do not contain information on how SSCs are operated or controlled do not meet the definition of "procedures as described in the UFSAR" and are not subject to 10 CFR **72.48**. Sections **B**4.1.4 identifies examples of procedures that are not subject to 10 CFR **72.48.**

10 CFR 72.48 screening of procedures is discussed in Section **B**4.2.1.2.

B3.12 SAFETY ANALYSES

Definition:

Safety analyses are analyses performed pursuant to NRC requirements to demonstrate the design and performance of structures, systems, and components important to safety, with the objective of assessing the impact on public health and safety, resulting from operation of the ISFSI or MRS and including determination of:

(1) The margins of safety during normal operations and expected operational occurrences during the life of the ISFSI or MRS; and

(2) The adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents, including natural and manmade phenomena and events.

Discussion:

Safety analyses are those analyses or evaluations that demonstrate that acceptance criteria for the **ISFSI** facility's **or cask design's** capability to withstand or respond to postulated events are met. **Cask** accident analyses typically presented in **the accident analyses section(s)** of the UFSAR clearly fall within the meaning of "safety analyses" as defined above. Also within the meaning of this definition for purposes of **72.48** are:

- Supporting UFSAR analyses that demonstrate that SSC design functions will be accomplished as credited in the accident analyses;
- UFSAR analyses of events that the **ISFSI** facility **or cask design** is required to withstand such as tornado missiles, fires, floods, and earthquakes; and
- **UFSAR analyses that demonstrate the design and performance of structures, systems, and components important to safety during normal operations and expected operational occurrences.**

B3.13 SCREENING

Definition:

Screening is the process for determining whether a proposed activity requires a 10 CFR **72.48** evaluation to be performed.

Discussion:

Screening is that part of the 10 CFR **72.48** process that determines whether a 10 CFR **72.48** evaluation is required prior to implementing a proposed activity.

The definitions of "change," "facility **or spent fuel storage cask design** as described...," "procedures as described...," and "test or experiment not described..." constitute criteria for the 10 CFR **72.48** screening process. Activities that do not meet these criteria are said to "screen out" from further review under 10 CFR **72.48**, i.e., may be implemented without a 10 CFR **72.48** evaluation.

Engineering and technical information concerning a proposed activity may be used along with other information as basis for determining if the activity screens out or requires a 10 CFR **72.48** evaluation.

Further discussion and guidance on screening is provided in Section **B**4.2.

B3.14 TESTS OR EXPERIMENTS NOT DESCRIBED IN THE FSAR (AS UPDATED)

Definition:

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:

- Outside the reference bounds of the design bases as described in the UFSAR, or

- Inconsistent with the analyses or descriptions in the UFSAR.

Discussion:

10 CFR **72.48** is applied to tests or experiments not described in the UFSAR. The intent of the definition is to ensure that tests or experiments that put the **ISFSI** facility **or cask design** in a situation that has not previously been evaluated (e.g., unanalyzed storage conditions) or that could affect the capability of SSCs to perform their intended design functions (e.g., high stresses, high temperatures) are evaluated before they are conducted to determine if prior NRC approval is required.

B4 IMPLEMENTATION GUIDANCE

ISFSI Licensees **and Cask CoC holders** may determine applicability and screen activities to determine if 10 CFR **72.48** evaluations are required as described in Sections **B**4.1 and **B**4.2, or equivalent manner.

B4.1 APPLICABILITY

As stated in Section (b) of 10 CFR **72.48**, the rule applies to:

- **Each holder of a general or specific license issued under Part 72, and**
- **Each holder of a Certificate of Compliance (CoC) issued under Part 72.**

B4.1.1 Applicability to Licensee **and Cask CoC holder** Activities

10 CFR **72.48** is applicable to tests or experiments not described in the UFSAR and to changes to the **ISFSI** facility**, spent fuel storage cask design,** or procedures as described in the UFSAR, including changes made in response to new requirements or generic communications, except as noted below:

- Per 10 CFR **72.48**(c)(1)(i) **and (ii)**, proposed activities that require a change to the technical specifications **or CoC** must be made via the license amendment **or CoC amendment** process, 10 CFR **72.56 or 72.244**. Aspects of proposed activities that are not directly related to the required technical specification **or CoC** change are subject to 10 CFR **72.48**.

- To reduce duplication of effort, 10 CFR **72.48**(c)(4) specifically excludes from the scope of 10 CFR **72.48** changes to the **ISFSI** facility**, spent fuel storage cask design,** or procedures that are controlled by other more specific requirements and criteria established by regulation. For example, 10 CFR **72.44(e) and (f)** specifies criteria and reporting requirements for changing physical security and emergency plans **for ISFSI specific licensees.**

Activities controlled and implemented under other regulations may require related information in the UFSAR to be updated. To the extent the UFSAR changes are directly related to the activity implemented via another regulation, applying 10 CFR **72.48** is not required. UFSAR changes should be identified to the NRC as part of the required UFSAR update, per 10 CFR **72.70 (specific licensee) or 72.248 (cask CoC holder)**. However, there may be certain activities for which a licensee **or cask CoC holder** would need to apply both the requirements of 10 CFR **72.48** and that of another regulation. For example, a modification to a**n ISFSI** facility **or cask design** involves **revising the method of transfer of a loaded spent fuel storage cask from the power plant to the ISFSI. The change would affect the method of transfer that is identified in the UFSAR, and also would affect a specific transfer method requirement contained in the cask technical specifications.** Thus, a license**/CoC** amendment to revise the technical specifications under 10 CFR **72.56 (specific licensee) or 72.244 (cask CoC holder for itself and the general licensee)** would be required to implement the **revised transfer requirements that are in the technical specifications**. 10 CFR **72.48** should be applied to the balance of the **change**.

A second situation that could require a licensee to apply both 72.48 and another regulation is when proposed changes could affect both the 10 CFR Part 50 reactor facility described in the reactor UFSAR and the 10 CFR Part 72 ISFSI facility or cask design described in the ISFSI/cask UFSAR. An example could be a change to a cask loading activity in the reactor spent fuel building. In this case, both a 50.59 and 72.48 screening/evaluation may need to be performed.

A third situation that could involve 72.48 and another regulation would be when a change is proposed for a dual-

purpose cask system that is certified under both 10 CFR Part 71 and 10 CFR Part 72. See Section B1.2.5.

B4.1.2 Maintenance Activities

Maintenance activities are activities that restore SSCs to their as-designed condition, including activities that implement approved design changes. Maintenance activities are subject to 10 CFR **72.48**.

Maintenance activities include troubleshooting, calibration, refurbishment, maintenance-related testing, identical replacements, housekeeping and similar activities that do not permanently alter the design, performance requirements, operation, or control of SSCs. Maintenance activities also include temporary alterations to the **ISFSI** facility**, cask design,** or procedures that directly relate to and are necessary to support the maintenance. Examples of temporary alterations that support maintenance include jumpering terminals, lifting leads, placing temporary lead shielding on pipes and equipment, removal of barriers, and use of temporary blocks, bypasses, scaffolding and supports.

The Maintenance Rule, 10 CFR 50.65, does not apply to an ISFSI or to a spent fuel storage cask licensed or certified under 10 CFR Part 72. The guidance of NEI 96-07, Revision 1, for assessing and managing the risk impact of maintenance activities in accordance with 10 CFR 50.65(a)(4) would not apply to ISFSI/cask changes.

10 CFR **72.48** should be applied to temporary changes proposed as compensatory measures for degraded or non-conforming conditions, as discussed in Section **B**4.4.

B4.1.3 UFSAR Modifications

For Part 50 reactor licensees, per NEI 98-03 (Revision 1, June 1999), as endorsed by Regulatory Guide 1.181 (September 1999), modifications to the UFSAR that are not the result of activities performed under 10 CFR 50.59 are not subject to control under 10 CFR 50.59. Such modifications include reformatting and simplification of UFSAR information and removal of obsolete or redundant information and excessive detail. **As discussed in Section B1.2.3, the guidance of NEI 98-03, Revision 1 may also be useful to Part 72 licensees and CoC holders for**

updating the ISFSI and cask UFSARs required by 10 CFR 72.70 and 72.248.

Therefore, 10 CFR **72.48** need not be applied to the following types of activities:

- Editorial changes to the UFSAR (including referenced procedures, topical reports, etc.)
- Clarifications to improve reader understanding
- Correction of inconsistencies within the UFSAR (e.g., between sections)
- Minor corrections to drawings, e.g., correcting mislabeled valves
- Similar changes to UFSAR information that do not change the meaning or substance of information presented

B4.1.4 Changes to Procedures Governing the Conduct of Operations

Even if described in the **ISFSI or cask** UFSAR, changes to managerial and administrative procedures governing the conduct of **ISFSI** facility operations are controlled under 10 CFR **72, Subpart G (quality assurance)**, programs and are not subject to control under 10 CFR **72.48**. These include, but are not limited to, procedures in the following areas:

- Administrative controls for creating or modifying procedures
- Training programs
- **ISFSI/cask design** modification process
- Calculation process

B4.1.5 Changes to Approved Fire Protection Programs

The guidance of NEI 96-07, Revision 1 for this section in the context of 10 CFR 50.59 is not applicable to implementation of 10 CFR 72.48, because the standard fire protection license condition focuses on the capability of a reactor to achieve and maintain safe shutdown, and does not consider ISFSI or spent fuel storage cask considerations.

B4.1.6 Changes to Written Evaluations Required by 10 CFR 72.212

10 CFR 72.212((b)(2)(ii) requires that a general licensee evaluate any changes to the written evaluations required by 10 CFR 72.212 using the requirements of 10 CFR 72.48(c).

B4.1.7 Cask Design Changes Made by a CoC Holder and Adopted by a General Licensee

The Federal Register notice issuing the current final rule for 10 CFR 50.59 and 72.48 (64 FR 53582, October 4, 1999) stated the following in Section O.1 on page 53601:

> "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 Sec. 72.48–would be required to perform a separate evaluation under the provisions of Sec. 72.48 to determine the suitability of the change for itself."

As discussed in detail in this guidance document, per 10 CFR 72.48, a general licensee may make changes in the spent fuel storage cask design as described in the FSAR (as updated) without obtaining prior NRC approval if a change in the terms, conditions, or specifications incorporated in the CoC is not required, and the change does not meet any of the eight evaluation criteria in 10 CFR 72.48(c)(2). When the cask CoC holder has screened/evaluated a cask design change under 72.48 and determined that prior NRC approval is not required, a general licensee wanting to adopt the change would not be required to do a separate screening/evaluation for the change if the site-specific 72.212 evaluations are not changed. However, the general licensee should review their site-specific 72.212 evaluations to determine if any would be changed by the cask design change, and, if so, perform a 72.48 screening/evaluation as required by 10 CFR 72.212(b)(2)(ii). The answers and/or justification used in the 72.48 screening/evaluation may be taken from the CoC holder's 72.48 screening/evaluation if they could also apply to the general licensee screening/evaluation.

B4.2 SCREENING

Once it has been determined that 10 CFR **72.48** is applicable to a proposed activity, screening is performed to determine if the activity should be evaluated against the evaluation criteria of 10 CFR **72.48**(c)(2).

Engineering, design and other technical information concerning the activity and affected SSCs should be used to assess whether the activity is a test or experiment not described in the UFSAR or a modification, addition or removal (i.e., change) that affects:

- A design function of an SSC **or cask design**
- A method of performing or controlling the design function, or
- An evaluation for demonstrating that intended design functions will be accomplished

Sections **B**4.2.1 and **B**4.2.2 provide guidance and examples for determining whether an activity is (1) a change to the **ISFSI** facility**, spent fuel storage cask design,** or procedures as described in the UFSAR or (2) a test or experiment not described in the UFSAR. If an activity is determined to be neither, then it screens out and may be implemented without further evaluation under 10 CFR **72.48**. Activities that are screened out from further evaluation under 10 CFR **72.48** should be documented as discussed in Section **B**4.2.3.

Each element of a proposed activity must be screened except in instances where linking elements of an activity is appropriate, in which case the linked elements can be considered together. A test for linking elements of proposed changes is interdependence.

It is appropriate for discrete elements to be considered together 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; or (2) they are performed collectively to address a design or operational issue.

If concurrent changes are being made that are not linked, each must be screened separately and independently of each other.

Activities that screen out may nonetheless require UFSAR information to be updated. Updated UFSAR information **must be provided** to the NRC **by specific licensees** in accordance with 10 CFR **72.70, and by cask CoC holders in accordance with 10 CFR 72.248. CoC holders should also provide a record of changes that screen-out but result in needed UFSAR updates to cask users within 60 days of implementing the change.**

Specific guidance for applying 10 CFR **72.48** to temporary changes proposed as compensatory measures for degraded or non-conforming conditions is provided in Section **B**4.4.

B4.2.1 Is the Activity a Change to the **ISFSI** Facility**, Spent Fuel Storage Cask Design,** or Procedures as Described in the UFSAR?

To determine whether or not a proposed activity affects a design function, method of performing or controlling a design function, or an evaluation that demonstrates that design functions will be accomplished, a thorough understanding of the proposed activity is essential. A given activity may have both direct and indirect effects that the screening review must consider. The following questions illustrate a range of effects that may stem from a proposed activity:

- Does the activity decrease the reliability of the SSC **or cask** design function, including functions that are relied upon for **prevention of a radioactivity release**?
- Does the activity reduce existing redundancy, diversity or defense-in-depth?
- Does the activity add or delete an automatic or manual design function **or passive design characteristics** of the SSC **or cask**?
- Does the activity convert a feature that was automatic to manual or vice versa?
- Does the activity introduce an unwanted or previously unreviewed system interaction?
- Does the activity adversely affect the ability or response time to perform required actions, e.g., alter equipment access or add steps necessary for performing tasks?

- Does the activity degrade the seismic, **structural, heat removal, shielding, or criticality control capability** of the SSC **or cask**?

- Does the activity adversely affect other **casks that are in use at the ISFSI**?

- Does the activity affect a method of evaluation used in establishing the design bases or in the safety analyses?

- For activities affecting SSCs, procedures, or methods of evaluation that are not described in the UFSAR, does the change have an indirect effect on structural integrity, environmental conditions or other UFSAR-described design functions?

Per the definition of "change" discussed in Section **B**3.3, 10 CFR **72.48** is applicable to additions as well as to changes to and removals from the **ISFSI** facility**, cask design,** or procedures. Additions should be screened for their effects on the existing facility**, cask design,** and procedures as described in the UFSAR and, if required, a 10 CFR **72.48** evaluation should be performed. NEI 98-03 **can** provide guidance for determining whether additions to the **ISFSI** facility and procedures should be reflected in the UFSAR per 10 CFR **72.70 (specific licensee) or 72.248 (cask CoC holder)**.

Consistent with historical practice, changes affecting SSCs or functions not described in the UFSAR must be screened for their effects (so-called "indirect effects") on UFSAR-described design functions. A 10 CFR **72.48** evaluation is required when such changes adversely affect a UFSAR-described design function, as described below.

Screening for Adverse Effects

A 10 CFR **72.48** evaluation is required for changes that adversely affect design functions, methods used to perform or control design functions, or evaluations that demonstrate that intended design functions will be accomplished (i.e., "adverse changes"). Changes that have none of these effects, or have positive effects, may be screened out because only adverse changes have the potential to increase the likelihood of malfunctions, increase consequences, create new accidents or otherwise

meet the 10 CFR **72.48** evaluation criteria.[2]

Per the definition of "design function," SSCs may have preventive, as well as mitigative, design functions. Adverse changes to either must be screened in. Thus a change that decreases the reliability of a function whose failure could initiate an accident would be considered to adversely affect a design function and would screen in. In this regard, changes that would relax the manner in which Code requirements are met for certain SSCs should be screened for adverse effects on design function. Similarly, changes that would introduce a new type of accident or malfunction would screen in. This reflects an overlap between the technical/engineering ("safety") review of the change and 10 CFR **72.48**. This overlap reflects that these considerations are important to both the safety and regulatory reviews.

If a change has both positive and adverse effects, the change should be screened in. The 10 CFR **72.48** evaluation should focus on the adverse effects.

The screening process is not concerned with the magnitude of adverse effects that are identified. Any change that adversely affects a UFSAR-described design function, method of performing or controlling design functions, or evaluation that demonstrates that intended design functions will be accomplished, is screened in. The magnitude of the adverse effect (e.g., Is the minimal increase standard met?) is the focus of the 10 CFR **72.48** evaluation process.

Screening determinations are made based on the engineering/technical information supporting the change. The screening focus on design functions, etc., ensures the essential distinction between (1) 10 CFR **72.48** screenings, and (2) 10 CFR **72.48** evaluations, which focus on whether changes meet any of the eight criteria in 10 CFR **72.48**(c)(2). Technical/engineering information, e.g., design evaluations, etc., that demonstrates changes have no adverse effect on UFSAR-described design functions, methods of performing or controlling design functions, or evaluations that demonstrate that intended design functions will be accomplished may be used as basis for screening out the change. If the effect of a change is such that existing safety analyses would no longer be bounding and therefore UFSAR safety analyses must be re-run to demonstrate that all required safety functions and design requirements are met, the change is considered to be adverse and must be screened in.

[2] Note that as discussed in Section **B**4.2.1.1, any change that alters a design basis limit for a fission product barrier—positively or negatively—is considered adverse and must be screened in.

The revised safety analyses may be used in support of the required 10 CFR **72.48** evaluation of such changes.

Changes that entail update of safety analyses to reflect improved performance, capacity, timing, etc., resulting from a change (beneficial effects on design functions) are not considered adverse and need not be screened in, even though the change calls for safety analyses to be updated.

Additional specific guidance for identifying adverse effects due to a procedure or methodology change is provided in subsections **B**4.2.1.2 and **B**4.2.1.3, respectively.

B4.2.1.1 Screening of Changes to the **ISFSI** Facility **or Spent Fuel Storage Cask Design** as Described in the UFSAR

Screening to determine that a 10 CFR **72.48** evaluation is required is straightforward when a change adversely affects an SSC **or cask** design function, method of performing or controlling a design function, or evaluation that demonstrates intended design functions will be accomplished as described in the UFSAR.

However, a**n** **ISFSI** facility **or cask design may** also contain SSCs not described in the UFSAR. These can be components, subcomponents of larger components or even entire systems. Changes to SSCs that are not explicitly described in the UFSAR can have the potential to adversely affect SSC **or cask** design functions that are described and thus may require a 10 CFR **72.48** evaluation. In such cases, the approach for determining whether a change involves a change to the **ISFSI** facility **or spent fuel storage cask design** as described in the UFSAR, is to consider the larger, UFSAR-described SSC of which the SSC being modified is a part. If for the larger SSC, the change adversely affects a UFSAR-described design function, method of performing or controlling the design function, or an evaluation demonstrating that intended design functions will be accomplished, then a 10 CFR **72.48** evaluation is required.

Another important consideration is that a change to non-**important-to-safety** SSCs not described in the UFSAR can indirectly affect the capability of SSCs **or a cask** to perform their UFSAR-described design function(s). For example, increasing the heat **generation from** non-**important-to-safety** equipment **near the ISFSI** could compromise the **cask** cooling system's ability to **remove heat from the spent fuel**.

Seismic qualification, missile protection, flooding protection, **and** fire protection are some of the areas where changes to non-**important-to-safety** SSCs, whether or not described in the UFSAR, can affect the UFSAR-described design function of SSCs **or casks** through indirect or secondary effects.

Equivalent replacement is a type of change to the **ISFSI** facility **or spent fuel storage cask design** that does not alter the design functions of SSCs. Licensee**/certificate holder** equivalence assessments, e.g., consideration of performance/operating characteristics and other factors, may thus form the basis for screening determinations that no 10 CFR **72.48** evaluation is required.

As discussed in Section **B**4.2.1, only proposed changes to SSCs that would, based on supporting engineering and technical information, have adverse effects on design functions require evaluation under 10 CFR **72.48**. Changes that have positive or no effect on design functions may generally be screened out. In addition, any change to a design bases limit for a fission product barrier must be considered adverse and screened in. This is because 10 CFR **72.48**(c)(2)(vii) requires prior NRC approval any time a proposed change would "exceed *or alter*" a design bases limit for a fission product barrier.

The following examples illustrate the 10 CFR **72.48** screening process as applied to proposed **ISFSI** facility **or cask design** changes:

<u>Example 1</u>

A licensee**/certificate holder** proposes to replace a globe valve with a ball valve in a vent/drain application **that is used in the loading process** to reduce the propensity of this valve to leak. The UFSAR-described design function of this valve is to **allow the cask to be filled, drained, and vented in the loading process**. The vent/drain function of the valve does not relate to design functions credited in the safety analyses, and the licensee has determined that a ball valve is adequate to support the vent/drain function and is superior to the globe valve in terms of its isolation function. Thus the proposed change affects the design of the existing vent/drain valve—not the design function that supports system performance credited in the safety analyses—and evaluation/reporting **to NRC** under 10 CFR **72.48** is not required. The screening determination should be documented, and the UFSAR should be updated per 10 CFR **72.70 (specific licensee) or 10 CFR 72.248 (cask CoC**

holder) to reflect the change. **If this change were being made by a general licensee for a site-specific implementation, the general licensee should consider updating their 10 CFR 72.212 evaluation to reflect this deviation from the cask UFSAR.**

Example 2

The bolts for retaining the **outside lid of the outer concrete cask** are being replaced with bolts of a different material **with similar properties including load capacity and strength** and with no other design function affected such that the **lid** will still **be secured with the same strength** as before the change. Because the replacement bolts are equivalent in function to the original bolts and the **outer lid of the concrete cask** continues to meet the same functional requirements, this activity may be screened out as an equivalent change. **If the replacement bolts have a reduced load capacity or strength, the activity would screen in and would require a full 10 CFR 72.48 evaluation.**

Example 3

A licensee/certificate holder would like to change the brand of coating used on the cask. The current coating brand is identified in the cask UFSAR. The licensee/certificate holder has determined that the new brand of coating is equivalent to the current brand, based on a demonstrated laboratory qualification process (i.e., meets the performance and operating characteristics, functional requirements, corrosion resistance, heat transfer characteristics, adherence properties, etc.). This change may be screened out as an equivalent change, and an evaluation is not required. The UFSAR should be updated per 10 CFR 72.70 (specific licensee) or 10 CFR 72.248 (cask CoC holder) to reflect the change. If this change were being made by a general licensee for a site-specific implementation, the general licensee should consider updating their 10 CFR 72.212 evaluation to reflect this deviation from the cask UFSAR, if necessary.

Example 4

A licensee plans to place a motor vehicle fuel storage tank in close proximity to the cask transfer route from the fuel

building to the ISFSI. A 72.48 screening identifies that a fire or explosion of the tank could impact the UFSAR described design capability of a cask to withstand a fire or explosion. The screening would conclude that a 72.48 evaluation of the change is needed. Alternatively, if the screening identifies that the tank would be far enough away from the cask transfer route that the cask could not be affected by a tank fire or explosion, the screening would conclude that no 72.48 evaluation is needed.

B4.2.1.2 Screening of Changes to Procedures as Described in the UFSAR

Changes are "screened in" (i.e., require a 10 CFR **72.48** evaluation) if they adversely affect how SSC **or cask** design functions are performed or controlled (including changes to UFSAR-described procedures, assumed operator actions and response times). Changes to a procedure that does not affect how SSC **or cask** design functions described in the UFSAR are performed or controlled would screen out. Proposed changes that are determined to have positive or no effect on how SSC design functions are performed or controlled may be screened out.

For purposes of 10 CFR **72.48** screening, changes that fundamentally alter (replace) the existing means of performing or controlling design functions should be conservatively treated as adverse and screened in. Such changes include replacement of automatic action by manual action (or vice versa), changes to the man-machine interface, changing a valve from "locked closed" to "administratively closed" and similar changes.

The following examples illustrate the 10 CFR **72.48** screening process as applied to proposed changes affecting how SSC design functions are performed or controlled :

- **Operating Procedures include operator actions for transport and placement of the filled cask, which are described in the UFSAR, but also address operator actions for maintenance of the transport equipment that are outside the cask and ISFSI design basis and not described in the UFSAR. A change would screen out at this step if the change was to those procedures or parts of procedures dealing with maintenance of the transport equipment.**

- **If the UFSAR description of the cask loading procedure contains eight fundamental sequences, the licensee's or CoC holder's decision to eliminate one of the sequences would screen in. On the other hand, if the licensee or CoC holder consolidated the eight fundamental sequences and did not affect the method of controlling or performing cask loading, the change would screen out.**

- **The UFSAR describes that a dry lubricant will be used in the dry shielded canister insertion process. A procedure change to delete the use of the lubricant or use a wet lubricant would screen in as a change in the procedures as described in the UFSAR and require an evaluation. If a licensee/CoC holder wishes to utilize a different brand of dry lubricant that is equivalent to the current brand (justified in the screening), the change would screen out and no evaluation would be required.**

B4.2.1.3 Screening Changes to UFSAR Methods of Evaluation

As discussed in Section **B**3.6, methods of evaluation included in the UFSAR to demonstrate that intended SSC **or cask** design functions will be accomplished are considered part of the "facility **or spent fuel storage cask design** as described in the UFSAR." Thus use of new or revised methods of evaluation (as defined in Section **B**3.10) is considered to be a change that is controlled by 10 CFR **72.48** and needs to be considered as part of this screening step. Adverse changes to elements of a method of evaluation included in the UFSAR, or use of an alternative method, must be evaluated under 10 CFR **72.48**(c)(2)(viii) to determine if prior NRC approval is required (see Section **B**4.3.8). Changes to methods of evaluation (only) do not require evaluation against the first seven criteria.

Changes to methods of evaluation not included in the UFSAR or to methodologies included in the UFSAR that are not used in the safety analyses or to establish design bases would screen out at this step.

Methods of evaluation that may be identified in references listed at the end of UFSAR sections or chapters are not subject to control under10 CFR **72.48** unless the UFSAR states they were used for specific analyses within the scope of 10 CFR **72.48**(c)(2)(viii).

Changes to methods of evaluation included in the UFSAR are considered adverse and require evaluation under 10 CFR **72.48** if the changes are outside the constraints and limitations associated with use of the method, e.g., identified in a topical report and/or SER. If the changes are within constraints and limitations associated with use of the method, the change is not considered adverse and may be screened out.

Proposed use of an alternative method is considered an adverse change that must be evaluated under 10 CFR **72.48**(c)(2)(viii).

The following example illustrates the screening of changes to methods of evaluation:

- The UFSAR identifies the name of the computer code used for performing **cask** containment performance analyses, with no further discussion of the methods employed within the code for performing those analyses. Changes to the computer code may be screened out provided that the changes are within the constraints and limitations identified in the associated topical report and SER. A change that goes beyond restrictions on the use of the method should be evaluated under 10 CFR **72.48**(c)(2)(viii) to determine if prior NRC approval is required.

B4.2.2 Is the Activity a Test or Experiment Not Described in the UFSAR?

As discussed in Section **B**3.14, tests or experiments not described in the UFSAR are activities where an SSC **or cask** is utilized or controlled in a manner that is outside the reference bounds of the design for that SSC **or cask** or inconsistent with analyses or description in the UFSAR.

Tests and experiments that are described in the UFSAR may be screened out at this step. Tests and experiments that are not described in the UFSAR may be screened out provided the test or experiment is bounded by tests and experiments that are described. Similarly, tests and experiments not described in the UFSAR may be screened out provided that affected SSCs will be appropriately isolated from the **ISFSI** facility **and cask**.

Examples of tests that would "screen in" at this step (assuming they were not described in the UFSAR) would be:

- **Testing the heat transfer capabilities of a loaded spent fuel storage cask by blocking the air vents.**

- **Drawing gas from a loaded canister by penetrating the canister after it has been sealed.**

- **Testing a pressure switch on a loaded cask by raising the internal pressure beyond that described in the UFSAR**

Examples of tests that would "screen out" would be:

- **Performing a radiography check of a concrete overpack prior to loading spent fuel.**

- Information gathering that is nonintrusive to the operation or design function of the associated SSC.

B4.2.3 Screening Documentation

10 CFR **72.48** record-keeping requirements apply to 10 CFR **72.48** evaluations performed for activities that screened in, not to screening records for activities that screened out. However, documentation should be maintained in accordance with procedures of screenings that conclude a proposed activity may be screened out (i.e., that a 10 CFR **72.48** evaluation was not required). The basis for the conclusion should be documented to a degree commensurate with the safety significance of the change. For changes, the documentation should include the basis for determining that there would be no adverse effect on design functions, etc. Typically, the screening documentation is retained as part of the change package. This documentation does not constitute the record of changes required by 10 CFR **72.48**, and thus is not subject to 10 CFR **72.48** documentation and reporting requirements. Screening records need not be retained for activities for which a 10 CFR **72.48** evaluation was performed or for activities that were never implemented.

B4.3 EVALUATION PROCESS

Once it has been determined that a given activity requires a 10 CFR **72.48** evaluation, the written evaluation must address the applicable criteria of 10 CFR **72.48** (c)(2). These eight criteria are used to evaluate the effects of proposed activities on accidents and malfunctions previously evaluated in the UFSAR and their potential to

cause accidents or malfunctions whose effects are not bounded by previous analyses.

Criteria (c)(2)(i—vii) are applicable to activities other than changes in methods of evaluation. Criterion (c)(2)(viii) is applicable to changes in methods of evaluation. Each activity must be evaluated against each applicable criterion. If any of the criteria are met, **a specific** licensee must apply for and obtain a license amendment per 10 CFR **72.56, and a CoC holder must apply for and obtain a CoC amendment per 10 CFR 72.244 (for itself or for a general licensee)** before implementing the activity. The evaluation against each criterion should be appropriately documented as discussed in Section **B**4.5. Subsections **B**4.3.1 through **B**4.3.8 provide guidance and examples for evaluating proposed activities against the eight criteria.

Each element of a proposed activity must undergo a 10 CFR **72.48** evaluation, except in instances where linking elements of an activity is appropriate, in which case the linked elements can be evaluated together. A test for linking elements of proposed changes is interdependence.

It is appropriate for discrete elements to be evaluated together 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; or (2) they are performed collectively to address a design or operational issue.

If concurrent changes are being made that are not linked, each must be evaluated separately and independently of each other.

The effects of a proposed activity being evaluated under 10 CFR **72.48** should be assessed against each of the evaluation criteria separately. For example, an increase in frequency/likelihood of occurrence cannot be compensated for by additional mitigation of consequences. Evaluations should consider the effects of the proposed activity on operator actions.

Specific guidance for applying 10 CFR **72.48** to temporary changes proposed as compensatory measures for degraded or nonconforming conditions is provided in Section **B**4.4.

B4.3.1 Does the Activity Result in More than a Minimal Increase in the Frequency of Occurrence of an Accident?

In answering this question, the first step is to identify the accidents that have been evaluated in the UFSAR that are affected by the

proposed activity. Then a determination should be made as to whether the frequency of these accidents occurring would be more than minimally increased.

ISFSI design events have been divided into categories based upon a qualitative assessment of frequency. **The design events, as discussed in NUREG-1567 and ANSI/ANS-57.9, are**:

- **<u>Design Event I - Normal Operations</u>: Events that are expected to occur regularly or frequently in the course of normal operation of the ISFSI.**

- **<u>Design Event II - Anticipated Occurrences (Off-normal Events)</u>: Events that can be expected to occur with moderate frequency or on the order of once during per calendar year of ISFSI operation.**

- **<u>Design Events III and IV - Accident Events</u>: Events considered to occur infrequently, if ever, during the lifetime of the ISFSI.**

During initial **ISFSI facility** licensing **or spent fuel storage cask certification**, **design events** were assessed in relative frequencies, as described above. Minimal increases in **the** frequency **of occurrence of an accident** resulting from subsequent licensee **or cask certificate holder** activities do not significantly change the licensing basis of the **ISFSI** facility **or cask** and do not impact the conclusions reached about acceptability of the **ISFSI** facility **or cask** design.

Since accident frequencies were considered in a broad sense as described above, a change from one frequency category to a more frequent category is clearly an example of a change that results in more than a minimal increase in the frequency of occurrence of an accident.

Changes within a frequency category could also result in more than a minimal increase in the frequency of occurrence of an accident. Normally, the determination of a frequency increase is based upon a qualitative assessment using engineering evaluations consistent with the UFSAR analysis assumptions. However, a **spent fuel storage cask**-specific accident frequency calculation or PRA may be used to evaluate a proposed activity in a quantitative sense. It should be emphasized that PRAs are just one of the tools for

evaluating the effect of proposed activities, and their use is not required to perform 10 CFR **72.48** evaluations.

Reasonable engineering practices, engineering judgment, and PRA techniques, as appropriate, should be used in determining whether the frequency of occurrence of an accident would more than minimally increase as a result of implementing a proposed activity. A large body of knowledge has been developed in the area of accident frequency and risk significant sequences through **reactor** plant-specific and generic studies. **Additional studies are being conducted for spent fuel storage cask PRA.** This knowledge, where applicable, should be used in determining what constitutes more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the UFSAR. The effect of a proposed activity on the frequency of an accident must be discernable and attributable to the proposed activity in order to exceed the more than minimal increase standard.

Although this criterion allows minimal increases, licensees **and CoC holders** must still meet applicable regulatory requirements and other acceptance criteria to which they are committed (such as 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 standards as outlined in the General Design Criteria (**Subpart F** to Part **72**) are not compatible with a "no more than minimal increase" standard.

Because frequencies of occurrence of natural phenomena were established as part of initial licensing **or certification** and are not expected to change, changes in design requirements for earthquakes, tornadoes and other natural phenomena should be treated as potentially affecting the likelihood of a malfunction rather than the frequency of occurrence of an accident.

The following are examples where there is not more than a minimal increase in the frequency of occurrence of an accident:

1. The proposed activity has a negligible effect on the frequency of occurrence of an accident. A negligible effect on the frequency of occurrence of an accident exists when the change in frequency is so small or the uncertainties in determining whether a change in frequency has occurred are such that it cannot be reasonably concluded that the frequency has actually changed (i.e., there is no clear trend towards increasing the frequency).

2. The proposed activity meets applicable NRC requirements as well as the design, material, and construction standards applicable to the SSC being modified. If the proposed activity would not meet applicable requirements and standards, the change is considered to involve more than a minimal increase in the frequency of occurrence of an accident, and prior NRC approval is required.

3. The change in frequency of occurrence of an accident is calculated to support the evaluation of the proposed activity, and one of the following criteria are met:

   - The increase in the pre-change accident or transient frequency does not exceed 10 percent. or

   - The resultant frequency of occurrence remains below 1E-6 per year or applicable **ISFSI site**-specific threshold.

   If the proposed activity would not meet either of the above criteria, the change is considered to involve more than a minimal increase in the frequency of occurrence of an accident, and prior NRC approval is required.

<u>**Example**</u>

A change is made to the ISFSI such that electrical power must be interrupted for a short time to allow connection of the pressure monitoring system to each cask as it is placed on the storage pad. Such interruptions would occur several times each year, since more than one cask is loaded at this ISFSI each year. While this power interruption does not affect the safety or confinement capability of the previously stored casks, the ability to monitor confinement integrity is lost for a short period of time. While such interruptions would be permitted under the Technical Specifications for the cask, the UFSAR evaluates loss of power to the ISFSI pressure monitoring system as an off-normal event assumed to occur once per year.

In this case, prior NRC approval would be required, since the loss of power to the pressure monitoring system would occur more than once per year and would become a normal event.

B4.3.2 Does the Activity Result in More than a Minimal Increase in the Likelihood of Occurrence of a Malfunction of an SSC Important to Safety?

The term "malfunction of an SSC important to safety" refers to the failure of structures, systems and components (SSCs) to perform their intended design functions— including both **important to safety (ITS) SSCs and not-important to safety (NITS) SSCs when the failure of the NITS SSCs to perform their design functions could affect the ability of the ITS SSCs to perform their design functions**. The cause and mode of a malfunction should be considered in determining whether there is a change in the likelihood of a malfunction. The effect or result of a malfunction should be considered in determining whether a malfunction with a different result is involved per Section **B**4.3.6.

In determining whether there is more than a minimal increase in the likelihood of occurrence of a malfunction of a SSC to perform its design function as described in the UFSAR, the first step is to determine what SSCs are affected by the proposed activity. Next, the effects of the proposed activity on the affected SSCs should be determined. This evaluation should include both direct and indirect effects.

Direct effects are those where the proposed activity affects the SSCs. Indirect effects are those where the proposed activity affects one SSC and this SSC affects the capability of another SSC to perform its UFSAR-described design function. Indirect effects also include the effects of proposed activities on the design functions of SSCs credited in the safety analyses. The safety analysis assumes certain design functions of SSCs in demonstrating the adequacy of design. Thus, certain design functions, while not specifically identified in the safety analysis, are credited in an indirect sense.

After determining the effect of the proposed activity on the important-to-safety SSCs, a determination is made of whether the likelihood of a malfunction of the important-to-safety SSCs has increased more than minimally. Qualitative engineering judgment and/or an industry precedent is typically used to determine if there is more than a minimal increase in the likelihood of occurrence of a malfunction. An appropriate calculation can be used to demonstrate the change in likelihood in a quantitative sense, if available and practical. The effect of a proposed activity on the likelihood of malfunction must be discernable and attributable to the proposed activity in order to exceed the more than minimal

increase standard. A proposed activity is considered to have a negligible effect on the likelihood of a malfunction when a change in likelihood is so small or the uncertainties in determining whether a change in likelihood has occurred are such that it cannot be reasonably concluded that the likelihood has actually changed (i.e., there is no clear trend towards increasing the likelihood). A proposed activity that has a negligible effect satisfies the minimal increase standard.

Evaluations of a proposed activity for its effect on likelihood of a malfunction would be performed at level of detail that is described in the UFSAR. The determination of whether the likelihood of malfunction is more than minimally increased is made at a level consistent with existing UFSAR-described failure modes and effects analyses. While the evaluation should take into account the level that was previously evaluated, it also needs to consider the nature of the proposed activity.

Changes in design requirements for earthquakes, tornadoes, and other natural phenomena should be treated as potentially affecting the likelihood of malfunction.

Although this criterion allows minimal increases, licensees must still meet applicable regulatory requirements and other acceptance criteria to which they are committed (such as 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 standards as outlined in the General Design Criteria (Appendix **F** to Part **72**) are not compatible with a "no more than minimal increase" standard.

Examples 1-4, below, illustrate cases where there would not be more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC important to safety:

Example 1

The change involves installing additional equipment or devices (e.g., cabling, manual valves, protective features) provided all applicable design and functional requirements (including applicable codes, standards, etc.) continue to be met.

Example 2

The change involves substitution of one type of component for another of similar function, provided all applicable design and functional requirements (including applicable codes, standards, etc.) continue to be met and any new failure modes are bounded by the existing analysis.

Example 3

The change satisfies applicable design bases requirements (e.g., seismic and wind loadings, separation criteria, environmental qualification, etc.).

Example 4

The change involves a new or modified **fuel handling** action that supports a design function credited in safety analyses, provided:

- The action (including required completion time) is reflected in procedures and training programs
- 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
- The evaluation of the change considers the ability to recover from credible errors in performance of manual actions and the expected time required to make such a recovery
- The evaluation considers the effect of the change on **ISFSI and cask design functions**

Examples 5-**8** are cases that would require prior NRC approval because they would result in more than a minimal increase in the likelihood of occurrence of a malfunction of a SSC important to safety:

Example 5

The change would cause design stresses to exceed their code allowables or other applicable stress or deformation limit (if any), including vendor-specified stress limits.

Example 6

The change would reduce system/equipment redundancy, diversity, separation, or independence.

Example 7

The change would (permanently) substitute manual action for automatic action for performing UFSAR-described design functions. (Guidance for temporary substitution of manual action for automatic action to compensate for a degraded/nonconforming condition is provided in NRC Generic Letter 91-18, Revision 1, **which was written for reactor licensees and may also be useful to ISFSI licensees and cask CoC holders.**)

Example 8

The change in likelihood of occurrence of a malfunction is calculated in support of the evaluation and increases by more than a factor of two. Note: The factor of two should be applied at the component level. Certain changes that satisfy the factor of two limit on increasing likelihood of occurrence of malfunction may meet one of the other criteria for requiring prior NRC approval, e.g., exceed the minimal increase standard for accident frequency under criterion 10 CFR **72.48**(c)(2)(i).

Example 9

The elapsed time to transfer a loaded spent fuel storage cask from the fuel building to the ISFSI pad is prescribed in the UFSAR (with considerations for ambient temperature) to limit the exposure to potential weather phenomena. If the transfer time is to be extended (adjusting for any ambient temperature considerations), but not doubled, it would not be more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC important to safety and NRC approval would not be required. However, if the transfer time were to increase by a factor of two or greater, prior NRC approval would be required.

B4.3.3 Does the Activity Result in More than a Minimal Increase in the Consequences of an Accident?

The UFSAR, based on logic similar to ANSI standards, provides an acceptance criterion and frequency relationship for "conditions for design." When determining which activities represent "more than a

minimal increase in consequences" pursuant to 10 CFR **72.48**, it must be recognized that "consequences" means dose. Therefore, an increase in consequences must involve an increase in radiological doses to the public. Changes in barrier performance or other outcomes of the proposed activity that do not result in increased radiological dose to the public are addressed under Section **B**4.3.7, concerning integrity of fission product barriers, or the other criteria of 10 CFR **72.48**(c)(2).

NRC regulates compliance with the provisions of 10 CFR **72** to assure adequate protection of the public health and safety. Activities affecting onsite dose consequences that may require prior NRC approval are those that impede required actions to mitigate the consequences of accidents **involving an ISFSI or a cask**.

The consequences covered include dose resulting from any accident evaluated in the UFSAR. The accidents include those typically covered in **the accident analyses section(s) of the** UFSAR and other events with which the **cask** is designed to cope and are described in the UFSAR (e.g., **tornado** missiles and flooding). The consequences referred to in 10 CFR **72.48** do not apply to occupational exposures resulting from routine operations, maintenance, testing, etc. Occupational doses are controlled and maintained As Low As Reasonably Achievable (ALARA) through formal licensee programs.

10 CFR Part 20 **and 10 CFR 72.104** establish requirements for protection against radiation during normal operations **and anticipated occurrences**, including dose criteria relative to radioactive waste handling and effluents. 10 CFR **72.48** accident dose consequence criteria and evaluation guidance are not applicable to proposed activities **affecting normal operations** governed by 10 CFR Part 20 and **10 CFR 72.104** requirements. **An ISFSI must not exceed the limits of 10 CFR 20 and 10 CFR 72.104 as a result of a proposed activity.**

The dose consequences referred to in 10 CFR **72.48** are those calculated by licensees **or certificate holders**—not the results of independent, confirmatory dose analyses by the NRC that may be documented in Safety Evaluation Reports.

The evaluation should determine the dose that would likely result from accidents associated with the proposed activity. If a proposed activity would result in more than a minimal increase in dose from the existing calculated dose for any accident, then the activity would require prior NRC approval. 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.

10 CFR **72.106** establishes **the dose limits for ISFSI design bases accidents**. **The** calculated dose values for **a given** accident would be identified in the UFSAR. **If a general licensee has calculated a lower offsite dose consequence, the higher cask UFSAR value would be the bounding value.** These dose values should be within the 10 CFR **72.106** limits, as applicable. An increase in **accident** consequences from a proposed activity is defined to be no more than minimal if the increase is less than or equal to 10 percent of the difference between the current **bounding** calculated dose value and the regulatory **limit** (10 CFR **72.106**, as applicable). The current calculated dose values are those documented in the most up-to-date analyses of record.

10 CFR 72.104 establishes the annual dose limits for ISFSI anticipated occurrences (off-normal events) combined with normal ISFSI operations and other site operations (e.g., 25 mrem whole body to any real individual beyond the controlled area). In order to comply with 10 CFR 72.104, no activity would be allowed to result in the ISFSI exceeding the 10 CFR 72.104 limits. For anticipated occurrences, a *minimal increase* would include any increase up to the 10 CFR 72.104 limits. Any increase in consequences of an anticipated occurrence previously evaluated in the UFSAR that is still within the 10 CFR 72.104 limits would always be less than a minimal increase in consequences.

10 CFR **72.106** establishes requirements for **a controlled area for each ISFSI site** so that an individual located **on or beyond the nearest boundary of the controlled area may not receive from any design basis accident the more limiting of a total effective dose equivalent of 5 rem, or the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 50 rem. The lens dose equivalent shall not exceed 15 rem and the shallow dose equivalent to skin or to any extremity shall not exceed 50 rem.**

Therefore, for a given accident, calculated or bounding dose values for that accident would be identified in the UFSAR. **If a general licensee has calculated a lower offsite dose consequence in their on-site 72.212 evaluation, the higher cask UFSAR value**

would be the bounding value. These dose values should be within the 10 CFR **72.106** limits, as applicable. An increase in consequences from a proposed activity is defined to be no more than minimal if the increase is less than or equal to 10 percent of the difference between the current **bounding** calculated dose value and the regulatory guideline value (10 CFR **72.106**, as applicable). The current calculated dose values are those documented in the most up-to-date analyses of record.

In determining if there is more than a minimal increase in consequences, the first step is to determine which accidents evaluated in the UFSAR may have their radiological consequences affected as a direct result of the proposed activity. Examples of questions that assist in this determination are:

(1) Will the proposed activity change, prevent or degrade the effectiveness of actions described or assumed in an accident discussed in the UFSAR?

(2) Will the proposed activity alter assumptions previously made in evaluating the radiological consequences of an accident described in the UFSAR?

(3) Will the proposed activity play a direct role in mitigating the radiological consequences of an accident described in the UFSAR?

The next step is to determine if the proposed activity does, in fact, increase the radiological consequences of any of the accidents evaluated in the UFSAR. If it is determined that the proposed activity does have an effect on the radiological consequences of any accident analysis described in the UFSAR, then either:

(1) Demonstrate and document that the radiological consequences of the accident described in the UFSAR are bounding for the proposed activity (e.g., by showing that the results of the UFSAR analysis bound those that would be associated with the proposed activity), or

(2) Revise and document the analysis taking into account the proposed activity and determine if more than a minimal increase has occurred as described above.

The following examples illustrate the implementation of this criterion. In each example it is assumed that the calculated consequences do not include a change in the methodology for calculating the consequences.

Changes in methodology would need to be separately considered under 10 CFR **72.48**(c)(2)(viii) as discussed in Section **B**4.3.8.

Example 1

A cask CoC holder has prepared a calculation showing that the ISFSI boundary fence may be moved closer to the casks than currently described in the UFSAR, and the ISFSI would still meet the 10 CFR 72.106 accident dose limits and all other regulatory requirements, including 10 CFR 72.104 limits. The new calculated offsite accident dose would be 1.1 rem. The calculated accident dose described in the UFSAR is 1.0 rem, and the 10 CFR 72.106 limit is 5 rem. Since 10% of the difference between the UFSAR calculated dose (1.0 rem) and the regulatory limit (5.0 rem) is 0.4 rem, the increase to 1.1 rem would be less than a minimal increase in consequences (less than 10% of the difference between 1.0 rem and 5.0 rem), and prior NRC approval is not required. If the new calculated dose was 1.5 rem, the change would be more than a minimal increase (more than 10% of the difference between the UFSAR value and the regulatory limit) and would require prior NRC approval. In either case, once the change is made, the new value would become the bounding value for the next 72.48 evaluation and would be put in the UFSAR.

If this change were to be made by a general ISFSI licensee on a site-specific basis, the record of the 72.48 evaluation containing the updated calculated offsite dose value would be retained and the revised value used as the bounding value for the next 72.48 evaluation. If prior NRC approval is required under 72.48, the general licensee could either request that the CoC holder for their cask system submit a CoC amendment request to the NRC under 10 CFR 72.244, if appropriate, or could submit, under 10 CFR 72.7, a request for an exemption to the 72.48(c)(2) requirementthat a general licensee shall request that the CoC holder obtain a CoC amendment. An exemption request should describe the proposed change and include justification for why the CoC holder is not requesting a CoC amendment for the change, and justification for the change itself.

Example 2

A site-specific licensee has evaluated the consequences of a tornado missile strike to the concrete storage modules which

house the spent fuel storage canisters. It is determined that the concrete shield blocks which cover the outlet air vents on the roof could be knocked off, resulting in a temporary reduction in radiological shielding. The offsite consequence of this accident as described in the UFSAR is 30 mrem TEDE (direct and scattered radiation) to a person located 100 meters away from the ISFSI for 8 hours per day during the 7 day recovery period. The onsite consequence of this accident is an increase in occupation exposure of 2.5 person-rem, incurred when replacing the shield blocks.

The licensee wishes to improve fabricability of the concrete storage module by removing the "dog leg" from the pathway of the outlet vents through the concrete, and instead, use a straight-line path. The change results in a negligible increase in dose rates during normal operation. However, in the accident scenario with the loss of the shield block, it is found that the dose consequences would be 200 mrem TEDE, or an increase of 170 mrem. The occupational exposure for recovery operations is calculated to be 15.0 person-rem.

The change would not require prior NRC approval since the increase of 170 mrem is only 3.4 percent of the difference between the current dose consequence and the 10CFR72.106 limit of 5000 mrem [i.e. (170)/(5000-30)= 0.034]. The occupational exposure need not be considered under 72.48.

Example 3

Following a gamma scan, it is determined that the effective thickness of the lead in a shield plug is 1/4 inch less than nominal. The fabrication specification and drawings permit only 1/8 inch less than nominal. It is proposed to accept the shield plug "as-is."

The direct effects of a decrease in effective lead thickness would be reviewed to identify potentially affected design basis parameters. In addition, the indirect effect of increased dose rates would be considered. In this case the review concludes that the offsite accident dose consequences would not increase. Therefore, no prior NRC approval would be required.

Note: For spent fuel storage systems that have Technical Specification limits on shield plug dose rates, the change would be evaluated separately for compliance with the

Technical Specification. Further, offsite dose consequences of the change must be evaluated per 10 CFR 72.104. This evaluation would be documented in the general licensee's 10 CFR 72.212 evaluation.

B4.3.4 Does the Activity Result in More than a Minimal Increase in the Consequences of a Malfunction?

In determining if there is more than a minimal increase in consequences, the first step is to determine which malfunctions evaluated in the UFSAR have their radiological consequences affected as a result of the proposed activity. The next step is to determine if the proposed activity does, in fact, increase the radiological consequences and, if so, are they more than minimally increased. The guidance for determining whether a proposed activity results in more than a minimal increase in the consequences of a malfunction is the same as that for accidents. Refer to Section B4.3.3.

B4.3.5 Does the Activity Create a Possibility for an Accident of a Different Type?

The set of accidents that a**n ISFSI** facility **or cask design** must postulate for purposes of UFSAR safety analyses, **typically** including **explosion, fire, earthquake, flood, etc.**, are often referred to as "design basis accidents." The terms accidents and **off-normal events** are often used in regulatory documents (e.g., in **the accident analyses section(s)** of the Standard Review Plan), where **off-normal events** are viewed as the more likely, low consequence events and accidents as less likely but more serious. This criterion deals with creating the possibility for accidents of similar frequency and significance to those already included in the licensing basis for the **ISFSI** facility. Thus, accidents that would require multiple independent failures or other circumstances in order to "be created" would not meet this criterion.

Certain accidents are not discussed in the UFSAR because their effects are bounded by other related events that are analyzed. For example**, a postulated cask drop of a certain distance** may not be specifically evaluated in the UFSAR because it has been determined to be less limiting than **the evaluated cask drop.** Therefore, if a proposed design **or ISFSI facility** change would introduce a **cask drop of a distance less than the evaluated cask drop, the** postulated **cask drop** need not be considered an accident of a different type.

The possible accidents of a different type are limited to those that are as likely to happen as those previously evaluated in the UFSAR. The accident must be credible in the sense of having been created within the range of assumptions previously considered in the licensing basis. A new initiator of an accident previously evaluated in the UFSAR is not a different type of accident. Such a change or activity, however, which increases the frequency of an accident previously thought to be incredible to the point where it becomes as likely as the accidents in the UFSAR, could create the possibility of an accident of a different type. For example, there are a number of scenarios that have been analyzed extensively. However, these scenarios are of such low probability that they may not have been considered to be part of the design basis. However, if a change or activity is proposed such that a scenario becomes credible, the change or activity could create the possibility of an accident of a different type. In some instances these example accidents could already be discussed in the UFSAR.

In evaluating whether the proposed change or activity creates the possibility of an accident of a different type, the first step is to determine the types of accidents that have been evaluated in the UFSAR. The types of credible accidents that the proposed activity could create that are not bounded by UFSAR-evaluated accidents are accidents of a different type.

4.3.6 Does the Activity Create a Possibility for a Malfunction of an SSC Important to Safety with a Different Result?

Malfunctions of SSCs are generally postulated as potential single failures to evaluate **ISFSI facility or cask design** performance with the focus being on the result of the malfunction rather than the cause or type of malfunction. A malfunction that involves an initiator or failure whose effects are not bounded by those explicitly described in the UFSAR is a malfunction with a different result. A new failure mechanism is not a malfunction with a different result if the result or effect is the same as, or is bounded by, that previously evaluated in the UFSAR. The following example illustrates this point:

- **A cask CoC holder desires to replace the fuel support breakaway clips used in a particular cask design by an energy absorption device. The breakaway clips are used to mitigate the effects of a cask drop event. This change may introduce a new failure mechanism that could affect the mitigation of a cask drop event. But if this effect (failure of the energy absorption device to mitigate the effects of a cask drop) was bounded by a UFSAR**

description of the effects of a failure of the breakaway clips to mitigate the effects of a cask drop, then a malfunction with a different result has not been created, and prior NRC approval under the criterion of 72.48(c)(2)(vi) would not be required. If failure of the breakaway clips to mitigate a cask drop event had not been described in the UFSAR, then the replacement of the clips with an energy absorption device would create a possibility for a malfunction of an SSC important to safety with a different result, and prior NRC approval under the criterion of 72.48(c)(2)(vi) would be required.

Certain malfunctions are not explicitly described in the UFSAR because their effects are bounded by other malfunctions that are described. For example, **failure of an air pad carrying a loaded cask and subsequent drop of the pad may not be explicitly described in the UFSAR because the drop would be bounded by the cask drop analysis.**

The possible malfunctions with a different result are limited to those that are as likely to happen as those described in the UFSAR. For example, a seismic induced failure of a component that has been designed to the appropriate seismic criteria will not cause a malfunction with a different result. However, a proposed change or activity that increases the likelihood of a malfunction previously thought to be incredible to the point where it becomes as likely as the malfunctions assumed in the UFSAR, could create a possible malfunction with a different result.

In evaluating a proposed activity against this criterion, the types and results of failure modes of SSCs that have previously been evaluated in the UFSAR and that are affected by the proposed activity should be identified. Attention must be given to whether the malfunction was evaluated in the accident analyses at the component level or the overall **ISFSI facility** level. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and resulting mitigation impacts, it also needs to consider the nature of the proposed activity. Thus, for instance, **if a single failure proof lifting device were to be replaced with a non-single failure proof lifting device, but the lift height is within the cask drop analysis, the consequences should still be evaluated to determine if any new outcomes are introduced.**

Once the malfunctions previously evaluated in the UFSAR and the results of these malfunctions have been determined, then the types

and results of failure modes that the proposed activity could create are identified. Comparing the two lists can provide the answer to the criterion question.

B4.3.7 Does the Activity Result in A Design Basis Limit for a Fission Product Barrier Being Exceeded or Altered?

For the purposes of 10 CFR 72.48 considerations, the fission product barriers for a spent fuel storage cask system would include the fuel cladding and the confinement boundary for the storage system. Dry spent fuel storage systems are designed in accordance with NRC requirements to preserve both fuel cladding integrity and confinement capability during all credible normal, off-normal, and accident events. Integrity of the fuel cladding is required to maintain retrievability and sub-criticality of the stored spent fuel. Even if the cladding is not explicitly credited in the UFSAR as a fission product boundary, such as when damaged fuel is stored in a cask, effects of a proposed activity on cladding should still be considered when answering this 72.48(c)(2)(vii) criteria because the cladding integrity would continue to be important to maintain retrievability and sub-criticality (fuel configuration).

Preservation of the confinement boundary is required to ensure against the uncontrolled release of radioactive materials. The makeup of the confinement boundary depends upon the storage system design as described in the UFSAR.

10 CFR **72.48** evaluation under criterion (c)(2)(vii) focuses on the fission product barriers and on the critical design information that supports their continued integrity. Guidance for applying this criterion is structured around a two-step approach:

- Identification of affected design basis limits for a fission product barrier
- Determination of when those limits are exceeded or altered.

<u>Identification of affected design basis limits for a fission product barrier</u>

The first step is to identify the fission product barrier design basis limits, if any, that are affected by a proposed activity. Design basis limits for a fission product barrier are the controlling numerical values

established during the licensing review as presented in the UFSAR for any parameter(s) used to determine the integrity of the fission product barrier. These limits have three key attributes:

- The parameter is fundamental to the barrier's integrity. Design basis limits for fission product barriers establish the reference bounds for design of the barriers, as defined in 10 CFR **72.3**. They are the limiting values for parameters that directly determine the performance of a fission product barrier. That is, design bases limits are fundamental to barrier integrity and may be thought of as the point at which confidence in the barrier begins to decrease.

  For purposes of this evaluation, design bases parameters that are used to directly determine fission product barrier integrity should be distinguished from subordinate parameters that can indirectly affect fission product barrier performance. Indirect effects of changes to subordinate parameters are evaluated in terms of their effect on the more fundamental design bases parameters/limits that ensure fission product barrier integrity. For example, **a heat transfer pathway** is a subordinate parameter for purposes of this evaluation, not a design bases parameter/limit. The acceptability of a reduction in a **heat transfer pathway** would be determined based on its effect on design bases limits for the **fuel clad and the canister** (e.g., **clad integrity and canister** pressure).

- The limit is expressed numerically. Design basis limits are numerical values used in the overall design process, not descriptions of functional requirements. Design basis limits are typically the numerical event acceptance criteria utilized in the accident analysis methodology. The **ISFSI** facility's **or cask's** design and operation associated with these parameters as described in the UFSAR will be at or below (more conservative than) the design basis limit.

- The limit is identified in the UFSAR. As required by **10 CFR 72.24(c) or 10 CFR 72.230**, design basis limits were presented in the original FSAR and continue to reside in the UFSAR. They may be located in a vendor topical report that is incorporated by reference in the UFSAR.

Consistent with the discussion of 10 CFR **72.48** applicability in Section **B**4.1, any design basis limit for a fission product barrier that is controlled by another, more specific regulation or Technical Specification would not require evaluation under Criterion (c)(2)(vii.) The effect of the proposed activity on those parameters would be

evaluated in accordance with the more specific regulation. Effects (either direct or indirect—see discussion below) on design basis parameters covered by another regulation or Technical Specification need not be considered as part of evaluations under this criterion.

Examples of typical fission product barrier design basis limits are identified in the following table:

Barrier	Design Bases Parameter	Typical Design Basis Limit
Fuel Cladding	Protection against gross rupture	Clad Temperature: consistent with model
		Criticality: K-eff < 0.95, fresh fuel assumed, 95/95 probability/confidence with appropriate consideration of uncertainties/biases
		Decay Heat : Each fuel assembly must meet the specified limit, consistent with heat transfer calculations (e.g., 1 kW max. for each assembly)
Confinement boundary	Preservation of confinement boundary	Pressure: Canister design pressure
		Stresses: Code compliance as described in the UFSAR
		Leak Rate: Specified leak rate to be verified by helium leak testing after closure

The list above may vary for a given **ISFSI** facility**/cask design** and/or **cask** vendor and may include other parameters for specific accidents. For example, **the design of a particular cask system may utilize a methodology for criticality control that credits partial burnup, within the guidance of NRC Interim Staff Guidance ISG-8 or NUREG-1536.** If a given **ISFSI** facility**/cask design** has this or other parameters incorporated into the UFSAR as a design basis limit for a fission product barrier, then changes affecting it should be evaluated under this criterion.

Two of the ways that a licensee**/certificate holder** can evaluate proposed activities against this criterion are as follows. The licensee**/certificate holder** may identify all design bases parameters for fission product barriers and include them explicitly in the procedure for performing 10 CFR **72.48** evaluations. Alternatively, the effects of a proposed activity could be evaluated first to determine if the change affects design bases parameters for fission product barriers. The results of these two approaches are equivalent provided the guidance for "exceeded or altered" described below is followed. In all cases, the direct and indirect effects of proposed activities must be included in the evaluation.

Exceeded or altered

A specific proposed activity requires a license **or cask CoC** amendment if the design basis limit for a fission product barrier is "exceeded or altered." The term "exceeded" means that as a result of the proposed activity, the **ISFSI** facility's **or cask's** predicted response would be less conservative than the numerical design basis limit identified above. The term "altered" means the design basis limit itself is changed.

The effect of the proposed activity includes both direct and indirect effects. **A reduction in the shell thickness (confinement boundary) that increases internal stresses beyond code allowables is a direct effect that would require a license amendment. Indirect effects provide for another parameter or effect to cascade from the proposed activity to the design basis limit. For example, increasing the size of structural components for greater strength in the internal fuel basket could decrease the free volume within the storage cask. That effect could increase the internal pressure, resulting in an increase in the shell (confinement boundary) stresses. The 10 CFR 72.48(c)(2)(vii) evaluation of this change would focus on whether the design basis ASME code allowables and pressure limits would be exceeded.**

Altering a design basis limit for a fission product barrier is not a routine activity, but it can occur. **An example of this would be re-evaluating the thermal performance of a storage system while taking credit for reduced decay heat in some of the stored fuel assemblies in order to increase the decay heat in other fuel assemblies. Another example is redesigning portions of the storage canister shell such that they no longer comply with the code of construction.** These are infrequent activities affecting key elements of the defense-in-depth philosophy. As such, no distinction has been made between a conservative and non-conservative change in the limit.

Evaluations performed under this criterion may incorporate a number of refinements to simplify the review. For example, if an engineering evaluation demonstrates that no parameters are affected that have design basis limits for fission product barriers associated with them, no 10 CFR **72.48**(c)(2)(vii) evaluation is required. Similarly, most parameters that require evaluation under this criterion have calculations or analyses supporting the **ISFSI** facility's **or cask's** design. If an engineering evaluation demonstrates that the analysis

presented in the UFSAR remains bounding, then no 10 CFR **72.48**(c)(2)(vii) evaluation is required. When using these techniques, both indirect and direct effects must be considered to ensure that important interactions are not overlooked.

Examples illustrating the two-step approach for evaluations under this criterion are provided below:

Example 1

The thickness of the material used for the fuel assembly basket tubes has been found below the minimum specified in the fabrication specifications and drawings. In this example, the basket tubes serve as structural components of the basket. It is proposed to accept the condition "as-is."

Identification of design basis limits

The effects of the reduced material thickness would be reviewed. The direct effect would include the impact on the criticality and heat transfer analyses. The indirect effects would include the impact on fuel cladding integrity caused by the attendant decrease in basket strength. Thus, the proposed activity may impact two design basis limits: criticality and cladding stress.

Exceeded or altered

Any increase in reactivity would be compared to the design basis limit. If the revised reactivity exceeded the design basis limit, then a license amendment would be required. Any effects to the heat transfer analyses would be compared to the design basis limits and the effects on cladding stresses.

In this example, the design basis limits are not being "altered." Therefore, this element of the review is not applicable.

Example 2

The as-built interior length of a concrete overpack is found to be less than the minimum length in the fabrication specification and drawings. An analysis shows that thermal

expansion of the storage canister when placed in the overpack would result in an interference when the canister is loaded with design basis fuel assemblies. It is proposed to limit the decay heat of the fuel to be stored in the concrete overpack to 75 percent of the value reflected in the safety analysis.

Identification of Design Basis Limit

The affected parameter is fuel assembly decay heat.

Exceeded or altered

In this case, the design basis limit has not been "exceeded" because the decay heat will be less than the limit. However, the design basis limit itself has been "altered" and thus prior NRC approval is required. The issue of conservative vs. non-conservative is not germane to requiring a submittal. That is, prior NRC approval is required regardless of direction because this is a fundamental change in the ISFSI facility or cask design.

B4.3.8 Does the Activity Result in a Departure from a Method of Evaluation Described in the UFSAR Used in Establishing the Design Bases or in the Safety Analyses?

The UFSAR contains design and licensing basis information for a**n** **ISFSI** facility **or spent fuel storage cask design**, including description on how regulatory requirements for design are met **(such as the requirements governing normal operations and anticipated occurrences), and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents**. Analytical methods are a fundamental part of demonstrating how the design meets regulatory requirements and why the **ISFSI** facility's **or cask's** response to accidents and events is acceptable. As such, in cases where the analytical methodology was considered to be an important part of the conclusion that the **ISFSI** facility **or cask** met the required design bases, these analytical methods were described in the UFSAR and received varying levels of NRC review and approval during licensing.

Because 10 CFR **72.48** provides a process for determining if prior NRC approval is required before making changes to the **ISFSI** facility **or spent fuel storage cask design** as described in the UFSAR, changes to the methodologies described in the UFSAR also fall under the provisions of the 10 CFR **72.48** process, specifically criterion (c)(2)(viii).

In general, licensees **or cask certificate holders** can make changes to elements of a methodology without first obtaining a license amendment **or cask CoC amendment** if the results are essentially the same as, or more conservative than, previous results. Similarly, licensees **or cask certificate holders** can also use different methods without first obtaining a license **or cask CoC** amendment if those methods have been approved by the NRC for the intended application.

If the proposed activity does not involve a change to a method of evaluation, then the 10 CFR **72.48** evaluation should reflect that this criterion is not applicable. If the activity involves only a change to a method of evaluation, then the 10 CFR **72.48** evaluation should reflect that criteria 10 CFR **72.48**(c)(2)(i—vii) are not applicable.

The first step in applying this criterion is to identify the methods of evaluation that are affected by the change. This is accomplished during application of the screening criteria in Section **B**4.2.1.3.

Next, the licensee **or cask CoC holder** must determine whether the change constitutes a departure from a method of evaluation that would require prior NRC approval. As discussed further below, for purposes of evaluations under this criterion, the following changes are considered a departure from a method of evaluation described in the UFSAR:

- Changes to any element of analysis methodology that yield results that are non-conservative or not essentially the same as the results from the analyses of record.

- Use of new or different methods of evaluation that are not approved by NRC for the intended application.

By way of contrast, the following changes are <u>not</u> considered departures from a method of evaluation described in the UFSAR:

- Departures from methods of evaluation that are not described, outlined or summarized in the UFSAR (such changes may have been screened out as discussed in Section **B**4.2.1.3);

- Use of a new NRC-approved methodology (e.g., new or upgraded computer code) to reduce uncertainty, 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. The basis for this determination should be documented in the licensee **or cask CoC holder** evaluation.

- Use of a methodology revision that is documented as providing results that are essentially the same as or more conservative than either the previous revision of the same methodology or with another methodology previously accepted by NRC through issuance of an SER.

- **Use of a methodology which is described in the UFSAR, but which has not been specifically approved by the NRC either through a Topical Report review or through endorsement in the storage system SER. The following are examples:**

  The UFSAR describes the methodology used for the heat transfer evaluations of the storage system. The methodology was never submitted to the NRC for approval in a Topical Report, and the storage system SER does not indicate whether the NRC has endorsed or approved the methodology. In this case, use of the methodology described in the UFSAR to support a change would NOT "result in a departure from a method of evaluation described in the UFSAR."

  The UFSAR describes the methodology used to evaluate the cask drop onto the storage pad. In this case, the SER is silent with regards to NRC approval of the methodology, but instead states that the NRC used an independent confirmatory analysis or alternate method to confirm acceptability of the applicant's results. In this case, use of the methodology described in the UFSAR would NOT "result in a departure from a method of evaluation described in the UFSAR."

Subsection **B**4.3.8.1 provides guidance for making changes to one or more elements of an existing method of evaluation used to establish the design bases or in the safety analyses. Subsection **B**4.3.8.2 provides guidance for adopting an entirely new method of evaluation to replace an existing one. Examples illustrating the implementation of this criterion are provided in Section **B**4.3.8.3.

It should be noted that the NRC staff, in reviewing dry cask storage designs, historically has not generically approved methodologies referenced in FSARs for use by other licensees or vendors. Instead it has made statements in its SERs, following the guidance in the Standard Review Plan, that the design has been found to be acceptable in each review discipline area. If, however, vendors or licensees choose to submit methodologies to the NRC for generic review and approval as part of applications for design approval or as separate topical reports, the staff will document NRC endorsement or approval in appropriate SERs. Such endorsements or approval will facilitate vendors and licensees to use the 10 CFR 72.48 process that deals with approved methodologies.

B4.3.8.1 Guidance for Changing One or More Elements of a Method of Evaluation

The definition of "departure ..." provides licensees with the flexibility to make changes under 10 CFR **72.48** to methods of evaluation whose results are "conservative" or that are not important with respect to the demonstrations of performance that the analyses provide. Changes to elements of analysis methods that yield conservative results, or results that are essentially the same **over the entire range of use for the method** would not be departures from approved methods.

Conservative vs. Non-Conservative Results

Gaining margin by changing one or more elements of a method of evaluation is considered to be a non-conservative change and thus a departure from a method of evaluation for purposes of 10 CFR **72.48**. Such departures require prior NRC approval of the revised method. Analytical results obtained by changing any element of a method are "conservative" relative to the previous results, if they are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines). For example, a change from 45 psig to 48 psig in the result of a **cask** peak pressure analysis (with design basis limit of 50 psig) using a revised method of evaluation would be considered a conservative change when applying this criterion. In other words, the revised method is more conservative if it predicts more severe conditions given the same set of inputs. This is because results closer to limiting values are considered conservative in the sense that the new analysis result provides less margin to applicable limits for making potential physical or procedure changes without a license amendment.

In contrast, if the use of a modified method of evaluation resulted in a change in calculated **cask** peak pressure from 45 psig to 40 psig, this would be a non-conservative change. That is because the change would result in more margin being available (to the design basis limit of 50 psig) for the licensee to make more significant changes to the physical **ISFSI** facility**, cask design,** or procedures.

"Essentially the Same"

Licensees **or cask CoC holders** may change one or more elements of a method of evaluation such that results move in the non-conservative direction without prior NRC approval, provided the revised result is "essentially the same" as the previous result. Results are "essentially the same" if they are within the margin of error for the type of analysis being performed. Variation in results due to routine analysis sensitivities or calculational differences (e.g., rounding errors and use of different computational platforms) would typically be within the analysis margin of error and thus considered "essentially the same." For example, when a method is applied using a different computational platform (mainframe vs. workstation), results of cases run on the two platforms differed by less than 1%, which is the margin of error for this type of calculation. Thus the results are essentially the same, and do not constitute a departure from a method that requires prior NRC approval.

The determination of whether a new analysis result would be considered "essentially the same" as the previous result can be made through benchmarking the revised method to the existing one, or may be apparent from the nature of the differences between the methods. When benchmarking a revised method to determine how it compares to the previous one, the analyses that are done must be for the same set of conditions to ensure that the results are comparable**, and the revised method should only be used where the bench marking has demonstrated it to be conservative or essentially the same**. Comparison of analysis methods should consider both the peak values and time behavior of results, and engineering judgement should be applied in determining whether two methods yield results that are essentially the same.

B4.3.8.2 Guidance for Changing from One Method of Evaluation to Another

The definition of "departure ..." provides licensees with the flexibility to make changes under 10 CFR **72.48** from one method of evaluation to another provided that the new method is approved by the NRC for the

intended application. A new method is approved by the NRC for intended application if it is approved for the type of analysis being conducted, and applicable terms, conditions and limitations for its use are satisfied.

NRC approval **would** typically follow one of two paths. **Some** utilities **and spent fuel storage cask vendors will** prepare and obtain NRC approval of topical reports that describe methodologies for the performance of a given type or class of analysis. Through a Safety Evaluation Report, the NRC **would** approve the use of the methodologies for a given class of **ISFSIs or spent fuel storage casks**. In some cases, the NRC **would** accord "generic" approval of analysis methodologies. Terms, conditions and limitations relating to the application of the methodologies **would** usually **be** documented in the topical reports, the SER, and correspondence between the NRC and the methodology owner that is referenced in the SER or associated transmittal letter.

The second path is the approval of a specific analysis rather than a more generic methodology. In these cases, the NRC's approval **would** typically be part of an **ISFSI or cask design's licensing basis and** limited to a given **ISFSI or spent fuel storage cask** design and a given application. Again, a thorough understanding of the terms, conditions and limitations relating to the application of the methodology is essential. This information **should be** documented in the original license **or CoC** application or license **or CoC** amendment request, the SER, and any correspondence between the NRC and the analysis owner that is referenced in the SER or associated transmittal letter.

It is incumbent upon the user of a new methodology—even one generically approved by the NRC—to ensure they have a thorough understanding of the methodology in question, the terms of its existing application and conditions/limitations on its use. A range of considerations is identified below that may be applicable to determining whether new methods are technically appropriate for the intended application. The licensee**/CoC holder** should address these and similar considerations, as applicable, and document in the 10 CFR **72.48** evaluation the basis for determining that a method is appropriate and approved for the intended application. To obtain an adequate understanding of the method and basis for determining it is approved for use in the intended application, licensees or **CoC holders** should consult various sources, as appropriate. These include SERs, topical reports, licensee correspondence with the NRC and licensee or **CoC holder** personnel familiar with the existing application of the

method. If adequate information cannot be found on which to base the intended application of the methodology, the method should not be considered "approved by the NRC for the intended application."

The applicable terms and conditions for the use of a methodology are not limited to a specific analysis; the qualification of the organization applying the methodology is also a consideration. **For Part 50 reactor licensees, the NRC,** through Generic Letter 83-11, Supplement 1, has established a method by which **reactor** licensees can demonstrate they are generally qualified to perform safety analyses. **Reactor** licensees thus qualified can apply methods that have been reviewed and approved by the NRC, or that have been otherwise accepted as part of another plant's licensing basis, without requiring prior NRC approval. **The guidance of Generic Letter 83-11, Supplement 1 may also be useful to ISFSI licensees and cask CoC holders as a method to demonstrate that they are generally qualified to perform safety analyses. ISFSI licensees or cask CoC holders thus qualified can apply methods that have been reviewed and approved by the NRC, or that have been otherwise accepted as part of another ISFSI's or cask design's licensing basis, without requiring prior NRC approval. ISFSI** Licensees **or cask CoC holders** that have not satisfied the guidelines of Generic Letter 83-11, Supplement 1, may, of course, continue to seek **ISFSI**-specific **or cask design-specific** approval to use new methods of evaluation.

When considering the application of a methodology, it is necessary to adopt the methodology *en toto* and apply it consistent with applicable terms, conditions and limitations. Mixing attributes of new and existing methodologies is considered a revision to a methodology and must be evaluated as such per the guidance in Section **B**4.3.8.1.

Considerations for Determining if New Methods May be Considered "Approved by the NRC for the Intended Application"

The following questions highlight important considerations for determining that a particular application of a different method is technically appropriate for the intended application, within the bounds of what has been found acceptable by NRC, and does not require prior NRC approval.

- Is the application of the methodology consistent with the **ISFSI** facility's **or cask design's** licensing basis (e.g., NUREG-**1536, NUREG-1567,** or other **ISFSI or cask design**-specific commitments)? Will the methodology supersede a methodology addressed by other regulations or the **ISFSI or cask** Technical

Specifications? Is the methodology consistent with relevant industry standards?

If application of the new methodology requires exemptions from regulations or **ISFSI- or cask**-specific commitments, exceptions to relevant industry standards and guidelines, or is otherwise inconsistent with a**n** **ISFSI** facility's **or cask's** licensing basis, then prior NRC approval may be required. The applicable change process must be followed to make the **ISFSI facility's or cask's** licensing basis consistent with the requirements of the new methodology.

- If a computer code is involved, has the code been installed in accordance with applicable software Quality Assurance requirements? Has the **ISFSI- or cask design**-specific model been adequately qualified through benchmark comparisons against test data, **empirical** data, or approved engineering analyses? Is the application consistent with the capabilities and limitations of the computer code? Has industry experience with the computer code been appropriately considered?

  The computer code installation and **ISFSI or cask design**-specific model qualification is not directly transferable from one organization to another. The installation and qualification should be in accordance with the licensee's **or cask CoC holder's** Quality Assurance program.

- Is the **ISFSI** facility **or cask design** for which the methodology has been approved designed and operated in the same manner as the **ISFSI** facility **or cask design** to which the methodology is to be applied? Is the relevant equipment the same? Does the equipment have the same pedigree? Are the relevant failure modes and effects analyses the same? If the **ISFSI facility or cask design** is designed and operated in a similar, but not identical, manner, the following types of considerations should be addressed to assess the applicability of the methodology:

  - How could those differences affect the methodology?
  - Are additional sensitivity studies required?
  - Should additional single failure scenarios be considered?
  - Are analyses of limiting scenarios, effects of equipment failures, etc., applicable for the specific **ISFSI or cask** design?

- Can analyses be made while maintaining compliance with both the intent and literal definition of the methodology?

- Differences in the **ISFSI or cask design** configurations and licensing bases could invalidate the application of a particular methodology. For example, the licensing basis of older vintage **cask designs may not have been required to consider the same isotopes for offsite dose calculations as those in the licensing basis for more recent vintage cask designs.** The existence of these differences does not preclude application of a new methodology to a**n ISFSI** facility **or cask design**; however, differences must be identified, understood and the basis documented for concluding that the differences are not relevant to determining that the new application is technically appropriate.

B4.4 APPLYING 10 CFR **72.48** TO COMPENSATORY ACTIONS TO ADDRESS NONCONFORMING OR DEGRADED CONDITIONS

Three general courses of action are available to licensees to address non-conforming and degraded conditions. Whether or not 10 CFR **72.48** must be applied, and the focus of a 10 CFR **72.48** evaluation if one is required, depends on the corrective action plan chosen by the licensee **or cask CoC holder**, as discussed below:

- If the licensee **or cask CoC holder** intends to restore the SSC back to its as-designed condition, then this corrective action should be performed in accordance with 10 CFR **72**, **Subpart G** (i.e., in a timely manner commensurate with safety). This activity is not subject to 10 CFR **72.48**.

- If an interim compensatory action is taken to address the condition and involves a temporary procedure or **ISFSI** facility **or cask design** change, 10 CFR **72.48** should be applied to the temporary change. The intent is to determine whether the temporary change/compensatory action itself (not the degraded condition) impacts other aspects of the **ISFSI** facility, **cask design,** or procedures described in the UFSAR. In considering whether a temporary change impacts other aspects of the **ISFSI** facility **or cask design**, a licensee **or cask CoC holder** should pay particular attention to ancillary aspects of the temporary change that result from actions taken to directly compensate for the degraded condition.

- If the licensee **or cask CoC holder** corrective action is either to accept the condition "as-is" resulting in something different than its as-designed condition, or to change the **ISFSI** facility, **cask design,** or procedures, 10 CFR **72.48** should be applied to the corrective action, unless another regulation applies. In these cases, the final corrective action becomes the proposed change that would be subject to 10 CFR **72.48**.

In resolving degraded or nonconforming conditions, the need to obtain NRC approval for a proposed activity does not affect the licensee's authority to operate the **ISFSI**. The licensee may **load or unload casks**, etc., provided that necessary SSCs are operable and the degraded condition is not in conflict with the technical specifications, the license**, or the CoC**.

The following example**s** illustrate the process for implementing a temporary change as a compensatory action to address a degraded/nonconforming condition:

<u>Example 1</u>

In reviewing cask documentation, a licensee discovers that a loaded cask does not meet the drop analysis and is outside the analyzed space for cask transfer activities. The licensee will perform a new analysis in a timely manner and leave the cask in place until the new analysis is completed. The degraded condition would not be subject to 10 CFR 72.48.

<u>Example 2</u>

While digging a trench outside of the ISFSI, a licensee accidently cuts some cask temperature monitoring wires. An interim compensatory measure is implemented to connect a temporary temperature monitoring instrument. The cut wires will be repaired in a timely manner. This temporary condition would not be subject to 10 CFR 72.48. The compensatory measure to connect the temporary instrument would be subject to 10 CFR 72.48 to determine if it has any impact on other aspects of the ISFSI facility or cask.

<u>Example 3</u>

A pressure switch on a canister is found to be defective. It is a redundant switch that is described in the UFSAR but not required by the CoC or Technical Specifications. The licensee

determines that the switch is not needed for any safety analyses purposes and chooses to leave the failed switch "as is." This would be a change to the ISFSI facility or spent fuel storage cask design and subject to 10 CFR 72.48.

B4.5 DISPOSITION OF 10 CFR **72.48** EVALUATIONS

There are two possible conclusions to a 10 CFR **72.48** evaluation:

(1) The proposed activity may be implemented without prior NRC approval.

(2) The proposed activity requires prior NRC approval.

Where an activity requires prior NRC approval, the activity must be approved by the NRC via license amendment in accordance with 10 CFR **72.56 for a specific license, or via cask CoC amendment in accordance with 10 CFR 72.244 for a CoC holder for itself or a general license,** prior to implementation. **If prior NRC approval is required under 72.48 for a general licensee, the licensee could either request that the CoC holder for their cask system submit a CoC amendment request to the NRC under 10 CFR 72.244, if appropriate, or, if the change would only apply to their site, could submit, under 10 CFR 72.7, a request for an exemption to the 72.48(c)(2) requirement that a general licensee shall request that the CoC holder obtain a CoC amendment. An exemption request should describe the proposed change and include justification for why the CoC holder is not requesting a CoC amendment for the change, and justification for the change itself.** An activity is considered "implemented" when it provides its intended function, that is, when it is placed in service and declared operable. Thus, a licensee **or cask CoC holder** may design, plan, install, and test a modification prior to receiving the license **or CoC** amendment to the extent that these preliminary activities do not themselves require prior NRC approval under 10 CFR **72.48**.

For proposed activities that are determined to require prior NRC approval, there are three possible options:

(1) Cancel the planned activity.

(2) Redesign the proposed activity so that it may proceed without prior NRC approval.

(3) Apply for and obtain a license **or cask CoC** amendment under 10 CFR **72.56 or 10 CFR 72.244** prior to implementing the activity. Technical and licensing evaluations performed for such activities may be used as part of the basis for license amendment requests.

It is important to remember that determining that a proposed activity requires prior NRC approval does not determine whether it is safe. In fact, a proposed activity that requires prior NRC approval may significantly enhance overall **ISFSI facility or cask** safety at the expense of a small adverse impact in a specific area. It is the responsibility of the **ISFSI licensee or cask CoC holder** to ensure that proposed activities are safe, and it is the role of the NRC to confirm the safety of those activities that are determined to require prior NRC review.

B5 DOCUMENTATION AND REPORTING

10 CFR **72.48**(d) requires the following documentation and recordkeeping:

(1) The licensee **and certificate holder** shall maintain records of changes in the **ISFSI** 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 Section **72**.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 **ISFSI** facility **or spent fuel storage cask design shall** be maintained until **(i) spent fuel is no longer stored in the ISFSI 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) Records of changes in procedures and records of tests and experiments must 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 Sec. 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.

The documentation and reporting requirements of 10 CFR **72.48**(d) apply to activities that require evaluation against the eight criteria of 10 CFR **72.48**(c)(2) and are determined not to require prior NRC approval. That is, the phrase in 10 CFR **72.48**(d)(1), "made pursuant to paragraph (c)," refers to those activities that were evaluated against the eight evaluation criteria (because, for example, they affect the **ISFSI** facility **or cask design** as described in the UFSAR), but not to those activities or changes that were screened out. Similarly, documentation and reporting under 10 CFR **72.48** is not required for activities that are canceled or that that are determined to require prior NRC approval and are implemented via the license amendment request process.

<u>Documenting 10 CFR **72.48** Evaluations</u>

In performing a 10 CFR **72.48** evaluation of a proposed activity, the evaluator must address the eight criteria in 10 CFR **72.48**(c)(2) to determine if prior NRC approval is required. Although the conclusion in each criterion may be simply "yes," "no," or "not applicable," there must be an accompanying explanation providing adequate basis for the conclusion. Consistent with the intent of 10 CFR **72.48**, these explanations should be complete in the sense that another

knowledgeable reviewer could draw the same conclusion. Restatement of the criteria in a negative sense or making simple statements of conclusion is not sufficient and should be avoided. It is recognized, however, that for certain very simple activities, a statement of the conclusion with identification of references consulted to support the conclusion would be adequate and the 10 CFR **72.48** evaluation could be very brief.

The importance of the documentation is emphasized by the fact that experience and engineering knowledge (other than models and experimental data) are often relied upon in determining whether evaluation criteria are met. Thus the basis for the engineering judgment and the logic used in the determination should be documented to the extent practicable and to a degree commensurate with the safety significance and complexity of the activity. This type of documentation is of particular importance in areas where no established consensus methods are available, such as for software reliability, or the use of commercial-grade hardware and software where full documentation of the design process is not available.

Since an important goal of the 10 CFR **72.48** evaluation is completeness, the items considered by the evaluator must be clearly stated.

Each 10 CFR **72.48** evaluation is unique. Although each applicable criteria must be addressed, the questions and considerations listed throughout this guidance document to assist evaluating the criteria are not requirements for all evaluations. Some evaluations may require that none of these questions be addressed while others will require additional considerations beyond those addressed in this guidance.

When preparing 10 CFR **72.48** evaluations, licensees may combine responses to individual criteria or reference other portions of the evaluation.

As discussed in Section **B**4.2.3, licensees may elect to use screening criteria to limit the number of activities for which written 10 CFR **72.48** evaluations are performed. A documentation basis should be maintained for determinations that the changes meet the screening criteria, i.e., screen out. This documentation does not constitute the record of changes required by 10 CFR **72.48**, and thus is not subject to the recordkeeping requirements of the rule.

<u>Reporting to NRC</u>

A summary of 10 CFR **72.48** evaluations for activities implemented under 10 CFR **72.48** must be provided to NRC. Activities that were screened out, canceled or implemented via license **or CoC** amendment need not be included in this report. The 10 CFR **72.48** reporting requirement (every 24 months) is identical to that for UFSAR updates such that licensees **and CoC holders** may provide these reports to NRC on the same schedule.

Reporting cask design changes to CoC holders or cask users

10 CFR 72.48(d)(6) requires:

(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.

The records required to be provided in the 60-day reports would be those for changes to a spent fuel storage cask design that require evaluation against the eight criteria of 10 CFR 72.48(c)(2) and are determined not to require prior NRC approval. These records must include the written evaluation which provides the bases for the determination that the change does not require prior NRC approval pursuant to paragraph 10 CFR 72.48(c)(2).

The records required to be reported by the CoC holders to the cask users are only those records created by the CoC holders. These would include the records of 72.48 evaluations created by the CoC holders as a result of adopting changes that were reported to the CoC holders by the cask users. Records of changes reported to a CoC holder by a user but not adopted by the CoC holder do not need to be provided to other cask users.

10 CFR 72.48 evaluations performed to resolve fabrication non-conformances for specific storage casks during fabrication do not necessarily represent a change to a "spent fuel storage cask design." When such evaluations do not constitute a change to a cask design, they are not required to be reported in a 60-day report but they would be included in the routine 72.48 report to the NRC.

For the purposes of the 60-day report, licensees and CoC holders should transmit the report for a cask design change within 60 days of final approval of the 10 CFR 72.48 evaluation. Utilizing this milestone to establish the timing of transmitting the report will ensure that potentially affected entities are provided timely notification of the approved change, even if the change may not be actually implemented for some time.

Due to the nature of the spent fuel storage casks, cask users are limited in their ability to incorporate changes to the cask design after the cask is loaded with spent fuel and placed in storage. Accordingly, the 60-day report of cask design changes evaluated in accordance with the provisions of 10 CFR 72.48 provided to the cask users (specific and general licensees) by the CoC holders are provided for information only and do not require specific action by the cask user. Cask users are required to report defects in any spent fuel storage structure, system, or component which is important to safety or results in a significant reduction in the effectiveness of any spent fuel storage confinement system during use to the NRC (10 CFR 72.75 for site specific and general licensees; 10 CFR 72.216 for general licensees). Additionally, cask certificate holders are required to provide written reports to the NRC within 30 days of discovery of a design or fabrication deficiency for any spent fuel storage cask which has been delivered to a licensee when the design or fabrication deficiency affects the ability of systems, structures, or components important to safety to perform their intended safety function. Accordingly, safety significant information related to a specific spent fuel cask design will be provided to the NRC in a timely manner and any safety significant concerns communicated to the cask users via NRC generic correspondence for disposition.

If a general licensee determines that a cask design change should be adopted on site, they should review their site-specific 72.212 evaluations to determine if any would be changed by adopting the cask design change. If a 72.212

evaluation is changed, the general licensee would perform a 72.48 screening/evaluation as required by 10 CFR 72.212(b)(2)(ii). The answers/justification used in the 72.48 screenings/evaluations may be taken from the CoC holder's 72.48 screening/evaluation if they could also apply to the general licensee's screening/evaluation. A cask design change that has been reported to the general licensee by the CoC holder and then adopted by the general licensee would not need to be reported back to the CoC holder in a 60-day report because it would not be a change from the CoC holder's design change.

If a specific licensee determines that a cask design change should be adopted on site, they would review their site-specific ISFSI UFSAR to determine if a 72.70 update and 72.48 screening/evaluation would be required. The answers/justification used in the 72.48 screenings/evaluations may be taken from the CoC holder's 72.48 screening/evaluation if they could also apply to the specific licensee's screening/evaluation. A cask design change that has been reported to the specific licensee by the CoC holder and then adopted by the specific licensee would not need to be reported back to the CoC holder in a 60-day report because it would not be a change from the CoC holder's design change.

When a CoC holder receives a copy of the record for a cask design change from a cask user, they should review the record in a timely manner (within 60 days of receipt) to determine if they should adopt the change (see Figure B.3). If so, the certificate holder would review the cask UFSAR to determine if a 72.48 screening/evaluation and 72.248 update would be required. The answers/justification used in the 72.48 screenings/evaluations may be taken from the cask user's 72.48 screening/evaluation if they could also apply to the CoC holder's screening/evaluation. A cask design change that has been reported to the CoC holder by a general or specific licensee and then adopted by the CoC holder would not need to be reported back to the general or specific licensee in a 60-day report because it would not be a change from the licensee's design change, but it would need to be reported to other cask users in a 60-day report.

Although records of changes to the ISFSI facility, to procedures, and to tests or experiments are not required to be provided in a 60-day report, ISFSI licensees and cask CoC

holders may wish to exchange these documents on an agreed-upon schedule. These records may aid the general or specific licensee to comply with the 10 CFR 72.48(c)(3) requirement that, for purposes of implementing 72.48, the FSAR (as updated) is considered to include UFSAR changes resulting from 72.48 evaluations and 72.56/72.244 analyses performed since the last UFSAR update. Other configuration management process may also be used to ensure compliance with this requirement.

Any documentation of reviews of the 60-day reports by the recipients should be maintained, but is not required by 10 CFR 72.48.

ATTACHMENT 4

Text of 10 CFR 72.48

§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 an accident previously evaluated in the FSAR (as updated);

(ii) Result in more than a minimal increase in the likelihood 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.

ATTACHMENTS

1. **Figure B-1 10 CFR 72.48 Process Site Specific Licensee, General Licensee, Certificate Holder**

2. **Figure B-2 General or Specific Licensee (Cask User) 60-Day reports to CoC Holder**

3. **Figure B-3 CoC Holder 60-Day Reports to Cask Users**

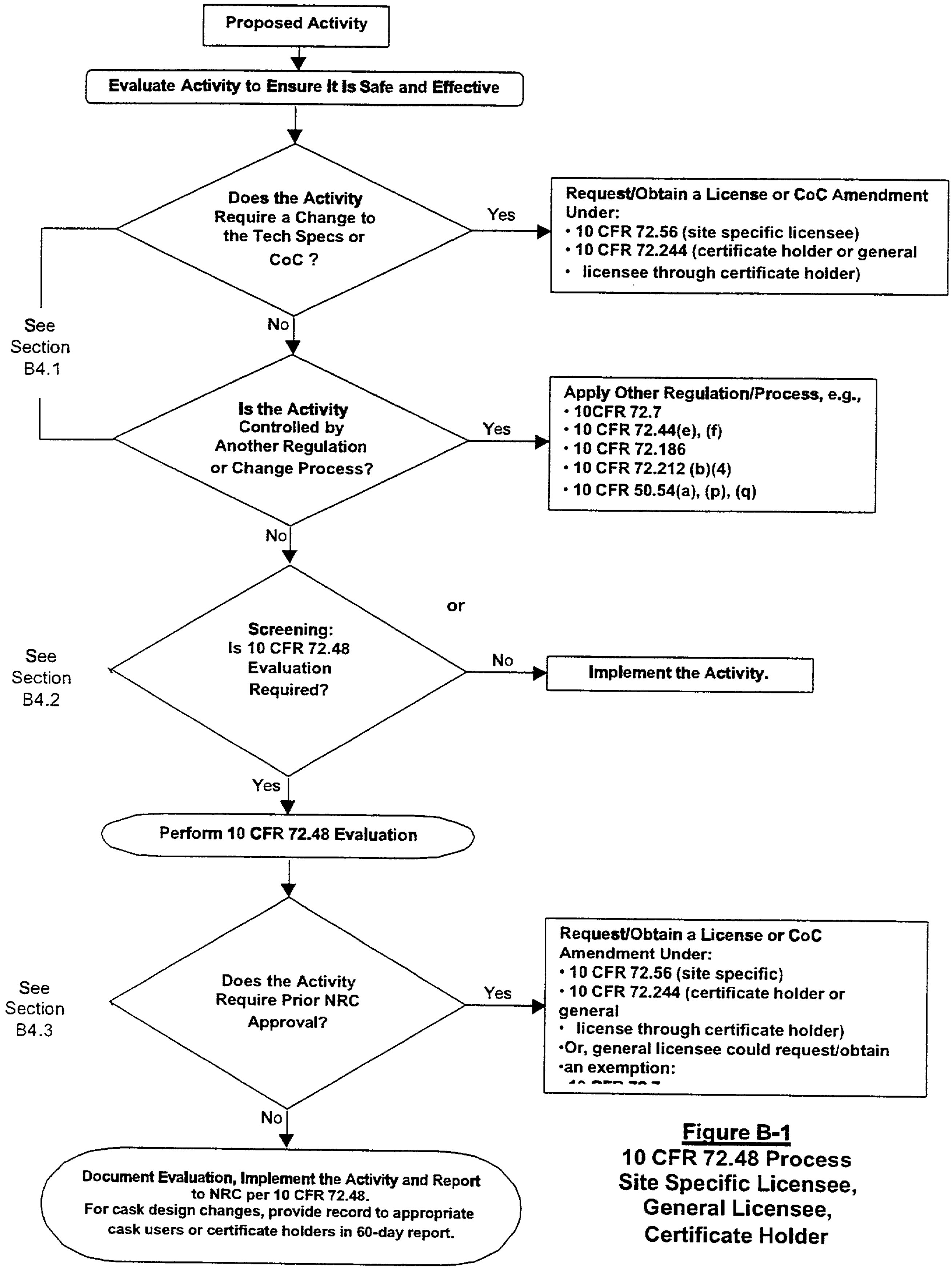
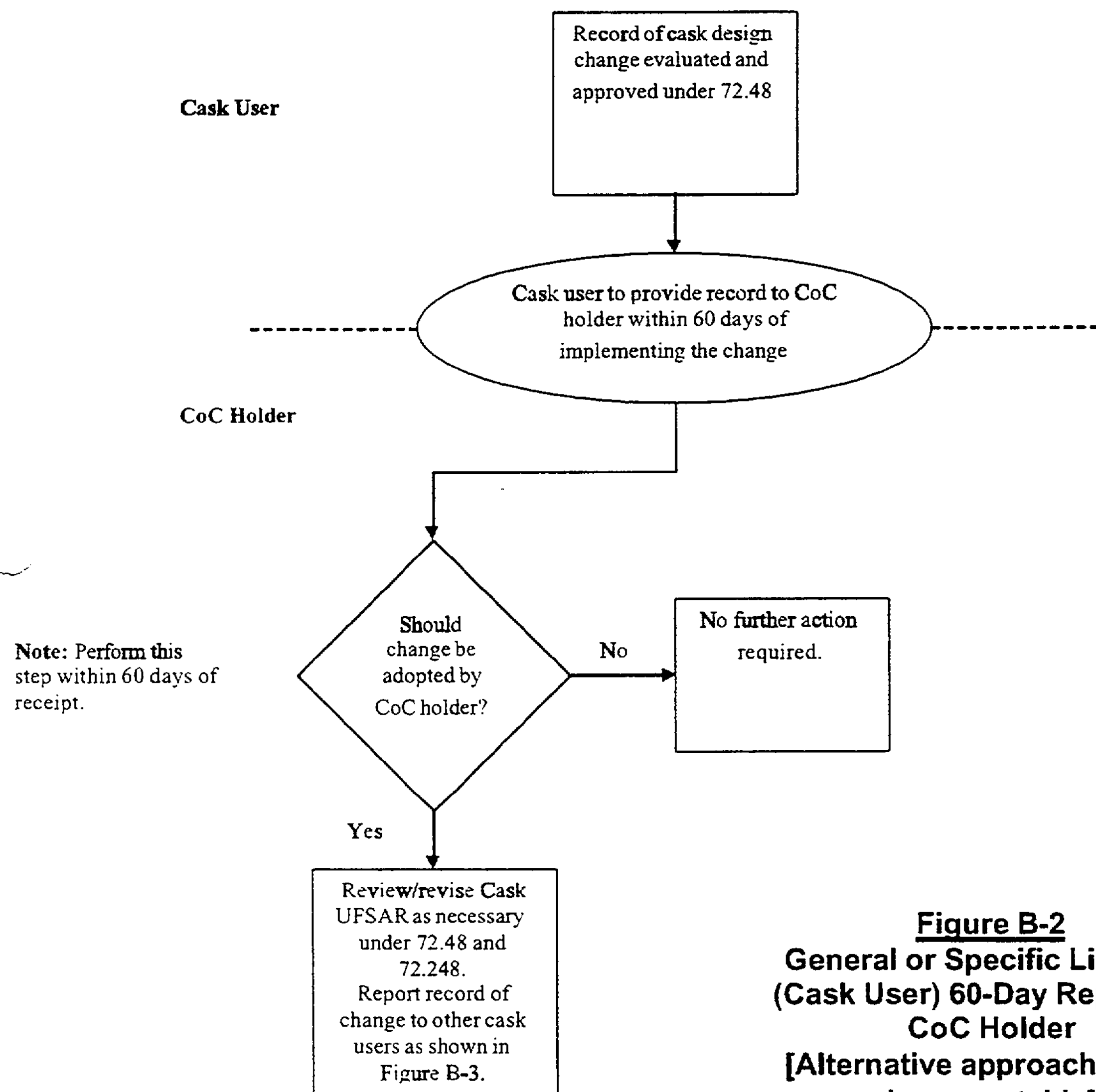


Figure B-1
10 CFR 72.48 Process Site Specific Licensee, General Licensee, Certificate Holder



<u>Figure B-2</u>
General or Specific Licensee (Cask User) 60-Day Reports to CoC Holder
[Alternative approaches may be acceptable]

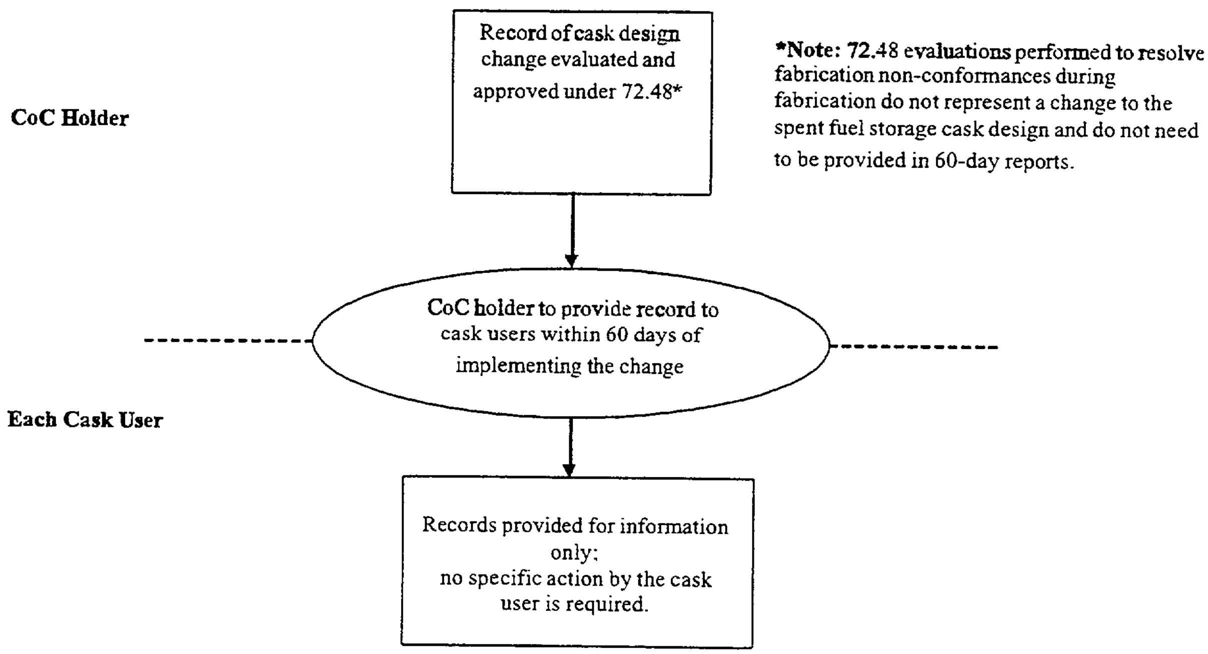


Figure B-3
CoC Holder 60-Day Reports to Cask Users [Alternative

ATTACHMENT

4. 10 CFR 72.48 Changes, Tests, and Experiments

Attachment 4
10 CFR 72.48 Changes, Tests, and Experiments

§ 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 (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 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 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 §§ 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.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

January 23, 2001

NRC REGULATORY ISSUE SUMMARY 2001-03
CHANGES, TESTS, AND EXPERIMENTS

ADDRESSEES

All U.S. NRC Part 50 and Part 72 licensees and Part 72 Certificate of Compliance holders.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) as guidance to addressees in making the transition to the requirements of recently amended regulations in Title 10 of the *Code of Federal Regulations*, namely, Sections 50.59 and 72.48 (10 CFR 50.59 and 10 CFR 72.48). Both sections are titled "Changes, tests, and experiments." This RIS requires no action or written response on the part of an addressee.

BACKGROUND INFORMATION

On October 4, 1999, the NRC published final rules (64 FR 53582) amending 10 CFR 50.59 and 10 CFR 72.48. These regulations address licensee requirements for making changes to a facility (reactor facility, independent spent fuel storage installation, or monitored retrievable storage installation) without prior NRC approval. The effective date of 10 CFR 50.59, as amended, is 90 days after the issuance of applicable regulatory guidance. On November 14, 2000, the Commission approved for publication Regulatory Guide (RG) 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments." The NRC noticed the availability of RG 1.187 in the *Federal Register* on December 13, 2000 (65 FR 77773). Therefore, the effective date of 10 CFR 50.59, as amended, is March 13, 2001. RG 1.187 endorses the industry guidance document developed by the Nuclear Energy Institute (NEI), NEI 96-07, Revision 1, "Guidelines for 10 CFR 50.59 Implementation," dated November 2000. A separate RG is being prepared to address the implementation of 10 CFR 72.48, as amended.

During the public comment process on the draft RG, the concern was expressed that it would be difficult for licensees to schedule and complete necessary procedure revisions and training within 90 days of the publication of the RG because of planned outage schedules and other activities. It was further noted that the effective date for 10 CFR 72.48, as amended, is a different date (April 5, 2001). This raised questions about how licensees could effectively transition from the existing rule to the amended rule.

ML010040446

SUMMARY OF ISSUE

The issue addressed in this RIS is how the NRC will view licensee compliance with 10 CFR 50.59 or 10 CFR 72.48, as amended, when it finds a licensee observing the original requirements of either rule, as appropriate, after the effective date of the revision to each regulation. It is the NRC's view that since the amended 10 CFR 50.59 is a relaxation of the existing requirements, as a general matter, if a licensee is in compliance with the old rule, the licensee also satisfies the requirements of the amended rule. With regard to 10 CFR 72.48, the revisions to the rule were more extensive than those made to 10 CFR 50.59, particularly with regard to the reporting requirements. As a result, it is not possible to conclude that compliance with old rule also demonstrates compliance with the revised rule. However, it is the NRC's view that both the old rule and the new rule provide an acceptable level of safety. As a result, the NRC will consider scheduler exemptions to the effective date of 10 CFR 72.48 on a case-by-case basis for power reactor licensees that want to implement the revised 10 CFR 50.59 and 10 CFR 72.48 together. The NRC endorses the orderly transition to the requirements of the amended rules, even if a licensee implements them after their effective dates. More information on this matter is given in Attachment 1.

BACKFIT DISCUSSION

This RIS requires no action or written response. Consequently, the staff did not perform a backfit analysis.

FEDERAL REGISTER NOTIFICATION

The staff did not publish a notice of opportunity for public comment in the *Federal Register* because the RIS is informational and pertains to a staff position that does not represent a departure from current regulatory requirements and practice.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not request any information collection.

If you have any questions about this issue, please call or e-mail one of the technical contacts listed below.

/RA/
David B. Matthews, Director
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

/RA/
E. William Brach, Director
Spent Fuel Project Office
Office of Nuclear Materials Safety and Safeguards

Technical Contacts: Eileen M. McKenna, NRR
301-415-2189
E-mail: emm@nrc.gov

Christopher Jackson, NMSS
301-415-2947
E-mail: cpj@nrc.gov

Attachments:
1. Guidance on the Transition From the Original to the Amended Requirements of 10 CFR 50.59 and 10 CFR 72.48
2. List of Recently Issued NRC Regulatory Issue Summaries

PAPERWORK REDUCTION ACT STATEMENT

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Distribution: RIS File PUBLIC

Attachments:
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Accession No.: ML010040446 Template No.: NRR-052

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REXB	C:REXB	D:DRIP
JShapaker*	LMarsh*	DMatthews
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GUIDANCE ON THE TRANSITION FROM THE ORIGINAL TO THE AMENDED REQUIREMENTS OF 10 CFR 50.59 and 10 CFR 72.48

BACKGROUND

On October 4, 1999 (64 FR 53582), the NRC published a final rule revising 10 CFR 50.59 (and related requirements in 10 CFR Part 50 and 10 CFR Part 72). The Part 50 requirements were to become effective 90 days after issuance of applicable regulatory guidance. The effective date for the revised 10 CFR 50.59 is March 13, 2001, the amendments to 10 CFR 72.48 will become effective April 5, 2001. During the development of an industry guidance document on the implementation of 10 CFR 50.59 (endorsed by RG 1.187), certain issues arose concerning the transition from the old rule to the new rule. This attachment addresses these issues.

DISCUSSION OF ISSUES

Issue 1: Licensees have planned refueling outages and other activities for the period between December and March 2001 and will find it difficult to complete necessary procedure revisions and train affected personnel before the rules become effective. To ease the transition to the new rules, may a licensee continue using the old rule after the effective date of either 10 CFR 50.59 or 10 CFR 72.48 until procedure revisions and training can be completed? Alternatively, could a licensee implement the revised Section 50.59 on the same date as the revised Section 72.48 (i.e., April 5, 2001)? What licensee actions are needed to do this?

Response: In promulgating the revisions to Sections 50.59 and 72.48, the Commission noted that the revised rules allow licensees greater flexibility than the existing rules to make changes without prior NRC approval. With regard to 50.59, if a licensee is appropriately implementing the old rule, it is complying with the amended rule. Some delay in implementation beyond the effective dates of the revised rules (a few months) is reasonable and acceptable. To make an orderly transition, licensees must have sufficient time to prepare procedures and train personnel. Although no formal notification of the NRC or NRC approval is needed to delay implementation, a licensee is encouraged to communicate its plans and implementation schedule to the NRC resident inspector and regional staff. A licensee may use the sample letter at the end of this attachment to communicate its plans to NRC staff. With regard to 10 CFR 72.48, because there are additional reporting requirements associated with the new rule, implementation of the revised 10 CFR 72.48 beyond April 5, 2001 date will require a scheduler exemption.

Issue 2: Which version of 10 CFR 50.59 or 10 CFR 72.48 applies when the evaluation of a change is begun before the effective date of the amended rule but not completed until after the amended rule becomes effective?

Response: The 10 CFR 50.59 or 10 CFR 72.48 requirements in effect when a licensee completes its evaluation of a change (i.e., when the safety review committee approves the change) will apply. Evaluations started after the effective date, should follow the revised rule.

Since the revised rule is a relaxation of the old rule, the NRC staff will consider an evaluation begun under the old rule and based on the procedures for the old rule but completed after the effective date of the revised rule to comply with the revised rule during the transition period. However, without a scheduler exemption, the reporting requirements associated with the revised 10 CFR 72.48 are applicable to all changes completed following the April 5, 2001 rule implementation date.

Issue 3: If a licensee completes an evaluation under the old rule but discovers new information after the revised rule takes effect and must revise the 10 CFR 50.59 or 10 CFR 72.48 evaluation, should the licensee use the new rule or the old rule to revise the evaluation?

Response: The licensee would need to comply with the rule that is in effect at the time the evaluation is revised. However, for 10 CFR 50.59 as previously noted, since the new rule is effectively a relaxation of the old rule, using the old rule to revise the evaluation is also acceptable. Only the parts of the evaluation affected by the new information need to be revised.

Issue 4: The effective date of the revised maintenance rule (10 CFR 50.65), including the new paragraph 50.65(a)(4), is November 28, 2000, which is before the effective date of the amended 10 CFR 50.59. During the time before 10 CFR 50.59 becomes effective, are licensees required to perform both paragraph 50.65(a)(4) assessments and 10 CFR 50.59 reviews for temporary alterations in support of maintenance?

Response: The guidance in RG 1.182 is that maintenance activities, including associated temporary alterations, are to be evaluated in accordance with paragraph 50.65(a)(4) of the maintenance rule. A 10 CFR 50.59 evaluation is not required (provided the temporary alteration will be in effect for less than 90 days at power). This same guidance is given in RG 1.187 for the implementation of 10 CFR 50.59. The revised rule explicitly states that a 10 CFR 50.59 evaluation is not needed when another regulation establishes the control process for such activities. However, the Commission, in approving RG 1.182, allowed licensees to use the guidance in RG 1.182 before the effective date of the amended 10 CFR 50.59. Therefore, if a licensee evaluates temporary alterations in accordance with paragraph 50.65(a)(4) of the maintenance rule, a 10 CFR 50.59 review is not needed.

Issue 5: If an evaluation has been completed before the effective date of either 10 CFR 50.59 or 10 CFR 72.48, as amended, but the change has not yet been implemented, what action (if any) is required?

Response: The new rule requires no action for changes evaluated but not implemented before the effective date of the rule. The licensee has the option of doing a new evaluation under the revised rule for changes that might have required prior approval under the old rule but do not require prior approval under the new rule. Such an evaluation would provide the basis for not seeking NRC approval for the change.

Issue 6: May a licensee continue to reference 10 CFR 50.59 or 10 CFR 72.48 evaluations performed under the old rule and guidance when making a similar change in the future?

Response: Past evaluations will continue to be a valuable resource to licensees for 10 CFR 50.59 or 10 CFR 72.48 screening and evaluations of similar changes. However, a licensee should use the definitions and criteria of the new rule and approved guidance for evaluations of proposed changes that are begun after the revised rule becomes effective (except as noted in Issue 1, above).

Issue 7: Some previous NRC documents that discuss 10 CFR 50.59 or 10 CFR 72.48 may be inconsistent with the revised rule or the new regulatory guidance, for example, Generic Letter (GL) 95-02 (regarding analog-to-digital upgrades under 10 CFR 50.59) and Bulletin (BL) 96-02 (regarding the movement of heavy loads). How should these documents be viewed now?

Response: NRC documents such as those noted were written to be used with the old rule. To the extent that the rule requirements that led to particular statements or conclusions have been revised, the impact of the rule revisions on those statements must be taken into account. For example, GL 95-02 discusses the evaluation criterion "malfunction of a different type." This criterion will no longer apply, having been revised to "malfunction with a different result." However, other aspects of the guidance (for example, the effect of the digital instrumentation on the system in which it is used) will remain applicable.

With respect to BL 96-02, if a heavy load movement is part of a maintenance activity, there is no 10 CFR 50.59 evaluation needed. The fact that the load is larger or is moving in a different load path than previously evaluated would enter into the risk assessment required by 10 CFR 50.65 (a)(4) and determine under what plant conditions the load lift should occur. If the heavy load lift is not maintenance related, and so requires a 10 CFR 50.59 evaluation, the licensee should follow the requirements of the revised rule to determine whether prior NRC approval is needed. For example, the licensee should consider whether the change would increase the consequences of an accident previously evaluated or creates an accident of a different type.

Issue 8: The implementation guidance endorsed in RG 1.187 appears to be written with power reactors in mind. How does implementation of the revised 10 CFR 50.59 apply to non-power reactors?

Response: The effective date of the revised 10 CFR 50.59 requirements, as established by publication of the *Federal Register* notice (65 FR 77773) announcing the availability of RG 1.187, applies to non-power reactors. As noted above, flexibility is allowed in the implementation period to accommodate training and procedural updating needs, and a properly executed program for complying with the old rule requirements will likely satisfy the new rule requirements during the implementation period. Non-power reactor licensees should note that some concepts in the revised rule such as a "method of evaluation described in the FSAR" may not have an equivalent in programs based on the old rule. The NRC staff will accept and reply to questions from non-power reactor licensees that my arise during implementation of the new rule.

ISSUE 1 — SAMPLE LETTER

TO: NRC, Document Control Desk, Washington DC 20555

FROM: Appropriate Licensee Point of Contact

SUBJECT: IMPLEMENTATION OF REVISED 10 CFR 50.59

The effective date for the revised 10 CFR 50.59, was established in a December 13, 2000, *Federal Register* notice (65 FR 77773), as March 13, 2001. As discussed in Regulatory Issue Summary (RIS) 2001-03, dated January 23, 2001, the NRC has stated that to permit an orderly transition to the revised rule, licensees may implement the rule later than this date. Although an exemption is not necessary, the RIS suggested that a licensee may want to communicate its implementation plan to the NRC. It is our intention to implement the revised requirements of 10 CFR 50.59 on [date]. [Here the licensee may add any information about its plans to phase in 10 CFR 50.59 implementation; for example, the licensee will follow the new rule requirements for evaluations begun after the date provided, but will finish other evaluations under the old process]. Until that time, we will continue to implement our existing 10 CFR 50.59 review processes.

[The licensee may discuss its reasons for delaying implementation. For example, the plant will be in a refueling outage shortly after the effective date, and there is insufficient time to train personnel in the revised process; or the licensee does not want to transition during a refueling outage since this activity already places demands on staff and would not be in the best interests of safety; or the licensee wants to implement the revised section 50.59 at the same time as the revised section 72.48, to minimize confusion.]

cc: NRC Regional Office
NRC Resident Inspection Office(s) [as applicable]
NRR Project Managers (for affected facilities)
E. McKenna, NRR/RGEB

LIST OF RECENTLY ISSUED
NRC REGULATORY ISSUE SUMMARIES

Regulatory Issue Summary No.	Subject	Date of Issuance	Issued to
2001-02	Guidance on Risk-Informed Decisionmaking in License Amendment Reviews	01/18/01	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2001-01	Eligibility of Operator License Applicants	01/18/01	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2000-25	Potential Deficiency in Qualification of Okonite Single-Conductor Electrical Control Cables	12/26/00	All holders of OLs for pressurized-water reactors (PWRs), except those who have permanently ceased operations and have certified that fuel have been permanently removed from the reactor vessel
2000-24	Concerns about Offsite Power Voltage Inadequacies and Grid Reliability Challenges Due to Industry Deregulation	12/21/00	All holders of OLs for pressurized-water reactors (PWRs), except those who have permanently ceased operations and have certified that fuel have been permanently removed from the reactor vessel
2000-23	Recent Changes to Uranium Recovery Policy	11/30/00	All holders of materials licenses for uranium and thorium recovery facilities

OL = Operating License
CP = Construction Permit

OMB Control No. 3150-0011

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
WASHINGTON, DC 20555-0001

June 24, 1999

NRC GENERIC LETTER 83-11, SUPPLEMENT 1: LICENSEE QUALIFICATION FOR PERFORMING SAFETY ANALYSES

Addressees

All holders of operating licenses for nuclear power plants, including those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this supplement to Generic Letter (GL) 83-11 to notify licensees and applicants of modifications to the Office of Nuclear Reactor Regulation (NRR) practice regarding licensee qualification for performing their own safety analyses. This includes the analytical areas of reload physics design, core thermal-hydraulic analysis, fuel mechanical analysis, transient analysis (non-LOCA), dose analysis, setpoint analysis, containment response analysis, criticality analysis, statistical analysis, and Core Operating Limit Report (COLR) parameter generation. It is expected that recipients will review the information for applicability to their facilities. However, suggestions contained in this supplement to the generic letter are not NRC requirements; therefore, no specific action or written response is required.

Background

Over the past decade, substantially more licensees have been electing to perform their own safety analyses to support such tasks as reload applications

and technical specification amendments, rather than to contract the work out to their nuclear steam supply system (NSSS) vendor, fuel vendor, or some other organization. The NRC encourages utilities to perform their own safety analyses, since doing this significantly improves licensee understanding of plant behavior. GL 83-11 presented guidance on the information that NRC needs in order to qualify licensees to perform their own safety analyses using approved computer codes.

Description of Circumstances

NRC's experience with safety analyses using large, complex computer codes has shown that errors or discrepancies discovered in safety analyses are more likely to be traced to the user rather than to the code itself. This realization has led the NRC to place additional emphasis on assuring the capabilities of the code users as well as on assuring the codes themselves. In the past, NRC obtained this assurance by reviewing the code verification information submitted by the licensee. The reviews focused primarily on the licensee's quality assurance practices and the technical competence of the licensee with respect to their ability to set up an input deck, execute a code, and properly interpret the results. The information which was reviewed generally included comparisons (performed by the user of the code results) with experimental data, plant operational data, or other benchmarked analyses, as well as compliance with any restrictions or limitations stated in the generic NRC Safety Evaluation Report (SER) that approved the code.

Since GL 83-11 was issued, many licensees have submitted information in the form of topical reports demonstrating their ability to perform their own safety analyses, such as reload analyses using NRC-approved methods and codes. Preparation and review of a qualification topical report is resource intensive on the part of the staff and the licensee, and because the review is usually assigned a low priority, it is difficult to schedule the review for timely completion.

Discussion

To help shorten the lengthy review and approval process, the NRC has adopted a generic set of guidelines which, if met, would eliminate the need to submit detailed topical reports for NRC review before a licensee could use approved codes and methods. These guidelines are presented in the Attachment to this Generic Letter. Using this approach, which is consistent with the regulatory basis provided by Criteria II and III of Appendix B to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50), the licensee would institute a program (such as training, procedures, and benchmarking) that follows the guidelines, and would notify NRC by letter that it has done this and that the documentation is available for NRC audit.

Summary

The revised guidance on licensee qualification for using safety analysis codes is intended for licensees who wish to perform their own licensing analyses using methods that have been reviewed and approved by the NRC, or that have otherwise been accepted as part of a plant's licensing basis.

Backfit Discussion

This supplement does not involve a backfit as defined in 10 CFR 50.109(a)(1), since it does nothing more than offer guidance as to an acceptable means by which a licensee may verify to the NRC its qualifications to use approved codes and methods for performing safety analyses. Therefore, the staff has not prepared a backfit analysis.

Federal Register **Notification**

A notice of opportunity for public comment was published in the *Federal Register* (60 FR 54712) on October 25, 1995. Comments were received from 13 licensees, 3 fuel vendors, and 3 industry interest groups. Copies of the comment letters received and the staff's evaluation of these comments are available in the NRC Public Document Room. Because of concurrent issues that arose at the Maine Yankee nuclear power reactor facility regarding the improper application of approved methods, the NRC decided to withdraw the issuance of the supplement to GL 83-11 pending a complete review of these issues. Subsequent review of the lessons learned from Maine Yankee indicated that the issues involved were adequately addressed in the GL 83-11 supplement as published for public comment. Therefore, the NRC decided to proceed with the issuance of the supplement.

In addition to the proposed supplement to GL 83-11, the staff also requested comments on modified procedures for reducing the resource effort for acceptance of new or revised licensee or vendor analysis methods. These comments will be addressed in a future staff action.

Paperwork Reduction Act Statement

This generic letter contains a voluntary collection that is subject to the Paperwork Reduction Act of 1995 (22 U.S.C. 3501 et seq.). This information collection was approved by the Office of Management and Budget, approval number 3150-0011, through September 30, 2000.

The public reporting burden for this collection of information is estimated to average 100 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The NRC is seeking public comment on the potential impact of the collection of information contained in the generic letter and on the following issues:

(1) Is the proposed collection of information necessary for the proper performance of the functions of the NRC, including consideration of whether the information will have practical utility?
(2) Is the estimate of burden accurate?
(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 consideration of the use of automated collection techniques?

Send comments on any aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch, T-6 F33, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0011), Office of Management and Budget, Washington, D.C. 20503.

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.

This generic letter requires no specific action or written response. If you have any questions about this matter, please contact the technical contact or the lead project manager listed below.

/s/'d by S. F. Newberry
for David B. Matthews, Director
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

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Attachments: 1. Guidelines for Qualifying Licensees to Use Generically Approved Analysis Methods
2. List of Recently Issued NRC Generic Letters

(NUDOCS Accession Number 9906210103)

ATTACHMENT 1

GL 83-11, Supp. 1
June 24, 1999

GUIDELINES FOR QUALIFYING LICENSEES TO USE
GENERICALLY APPROVED ANALYSIS METHODS

1.0 INTRODUCTION

This attachment presents a simplified approach for qualifying licensees to use NRC-approved analysis methods. Typically, these methods are developed by fuel vendors, utilities, national laboratories, or organizations such as the Electric Power Research Institute, Incorporated, (EPRI). To use these approved methods, the licensee would institute a program (e.g., training, procedures) that follows the guidelines below and notify the NRC that it has done so.

The words "code" and "method" are used interchangeably within this document, i.e., a computer program. In many cases, however, an approved method may refer not only to a set of codes, an algorithm within a code, a means of analysis, a measurement technique, a statistical technique, etc., but also to selected input parameters which were specified in the methodology to ensure conservative results. In some cases, due to limitations or lack of appropriate data in the model, the code or method may be limited to certain applications. In these cases, the NRC safety evaluation report (SER) specifies the applicability of the methodology.

2.0 GUIDELINES

A commitment on the part of a licensee to implement the guidelines delineated in this document is sufficient information for the NRC to accept the licensee's qualification to use an approved code or method to perform safety-related evaluations such as reload physics design, core thermal-hydraulic analysis, fuel mechanical analysis, non-LOCA transient analysis, dose analysis, setpoint analysis, containment response analysis, criticality analysis, statistical analysis, and Core Operating Limit Report (COLR) parameter generation. To document its qualification in this manner, the licensee should send the NRC a notification of

its having followed the guidelines at least 3 months before the date of its intended first licensing application.

2.1 Eligibility

The only codes and methods that are addressed by this process are those that NRC has reviewed and approved generically, or those that have been otherwise accepted as part of a plant's licensing basis. The use of a new methodology or a change to an existing methodology is not applicable to this process.

2.2 Application Procedures

In-house application procedures, which ensure that the use of approved methods is consistent with the code qualification and, in most instances, with the approved application of the methodology, should be established and implemented. Because of the bounding nature of many licensing transient analyses, it may not be necessary to have formulated application procedures for each transient. These procedures should contain a section describing the application of the code and a section delineating the code limitations and restrictions, including any defined in the licensing topical report, correspondence with the NRC, and the SER. The applicability of a particular method to either a specific fuel design or to a core which contains a mixture of fuel types is important. For example, the use of one vendor's hot channel analysis code with a different vendor's transient codes may not necessarily yield conservative results and, in fact, may not be consistent with the NRC-approved reload analysis package. Therefore, in-house application procedures should have the proper controls to preclude such a misapplication but should also include the flexibility to allow comparison tests between the different methodologies to show that a conservative assessment can be made.

2.3 Training and Qualification of Licensee Personnel

A training program should be established and implemented to ensure that each qualified user of an approved methodology has a good working knowledge of the codes and methods, and will be able to set up the input, to understand and interpret the output results, to understand the applications and limitations of the code, and to perform analyses in compliance with the application procedure. Training should be provided by either the developer of the code or method, or someone who has been previously qualified in the use of the code or method.

2.4 Comparison Calculations

Licensees should verify their ability to use the methods by comparing their calculated results to an appropriate set of benchmark data, such as physics startup tests, measured flux detector data during an operating cycle, higher order codes, published numerical benchmarks, analyses of record, etc. These

comparisons should be documented in a report which is part of the licensee's quality assurance (QA) records. Significant, unexpected, or unusual deviations in the calculations of safety-related parameters should be justified in the report. All comparisons with startup test data should agree within the acceptance criteria defined in the plant startup test plan.

2.5 Quality Assurance and Change Control

All safety-related licensing calculations performed by a licensee using NRC-approved codes and methods should be conducted under the control of a QA program which complies with the requirements of Appendix B to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50). The licensee's QA program should also include the following:

(1) a provision for evaluating vendor (or other code developer) updates and implementing those updates, if applicable, in codes, methods, and procedures; and

(2) a provision for informing vendors (or code developers) of any problems or errors discovered while using their codes, methods, or procedures.

NEI 99-04 [REVISION 0]

Guidelines for Managing NRC Commitment Changes

July 1999

NEI 99-04 [REVISION 0]

Nuclear Energy Institute

Guidelines For Managing NRC Commitment Changes

July 1999

ACKNOWLEDGMENTS

NEI appreciates the invaluable assistance of the Commitment Management Task Force in development of this guidance.

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TABLE OF CONTENTS

APPENDICES

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1 INTRODUCTION

Licensees are required to comply with NRC rules, regulations and orders, and with their licenses. A plant's license includes its technical specifications, as well as any general or specific license conditions. These requirements frequently are referred to as "obligations" to differentiate from licensee-generated tasks—for example, a task designed to improve the cost-effectiveness of a maintenance or operations program. The method of compliance with a regulatory requirement frequently is the subject of NRC guidance, such as a NUREG report or a regulatory guide. However, the licensee generally has the authority to determine what method of compliance is appropriate for its plant(s) to meet these obligations (see § 50.109(a)(7)).

As part of their routine interface with the NRC staff, licensees may agree to take actions covering a wide range of topics. Some of these topics have high safety significance, while others have low or no safety significance. The agreed-upon actions may exceed regulatory requirements or involve a specific method for meeting an obligation. Historically, the licensee's statements of action related to these obligations have been called "commitments."

With the advent of risk-informed and performance-based regulations, the classic definition of a commitment has changed from one of process orientation, to one of outcomes orientation. Therefore, the *method used* by a licensee to restore compliance with an obligation—for example, corrective action taken in a Notice of Violation or Licensee Event Report usually will not be considered a *commitment*. In most cases, the term commitment refers to the licensee's promise to restore compliance with the violated obligation, by a given date.

As part of normal business practice, licensees routinely track a variety of commitments. These include commitments made to non-regulatory organizations such as the Institute of Nuclear Power Operations, as well as corrective actions and self-assessments. Previously, guidance for managing regulatory commitments has been provided in NEI's *Guideline for Managing NRC Commitments*, Revision 2, December 1995. The NRC determined that the NEI guidance document was an acceptable method for licensees to follow for managing and changing their regulatory commitments to the NRC. The industry guideline reflects lessons learned and changes in the changing regulatory environment.

Licensee correspondence dealing with regulatory commitments should distinguish clearly between regulatory commitments to restore compliance with NRC rules and regulations and voluntary commitments—for example, enhancements, routine corrective actions taken in accordance with quality assurance programs, or other descriptive information.

In the past, responses to Notices of Violation (NOV) and Licensee Event Reports (LER) have identified corrective actions. Historically, licensees have identified as commitments those corrective actions taken to address a NOV or plant incidents that resulted in a Licensee Event Report. Typically, the licensee would track these corrective actions as commitments in commitment management and corrective action programs. Under the revised definition of "regulatory commitment," dual tracking is not required. In addition, some corrective actions

represent enhancements to ongoing practices that were not directly related to the cause of the event.

Future correspondence with the NRC should distinguish between:

- regulatory commitments and promises to restore compliance, and
- licensee-generated tasks, enhancements, or routine or ancillary information.

It may be useful to include in correspondence specific statements regarding the classification of information.

The nuclear industry and the NRC have the same fundamental objective: to identify and accomplish those actions that provide the level of nuclear plant performance necessary to ensure adequate protection of public health and safety. The lack of distinction between commitments of high and low (or even no) safety significance—and the lack of a readily acceptable and practical method for eliminating or changing resulting commitments when warranted—impedes the achievement of this objective.

Licensees historically have treated commitments seriously, making changes to these commitments only after due consideration of any safety impacts. At times, licensees have hesitated to change commitments even when justified from a safety standpoint. There are two major reasons for this hesitation. First, some licensees are concerned that the NRC may view the commitment change negatively. Second, licensees may perceive that the process for changing commitments is burdensome.

A uniform practice regarding commitments and commitment change mechanisms within the industry would assist individual utilities in focusing resources on significant issues and in changing past commitments that no longer serve their intended purpose.

This guidance document describes a baseline set of commitment change concepts that licensees can use to supplement their plant-specific programs for changing both past and future commitments. The guideline is intended to be used either to change commitments on a case-by-case basis, or as part of a comprehensive effort to re-baseline the total population of docketed commitments. The guidance applies to commitments communicated to the NRC under the current regulatory structure. Licensees must decide how they will address commitments communicated to the NRC prior to the promulgation of this guidance document.

It is important to understand that the guidance does not imply that licensee managers act only in response to regulatory requirements or initiatives. Indeed, licensees take many actions designed to maintain or improve safety without interacting with the NRC staff.

2 RECOMMENDED ACTIONS

2.1 MANAGING COMMITMENTS

Any significant commitment of utility resources—whether to satisfy a concern of an NRC inspector, to respond to a generic NRC communication, or to determine the appropriate manner to implement a regulatory requirement—should follow a reasoned management decision-making process. To ensure proper management control of utility resources, licensees should establish an internal process to control commitments. For example:

- Commitments and their relative priority should be based upon an evaluation of the safety benefit that will be attained; the pertinent legal requirement, if any; the technical bases for the contemplated action or activity; and the resources available, in the context of other requirements and commitments. The licensee also should consider carefully both the cost of an action being considered (its initial cost, as well as any costs that would be incurred over the life of the unit) and the value added. These elements should be considered in the context of any pertinent regulatory requirement(s).

- Commitments should be made only by previously designated persons. Consistent with the utility's management approach, the number of individuals designated could be very few, or the responsibility could be delegated fairly broadly within each area of responsibility.

- The designated individuals(s) should be identified both internally and externally as the only licensee personnel with the authority to commit utility resources. Similarly, the utility should encourage the NRC to designate one or more points of contact to represent the NRC in resolving questions related to the prioritization of issues and utility resource commitments.

- The NRC should be advised that oral statements to take certain action represent an *intent* to make a commitment, but do not constitute a *commitment* until submitted in writing on the docket by a designated utility representative. (This would not apply to "discretionary enforcement" situations.)

- In general, licensees should avoid making oral statements of intent to take specific actions requiring significant levels of resources without first obtaining the approval of the designated senior management person responsible. Oral statements to take certain actions should not be made in response to inspection findings until (1) after receipt of the written inspection report that identifies the particular matter and describes the NRC's concern regarding that matter, and (2) after the utility has completed an evaluation to ensure that the root cause of the NRC's concern will be corrected by the proposed action. However, nothing in these guidelines should be construed to suggest that a licensee should not take action immediately to correct an emerging

safety issue or a safety issue arising from noncompliance with a rule or regulation or a licensee's programs or procedures.

- Licensees should review carefully any confirmatory action letters, NRC inspection reports and NRC safety evaluation reports to ensure that (1) any implicit or explicit re-statements of the licensee's regulatory commitments are accurate, and (2) the NRC has not misconstrued oral or written communications as commitments. Inaccurate statements should be corrected promptly by written notification to the NRC.

- Routine licensee programs and processes should be sufficient to ensure that routine corrective actions reported to the NRC are not undermined by subsequent changes. If concerns exist regarding the adequacy of normal processes to maintain desired changes or prevent recurring problems, licensees may use the commitment management system to ensure that future changes receive additional reviews and/or management attention.

- In some cases, licensees may choose to allow NEI, an owners group, or another organization to work with the NRC staff on their behalf to resolve generic issues or issues germane to a vendor type. Licensees should ensure that statements made by such organizations, and represented as commitments by the participating licensees, are appropriate and are managed in accordance with the licensees' commitment management programs. Alternatively, individual licensees may commit to implement programs agreed to by NRC staff and industry organizations. In these cases, licensees should identify any initial deviations from the generic programs when making the commitment and should evaluate and report to the NRC staff subsequent departures from the generic programs in accordance with the licensee's commitment management program.

- Each licensee should consider including a "sunset clause" in commitments, where appropriate, to establish a period of time to evaluate the effectiveness of the commitment.

2.2 Implementation of Regulatory Commitments

Regulatory commitments should be implemented as described in the information provided to the NRC staff. Changes to the plans for implementation—including the schedule and the planned actions themselves—should be communicated to the NRC staff in a timely manner. Information management systems, annotations to procedures, and other methods may be useful for licensees to assure the traceability of regulatory commitments. Such systems can help ensure that subsequent changes to regulatory commitments are evaluated using the guidance in the following section.

Licensees should consider carefully the need to inform the NRC staff prior to implementation if the licensee changes its plans for corrective actions taken to restore compliance with regulatory requirements, even if the specific actions planned were not considered regulatory commitments. In general, the NRC staff should be informed of significant changes in a manner similar to that used to provide the original information (e.g., revised LER, revised NOV response, etc.).

2.3 CHANGING COMMITMENTS

Changes to commitments also should be the result of a reasoned management decision-making process. To ensure continued management control of resources applied to commitments, the following commitment change practices are recommended:

- Each licensee should consider periodically evaluating its outstanding commitments and the manner in which those commitments have been implemented, focusing on those commitments that have a major impact on the utility's costs. The licensee should determine whether the current commitment represents the most cost-effective way of satisfying the safety issue that prompted the commitment and should change those commitments as appropriate.

- Each licensee should establish a practical commitment change process that identifies the relative safety significance and regulatory interest of commitments communicated to the NRC staff.

  [Figure A-1 in Appendix A provides a sample commitment change process.]

3 COMMITMENT CHANGE PROCESS

3.1 DEFINITIONS

The following definitions and their bases are intended to facilitate a common understanding of the distinction between the safety importance and regulatory significance of different types of licensee actions communicated to the NRC.

<u>Obligation</u> refers to any condition or action that is a legally binding requirement imposed on licensees through applicable rules, regulations, orders and licenses (including technical specifications and license conditions). These conditions (also referred to as regulatory requirements) generally require formal NRC approval as part of the change-control process. Also included in the category of obligations are those regulations and license conditions that define change-control processes and reporting requirements for licensing basis documents such as the updated FSAR, quality assurance program, emergency plan, security plan, fire protection program, etc.

Regulatory Commitment means an explicit statement to take a specific action agreed to, or volunteered by, a licensee *and* submitted in writing on the docket to the NRC.

Licensees frequently communicate their intent to take certain actions to restore compliance with Obligations, to define a certain method for meeting Obligations, to correct or preclude the recurrence of adverse conditions, or to make improvements to the plant or plant processes. A Regulatory Commitment is an intentional undertaking by a licensee to (1) restore compliance with regulatory requirements, or (2) complete a specific action to address an NRC issue or concern (e.g., generic letter, bulletin, order, etc.). With respect to corrective actions identified in a NOV response or LER, the specific method(s) used by licensees to restore compliance with an obligation are not normally considered a Regulatory Commitment. The Regulatory Commitment in this instance is the promise to restore compliance with the violated obligation.

In the past, not all licensee correspondence has clearly distinguished between Regulatory Commitments (e.g., promises to restore compliance to a violated obligation by a certain date) and factual statements, descriptive information and voluntary enhancements not intended to constitute a Regulatory Commitment. Potential confusion resulting from this lack of clarity may require dialogue between a licensee and the NRC on a case-by-case basis. To avoid confusion, licensees should distinguish clearly between regulatory commitments to restore compliance with NRC rules and regulations and voluntary enhancements, routine corrective actions taken in accordance with quality assurance programs, and other descriptive information. [In addition to the change process described in the following section, licensees may wish to evaluate existing open, continuous/cyclical or one-time commitments in light of the definitions included in this document.]

4 CHANGE PROCESS

The following outlines a recommended change process intended to provide licensee management with the flexibility necessary to effectively manage the safe and efficient operation of their nuclear plants, while ensuring that changes that are significant to safety and/or of high regulatory interest are communicated to the NRC. The recommended change process does not apply to confirmatory action letter commitments as described in the NRC's Enforcement Policy, NUREG-1600.

4.1 OBLIGATIONS

No changes from current requirements are needed. The available statutory-based mechanisms include petitions for rulemaking under 10 CFR 2.802, exemption requests under 10 CFR 50.12, license amendment requests under 10 CFR 50.90, changes to certain plans under 10 CFR 50.54 and requests to modify or rescind orders issued under 10 CFR 2.202.

4.2 REGULATORY COMMITMENTS

The attached flowcharts, Figures A-1 and A-2, outline a regulatory commitment management change process that (1) delineates commitments that have safety significance and/or regulatory interest; (2) establishes guidance for notifying the NRC of changes to commitments that have safety significance and/or regulatory interest; and, (3) establishes a rationale for eliminating past regulatory commitments that have negligible safety significance and/or regulatory interest. Figure A-3 is a summary sheet that, when completed, provides an adequate level of documentation for the decisions made in revising a commitment using this change process.

[As part of normal business practice, licensees routinely track a variety of actions, including those from non-regulatory sources such as INPO, and other corrective actions or self-assessments. The change process for these actions should be consistent with site management expectations and programs.]

(Figure A-1, <u>COMMITMENT MANAGEMENT CHANGE PROCESS</u>, has five decision steps which are described below.)

<u>STEP 1: IS THERE A CODIFIED CHANGE PROCESS FOR THE COMMITMENT?</u>

Commitments that are embodied in the Updated Final Safety Analysis Report as descriptions of the facility or procedures are changed by applying the provisions of 10 CFR 50.59 to determine if a change requiring prior NRC approval exists. If a complete 10 CFR 50.59 review determines that a change requiring prior NRC approval does not exist, licensees may make the change and provide a description of the change to the NRC annually or coincident with filing FSAR updates. Otherwise, prior NRC review and approval of the change is required.

Licensees apply NEI-96-07 in implementing 10 CFR 50.59. NEI-96-07 provides screening criteria to identify items that clearly do not constitute a change requiring prior NRC approval to eliminate the need for performing a complete 10 CFR 50.59 analysis. Regulatory commitments thus screened from complete application of the 10 CFR 50.59 criteria need not be further evaluated for their safety significance under Step 2 and should proceed to Step 3.

[NOTE: This guideline is not to be used to evaluate individual changes to regulatory commitments embodied in the FSAR or to justify reductions in scope of a FSAR. NEI-98-03 provides guidance for updating the FSAR.]

Commitments that are contained in certain programs and plans required by 10 CFR 50.54 are changed by applying the provisions of the applicable section of 10 CFR 50.54 (50.54(a) for Quality Assurance Plan, 50.54(p) for Safeguards Contingency Plan or 50.54(q) for Emergency

Plan). Changes that do not "reduce commitments" in the Quality Assurance Plan or that do not "reduce the effectiveness" of the Safeguards Contingency Plan or Emergency Plan may be made without prior NRC review and approval with notification of the change as specified in the applicable 50.54 section. Otherwise, prior NRC review and approval of the change is required.

Licensees who employ a formal commitment tracking system may choose to remove items from their tracking systems upon placement of the information into another licensing basis document (e.g., updated FSAR and QA Program), to the extent that controls and reporting requirements for subsequent changes are consistent with expectations mutually agreed upon by the licensee and NRC staff. [Decisions to maintain or delete items covered by other controls are left to the discretion of licensees considering the site-specific procedures, information management systems and other factors.]

Commitments made under 10 CFR 50.82(a) apply to plants seeking license termination (decommissioning). Changes to regulatory commitments under this section follow the same guidelines as operating plants

STEP 2: IS THE CHANGE SIGNIFICANT TO SAFETY?

Commitment changes that are not captured by the codified processes identified in Step 1 above still need to be evaluated in terms of their safety significance unless application of the NEI-96-07 screening criteria under Step 1 determined that the change does not impact the ability of a SSC to perform its safety function. Figure A-2 outlines a deterministic approach for conducting safety assessments. The process is briefly described below:

The first step is to evaluate if the change could negatively impact the ability of a SSC to perform its intended safety function. NEI-96-07, Section 4, contains useful criteria for performing this evaluation. Other relevant information in performing this evaluation is an understanding of the safety basis for the original commitment. A review of pertinent documentation (e.g., NRC bulletin or generic letter, LER, NOV, etc.) that prompted the original commitment is a source for basis information. A further factor to be considered in performing the evaluation is whether the change could negatively impact the ability of licensee personnel to ensure the SSC is capable of performing its intended safety function as a result of changes to procedures, programs and other human performance elements. If the evaluation determines that the change could not negatively impact the ability of a SSC to perform its intended safety function, the change is not safety significant.

If the evaluation determines that the change could impact the ability of a SSC to perform its intended safety function, then an assessment applying the criteria of 10 CFR 50.92 (c), (1) through (3), should be performed to determine if the change involves a significant hazards consideration. Probabilistic Safety Assessment (PSA) insights can be used to supplement deterministic-based assessments. If the assessment determines that a significant hazards consideration exists, the change is significant to safety. Otherwise, the change is not safety significant.

Changes to commitments that are evaluated as being significant to safety would either not be implemented or would require discussion with the NRC and review and approval, as appropriate, or written notification. Changes evaluated as not significant to safety would proceed to Step 3 to assess if a compliance issue exists.

STEP 3: WAS THE ORIGINAL COMMITMENT DESIGNED TO ACHIEVE COMPLIANCE WITH AN OBLIGATION?

Non-compliance with obligations are identified to licensees through (NOVs) and non-cited violations. Responses to NOVs and some LERs include the immediate corrective actions taken to restore compliance with the obligation. Historically, these corrective actions (e.g., one-time, recurring, etc.) typically prescribed the method(s) of complying with obligations. In the future, the method(s) used by licensees to restore compliance with an obligation will normally not be considered a commitment. The commitment, in this example, (corrective actions taken in a NOV response or LER) is the licensee's promise to restore compliance with a violated obligation by a certain date.

Additionally, NRC must be notified of changes to the date committed to restore compliance with an obligation. If a revision to the regulatory commitment date is necessary, and can be justified, then notify NRC prior to the original commitment date. If the revision to the commitment date can not be justified, then either meet the original commitment date or apply for the appropriate regulatory relief. Changes to the associated corrective actions will need to be evaluated (by the licensee) to determine if the change would still achieve compliance with the obligation.

It may be prudent to discuss changes in methods of restoring compliance with the NRC staff to determine if the description of the corrective actions planned or taken to restore compliance may be of a sufficient interest to warrant a submittal.

STEP 4: DID THE NRC RELY UPON THE ORIGINAL COMMITMENT BEING CONSIDERED FOR CHANGE?

Some commitments are made in response to a subject of regulatory interest. For example, the NRC may have either reviewed and approved the action volunteered or agreed to by the licensee or relied upon the commitment in lieu of taking other action, such as issuing orders. Items in this category include: (1) specific statements in NRC safety evaluation reports crediting specific licensee commitments as being the basis for an NRC staff safety conclusion (general references to an entire licensee report, such as a fire hazards analysis, are not considered to be specific commitments in this context); (2) commitments made in response to NRC bulletins and generic letters; and (3) commitments made in response to requests for information under 10 CFR 50.54(f) or 10 CFR 2.204.

Regulatory commitments may involve new actions as well as existing actions credited by licensees in responding to NRC requests. For example, responses to an item in an NRC bulletin crediting an existing program, practice or plant feature as meeting the intent of the requested action is a regulatory commitment. Changes to regulatory commitments not captured in categories (1) through (3) would proceed to Step 5.

If the original commitment has yet to be implemented, the licensee can proceed with the change, but the NRC should be notified of the change as soon as practicable after the change is approved by licensee management, but before any committed completion date. Notification should be accomplished by supplementing the docketed correspondence containing the original commitment.

If the original commitment has been implemented, the licensee can revise the commitment and the NRC should be notified in a summary report (annual, refueling outage, or for decommissioning plants, 24 months).

STEP 5: WAS THE ORIGINAL COMMITMENT MADE TO MINIMIZE RECURRENCE OF A CONDITION ADVERSE TO QUALITY?

Commitments to take long-term corrective actions in Licensee Event Reports (LERs) are made to minimize recurrence of adverse conditions. Licensees may find it useful to periodically review the necessity of commitments related to minimizing recurrence of adverse conditions. Licensees need the flexibility to change or eliminate commitments they determine are no longer necessary based on:

- The committed corrective action may not have been successful in minimizing recurrence of the condition; or,
- There may be a more effective way to minimize recurrence of the condition other than the method selected; or,
- The commitment may no longer be necessary due to changing conditions at the plant; or,
- In hindsight and based on experience, the commitment may never have been necessary to minimize the potential for future non-compliance.
- The commitment may subsequently have been captured as part of an on-going program or other administrative control that is subject to a revision review process (e.g., procedure changes governed by administrative technical specifications).

If the changed commitment is necessary to minimize recurrence of an adverse condition, the NRC should be notified of the change in a summary report (annual, refueling outage, or for decommissioning plants, 24 months).

If the commitment is no longer considered necessary, the licensee may change the commitment without notifying the NRC.

CAUTION: Due to the sensitivity of some issues, licensees may choose to notify the NRC prior to making changes to Regulatory Commitments even though the above change process would not require such action.

5 REPORTING AND DOCUMENTATION

5.1 Reporting

The above process identifies various commitments that can be changed with notification to the NRC made in a report submitted annually or along with the FSAR updates as required by 10 CFR 50.71(e). The intent of this report is to provide a brief summary of commitments changed since the last report in lieu of filing individual notifications as commitments are revised. A brief statement of the basis for the change should be included. However, items with similar bases for change can be grouped by bases. For example, all LER commitment changes related to procedures for which a revised commitment was identified that minimized recurrence of the original adverse condition could be provided as a listing in the report under a general basis description.

5.2 Documentation

Figure A-3, "Revised Commitment Evaluation Summary," provides documentation of the decisions made in applying the above change process. The form would serve as proof that an evaluation was performed and should be retained by the licensee either (1) until submittal of the annual report or report filed coincident with the FSAR updates per 10 CFR 50.71(e) for commitment changes that require NRC notification, or (2) for the life of the facility for commitment changes that do not require NRC notification. Where the form calls for a description of the rationale for a decision, it is expected that, in the majority of instances, a justification of one or two sentences would be sufficient. In some cases a more detailed explanation or reference to a backup assessment may be appropriate. It is not the intent to generate lengthy descriptions supported by detailed analyses, but rather to capture the essence of the basis for changing the commitment.

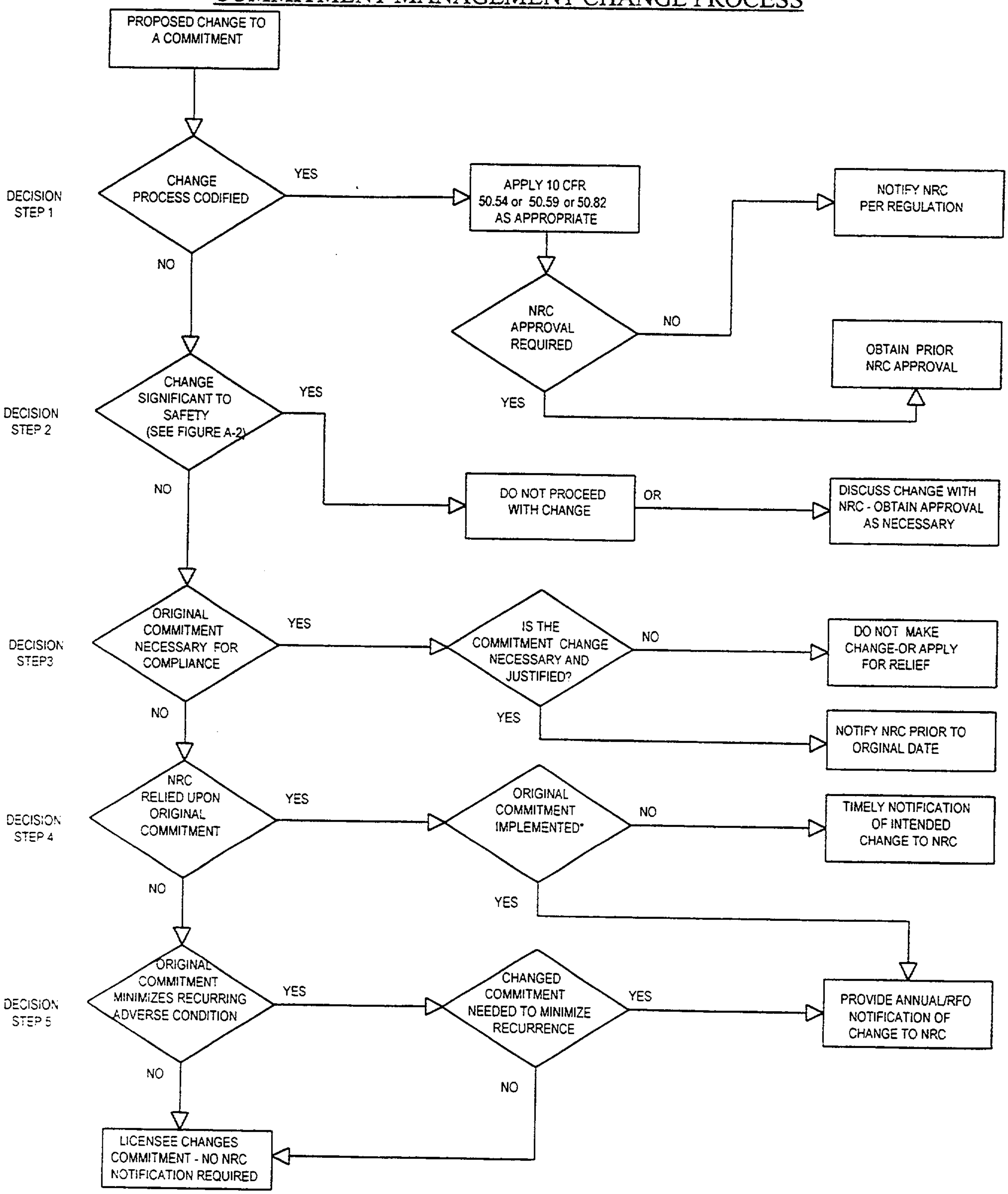
6 REFERENCES

NEI 96-07 (Rev. 0), September 1997 "Guidelines For 10CFR 50.59 Safety Evaluations"

NEI 98-03 (Rev.0), October 1998 *"Guidelines For Updating Final Safety Analysis Reports"*

NEI 98-05 (Rev.2), December 1995 "*Guideline for Managing NRC Commitments*"

FIGURE A-1
COMMITMENT MANAGEMENT CHANGE PROCESS



* FOR LONG-TERM CORRECTIVE ACTION COMMITMENTS MADE IN RESPONSE TO A NOTICE OF VIOLATION, SEE PAGE 9

FIGURE A-2

SAFETY SIGNIFICANCE ASSESSMENT (DECISION STEP 2)

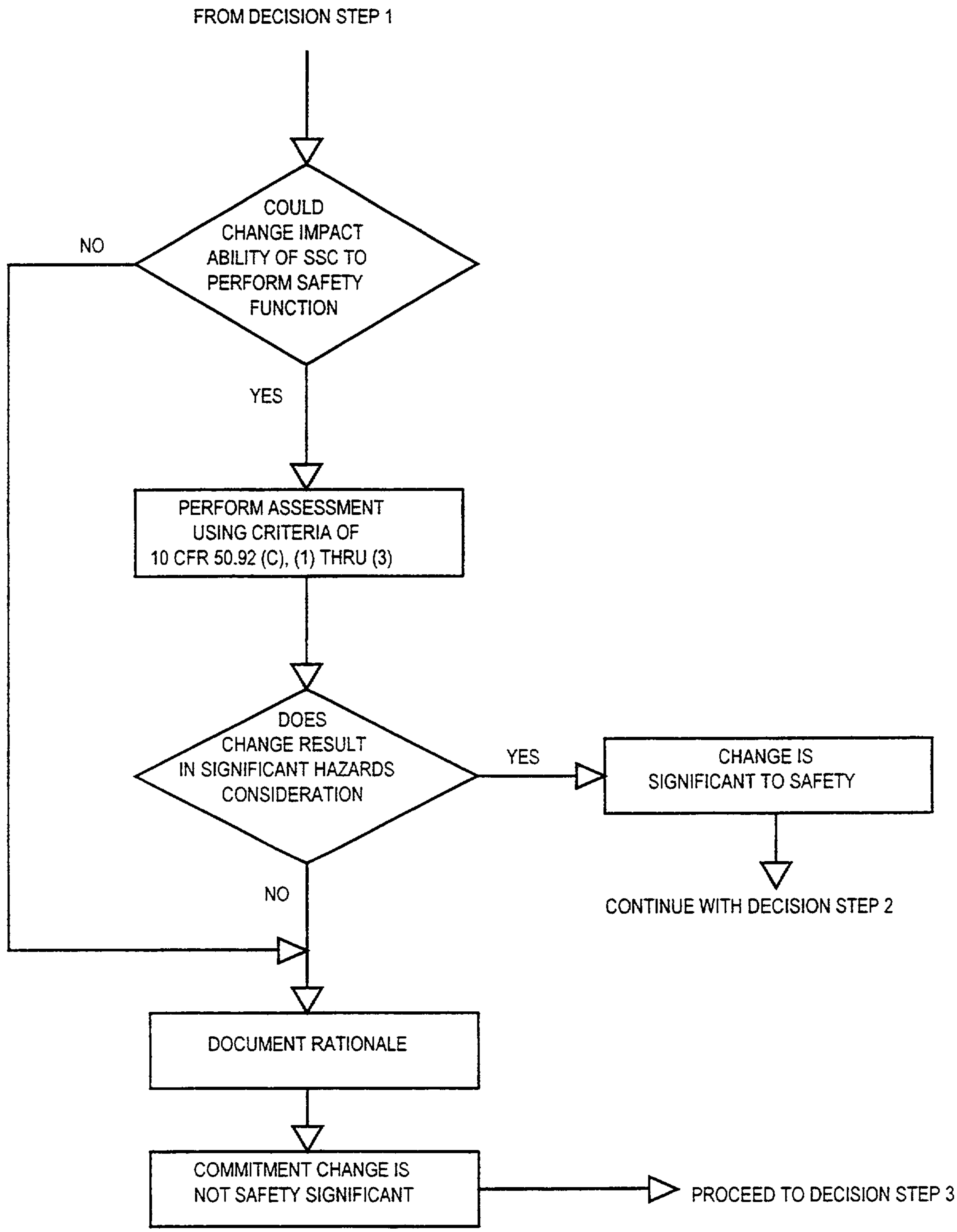


FIGURE A-3
COMMITMENT EVALUATION SUMMARY

Commitment Tracking Number (NCO): ____________________
Source Document: ____________________ Date: __________
Existing Commitment Description:

Revised Commitment Description:

Summarize Justification for Revising Commitment :

(Attach additional sheets, as necessary)
Refer to Figure A-2 for a flow diagram that outlines the commitment evaluation process.

PART I

1.1 Is the existing commitment located in the Updated Final Safety Analysis Report, Emergency Plan, Quality Assurance Plan, Fire Protection Program or Security Plan?

☐ Yes — STOP. Do not proceed with this evaluation. Instead, use the appropriate codified process (e.g., 10 CFR 50.71(e), 10 CFR 50.54) to evaluate commitment.

☐ No — Go to Part II.

PART II

2.1 Could the change negatively impact the ability of a system, structure or component (SSC) to perform its safety function or negatively impact the ability of licensee personnel to ensure the SSC is capable of performing its intended safety function?

☐ No — Continue with Part III. Briefly describe rationale:

☐ Yes — Go to Question2.2

2.2 Perform a safety evaluation using the following 10 CFR 50.92 criteria to determine if a significant hazards consideration exists:

Does the revised commitment involve a significant increase in the probability or consequences of an accident previously evaluated?

☐ Yes ☐ No

Basis:

(Attach additional information, as necessary.)

COMMITMENT EVALUATION FORM

Does the revised commitment create the possibility of a new or different kind of accident from any accident previously evaluated?

☐ Yes ☐ No

Basis:

Does the revised commitment involve a significant reduction in a margin of safety?

☐ Yes ☐ No

Basis:

If any of the above questions are answered Yes, STOP. Do not proceed with the revision, OR discuss change with NRC and obtain any necessary approvals prior to implementation of the proposed change. If all three questions are answered No, go to Part III.

(Attach additional sheets as necessary.)

PART III

3.1 Was the original commitment (e.g., response to NOV, etc.) to restore an OBLIGATION (i.e., rule, regulation, order, or license condition)?

☐ Yes Go to Question 3.2.

☐ No Go to Part IV.

3.2 Is the proposed revised commitment date necessary and justified?

☐ Yes Briefly describe rationale (attach additional sheets as necessary) and notify NRC of revised commitment date prior to the original commitment date.

☐ No STOP. Do not proceed with the revision, OR apply for appropriate regulatory relief.

PART IV

4.1 Was the original commitment: (1) explicitly credited as the basis for a safety decision in an NRC SER, (2) made in response to an NRC Bulletin or Generic Letter, or (3) made in response to a request for information under 10 CFR 50.54(f) or 10 CFR 2.204?

☐ Yes Go to Question 4.2.

☐ No Go to Part V.

COMMITMENT EVALUATION FORM

4.2 Has the original commitment been implemented?

- ☐ Yes — STOP. You have completed this evaluation. Revise the commitment and notify NRC of revised commitment in summary report.
- ☐ No — Go to Question 5.1.

PART V

5.1 Was the original commitment made to minimize recurrence of a condition adverse to quality (e.g., a long-term corrective action stated in an LER)?

- ☐ Yes — Go to Question 5.2.
- ☐ No — STOP. You have completed this evaluation. Revise the commitment. No NRC notification required.

5.2 Is the revised commitment necessary to minimize recurrence of the condition adverse to quality?

- ☐ Yes — Revise the commitment and notify NRC of revised commitment in next annual/RFO interval summary report.
- ☐ No — Revise commitment: no NRC notification is required.

REFERENCES

List documents (e.g., procedures, NRC submittals, etc.) affected by this change.

Description	EDMS #

Prepared by: ______________________

APPROVALS

Signature	______________________ *Lead Coordinator*	________ *Date*
Signature	______________________ *Nuclear Licensing*	________ *Date*

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
WASHINGTON, D.C. 20555-0001

September 21, 2000

NRC REGULATORY ISSUE SUMMARY 2000-17 MANAGING REGULATORY COMMITMENTS MADE BY POWER REACTOR LICENSEES TO THE NRC STAFF

ADDRESSEES

All holders of operating licenses for nuclear power reactors.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to inform the addressees that the Nuclear Energy Institute (NEI) guidance document, "Guidelines for Managing NRC Commitment Changes" (NEI-99-04)(ADAMS Accession No. ML003680088), describes an acceptable way for licensees to control regulatory commitments. The NRC encourages licensees to use the NEI guidance or similar administrative controls to ensure that regulatory commitments are implemented and that changes to the regulatory commitments are evaluated and, when appropriate, reported to the NRC. This RIS does not transmit any new requirements or staff positions. No specific action or written response is required.

BACKGROUND INFORMATION

Various activities undertaken by the staff and the nuclear industry in the early 1990s culminated in the issuance of SECY-95-300, "Nuclear Energy Institute's Guidance Document, 'Guideline for Managing NRC Commitments,'" dated December 20, 1995. The industry document and related Commission paper contained guidance for handling licensing basis information that was not subject to controls defined in NRC regulations. The NEI guidance described a process that licensees can use to modify or delete regulatory commitments and provided criteria to decide if and when changes to regulatory commitments should be reported to the NRC. The use of this guidance was intended to clarify the standing of regulatory commitments and give licensees the confidence and flexibility to modify or delete regulatory commitments shown to be inefficient or ineffective.

In SECY-98-224, "Staff and Industry Activities Pertaining to the Management of Commitments Made by Power Reactor Licensees to the NRC," dated September 28, 1998, the staff described its activities related to commitment management strategies, audits of commitment management programs at power reactor facilities, and discussions with stakeholders. In SECY-98-224, the staff also (1) discussed its rationale for maintaining regulatory commitments as an element of the licensing bases for power reactors and (2) described the expected management of regulatory commitments by licensees' administrative processes and the proposed internal

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guidance for the NRC staff. Following the plan described in SECY-98-224, the staff worked with NEI and licensees as they revised the industry guidance document. These efforts were reflected, along with the insights from participating licensees, in the development of NEI 99-04. The staff's review of NEI 99-04 and its finding that the revised guidance remained useful for controlling regulatory commitments are described in SECY-00-045, "Acceptance of NEI 99-04, 'Guidelines for Managing NRC Commitments,'" dated February 22, 2000, and in the letter from S. Collins (NRC) to R. Beedle (NEI) dated March 31, 2000 (ADAMS Accession No. ML003696998).

SUMMARY OF ISSUE

The NRC staff sees benefits in maintaining regulatory commitments as an integral part of control by licensees and the NRC staff of each facility's licensing basis information. The staff has described, in various Commission papers and internal guidance documents, a hierarchal structure for the various elements of a facility's licensing basis. The approach to the hierarchy is presented in terms of the change control, reporting requirements, and other attributes of the different elements of the licensing basis [see NRR Office Letter 807, "Control of Licensing Bases for Operating Reactors" (ADAMS Accession No. ML003693397)]. The levels of the hierarchy are (1) obligations or regulatory requirements that require prior NRC approval of proposed changes, (2) mandated licensing basis documents, such as the updated final safety analysis report, for which the NRC has established requirements for content, change control and reporting, and (3) regulatory commitments controlled by licensee and NRC administrative processes.

The guidance for licensees provided by NEI 99-04 and related guidance developed for the NRC staff [e.g., NRR Office Letter 900, "Managing Commitments Made by Licensees to the NRC" (ADAMS Accession No. ML003692416)] address the third level of the licensing bases hierarchy. The process and guidance provided in NEI 99-04 are a refinement of the process and guidance described in NEI's previous guidance document and SECY-95-300. The revised guidance clarifies that not all corrective actions described in correspondence with the NRC staff are regulatory commitments. The guidance in NEI 99-04 also suggests that licensees use information management systems, annotations to procedures, or other methods to ensure the traceability of regulatory commitments after implementation.

The staff has reviewed NEI 99-04 and finds that it offers an acceptable way to manage regulatory commitments. Definitions and other guidance in NEI 99-04 are consistent with the principles described in Commission papers and the staff's internal guidance. The NRC encourages licensees to use the NEI guidance or similar administrative controls to ensure that regulatory commitments are implemented and that changes to the regulatory commitments are evaluated and, when appropriate, reported to the NRC. The value of maintaining a working commitment management program is that it supports a common understanding by licensees, the staff, and other stakeholders of how a licensing issue is being resolved and how the matter will be controlled in the future. The NRC staff will continue to assess how the industry and individual licensees are managing regulatory commitments to determine if changes in policy or additional regulatory actions are called for.

BACKFIT DISCUSSION

This RIS does not require any action or written response; therefore, the staff did not perform a backfit analysis.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because it is informational and pertains to a staff position that does not represent a departure from current regulatory requirements and practice. This RIS requires no action or written response on the part of an addressee.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not request any information collection.

If there is any question about this matter, please contact the person listed below or the appropriate Office of Nuclear Reactor Regulation project manager for a specific nuclear power plant.

/RA/

David B. Matthews, Director
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

Technical contact: William D. Reckley, NRR
301-415-1323
E-mail: wdr@nrc.gov

Attachment: List of Recently Issued NRC Regulatory Issue Summaries

NEI 98-03 [Revision 1]

Guidelines for Updating Final Safety Analysis Reports

June 1999

NEI 98-03 [Revision 1]

Nuclear Energy Institute

Guidelines for Updating Final Safety Analysis Reports

June 1999

Nuclear Energy Institute, 1776 I Street N.W., Suite 400, Washington D.C. (202.739.8000)

ACKNOWLEDGMENTS

NEI appreciates the invaluable assistance of the FSAR Task Force and Regulatory Process Working Group toward development of this guideline.

TABLE OF CONTENTS

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1 INTRODUCTION

The purpose of this document is to provide licensees with guidance for updating final safety analysis reports (FSARs) consistent with the requirements of 10 CFR 50.71(e), the FSAR update rule. Guidance is also provided in Appendix A for making voluntary modifications to updated FSARs (UFSARs) (i.e., removal, reformatting and simplification of information, as appropriate) to improve their focus, clarity and maintainability. Figure 1 (page 5) depicts the overall process for updating and modifying the UFSAR.

2 BACKGROUND

FSARs originally served as the principal reference document in support of Part 50 license applications. The original FSAR described methods for conforming with applicable NRC regulations and contains the technical information required by 10 CFR 50.34(b), including "information that describes the facility, presents the design bases and the limits on its operation, and presents the safety analyses of the structures, systems and components and of the facility as a whole." In 1980, the NRC issued the FSAR update rule, 10 CFR 50.71(e), which requires licensees to update their FSARs periodically to assure that the information provided is the latest material developed.

Inspections in 1996-97 by the NRC and licensees identified numerous discrepancies between UFSAR information and the actual plant design and operation. These findings have raised questions about possible noncompliance with 10 CFR 50.71(e). The industry has developed this guidance in recognition of the importance of the UFSAR, the need to comply with 10 CFR 50.71(e) update requirements, and the need for UFSARs to be consistent with the plant design and operation.

3 DEFINITIONS

3.1 Commission Requirements

Commission requirements include regulations, license conditions, technical specifications and orders.

3.2 Design Bases

Design bases are information that 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. These values may be

(1) restraints derived from generally accepted "state-of-the-art" practices for achieving functional goals or (2) requirements derived from analysis (based on calculations and/or experiments) of the effects of a postulated accident for which a structure, system or component must meet its functional goals. (10 CFR 50.2).

Further discussion and examples of design bases are provided in NEI 97-04, *Design Bases Program Guidelines*.

3.3 Historical Information

Historical information is that which was provided in the original FSAR to meet the requirements of 10 CFR 50.34(b) and meets one or more of the following criteria:

- information that was accurate at the time the plant was originally licensed, but is not intended or expected to be updated for the life of the plant
- information that is not affected by changes to the plant or its operation
- information that does not change with time.

3.4 Obsolete Information

Obsolete information is information about (1) equipment that has been removed from the plant, (2) organizations, programs or procedures that are no longer in effect and do not meet the definition of historical information, or (3) design information, evaluations and other UFSAR description that no longer apply to the facility.

3.5 Original FSAR

The original FSAR is the FSAR submitted with the application for the operating license, as amended and supplemented, and reviewed by the NRC in granting the initial license to operate the facility. Note that for early licensees, the Final Hazards Summary Report performed the role of the FSAR in the licensing process.

3.6 Safety Analyses

Safety analyses are analyses performed pursuant to Commission requirement to demonstrate the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the guidelines in 10 CFR 50.34(a)(1) or 10 CFR 100.11. Safety analyses are required to be presented in the UFSAR per 10 CFR 50.34(b) or 10 CFR 50.71(e) and include, but are not limited to, the accident analyses typically presented in Chapter 14 or 15 of the UFSAR.

3.7 UFSAR DESCRIPTION

UFSAR description includes text, tables, diagrams, etc., that provide an understanding of the design bases, safety analyses and facility operation under conditions of normal operation, anticipated operational occurrences, design basis accidents, external events, and natural phenomena for which the plant is designed to function.

3.8 UPDATED FSAR

The updated FSAR (UFSAR) is the original FSAR as updated per the requirements of 10 CFR 50.71(e).

4 ROLE OF THE UPDATED FSAR

UFSARs provide a description of each plant and, per the Supplementary Information for the FSAR update rule, serve as a "reference document to be used for recurring safety analyses performed by licensees, the Commission, and other interested parties." The UFSAR is used by the NRC in its regulatory oversight of a nuclear power plant, including its use as a reference for evaluating license amendment requests and in the preparation for and conduct of inspection activities. For licensees, portions of the UFSAR are used as a reference in evaluating changes to the facility and procedures under the 10 CFR 50.59 change process. The UFSAR also serves to provide the general public a description of the plant and its operation.

5 SCOPE OF THE UPDATED FSAR

10 CFR 50.34(b) defined the scope of information required to be submitted in original FSARs and, by extension, the scope of UFSARs as they exist today. While original FSARs expanded greatly over the years as increasingly detailed information was required of new licensees, the scope given by 10 CFR 50.34(b) provided the common baseline for all original FSARs.

In addition to the scope of information contained in the original FSAR, the scope of today's UFSARs includes information added per the FSAR update rule[1]. The update rule requires licensees to update their UFSARs to reflect new Commission requirements and the effects of changes to the facility and procedures, safety evaluations and analyses of new safety issues requested by the Commission.

[1] The scope of the UFSAR also may be affected by the other NRC requirements, such as 10 CFR 54.21(d). This rule requires licensees to supplement their UFSARs as part of the technical information submitted with license renewal applications.

Just as the scope of the original FSAR was determined by the requirements of 10 CFR 50.34(b), it follows that the scope of information subsequently added to the original FSAR through the update process should be guided by the requirements used to establish the content of the original FSAR.

10 CFR 50.34(b) contains the following statement of general intent concerning the required content of FSARs submitted as part of original license applications:

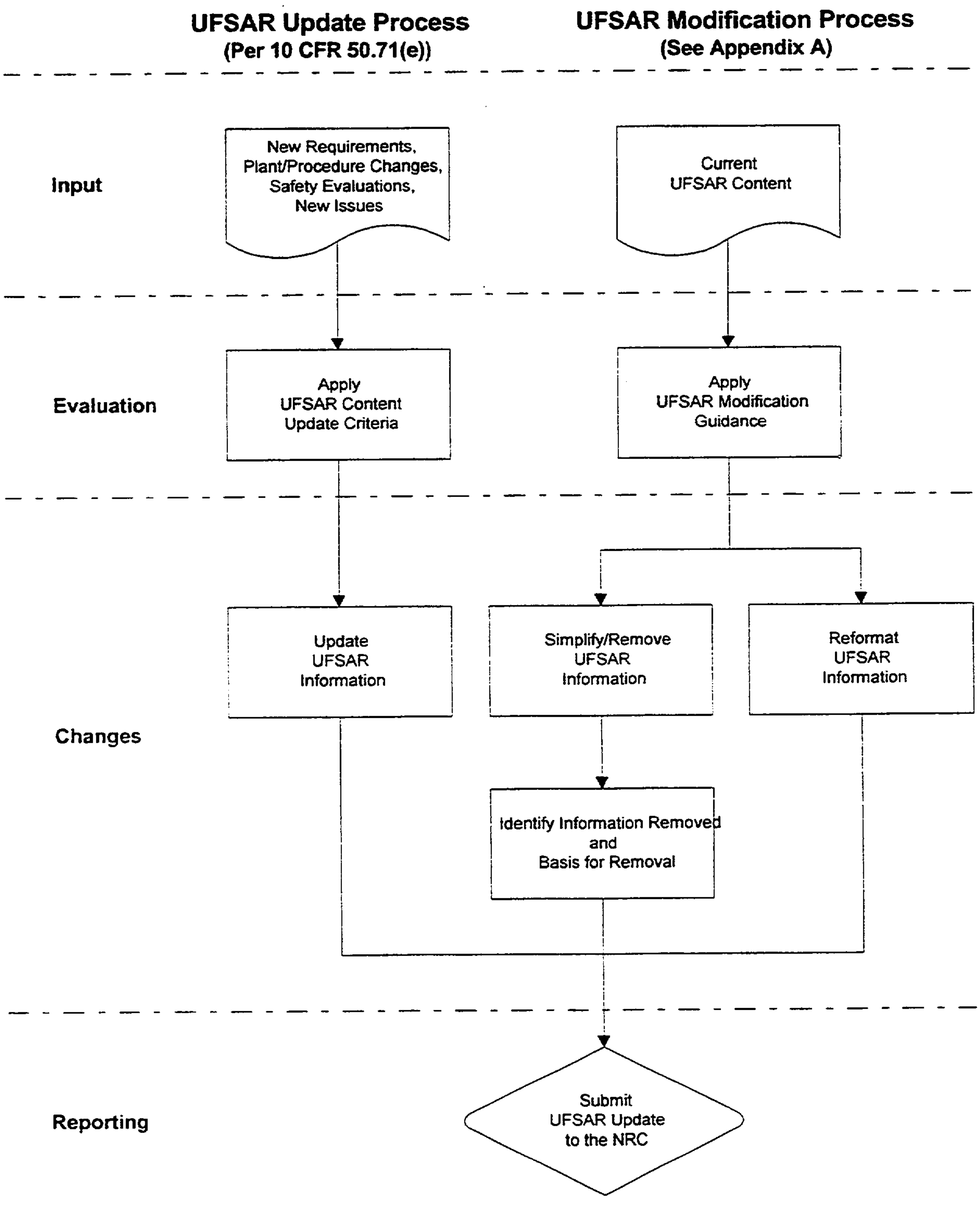
> The FSAR shall include information that describes the facility, presents the design bases and the limits on its operation, and presents the safety analyses of the structures, systems and components and of the facility as a whole.

Subsections (1) through (9) of 10 CFR 50.34(b) further define or amplify this statement of general intent. Certain information required to be included in original FSARs is now controlled in separate licensee documents in accordance with other NRC regulations. For example, the plant technical specifications establish the limits on facility operation, including safety limits; limiting safety system settings; and limiting conditions for operation for structures, systems and components. The technical specifications were required as part of the original FSAR under 10 CFR 50.34(b)(6)(vi), but are now controlled separately from the UFSAR per 10 CFR 50.36.

Based on analysis of 10 CFR 50.34(b), UFSAR updates should contain the following basic types of information concerning new requirements and information developed since the UFSAR was last updated that are required to be reflected in the UFSAR under 10 CFR 50.71(e):

- new or modified design bases
- summary of new or modified safety analyses
- UFSAR description sufficient to permit understanding of new or modified design bases, safety analyses, and facility operation (as defined in Section 3.7).

Figure 1
PROCESS FOR UPDATING AND MODIFYING THE UFSAR



6 UPDATING FSARs TO MEET 10 CFR 50.71(e)

6.1 WHAT THE REGULATIONS REQUIRE

10 CFR 50.71(e) requires licensees to periodically update their UFSARs to assure they remain up-to-date such that they accurately reflect the plant design and operation. Per 10 CFR 50.71(e)(4), the UFSAR is required to reflect changes up to a maximum of six months prior to the date that the last update was submitted to the NRC. The 10 CFR 50.71(e) requirements concerning the content of updates are as follows[2]:

> 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 contains the latest material 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 submission of the original FSAR or, as appropriate, the last updated FSAR. The updated FSAR shall be revised to include the effects of: all changes made in the facility or procedures as described in the FSAR; all safety evaluations performed by the licensee either in support of requested license amendments or in support of conclusions that changes did not involve an unreviewed safety question; 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 FSAR.

The rule does not require that licensees review all the information contained in the UFSAR for each periodic update. Rather, the intent of the rule is that licensees update only those portions that have been affected by licensee activities since the previous update. Per the Supplementary Information provided with the 1980 FSAR update rule,

> Submittal of updated FSAR pages does not constitute a licensing action but is only intended to provide information. It is not intended for the purpose of re-reviewing plants.... The material submitted may be reviewed by the NRC staff but will not be formally approved.

The rule specifies the types of new information that must be evaluated to determine if the UFSAR must be updated to reflect the new information, i.e., new requirements, changes to the facility or procedures, including supporting safety evaluations, and NRC-requested analyses. The following subsections provide guidance for implementing the requirements.

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[2] In addition to the update requirements of 10 CFR 50.71(e), the rule also includes certain administrative and reporting requirements. The full text of 10 CFR 50.71(e) is provided in Appendix B to this report.

6.1.1 New Regulatory Requirements

UFSARs must be updated to reflect changes to the facility resulting from new or amended requirements, e.g., Appendix R, the Station Blackout rule (10 CFR 50.63), the Anticipated Transient Without Scram (ATWS) rule (10 CFR 50.62), or plant-specific orders. As a result of such new requirements, the following information must be incorporated in the UFSAR, as applicable:

- new or modified design bases
- summary of new or modified safety analyses
- appropriate UFSAR description as defined in Section 3.7 of this guideline.

If a new NRC requirement does not result in these types of information, the UFSAR does not need to be updated to reflect the new requirement.

6.1.2 Changes to the Facility or Procedures

The UFSAR must be updated to reflect the following effects, as applicable, of changes implemented under 10 CFR 50.90 or 10 CFR 50.59, including supporting safety evaluations:

- a change requires update of the existing UFSAR information, including changes to existing design bases, safety analyses or description of existing structures, systems, components or functions described in the UFSAR

- a change results in the removal from the plant of SSCs described in the UFSAR or the elimination of functions or procedures described in the UFSAR

- a change or supporting safety evaluation results in new design bases or safety analyses, or associated description, that must be included in the UFSAR.

If a change or supporting safety evaluation does not affect existing UFSAR information and does not result in new design bases, safety analyses or UFSAR description, the UFSAR does not need to be updated to reflect the change.

6.1.3 Analyses of New Safety Issues

Licensees should evaluate the effects of analyses or similar evaluations performed by licensees in response to plant-specific NRC requests or NRC generic letters or bulletins. NRC-requested analyses and evaluations must be reflected in UFSAR updates only if, on the basis of the results of the requested analysis or evaluation, the licensee determines that the existing design bases, safety analyses or UFSAR description are either not accurate or not bounding or both. The existing design bases, safety analyses and UFSAR description must be updated to reflect the new information, as appropriate.

If the NRC-requested analyses or evaluations do not cause any of these effects, no change to the UFSAR is required.

6.1.4 Update Process Considerations

Licensees should establish a process to identify the types of new information that must be evaluated to determine if the UFSAR must be updated to reflect the new information. To be consistent with the requirements of the FSAR update rule, the process should include sufficient administrative controls to identify information and analyses submitted pursuant to Commission requirements; changes to the facility or procedures; safety evaluations; and analyses of new safety issues performed at Commission request.

In general, controls sufficient to identify information pursuant to Commission requirement should focus on changes to NRC regulations, license conditions, orders and technical specifications. The controls for identifying changes to the facility or procedures and safety evaluations should be integrated with existing licensee administrative controls for implementing design and procedure changes, including the process used by licensees in preparing, reviewing and approving 10 CFR 50.59 evaluations. The controls for identifying analyses of new safety issues performed at Commission request should focus on NRC bulletins, generic letters and analogous plant-specific communications, including NRC requests pursuant to 10 CFR 50.54(f).

6.2 Level of Detail for FSAR Updates

While not explicitly addressing the level of detail required for FSARs, 10 CFR 50.34(b)(2) required that original FSARs include:

> … description and analysis of the structures, systems, and components of the facility, with emphasis upon performance requirements, the bases, with technical justification therefor, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations.

In addition, the Supplementary Information provided with the 1980 FSAR update rule stated: "The level of detail to be maintained in the UFSAR should be at least the same as originally provided." Thus, existing UFSAR information of a similar nature may provide a guide for determining the level of detail for new information to be included in UFSAR updates. However, the primary consideration in determining the level of detail for new information is whether updated information is sufficient to permit understanding of new or modified safety analyses, design bases and facility operation.

6.3 EXAMPLES

The following examples illustrate the application of the UFSAR update guidance.

CASE 1: The licensee action is not in response to a new Commission requirement, does not involve a change, safety evaluation or analysis of a new issue, and does not affect existing UFSAR information. Therefore, no update to the UFSAR is required by 10 CFR 50.71(e).

Example

> Generic Letter 96-01, "Testing of Safety-Related Circuits," requested licensees to conduct a review of Logic System Testing to ensure that all elements of the logic circuits were being adequately tested and met the technical specification surveillance requirement for adequate logic system functional testing.
>
> This generic correspondence did not constitute a new regulatory requirement and did not request a new analysis. Provided the licensee response to Generic Letter 96-01 did not result in a change to the facility or actions that affected existing UFSAR information, no change to the UFSAR is required.

CASE 2: The licensee action responds to a new Commission requirement or involves a change, safety evaluation or analysis of a new issue, and update of the UFSAR is required to change existing information.

Example

> A change to the safety injection system was initiated to address an operability concern identified in NRC Bulletin 88-04, "Potential for Safety-Related Pump Loss." An evaluation of safety injection pump minimum-flow lines resulted in an increase in the recommended minimum-flow rate to preclude hydraulic instability at low flow conditions and assure pump operability. As a result of this evaluation, the orifices in the safety injection recirculation lines were modified to provide for increased minimum-flow rate for the pumps.
>
> Unlike the generic letter in the example of Case 1, NRC Bulletin 88-04 requested that licensees evaluate safety-related pump performance under minimum flow conditions, and the licensee evaluation resulted in a change to the safety injection recirculation lines. Because sufficient minimum-flow is necessary to ensure the system is able to perform its intended safety function, the UFSAR description associated with the safety injection system should be modified to include a discussion of the minimum-flow function as it relates to maintaining operability of the safety injection pumps. In some cases, this may entail adding UFSAR discussion of the minimum-flow function where none previously existed.

If licensee evaluations requested by Bulletin 88-04 determined the existing minimum-flow design to be acceptable, no change to the UFSAR is required.

CASE 3: The licensee action responds to a new Commission requirement or involves a change, safety evaluation or analysis of a new issue, and update of the UFSAR is required to reflect new information.

Example

10 CFR 50.62 (the ATWS rule) required the installation of a new mitigation system specific to the type of plant (Westinghouse, Combustion Engineering, etc.). In response to the ATWS rule, the licensee installed new equipment in the facility. An evaluation was performed in accordance with the guidance in Section 6 to determine if update of the UFSAR was required. Because ATWS constitutes new Commission requirements for the plant, the design bases and associated description of the new ATWS equipment should be added to the UFSAR.

CASE 4: The licensee action responds to a new Commission requirement or involves a change, safety evaluation or analysis of a new issue, and update of the UFSAR is not required.

Example

The NRC issued a new requirement, 10 CFR Part 26, requiring licensees to implement a Fitness for Duty Program (FFD). An evaluation was performed in accordance with the guidance in Section 6 to determine if update of the UFSAR was required. The FFD program did not result in new or modified safety analyses or design bases. Provided that the UFSAR does not contain security-related information affected by FFD program implementation, no change or addition to the UFSAR is required as a result of the new requirement.

7 FREQUENCY OF REQUIRED UPDATES

As required by 10 CFR 50.71(e)(4), licensees are required to submit a periodic UFSAR update annually or within six months after each refueling outage provided the interval between successive updates does not exceed 24 months. Licensees may request an exemption from this requirement from the NRC. For example, the NRC has granted exemptions allowing licensees to submit a single, combined periodic update for multi-unit plants.

8 TREATMENT OF LONG-TERM TEMPORARY MODIFICATIONS

The UFSAR is revised periodically to assure that the information reflects the latest material developed. Nevertheless, at any given time there may be a number of temporary plant and/or procedure changes in effect to support corrective actions or other plant activity. Temporary changes in support of plant operations should be restored to the normal plant condition, e.g., consistent with the UFSAR, in a timely manner. For temporary conditions involving safety-related equipment, timely restoration is required by 10 CFR 50, Appendix B. Per Generic Letter 91-18, Revision 1, temporary conditions subject to Appendix B that exist longer than the next refueling outage are to be explicitly justified as part of tracking documentation.

Temporary changes generally should not be reflected in UFSAR updates. Because UFSAR information may lag the current plant status by up to 30 months, the UFSAR is an inefficient vehicle for documenting temporary conditions. This would cause licensees to needlessly revise information in the UFSAR that would shortly revert to its prior condition. The result would be a UFSAR that described temporary modifications that are no longer installed, and the UFSAR would not reflect their removal until the next periodic update.

Temporary changes are administratively controlled separately from the UFSAR, and the current status of each is tracked to completion. Tracking documentation ensures that plant staff can determine the current plant status to support ongoing plant operations, including evaluations performed under 10 CFR 50.59. For temporary changes subject to 10 CFR 50.59, evaluations are performed and a summary report is submitted to the NRC in accordance with 10 CFR 50.59(b).

In general, UFSARs should not duplicate the licensee's tracking and reporting of temporary changes. However, the licensee should reflect in periodic UFSAR updates temporary modifications meeting both of the following criteria:

- The temporary modification is expected to be in place throughout the next required periodic UFSAR update cycle[3], or no schedule for removal has been established; and

- The licensee determines based on the update guidance in Section 6 that the temporary modification should be reflected in the next required UFSAR update.

Temporary modifications reflected in the UFSAR should be clearly identified as such to distinguish temporary conditions from the permanent plant design and normal operation.

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[3] A periodic update cycle is the period between the cutoff dates for new information for successive required UFSAR updates, i.e., from six months (maximum) prior to submittal of one update until six months (maximum) prior to the next.

Consistent with licensee configuration control procedures, there may be temporary modifications reflected in the UFSAR that are not reflected in other permanent plant documentation.

If corrective action or other work associated with a temporary modification results in a permanent change to the plant as described in the UFSAR, the UFSAR should be updated to reflect the change.

<u>Examples</u>

1. A temporary modification was installed for six months to defeat an alarm that is explicitly discussed in the UFSAR. While the temporary modification affected information contained in the UFSAR, it would not be included in the periodic update because the alarm is expected to be restored to service before the end of the next required periodic UFSAR update cycle.

2. Temporary cables for an intercom system have been routed through one of the safety-related battery rooms, and the permanent installation is not planned for more than two years. Based on this schedule, and the schedule for the next UFSAR update, the temporary modification is expected to be in place until after the next UFSAR update cycle. Therefore, the temporary modification should be evaluated per Section 6 of the guideline for inclusion in the next required UFSAR update. Because the modification does not affect existing UFSAR information, and does not result in new safety analyses, design bases or UFSAR description, this modification would not be reflected in the next required UFSAR update.

3. A temporary modification was installed for a safety injection accumulator makeup water pump, and the permanent resolution of the issue will not be implemented for at least two more years. Based on this schedule, and the schedule for the next UFSAR update, the temporary modification is expected to be in place until after the next UFSAR update cycle and should be evaluated per Section 6 of the guidance for inclusion in the next required update. Because the modification affects the existing description of the makeup function for the safety injection accumulators, the UFSAR should be modified to reflect the temporary modification as part of the next required update.

9 TREATMENT OF DISCREPANCIES BETWEEN THE FACILITY AND THE UPDATED FSAR

If the licensee discovers a discrepancy between the facility and its description in the UFSAR, the licensee should address the discrepancy in accordance with its corrective actions program under 10 CFR 50, Appendix B. If evaluation of the discrepancy results in the identification of a nonconforming or degraded plant condition that may impact the operability of the associated structures, systems and components, the nonconforming or degraded condition should be addressed in accordance with Generic Letter 91-18, Revision 1[4].

If evaluation of the discrepancy determines that the UFSAR is incorrect, a correction should be initiated in accordance with licensee procedures for inclusion in the next UFSAR update.

[4] Licensees also should evaluate nonconforming or degraded conditions for reportability pursuant to NRC requirements.

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APPENDIX A: MODIFYING THE UPDATED FSAR

A1 INTRODUCTION

As discussed in this guideline, 10 CFR 50.71(e) requires that changes and certain new information be incorporated in periodic updates to the UFSAR. As provided in this appendix, the licensee also may initiate voluntary modifications to the UFSAR—unrelated to plant changes or required updates under 10 CFR 50.71(e)—to improve its focus, clarity and maintainability. The following sections provide guidance for reformatting, simplifying and removing existing UFSAR information. While not discussed in this document, licensees also may add information that goes beyond regulatory requirements and guidance to facilitate use of the UFSAR by plant staff or for other purposes.

A2 CONTROLLING MODIFICATIONS TO THE UPDATED FSAR

As discussed in the following sections, three types of modifications may be made to the information in the UFSAR: reformatting, simplification and removal. UFSAR modifications discussed in Sections A3 through A5 that are not the result of changes to the plant or procedures do not require evaluation under 10 CFR 50.59, but they should be administratively controlled through a process that has the following attributes:

- The licensee process controls what and how information is reformatted, simplified or removed from the UFSAR.

- The licensee process ensures that the UFSAR continues to contain the necessary scope of information as discussed in Section 5 of this guideline.

- As discussed in Section A6, the NRC should be informed of information removed from the UFSAR and the basis for the licensee's determination that such information may be removed. This information should be specifically identified to the NRC as part of required UFSAR updates, i.e., in addition to the changed pages and a list of effective pages currently required by 10 CFR 50.71(e).

- It is the intent of this guideline to help licensees remove unimportant information from UFSARs such as excessive detail, obsolete information, or redundant information. This guideline is not intended to be used to remove important information from UFSARs about features or functions of SSCs that insights from operating experience or probabilistic risk assessments indicate are risk-significant. The intent that risk-significant information be retained does not preclude removal of obsolete or redundant information, or excessive detail concerning the design or operation of risk-significant SSCs, provided that the action is consistent with the guidance in this Appendix.

A3 REFORMATTING OF UPDATED FSAR INFORMATION

Neither 10 CFR 50.34(b) nor 10 CFR 50.71(e) contain requirements on the format of FSARs. Thus the format of the UFSAR is at the option of the licensee, and the licensee may change the format of the UFSAR provided the content of the UFSAR is maintained consistent with these regulations, regulatory guidance committed to by the licensee (e.g., Regulatory Guide 1.70), and this guideline. For example, a licensee may elect to reformat the UFSAR to more clearly identify the design bases as defined in 10 CFR 50.2.

Historical information provided in the original FSAR may have become out-of-date and is not expected to be used to support current or future plant operations or regulatory activities. Accordingly, it may be appropriate to reformat such information to distinguish it from UFSAR information actively maintained by licensees to describe the updated plant design and operation.

By definition, reformatting UFSAR information—such as designating certain information as historical or relocating historical information to an appendix—does not remove that information from the UFSAR. As such, changes the licensee initiates to historical information constitute changes to the UFSAR that must be reported to the NRC per 10 CFR 50.71(e).

Absent an NRC requirement, licensees need not update historical information in UFSARs to reflect minor changes in population data or other such changes in the site environment. However, licensees should evaluate potentially significant changes in the site environs, e.g., a new natural gas line within the site boundary or a major new industrial facility near the plant site, to determine if notification of NRC and appropriate update of the UFSAR are required. For example, 10 CFR 50.9 requires licensees to "notify the Commission of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or common defense and security."

Because changes to historical information as defined in this guideline are generally not expected or required (except possibly to reflect a significant change in the site environs, as discussed above), licensee update of such information under 10 CFR 50.71(e) is not expected.

The following are examples of historical information:

- Description of pre-service inspections
- Description of preoperational tests
- Description of start-up tests
- Description of station organization for initial licensing
- Comparative plant data provided to support original plant licensing

- Industry or other data obtained to support or develop the original plant design bases, including that relating to natural or man-made phenomena such as geography, meteorology, hydrology, geology, seismology, population density and nearby facilities (typically in Chapter 2 of the UFSAR)[5]
- Lists of references, figures and submittals relevant only to the original licensing proceeding
- Description of original factory testing of plant equipment, e.g., emergency diesel generators.

Licensees may reformat such historical information by either of the following, or equivalent, methods:

- Qualifying information may be designated as historical via clear annotation in the UFSAR.
- Historical information may be relocated to separate volumes or to specially designated appendices of the UFSAR.

Reformatting of UFSAR information should be controlled in accordance with Section A2.

A4 SIMPLIFYING UPDATED FSAR INFORMATION

Licensees may elect to simplify information contained in the UFSAR to improve its focus, clarity and maintainability. As discussed in the subsections below, licensees may simplify UFSAR information by removing excessive detail and by using references to other documents where appropriate.

A4.1 REMOVING EXCESSIVE DETAIL

UFSARs contain the scope of information required for the original FSAR by 10 CFR 50.34(b) and the additions to that scope required by 10 CFR 50.71(e). Later license applicants included significantly more detailed information in original FSARs than did earlier applicants. More recent FSARs grew to be 20 to 30+ volumes and may include more detail in certain respects than was absolutely necessary to support NRC safety and licensing reviews.

Removal of excessively detailed text and drawings can improve the focus of UFSARs on significant descriptive, design bases, operational and analytical information that is relevant and useful to support current and future operational and regulatory activities.

[5] While data and information supporting the original plant design bases for natural and man-made phenomena may be designated as historical, the associated design bases themselves should not. This is because the original design bases continue to be part of the overall design bases for the facility, and new information may warrant their update.

Detailed text and drawings may be removed from the UFSAR to the extent that the information provided exceeds that necessary to present the plant design bases, safety analyses and appropriate UFSAR description.

The following types of excessively detailed textual information may be removed from UFSARs, except as indicated by applicable regulatory guidance or NRC Safety Evaluation Reports:

- Descriptive information that is not important to providing an understanding of the plant's design and operation from either a general or system functional perspective, e.g., component model numbers

- Design information that is not important to the description of the facility or presentation of its safety analysis and design bases, e.g., component details such as specific motor horsepower ratings for MOVs

- Design information that, if changed during the life of the plant, would have no impact on the ability of plant systems, structures and components described in the UFSAR to perform their design basis function(s), e.g., specific HVAC equipment capacity and flow rate information for structures that do not contain equipment that performs design basis functions

- Analytical information, e.g., detailed calculations, that is not important to providing an understanding of the safety analysis methodology, input assumptions and results, and/or compliance with relevant regulatory and industry standards.

Removal of excessively detailed information from the UFSAR should be controlled in accordance with Section A2, including reporting to NRC as discussed in Section A6.

A4.2 Replacing Detailed Drawings with Simplified Schematics

Detailed drawings, such as piping and instrumentation diagrams (P&IDs), typically contain engineering and component information that goes beyond that appropriate to complement the textual descriptions in the UFSAR and beyond that necessary to aid in understanding of the system design and principal functions. Examples of such information contained in detailed drawings include pipe line numbers, vents and drains, etc.

Simplified schematics may be substituted for detailed drawings under either of the following conditions: (1) the original FSAR contained simplified schematics that the licensee had later replaced with P&IDs or other detailed drawings as a matter of convenience, or (2) the original FSAR included detailed drawings, but simplified schematics will be substituted such that they will not result in removal of information required to be in the UFSAR.

In the first case, licensees may substitute simplified schematics for detailed drawings because simplified schematics were provided in the original FSAR. Returning simplified schematics to the UFSAR would be consistent with the intent of the FSAR update rule that the level of detail of the UFSAR should be at least the same as that provided in the original FSAR.

In the second case, the licensee would need to ensure that simplified drawings together with associated UFSAR text continue to provide sufficient understanding of design bases, safety analyses and facility operation. For example, if the licensee determines that design bases or safety analyses information is contained in detailed drawings that is not conveyed by text, tables or other means in the UFSAR, the licensee should incorporate the information into the simplified schematic or other UFSAR information so that the UFSAR continues to contain all necessary information. Substitution for detailed drawings as described in this paragraph should be controlled in accordance with Section A2, including reporting to NRC as discussed in Section A6.

In some cases, UFSAR drawings may contain little or no information that is necessary or important to provide sufficient understanding of a facility's design bases, safety analyses or operation. Such drawings may be eliminated completely from UFSARs provided both of the following conditions are met:

- Inclusion of the drawing in the UFSAR must not be part of an existing licensee commitment to the NRC (e.g., to Regulatory Guide 1.70)
- Existing UFSAR text, tables, and other information provide sufficient understanding of a facility's design bases, safety analyses and operation or the licensee supplements the existing information to compensate for the removal of the drawing.

Drawings should generally not be removed from the UFSAR where they are helpful in understanding the textual description of the design or function of important structures, systems and components. When removing drawings from the UFSAR that are to be maintained as part of other design documents, licensees should consider providing a reference in the UFSAR to the location of the drawing.

A4.3 REFERENCING OTHER DOCUMENTS IN UPDATED FSARS

When assessing the presentation of existing UFSAR information (or evaluating information to be added), there may be instances when the information exists in a separate source document and it is preferable to reference, rather than duplicate, all or part of the source document in the UFSAR. Referencing, rather than duplicating, information in the UFSAR can simplify the presentation and maintenance of UFSAR information and, in some cases, avoid the need for duplicative reporting of changes to the NRC.

There are two basic ways licensees can reference other documents in the UFSAR depending on the nature of the document and the purpose of the reference. Each is discussed below.

General References. General references are not considered part of the UFSAR, but are intended to provide background information or additional detail that the reader may refer to in order to learn more about particular material presented in the UFSAR. These may be texts, environmental studies or technical reports, as well as licensee-controlled documents such as operating or maintenance procedures, calculation manuals, etc. References to such information may be located at specific points in the UFSAR, or they may be listed at the end of UFSAR chapters or in introductory sections.

Licensees may wish to remove excessively detailed, duplicate UFSAR information that is controlled in a separate licensee source document. In some cases, it may be appropriate to provide a brief summary of the detail being removed and/or a general reference to the controlling document as an aid to the reader. Unless the referenced source document is "incorporated by reference" (as discussed below), referenced information is not part of the UFSAR and would not be subject to 10 CFR 50.71(e), except as specifically committed to by licensees. Replacement of detailed information with a brief summary and/or reference constitutes removal of UFSAR information that must be controlled consistent with guidance in Section A2 and reported to NRC as discussed in Section A6.

Incorporation by Reference. "Incorporation by reference" refers to a method by which all or part of a separate source document can be made part of the UFSAR without duplicating the desired information in the UFSAR. Information that is appropriate to include in the UFSAR that is also part of a separate licensee-controlled document or technical report may be incorporated in the UFSAR by appropriate reference to that information. By relying on information "incorporated by reference," licensees may simplify their UFSARs by removing information that is duplicated in separate, controlling program documents such as the Emergency Plan, Offsite Dose Calculation Manual, Fire Protection Plan and Fire Hazards Analysis Report, Security Plan, Environmental Protection Plan and Quality Assurance Plan.

Considerations when incorporating by reference include the following:

- Licensees should clearly identify in the UFSAR text the document or portion thereof to be incorporated, and state that the document or portion thereof is "incorporated by reference" in the UFSAR. For example, one option would be to locate in Chapter One of the UFSAR a single section or table that maintains the list of all documents considered incorporated. References should be as clear and specific as possible to avoid misunderstandings about the extent of information incorporated by reference and thus considered part of the UFSAR.

- For information to be incorporated by reference, the information must be publicly available (i.e., it must have been submitted to the NRC) unless there exists an explicit NRC requirement to maintain the information on site. Furthermore, information incorporated by reference into the UFSAR is subject to the update and reporting requirements of 10 CFR 50.71(e) and change controls of 10 CFR 50.59 unless separate NRC change control requirements apply (e.g., 10 CFR 50.54(a)).

Because documents incorporated by reference in UFSARs are subject to the requirements of 10 CFR 50.71(e) and 10 CFR 50.59 (except where separate NRC requirements apply), licensees should ensure that such documents are being maintained in accordance with these requirements. Documents incorporated by reference containing information that is not required to be in the UFSAR, e.g., by 10 CFR 50.34(b) or 10 CFR 50.71(e), may be appropriately reclassified as general references.

Licensees may control the Technical Requirements Manual and similar licensee controlled documents in either of the following ways:

- The TRM or other licensee controlled document is explicitly "incorporated by reference" into the UFSAR. Under this approach, the referenced document is subject to the change control requirements of 10 CFR 50.59 and the update/reporting requirements of 10 CFR 50.71(e), e.g., periodic submittal of change pages, etc.

- The TRM or other licensee controlled document is treated in a manner consistent with procedures fully or partially described in the UFSAR. Under this approach, the referenced document is maintained on-site in accordance with licensee administrative processes, and changes are evaluated using 10 CFR 50.59.

A5 REMOVING UNNECESSARY INFORMATION FROM UPDATED FSARs

Licensees may remove obsolete and redundant information and commitments from UFSARs. When removing information as described in this section, licensees should follow the guidance in Section A2 for controlling modifications to the UFSAR and Section A6 for reporting to the NRC.

Obsolete Information. Licensees should remove UFSAR information, as appropriate, in connection with removal of SSCs from the plant or elimination of functions or procedures described in the UFSAR. However, licensee review of UFSAR information may identify where this has not occurred, or where removal of UFSAR information in connection with a change was incomplete. In general, licensees should remove from UFSARs description of equipment that is no longer installed in the plant; organizations, programs or procedures that are no longer in effect; and design information, evaluations or other description that no longer apply to the facility. The exception to this guidance is that

programmatic information that was explicitly required under 10 CFR 50.34(b) to be included in original FSARs, e.g., plans for preoperational testing and initial operations, may not be removed from the UFSAR. Such information is considered historical; licensees may opt to reformat this information in accordance with Section A3.

Where the presence of obsolete information indicates a discrepancy between the UFSAR and the actual plant design or operation, the discrepancy should be evaluated in accordance with Section 9 of this guideline.

Organizations, programs and procedures no longer in effect are considered obsolete, as opposed to historical, if they were instituted and included in the UFSAR subsequent to initial plant licensing.

If equipment has been retired in place (equipment that is no longer in service but has not been physically removed from the plant), functional descriptions in the UFSAR that no longer apply to the equipment are considered obsolete information. To accurately reflect the condition of the plant, physical descriptions of equipment retired in place (e.g., component and location) in the form of text and/or drawings should be retained in the UFSAR.

Redundant Information. Licensees may remove duplicate information from the UFSAR. If some or all of the duplicated information is important to facilitate understanding of multiple sections of the UFSAR, the licensee should retain appropriate duplicate information where it is needed. Alternatively, the licensee may remove duplicate information and provide a reference to the location in the UFSAR where the information is to be retained.

Commitments. Some licensees may have incorporated specific commitments made to the NRC within the UFSAR. Consistent with Commission guidance[6], licensees may remove from the UFSAR commitments that are not integral to required UFSAR information, i.e., design bases, safety analyses and associated description. Removal from the UFSAR does not change the status or nature of commitments to the NRC. NEI 99-00, *Guideline for Managing NRC Commitment Changes,*[7] provides guidance for making changes to NRC commitments.

Licensees should ensure that NRC commitments removed from the UFSAR are included in licensee commitment management or corrective action programs as appropriate. If the

[6] In a Staff Requirements Memorandum dated May 20, 1997, the Commission directed the NRC staff to formulate an approach to FSAR updates that would "allow obsolete or less meaningful information and commitments to be readily removed from the FSAR."

[7] NEI 99-00 was in final draft form at time of publication of this document.

licensee committed to the NRC to incorporate a commitment in the UFSAR, then the licensee should inform the NRC of its removal from the UFSAR, consistent with the licensee's commitment change process.

A6 REPORTING TO THE NRC INFORMATION REMOVED FROM THE UFSAR

Information removed from the UFSAR should be specifically identified to the NRC as part of required UFSAR updates. A brief description of the information removed and the basis for its removal should be provided. This information should not be incorporated in the UFSAR but should be provided in addition to the changed pages and a list of effective pages currently required by 10 CFR 50.71(e).

The following are examples of description suitable for notifying the NRC that information was removed from the UFSAR:

- removed model number information for components of the Reactor Equipment Cooling System previously contained in UFSAR Section XYZ on the basis that this was excessively detailed information

- replaced the P&ID for the auxiliary feedwater system with a simplified schematic.

APPENDIX B: 10 CFR 50.71(e)

Note: The changes identified below to 10 CFR 50.71(e) are expected to be approved by the Commission in connection with rulemaking to amend 10 CFR 50.59 after publication of this document.

10 CFR 50.71(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 contains the latest material 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 submission of the original FSAR or, as appropriate, the last updated FSAR. The updated FSAR shall be revised to 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 ~~requested~~approved license amendments or in support of conclusions that changes did not ~~involve an unreviewed safety question~~ 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) The licensee shall submit revisions containing updated information to the Commission, as specified in § 50.4, on a replacement-page basis that is accompanied by a list which identifies the current pages of the FSAR following page replacement.

(2) The submittal 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, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and (ii) an identification of changes made under the provisions of § 50.59 but not previously submitted to the Commission.

(3) (i) A revision of the original FSAR containing those original pages that are still applicable plus new replacement pages shall be filed within 24 months of either July 22, 1980, or the date of issuance of the operating license, whichever is later, and shall

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

bring the FSAR up to date as of a maximum of 6 months prior to the date of filing the revision.

(ii) Not less than 15 days before §50.71(e) becomes effective, the Director of the Office of Nuclear Reactor Regulation shall notify by letter the licensees of those nuclear power plants initially subject to the NRC's systematic evaluation program that they need not comply with the provisions of this section while the program is being conducted at their plant. The Director of the Office of Nuclear Reactor Regulation will notify by letter the licensee of each nuclear power plant being evaluated when the systematic evaluation program has been completed. Within 24 months after receipt of this notification, the licensee shall file a complete FSAR which is up to date as of a maximum of 6 months prior to the date of filing the revision.

(4) Subsequent revisions must be filed annually or 6 months after each refueling outage provided the interval between successive updates does not exceed 24 months. The revisions must reflect all changes up to a maximum of 6 months prior to the date of filling. For nuclear power reactor facilities that have submitted the certifications required by §50.82(a)(1), subsequent revisions must be filed every 24 months.

(5) 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).

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

U.S. NUCLEAR REGULATORY COMMISSION

September 1999

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 1.181

(Draft was issued as DG-1083)

CONTENT OF THE UPDATED FINAL SAFETY ANALYSIS REPORT IN ACCORDANCE WITH 10 CFR 50.71(e)

A. INTRODUCTION

In 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Section 50.34, "Contents of Applications; Technical Information," contains requirements for the contents of applications for construction permits and operating licenses for nuclear power reactors. An application for a construction permit must include a preliminary safety analysis report (PSAR) pursuant to 10 CFR 50.34(a). An application for an operating license must include a final safety analysis report (FSAR) in accordance with 10 CFR 50.34(b). For holders of operating licenses, 10 CFR 50.71(e) requires updated FSARs[1] to be developed and periodically updated.

Guidance for the organization and contents of PSARs and FSARs has existed since June 30, 1966, when the "Guide to the Organization and Contents of Safety Analysis Reports" was issued. The most recent guidance document is Revision 3 of Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)," (November 1978). Limited guidance for the format and content of UFSARs was also provided in Generic Letter 80-110, "Periodic Updating of Final Safety Analysis Reports (FSARs)" (December 15, 1980).

As a result of lessons learned from the Millstone experience and other initiatives related to UFSARs, the NRC has determined that additional guidance regarding compliance with 10 CFR 50.71(e) is necessary. The staff recommended specific actions in SECY-97-036, "Millstone Lessons Learned Report, Part 2: Policy Issues," dated February 12, 1997. In a staff requirements memorandum dated May 20, 1997, the Commission directed the staff, in part, to issue guidance for complying with 10 CFR 50.71(e) so that UFSARs

[1]The terminology for "updated FSARs" varies throughout the industry. In this guide, the terms updated FSAR, UFSAR, and USAR (updated Safety Analysis Report) are equivalent and have the same meanings.

are updated to reflect changes to the design bases and to reflect the effects of other analyses performed since original licensing that should have been included under 10 CFR 50.71(e). This regulatory guide provides the guidance requested by the May 20, 1997, staff requirements memorandum.

The information collections contained in this regulatory guide are covered by the requirements of 10 CFR Part 50, which were approved by the Office of Management and Budget, approval number 3150-0011. 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.

B. DISCUSSION

OBJECTIVE

The objectives of 10 CFR 50.71(e) are to ensure that licensees maintain the information in the UFSAR to reflect the current status of the facility and address new issues as they arise, so that the UFSAR can be used as a reference document in safety analyses.

DEVELOPMENT OF INDUSTRY GUIDELINE, NEI 98-03

On November 14, 1997, the Nuclear Energy Institute (NEI) provided a draft guidance document, NEI 98-03, "Draft Industry Update Guidelines for Final Safety Analysis Reports," to the NRC staff for information. In parallel with industry's efforts, the staff developed a proposed generic letter, "Interim Guidance for Updated Final Safety Analysis Reports in Accordance with 10 CFR 50.71(e)." This proposed generic letter and NEI's draft guideline were provided to the Commission in SECY-98-087,[2] dated April 20, 1998. In SECY 98-087, the staff recommended that the Commission approve issuance of the proposed generic letter for public comment as interim guidance. The staff proposed to continue to work with NEI to resolve differences between the positions in the proposed generic letter and the draft industry guideline so that the industry guideline could be endorsed in a regulatory guide and thereby serve as permanent guidance for the content of UFSARs.

In a staff requirements memorandum dated June 30, 1998, the Commission disapproved issuance of the proposed generic letter and directed the staff to attempt to resolve differences between the draft industry guideline and the proposed generic letter so that the industry guideline could be endorsed.

Subsequently, the NRC staff held public meetings with NEI to resolve the differences between the documents, which resulted in NEI submitting Revision 0 of NEI 98-03 to the NRC staff for endorsement in November 1998. The NRC staff proposed endorsing Revision 0 of NEI 98-03 in the draft version, DG-1083, of this Regulatory Guide 1.181. DG-1083 was issued for public comment in March 1999.

After the public comment period, the staff held a public meeting with NEI to discuss the public comments received, the NRC staff comments, and the clarification of Regulatory Position 5 of DG-1083. NEI then submitted Revision 1 of NEI 98-03 in June 1999 for NRC endorsement in this regulatory guide. Revision 1 of NEI 98-03 incorporates the public comments, the NRC staff's comments, and addresses the concerns of Regulatory Position 5 of DG-1083.

[2]Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

C. REGULATORY POSITION

1. NEI 98-03

Revision 1 of NEI 98-03, "Guidelines for Updating Final Safety Analysis Reports,"[2] dated June 1999, provides methods that are acceptable to the NRC staff for complying with the provisions of 10 CFR 50.71(e).

2. OTHER DOCUMENTS REFERENCED IN NEI 98-03

NEI 98-03 references other documents, but NRC's endorsement of NEI 98-03 should not be considered an endorsement of the referenced documents.

3. USE OF EXAMPLES IN NEI 98-03

NEI 98-03 includes examples to supplement the guidance. These examples are illustrative only, and the NRC's endorsement of NEI 98-03 should not be considered a determination that the examples are applicable for all licensees. A licensee should ensure that an example is applicable to its particular circumstances before implementing the guidance as described in an example.

4. LICENSEES COMMITTED TO REGULATORY GUIDE 1.70

This regulatory guide does not supersede any prior commitments made by licensees with respect to their FSARs (and by extension, their UFSARs), such as Regulatory Guide 1.70 (any revision) or its predecessor guidance documents. Therefore, a licensee that has made such a commitment to updated FSAR format and content must continue to meet this prior commitment, or the commitment should be modified in accordance with the licensee's commitment management process to allow full implementation of NEI 98-03.

5. USE OF OTHER METHODS

Licensees may use methods other than those proposed in Revision 1 of NEI 98-03 to meet the requirements of 10 CFR 50.71(e). The NRC will determine the acceptability of other methods on a case-by-case basis.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which an applicant or licensee proposes or has previously established an acceptable alternative method for complying with specified portions of the NRC's regulations, the methods described in this guide will be used in the evaluation of licensee compliance with the requirements of 10 CFR 50.71(e).

CAUTION STATEMENT

Licensees are cautioned against possible deletion of information which may be important to risk-informed evaluation and decision making. Extent of the information which can be deleted without any adverse impact will be visited during efforts related to risk-informing Part 50.

VALUE/IMPACT STATEMENT

A separate Value/Impact Statement was not prepared for this regulatory guide. The Value/Impact Statement that was prepared for and printed with the draft of this guide, DG-1083, in March 1999, is still applicable. That Value/Impact Statement concluded that the value to individual licensees, the industry, the NRC, and the public that results from complete and accurate UFSARs outweighs the costs to licensees and the NRC that are presently associated with using UFSARs that are incomplete and inaccurate. Copies of the Value/Impact Statement are available for inspection or copying for a fee in the NRC's Public Document Room at 2120 L Street NW., Washington, DC, under Draft Regulatory Guide DG-1083. The PDR may be reached by telephone at (202)634-3273 or fax at (202)634-3343.

U.S. NUCLEAR REGULATORY COMMISSION

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REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

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GUIDANCE AND EXAMPLES FOR IDENTIFYING 10 CFR 50.2 DESIGN BASES

A. INTRODUCTION

In 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Section 50.2, "Definitions," contains a definition of "Design Bases." Although the NRC staff and the nuclear industry have always agreed that it is important to understand what constitutes the design bases of a plant, there has not been agreement about the implementation of the definition in 10 CFR 50.2.

The guidance presented here is not mandatory, and licensees may choose not to change their implementation of the definition of what constitutes design bases. Licensees who choose to implement this guidance are expected to apply it in a uniform manner.

The information collections contained in this regulatory guide are covered by the requirements of 10 CFR Part 50, which were approved by the Office of Management and Budget, approval number 3150-0011. 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.

B. DISCUSSION

OBJECTIVE

The staff's objective is to develop guidance that provides a better understanding of what constitutes design bases information. This guide is intended to clarify the term design bases in connection with the NRC's regulations that use this term.

BACKGROUND

In the mid-1980s, the NRC staff conducted many system-specific engineering inspections and developed inspection findings that demonstrated that some licensees had not adequately maintained their design bases information as required by NRC regulation. In response to the problems identified during the NRC inspections and those identified by licensees, most reactor licensees initiated design bases reconstitution programs. These programs sought to identify missing design documentation and to selectively regenerate missing documentation.

In October 1990, the Nuclear Management and Resources Council (NUMARC) published its "Design Bases Program Guidelines," NUMARC 90-12.[1] The staff concluded that these guidelines provided a useful standard framework for implementing design reconstitution programs. The guidelines briefly discussed the definition of design bases information but did not focus on it.

In February 1991, the NRC staff published NUREG-1397, "An Assessment of Design Control Practices and Design Reconstitution Programs in the Nuclear Power Industry."[2] This report gave the results of a survey reflecting the scope and performance of several utility design change control programs and design document reconstitution programs. This report included a definitions section that stated that design bases include only the design constraints that are included in current licensing bases and form the bases for the staff's safety judgments.

In August 1992, the Commission published a policy statement on "Availability and Adequacy of Design Bases Information at Nuclear Power Plants."[1] In the policy statement, the Commission concluded that:

> [M]aintaining current and accessible design documentation is important to ensure that (1) the plant physical and functional characteristics are maintained and are consistent with the design bases as required by NRC regulation, (2) systems, structures, and components can

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[1] Copies are available for inspection or copying for a fee from the NRC Public Document Room at 11555 Rockville Pike (first floor), Rockville, MD; the PDR's mailing address is USNRC PDR, Washington, DC 20555; telephone (301)415-4737 or 1-(800)397-4209; fax (301)415-3548; e-mail <PDR@NRC.GOV>.

[2] Copies are available at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-1800); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161; (telephone (703)487-4650; <http://www.ntis.gov/ordernow>. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 11555 Rockville Pike, Rockville, MD; the PDR's mailing address is USNRC PDR, Washington, DC 20555; telephone (301)415-4737 or (800)397-4209; fax (301)415-3548; email is PDR@NRC.GOV.

perform their intended functions, and (3) the plant is operated in a manner consistent with the design bases.

In the policy statement, the Commission also said that all power reactor licensees should assess the accessibility and adequacy of their design bases documentation and decide whether a design reconstitution program is necessary. With regard to the NUMARC guidance, the Commission stated that:

> The guidance outlines a framework to organize and collate nuclear power plant design bases information. This information provides the rationale for the design bases consistent with the definition of design bases contained in 10 CFR 50.2.

In response to the findings relating to the regulatory burden of team inspections identified in the 1991 Regulatory Impact Survey and voluntary implementation of the NUMARC guidance by licensees, the staff reduced its effort on specific, resource-intensive, design-related team inspections and followed the issue of accurate and accessible design documentation at plants principally as an element of inspection and follow up of operations-related activities.

In 1996, the staff's findings during inspections and reviews began to identify broad programmatic weaknesses that resulted in design and configuration deficiencies at some plants; these deficiencies could have affected the operability of required equipment, raised unreviewed safety questions, or indicated discrepancies between the plant's Updated Final Safety Analysis Report and the as-built or as-modified plant or plant operating procedures. As a result of these findings, the staff issued a letter[3] in accordance with 10 CFR 50.54(f) to all licensees requesting information to provide the NRC added confidence and assurance that the plants were operated and maintained within the design bases and any deviations were reconciled in a timely manner.

SECY-97-160,[1] dated July 24, 1997, informed the Commission of the follow up activities resulting from the staff's review of licensee responses to the 10 CFR 50.54(f) request. In this paper, the staff stated that--

> Based on the review of licensee responses to the 50.54(f) letter, the staff concluded that while licensees had established programs and processes to maintain their facility's design bases, there was a need to implement plant-specific follow up activities. This determination was based upon the staff having identified: (1) instances in which licensees failed to reconcile regulatory performance with their assertions that their programs and processes were effective in maintaining their design bases, or (2) that there was a need to gain a better understanding or to validate a particular aspect of a licensee's programs and processes.

SECY-97-160 referred to the above-mentioned follow-up activities as Phase 4 and stated that they were to be a combination of architect-engineer design team inspections led by the Office of Nuclear

[3] Letter from J. Taylor, EDO, NRC, to all nuclear utility CEOs, October 9, 1996. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 11555 Rockville Pike (first floor), Rockville, MD; the PDR's mailing address is USNRC PDR, Washington, DC 20555; telephone (301)415-4737 or 1-(800)397-4209; fax (301)415-3548; email <PDR@NRC.GOV>.

Reactor Regulation and region-led inspections, such as safety system functional inspections and safety system engineering inspections.

In addition to the 10 CFR 50.54(f) letters and the inspection activities, the staff conducted lessons-learned reviews regarding Millstone and Maine Yankee. One of the conclusions of these reviews was that the definition of design bases should be clarified. In SECY-97-205,[1] dated September 10, 1997, the staff provided the Commission with several options for an integrated approach to solving the problems identified during the lessons-learned reviews. In the staff requirements memorandum[1] on SECY-97-205, dated March 24, 1998, the Commission directed the staff to continue to develop guidance regarding design bases issues, such as specifying the type of information to be considered as design bases information. This effort was subsequently included in the staff's response to the Chairman's tasking memorandum[1] of August 7, 1998. This regulatory guide provides the guidance requested by the Commission.

DEVELOPMENT OF INDUSTRY GUIDELINE, NEI 97-04

In October 1997, NEI submitted NEI 97-04, "Design Bases Program Guidelines," which is an update to NUMARC 90-12. NEI 97-04 gave additional examples of design bases information and directly addressed the reportability of conditions outside the design bases of the plant. This submission started a series of letters and public meetings that led to the NRC staff proposing to endorse Appendix B to NEI 97-04, with exceptions, in Draft Regulatory Guide DG-1093. DG-1093 was issued for public comment in April 2000.

After the public comment period, the staff held a public meeting with NEI to discuss the public comments received and additional editorial changes to the NEI document proposed by the NRC staff. NEI agreed to make revisions to Appendix B to NEI 97-04 to address these comments and to incorporate some of the editorial changes. On July 27, 2000, NEI submitted a prepublication draft of a revised Appendix B to NEI 97-04 for NRC endorsement.

NEI 97-04 was developed to help utilities organize and collate design bases information and supporting design information. The staff has concluded that these guidelines provide a useful standard framework for implementing design reconstitution programs; however, the industry has not requested staff review and endorsement of the entire document. This regulatory guide only applies to Appendix B of NEI 97-04.

DEFENSE IN DEPTH

The staff considers aspects of the designed defense-in-depth strategies such as redundancy, diversity, and independence to be important aspects of the plant's principal design criteria. These strategies and criteria are specifically required by several regulations, especially the General Design Criteria. These criteria require that such capabilities be implemented for individual structures, systems, and components through plant design features, such as multiple components, independent power supplies, and physical separation. These criteria provide part of the standard for judging the adequacy of the plant's design bases.

C. REGULATORY POSITION

Appendix B, "Guidelines and Examples for Identifying 10 CFR 50.2 Design Bases" (dated November 27, 2000),[4] to NEI 97-04 provides guidance and examples that are acceptable to the staff for providing a clearer understanding of what constitutes design bases information.

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees and applicants regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which an applicant or licensee proposes an acceptable alternative method for complying with the specified portions of the NRC's regulations, the methods described in this guide will be used in the evaluation of submissions in regard to design bases information.

[4] Copies of Appendix B to NEI 97-04 are available on <WWW.NRC.GOV> through NRC's Public Electronic Reading Room under Accession Number ML003771698. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 11555 Rockville Pike (first floor), Rockville, MD; the PDR's mailing address is USNRC PDR, Washington, DC 20555; telephone (301)415-4737 or 1-(800)397-4209; fax (301)415-3548; e-mail <PDR@NRC.GOV>.

VALUE/IMPACT STATEMENT

A separate Value/Impact Statement was not prepared for this regulatory guide. The Value/Impact Statement that was prepared for and printed with the draft of this guide, DG-1093, in April 2000, is still applicable. That Value/Impact Statement concluded that the value to individual licensees, the industry, the NRC, and the public that results from a clearer understanding of the interpretation of 10 CFR 50.2 design bases outweighs the costs to licensees and the NRC that are currently associated with confusion regarding the definition.

Copies of the Value/Impact Statement are available for inspection or copying for a fee from the NRC Public Document Room at 11555 Rockville Pike (first floor), Rockville, MD; the PDR's mailing address is USNRC PDR, Washington, DC 20555; telephone (301)415-4737 or (800)397-4209; fax (301)415-3548; e-mail <PDR@NRC.GOV>.

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Questions and Answers on 10 CFR 50.59 and NEI 96-07, Revision 1
Update 3—January 11, 2001

These Q&A supplement the guidance provided in NEI 96-07, R1. They have been informally reviewed and found appropriate by cognizant NRC staff. The Q&A will be maintained on *Infospace*, the NEI member website, and may be revised or supplemented as a result of implementation experience. Redlining and revision bars indicate changes from when the Q&A were last posted (Oct. 26, 2000).

The following questions and answers are organized by topic as follows:

A.1. For the purpose of defining the scope of 10 CFR 50.59, my plant considers the UFSAR to include the COLR, Fire hazards report, calculation manuals (e.g., the ODCM), TRM, Technical Specifications Bases, and other licensing basis documents. Going forward, can we adopt a view of the UFSAR scope that is consistent with 10 CFR 50.59 and NEI 96-07, R1?

A. Yes. Technical specifications, technical specifications bases, NRC safety evaluations, and other licensing documents do not fall within the definition of UFSAR for purposes of 10 CFR 50.59, unless explicitly incorporated by reference in the UFSAR. A narrower UFSAR scope consistent with the revised rule and guidance should result in fewer 10 CFR 50.59 screenings and evaluations than if a broader view of the UFSAR is maintained. If you decide to redefine the UFSAR scope (and thus the plant-specific scope of 10 CFR 50.59) going forward, you must, of course, continue to meet technical specification administrative requirements and be mindful of commitments made to NRC.

~~For example,~~ Improved Technical Specifications licensees are required to control Technical Specifications Bases per 10 CFR 50.59, while others have commitments to NRC to do so. Licensees may maintain such commitments in addition to the required scope of 10 CFR 50.59.

A.2. Does 10 CFR 50.59 apply to revision of a fuel vendor topical report that is "incorporated by reference" in the UFSAR? Or is 10 CFR 50.59 applied only when a licensee performs an updated analysis using the revised topical?

A. 10 CFR 50.59 would need to be applied to a revision of a fuel vendor topical

report only when a licensee uses an updated analysis based on the revised topical.

A.3. Are 10 CFR 50.59 reviews required when removing excess detail or obsolete information from the UFSAR?

A. No. Removal of excess detail and redundant or obsolete information per the guidance of NEI 98-03, Appendix A, are considered modifications to the UFSAR, not changes to the facility or procedures. Therefore, per Section 4.1.3 of NEI 96-07, R1, 10 CFR 50.59 need not be applied to such UFSAR modifications.

A.4. When must 10 CFR 50.59 be applied to a proposed change in a licensee commitment to the NRC? During screening, how would the 10 CFR 50.59 definition of "change" be applied to changes to NRC commitments, which are typically of a programmatic nature (e.g., chemistry, rad con, erosion/corrosion, etc.) and thus not be expected to affect design functions, etc.?

A. Per NEI 99-04, *Guideline for Managing NRC Commitment Changes*, 10 CFR 50.59 should be applied to changes in commitments that are embodied in UFSAR descriptions of the facility or procedures. Screening of commitment changes should be performed in accordance with Section 4.2 of NEI 96-07, R1. If the commitment change screens out from evaluation under 10 CFR 50.59, the commitment change should continue to be processed in accordance with Steps 3, 4, and 5 of the NEI 99-04 commitment change process. If the commitment change screens in, the change is controlled in accordance with 10 CFR 50.59, and prior NRC approval is required if any of the eight 10 CFR 50.59 evaluation criteria are met.

A.5. Are detailed design calculations (not contained in the UFSAR), sensitivity studies and preliminary analyses of alternative methods of evaluation for a change subject to the "methods of evaluation" criterion of 10 CFR 50.59?

A. No. Analyses that are not part of the UFSAR and analyses of a preliminary nature are not considered "methods of evaluation" within the scope of 10 CFR 50.59(c)(2)(viii).

A.6. Must editorial changes to UFSAR-described procedures (otherwise subject to 50.59) be subject to 50.59 (screening/evaluation)?

A. No. Per Section 4.1.3 of NEI 96-07, R1, editorial changes to the UFSAR (including referenced procedures, topical reports, etc.) may be made without applying 10 CFR 50.59.

A.7. What constitutes a minor correction to a drawing?

A. Examples of minor corrections to a drawing include a correction to resolve an inconsistency with other UFSAR information (text, table or other drawing) or a correction to information on the drawing that is incidental—not material—to the

UFSAR description related to the drawing.

A.8. What if I correct information in the UFSAR to resolve an inconsistency with other UFSAR information and determine that I provided the incorrect information to the NRC in support of a past licensing action or in response to a request for information?

A. You should identify the mistake and the correct information to your NRC project manager as quickly as possible and take appropriate corrective action.

A.9. What is the status of a 10 CFR 50.59 evaluation for a proposed change that is determined to require prior NRC approval via license amendment?

A. For changes implemented via license amendment (or other more specific regulatory process), 10 CFR 50.59 requirements for evaluation, record keeping and reporting do not apply. Typically, the information contained in 10 CFR 50.59 evaluations for changes that require prior NRC approval is used as input to a license amendment request. The 10 CFR 50.59 evaluation itself (if any) may be retained by the licensee or discarded, because the LAR and SER essentially supersede the 10 CFR 50.59 evaluation as the documented basis for the change. Changes implemented via license amendment should not be included in periodic 10 CFR 50.59 summary reports to the NRC under 10 CFR 50.59(d).

A.10. Moved to E.20

A.11. (Restored) NEI 96-07, Revision 1, Section 4.1.4, identifies types of procedures that <u>do not affect control or performance of design functions and</u> would not be subject to control under 10 CFR 50.59. What criteria are to be used to evaluate and implement changes to such procedures if 10 CFR 50.59 (and Appendix B) do not apply?

A. Administrative and managerial procedures such as those identified in Section 4.1.4 should be controlled in accordance with licensee procedures, e.g., Quality Assurance Program. 10 CFR 50.59 should be applied to changes to plant procedures that affect performance or control of design functions. (See also Section 4.1.4).

A.12. If a change to the emergency preparedness or safeguards program implemented under 10 CFR 50.54 results in the need to update the UFSAR, is a 10 CFR 50.59 review of the change required because the UFSAR is affected?

A. No. While safeguards or EP program changes may indeed affect summary description of these programs in the UFSAR, no 10 CFR 50.59 review is required provided the changes do not impact other aspects of the facility or procedures. Of course, the UFSAR must be updated to reflect such changes in accordance with 10 CFR 50.71(e). If impacts are identified other than those related to security or EP, the change should also be reviewed under 10 CFR 50.59. For

example, if erection of a new security barrier would affect the ability of operators to take required action, the new barrier should be reviewed under 10 CFR 50.59 as well as 10 CFR 50.54(p).

A.13. How would a change to a BWR operating limit for MCPR (minimum critical power ratio) be treated under the new 10 CFR 50.59 rule? Is the OLMCPR a design basis limit for the fuel cladding?

A. The MCPR operating limit is typically identified in the Core Operating Limits Report (COLR) which is controlled in accordance with the administrative technical specification. Because a more specific change control process applies, 10 CFR 50.59 c(4) provides that 10 CFR 50.59 need not be applied in addition to administrative technical specification requirements.

As identified in NEI 96-07, R1, Section 4.3.7, MCPR is the associated design basis limit for BWR fuel cladding, not the OLMCPR. The OLMCPR is established such that the MCPR Safety Limit is not exceeded.

Maintenance Rule vs. 10 CFR 50.59

M.1. Consider a planned maintenance activity that involves placing the plant in a configuration other than that described in the UFSAR. The altered plant condition is expected to be in effect for less than 90 days at power, but a situation develops that will require the altered configuration to be in place longer than 90 days. Should 10 CFR 50.59 be applied to the altered plant configuration?

A. ~~Yes.~~ Temporary alterations to the facility or procedures to support maintenance that exist for more than 90 days at power should be treated as ~~temporary~~ changes~~to the plant design~~, and 10 CFR 50.59 applied accordingly. Upon determining that an unforeseen delay will cause ~~an altered plant~~ the temporary alteration to be in place longer than 90 days at power, timely 10 CFR 50.59 screening, and if required, evaluation should be performed. If the temporary alteration meets one or more of the 10 CFR 50.59 evaluation criteria, the licensee should promptly communicate the situation to cognizant NRC staff and submit a license amendment request, on an expedited basis if necessary, for NRC approval to leave the temporary alteration in effect past 90 days. Pending approval of the LAR, the licensee need not remove the temporary alteration.

When a maintenance configuration is to remain in effect longer than planned, the risk assessment performed in accordance with paragraph a(4) of the Maintenance Rule should be revisited to confirm it is still valid.

M.2. Deleted. Control of maintenance procedures addressed in guidance (Section 4.1.2).

M.3. When does the 90-day clock start for maintenance-related temporary alterations?

A. The 90-day clock pertains to temporary alterations that are put in effect during power operations to support a maintenance activity. The clock starts when the temporary alteration is implemented, e.g., when a barrier is removed. This may occur prior to the actual start of the maintenance activity. The clock stops when the temporary alteration is removed and the affected portion of the facility and/or procedures is restored to its as-designed condition.

M.4. When the same altered plant configuration is necessary to support separate maintenance work orders, how do you calculate the 90-day at power limit for triggering review under 10 CFR 50.59?

A. If the same temporary alteration ~~altered plant configuration~~ is necessary to support successive maintenance work orders, the 90 day clock begins when the plant alteration is put in effect (see previous question) and runs continuously until the plant is restored to its as-designed condition. If a temporary alteration ~~altered plant configuration~~ to facilitate one or more MWOs is expected to be in effect longer than 90 days, the altered plant configuration should be treated as a ~~temporary~~ change, and 10 CFR 50.59 should be applied accordingly. If the first MWO completes in 60 days and the temporary alteration ~~altered plant configuration~~ is not restored before starting work on a second MWO, the 90-day clock does not reset. 10 CFR 50.59 should be applied if the temporary alteration ~~altered plant configuration~~ is to be continuously in effect for more than 90 days at power, without regard for the number of MWOs involved.

M.5. If a maintenance activity is to last for more than 90 days at power but does not involve ~~affect SSCs other than those being maintained (i.e., there is no~~ a temporary facility or procedure ~~plant~~ alteration, is 10 CFR 50.59 review required?

No. 10 CFR 50.59 is to be applied to facility or procedure ~~plant~~ alterations lasting more than 90 days at power that are implemented in support of a specific maintenance activity ~~to determine if SSCs other than those being maintained are affected~~. If there are no such ~~plant~~ alterations, then no 10 CFR 50.59 review is required in connection with the maintenance activity, regardless of how long it takes.

M.6. Since, by definition, a design change is not maintenance, must 10 CFR 50.59 be applied to temporary changes to support implementation of a design change?

A. No. As discussed in Section 4.1.2, the design change itself must be reviewed under 10 CFR 50.59, but the actual implementation of the change, including any required ~~plant~~ temporary alterations, is effectively a maintenance activity that is assessed and managed under Section a(4) of the maintenance rule. As with a temporary alteration to support maintenance, 10 CFR 50.59 should be applied to a temporary alteration that supports a design change if it is to be in effect more

than 90 days.

M.7. Why was "90 days at power" selected as the threshold for when a plant alteration in support of maintenance should be reviewed under 10 CFR 50.59 (in addition to the MR a(4) assessment)?

A. Ninety days was chosen because the vast majority of maintenance activities are completed in less time, thus requiring 10 CFR 50.59 reviews to be performed for a small percentage of cases. Ninety days was also viewed as the point at which a plant alteration to support maintenance begins to seem more like a change in terms of its effect on the facility design and ability to respond to events.

The focus on time "at power" (typically defined as Modes 1 & 2) reflects the NRC concern that long-term temporary alterations to support maintenance activities can raise questions about the validity of the safety analyses, which largely address at-power events.

M.8. What if I plan to attach a strip recorder to troubleshoot a recurring transient for as long as it takes to collect the information need to correct the problem? Do I need to track the time that the recorder is connected to determine when a 10 CFR 50.59 review is required?

A. If a testing or monitoring device is to be connected to plant systems for an indeterminate amount of time (i.e., there is no schedule established for removing the maintenance-related temporary alteration), the licensee should apply 50.59. 10 CFR 50.59 need not be applied to temporary alterations expected to be in effect 90 days or less at power. If, in the situation cited, the offending transient has occurred irregularly over a period of weeks/months, it is reasonable to expect that the recorder would need to be connected to the plant for more than 90 days, and 10 CFR 50.59 should be applied.

M.9. Is a surveillance test required by technical specifications considered a maintenance activity that is assessed and managed under 10 CFR 50.65(a)(4) and not 10 CFR 50.59?

A. Yes. However, it must be emphasized that compliance with technical specifications must be maintained regardless of whether an activity is reviewed under 10 CFR 50.59 or 10 CFR 50.65(a)(4).

M.10. While not a requirement of MRa(4), can I apply a "MRa(4)-like" risk assessment process to control changes to my maintenance/surveillance procedures?

Yes. And this practice may expedite / simplify the a(4) assessment required for each application of the maintenance procedure.

10 CFR 50.59 Screening

S.1. In the definition of change, what does "affect" mean? Does "affect" mean effect on SSC design functions, or does it mean effect on the UFSAR description of design functions?

A. "Affect" refers to the direct or indirect effects of an activity on SSC design functions. The actual UFSAR description of the design function may or may not require updating as a result of the activity. See also Q&A S.2.

S.2. If a proposed activity would not cause the description in the UFSAR to become inaccurate, can the activity be screened out?

A. Screening is a review of technical information supporting a proposed activity to determine whether UFSAR-described design functions would be adversely affected. A determination that an activity does not adversely affect design functions should be based on a thorough understanding of affected SSCs and the effects of the proposed activity on them. Determination that an activity would not cause the UFSAR description of SSC design functions to be inaccurate is an indicator, but is not the determining factor for screening the activity out. The documented basis for screening an activity out should be expressed in terms of the lack of adverse effect (direct or indirect) that the proposed activity would have on design functions, not on whether or not the description in the UFSAR is affected.

For example, if a proposed change would reduce the reliability of a design function, the change may not cause the UFSAR description to become inaccurate (unless the UFSAR discusses the reliability of the design function). However, this change should be screened in because there is an adverse effect on a design function. Upon 10 CFR 50.59 evaluation of such a change, the licensee may determine that the reduced reliability results in a negligible or minimal increase in the likelihood of malfunction. Assuming none of the other seven evaluation criteria are met, the change may be made without prior NRC approval.

Focusing screening determinations primarily on whether the change renders the UFSAR inaccurate may result in unnecessary 10 CFR 50.59 evaluations being performed for activities that do not meet the definition of "change." This is because changes that do not adversely affect design functions may nonetheless require the UFSAR to be updated to reflect the change, but would not require a 10 CFR 50.59 evaluation. The key point in determining that a 10 CFR 50.59 evaluation is not required is that no design function, method of performing or controlling a function, or evaluation that demonstrates intended functions will be accomplished, is adversely affected. Whether the words in the UFSAR need to be changed is a secondary matter. 10 CFR 50.59 is not a UFSAR change

control process; its purpose is to identify changes to the facility or procedures that require prior NRC review and approval.

S.3. Deleted. Benign/beneficial effects addressed in guidance (Section 4.2.1).

S.4. How, if at all, has the concept of "indirect" effects changed in the revised NEI 96-07 guidance?

A. The concept of indirect effects has not changed. There are two common historical usages for the term "indirect effects," and both are relevant under the revised guidance. First, the term may be used to reflect that in addition to a primary or direct effect on a particular design function (and associated UFSAR information), a change may have subtler or indirect effects on other design functions that must be considered. For example, in addition to considering the effect on diesel loading and sequencing of a new or larger load, there may be environmental effects on SSCs in the room as a result of the additional heat generation.

"Indirect effects" will also continue to be used to describe changes affecting SSCs that are not explicitly described in the UFSAR, but nonetheless affect the UFSAR-described design function of a larger or connected SSC.

S.5. A licensee proposes to move a load from the nonsafety-related power supply to a safety-related dc bus. This change therefore affects the calculations/analyses that demonstrate that the plant can withstand and respond to a station blackout. Does this change screen in because it affects "an evaluation that demonstrates intended functions will be accomplished?"

A. No. This is a change to the facility that would be screened to determine whether UFSAR-described design functions are adversely affected. For example, the licensee would consider whether the new load or new load sequence would cause station batteries to be unable to power other required loads for the entire SBO coping duration.

The third part of the "change" definition covering changes that affect "an evaluation that demonstrates intended functions will be accomplished" pertains only to changes in methods of evaluation used to establish the design bases or in the safety analyses—not to physical or procedure changes that may affect evaluations.

S.6. The three-part definition of change uses the terms "design function," "function," and "intended function." Do these terms mean the same thing?

A. Yes. All three parts of the "change" definition refer to "design functions" as that term is discussed in Section 3.3 of NEI 96-07, R1.

S.7. NEI 96-07, Revision 0, considers equivalent replacements to be a maintenance activity that is not subject to 10 CFR 50.59 screening or evaluation. In Revision 1, equivalent replacements are considered changes that must be screened. Why the difference?

A. Equivalent replacements were moved into screening because the engineering (equivalence) assessment performed to determine that a full 50.59 evaluation is not required is analogous to the 10 CFR 50.59 screening review. Equivalence assessments of the physical and performance characteristics of non-identical replacement items are qualitatively different than assessments to determine whether 10 CFR 50.59 must be applied (as discussed in Section 4.1 of the guidance). If an equivalence assessment determines that a replacement item is equivalent to the item it is replacing, this is tantamount to the screening determination that the change does not adversely affect design functions. Thus, equivalence assessments can serve as the basis for determining that a change may be screened out.

Provided the licensee's equivalence assessment (and corresponding 50.59 screening) confirms that there is no adverse effect on design functions, the end result is the same as with the Revision 0 guidance: there is no need for a full 50.59 evaluation of equivalent replacements. (Of course, the UFSAR should be updated per 10 CFR 50.71(e), as appropriate.)

S.8. Must the determination of whether a change is adverse (and therefore requires evaluation under 10 CFR 50.59) be based solely on the UFSAR description of the design function, or can additional design information be considered?

A. Screening determinations are based on the technical/engineering information supporting the proposed change, which typically includes UFSAR information as well as more detailed design calculations, analyses, etc., from outside the UFSAR. For example, a licensee proposes to compensate for noise affecting a transmitter's output with a change to the transmitter's electronics. The UFSAR states that this transmitter provides indication in the control room and an auto-close signal to control room ventilation system dampers upon detection of radiation above the setpoint. The electronics change will cause a two-second delay in the generation of the auto-close signal.

From detailed analyses of the control room HVAC system (maintained outside the UFSAR), it is determined that the damper moves from full open to full closed in 15 seconds and that the dose consequence analysis for the control room does not take credit for closure of the dampers until one minute following the high radiation signal. Based on this information, the change to the transmitter electronics, including the two-second delay in generation of the high radiation signal, is determined to have no adverse effect on UFSAR-described design functions.

S.9. NEI 96-07, Rev. 0, specifies that a "reduction in margin of safety" exists when the difference between the "acceptance limit" and the design failure point of an SSC is reduced. This may occur by increasing acceptance limit or decreasing the design failure point (or both). In criterion (c)(2)(vii) of the revised rule and the associated NEI 96-07, Revision 1, guidance, the focus is on exceeding/altering design bases limits (which equate to the "acceptance limits" in Revision 0), and there is no specific reliance on the design failure point. Under the revised rule and guidance, if a proposed activity reduces the design failure point of an SSC but maintains the design bases limit, is this an adverse affect on a design function (i.e., would the activity screen in?), and if so, would prior NRC approval be required for this activity?

A. No, the proposed activity would not adversely affect a design function. Reducing the failure point of an SSC does not affect the design bases limit, therefore the change would screen out. No 10 CFR 50.59 evaluation would be required.

Note: It must be ensured that the reduction in failure point does not violate a licensing bases commitment to maintain a minimum margin between the design failure point and the acceptance/design bases limit, e.g., that the failure point must exceed the acceptance/design bases limit by at least a factor of three.

10 CFR 50.59 Evaluation

E.1. For purposes of Criteria 3 & 4 on consequences, is the 10% maximum increase a one time total that licensees must track, or do licensees re-baseline after every change and have a new 10% for each successive change?

A. The dose consequence results are re-baselined after each change and a new 10% increase is permitted for each successive change up to the applicable SRP guideline.

E.2. My UFSAR references a vendor topical on fuel design, and the vendor plans to revise certain analyses, including elements of methodology, as part of my next reload. Do those methodology changes require prior NRC approval?

A. Even though the methodology "belongs to the vendor," the licensee must evaluate the proposed change against criterion c(2)(viii) prior to implementation. In this case, dialog between the licensee and the vendor needs to establish what methodology elements were changed and whether the results are conservative or essentially the same.

E.3. A <u>revision</u> to the <u>existing</u> method for calculating post-LOCA containment pressure that maximizes containment pressure after LOCA is obviously worse for containment performance but results in improved ECCS performance. Is this a conservative or non-conservative change? Does increased containment

pressure constitute a reduction in margin that would require prior NRC approval based on the evaluation of consequences under (c)(2)(iii)?

A. In the context of criterion 8, a revised LOCA analysis method that results in higher peak containment pressure is considered conservative with respect to the old method. Containment performance, considered under criterion 7, would not be affected so long as the design basis limit for containment integrity (e.g., 50 psig) is not exceeded. The concept of reduction in margin has been eliminated in favor of objective evaluation against design basis limits for fission product barriers. Because the containment barrier is assumed to be intact up to its design basis limit, the higher calculated containment pressure would have no effect on dose or the consequence evaluation required by criterion 3.

If a change to a method would result in a lower peak containment pressure, the change would be non-conservative with respect to the Criterion 8 evaluation.

If the purpose of the revised containment pressure analysis was to demonstrate increased backpressure in support of ECCS performance, the higher calculated peak containment pressure would be a non-conservative result, and the methodology revision would require prior NRC approval.

E.4. If a number of non-linked changes collectively do not trigger any of the 10 CFR 50.59 criteria, must they be evaluated separately?

A. Yes.

E.5. When using a new NRC-approved methodology (e.g., new or upgraded computer code) to provide more precise results, if the end result is an increase in margin to the acceptance criteria (i.e., non-conservative and not essentially the same), would this be considered a departure requiring prior NRC approval?

A. No. Per the rule definition of *departure*, the "conservative or essentially the same" criterion is inoperative when using a new method approved by the NRC for the intended application.

E.6. Suppose a new, NRC approved methodology is evaluated and found appropriate for the intended application under Criterion 8. The new method specifies a new design basis limit for a fission product barrier. May the proposed methodology change be implemented without prior NRC approval based on Criterion 8, or is prior NRC approval required based on Criterion 7?

A. The proposed methodology change may be implemented without prior NRC approval based on Criterion 8. The Criterion 8 review combines the NRC approval of the new methodology, including the specified fission product barrier design basis limit, and the licensee evaluation that ensures the new methodology is appropriate for the intended application. This integrated review provides basis for implementing the change without prior NRC approval. This is

consistent with the intent that the "conservative or essentially the same" criterion be inoperative when evaluating use of a new, NRC-approved methodology. Similarly, the 10% minimal increase limit in Section 4.3.3 does not apply if a higher dose is calculated using a new, NRC approved methodology that was found appropriate for the intended application under Criterion 8.

Of course, if the new barrier design basis limit differs from a limit specified in the technical specifications, a technical specification amendment request must be submitted under 10 CFR 50.90 to make the change.

E.7. (a) When an analysis yields a result that is an input to a UFSAR safety analysis, is the result/input considered an element of the safety analysis method that is subject to control under criterion 8? (b) Are the methods used in the subsidiary analysis that yielded the result/input subject to control under criterion 8?

A.a Not unless the safety analysis methodology, described or referenced in the UFSAR, requires that a specific input parameter be calculated in a specific manner (e.g., 95/95 limit value, 10-year average, etc.),

A.b Yes.

As an example, auxiliary feedwater flow rate as a function of steam generator pressure is an input to the safety analyses commonly presented in UFSAR Chapter 15. In this context, the flow rate is not part of the methodology. It is also necessary to ensure that the assumed auxiliary feedwater flow rate can be delivered. To the extent that the methodology used to calculate the deliverable flow rate is described in the FSAR, it is subject to evaluation against Criterion viii.

E.8. "Specified factors to account for uncertainty in measurements or data" is identified in definition 3.10 as one element of methodology controlled under (c)(2)(viii). If the UFSAR reflects that a licensee has assumed a 3-sigma uncertainty on an input parameter, without having to do so because of an NRC requirement, is prior NRC approval required to change this assumption?

A. If the licensee can conclude, based on review of the SER, related correspondence and other sources, that NRC did not credit the use of the 3-sigma uncertainty to offset other input parameters or model limitations, then the 3-sigma uncertainty may be considered as "discretionary conservatism" and changed without prior NRC approval.

E.9. If a value is taken from a reference document for use in a safety analysis or to establish design bases, is the value an input or part of the method? Does it matter if the reference document is an ANSI standard (not approved by the NRC) versus a topical report that was approved by NRC?

A. The value is an input unless the acceptability of the methodology is dependent on the degree of conservatism inherent in the value. If the NRC accepted a methodology (vs. an analysis) because the initial power was 4.5% higher than necessary, the value (regardless of its source) is a part of the methodology.

E.10. If a proposed activity would cause a miniscule exceedence (e.g., 0.01%) of a design basis limit for a fission product barrier evaluated under Criterion 7, is prior NRC approval required?

A. Yes. Design Basis Limits for fission product barriers are treated as absolute limits. On a more practical note, only the appropriate significant digits need be considered when making this determination.

E.11. 10 CFR 100.11(a)(1 & 2) provide whole-body and thyroid dose limits for, respectively, the exclusion area boundary (initial two hours following an accident) and the low population zone (event duration). Should the guidance in Section 4.3.3 be applied to the UFSAR-described EAB or the LPZ dose? For example, if a change would increase the LPZ dose by more than 10% of the margin to the Part 100 limit, but increases the two-hour EAB dose only minimally, is prior NRC approval required?

A. The limiting acceptance criterion would be considered when determining if the minimum criterion was met. In this case, the more limiting criterion is the LPZ dose, and prior NRC approval would be required because the increase was more than minimal.

E.12. Section 4.3.2 of NEI 96-07, R1, says that a change that reduces system/equipment redundancy, diversity, separation or independence requires prior NRC approval. Does this mean reductions from redundancy, diversity, separation or independence described in the UFSAR? Or is prior NRC approval required only if the change reduces redundancy, diversity, separation or independence below the level required by the regulations?

A. A change that reduces redundancy, diversity, separation or independence of UFSAR-described design functions is considered more than a minimal increase in the likelihood of malfunction and requires prior NRC approval. Licensees may, however, without prior NRC approval, reduce excess redundancy, diversity, separation or independence, if any, to the level credited in the UFSAR.

E.13. Deleted. "Mission doses" addressed in guidance (Section 4.3.3).

E.14. Section 4.3.8.2 of NEI 96-07, R1, includes a number of considerations for determining whether or not a new, NRC approved method of evaluation may be considered "approved by the NRC for the intended application." What is the intent of this guidance and to what extent should documentation of criterion 8 evaluations reflect these considerations?

A. Recognizing that criterion 8 is new to licensees, the considerations in Section 4.3.8.2 were provided as examples to assist reviewers in identifying the range of factors that may be applicable when evaluating whether a methodology change may be implemented without prior NRC approval. Not all of the given considerations may be relevant to a given change, and knowledgeable analysts should consider additional factors that may be relevant to determining the acceptability of a change. The considerations should not be viewed as additional 10 CFR 50.59 criteria, but may indicate that a proposed methodology change is or is not "approved by the NRC for the intended application." Documentation of criterion 8 evaluations should address the considerations given in Section 4.3.8.2 and others, as applicable, in accordance with their significance to the evaluation.

E.15. Deleted. Question withdrawn.

E.16. Use of a particular analytical method is reflected in the UFSAR for Licensee A, however, the NRC did not discuss their review or acceptance of the methodology in their SER. Can Licensee B apply the methodology consistent with the application by Licensee A and consider the method "approved by the NRC for the intended application?"

A. The method used by Licensee A is considered implicitly approved by the NRC. Licensee B must first be qualified to perform safety analyses per Generic Letter 83-11, Supplement 1. Then, since the SER is silent on the matter, Licensee B must be able to obtain an adequate understanding of the methodology, its existing application, and limitations on its use from other sources on which to base a further application of the methodology. If these two conditions are met, Licensee B may apply the method and consider it approved by the NRC for the intended application. The basis for determining the methodology is appropriate for the intended application should be documented in the 10 CFR 50.59 evaluation. Other sources of information about the methodology may include the FSAR, topical report, licensee responses to NRC requests for additional information, other licensee correspondence with NRC, and Licensee A personnel familiar with the existing application.

E.17. Section 4.2.1.3 says a change to an existing methodology may be screened out if the change is within the constraints and limitations associated with use of the method. What if no information exists concerning relevant constraints and limitations on use of the methodology?

A. If relevant constraints and limits on use of a methodology are not known, then changes to the method should be screened in for evaluation under Criterion

(c)(2)(viii) of 10 CFR 50.59. If results using the modified methodology are conservative or essentially the same, then the change does not require prior NRC approval.

E.18. May I switch from ICRP-2 to ICRP-30 dose conversion factors under Criterion (c)(2)(viii) of 10 CFR 50.59?

A. NRC has approved ICRP-30 dose conversion factors for use in certain applications. If a licensee proposes to use ICRP-30 in an application that is analogous to that for which it was approved by NRC for another licensee, and other conditions for use of ICRP-30 are met, then ICRP-30 may be considered a methodology that is "approved by the NRC for the intended application" and applied without prior NRC approval. Note: NRC has, in some cases, required that analyses based on ICRP-30 reflect use of the alternate source term. Per 10 CFR 50.67(b)(1), use of the AST may itself require prior NRC approval.

E.19. Are methodologies published by NRC in NUREGs or NUREG/CRs considered "approved by the NRC for the intended application?"

A. Not necessarily. In order to be considered "approved by the NRC for the intended application," such methods must be approved in an SER or otherwise accepted by NRC as part of a plant's licensing basis.

E.20. If I answer "Yes" to Criterion 1, does my 10 CFR 50.59 evaluation still have to address the other seven criteria because I know at that point that the proposed change will require prior NRC approval?

A. No. Given a "yes" answer to one of the eight 10 CFR 50.59 evaluation criteria, the licensee must decide whether to cancel or modify the change, or seek prior NRC approval via the license amendment process. If the decision is to request a license amendment, the licensee does not need to complete the 10 CFR 50.59 evaluation (see previous question). However, the licensee must ensure that complete information concerning the impact of the change is developed and provided to the NRC in support of the LAR. For example, in addition involving more than a minimal increase in the frequency of occurrence of the accident, the proposed change may also result in a more than minimal increase in consequences and other impacts. All relevant effects of the change would need to be addressed in the LAR.

Transition Issues

T.1. Which 10 CFR 50.59 (old or new) applies when evaluation of a change is begun before the effective date of the new rule, but either the evaluation is not complete or the change is not implemented until after the new rule becomes effective?

A. The version of 10 CFR 50.59 (old or new) that should be applied is based on the date on which the 10 CFR 50.59 screening/evaluation is begun. Thus, the old process may be applied for 10 CFR 50.59 reviews begun up to March 13, 2001, the effective date of the revised rule, or plant-specific implementation date, if later (see Q&A T.4). This is acceptable because the old rule is generally conservative with respect to the new. However, for changes to methods of evaluation proposed between the time the new rule takes effect and some later plant-specific implementation date, licensees should ensure that screening/evaluation is consistent with the intent of the new rule and approved guidance.

T.2. What can I do if I submitted a license amendment request for a change that met one of the three evaluation criteria of the existing/old 10 CFR 50.59, but meets the minimum increase standard and could be implemented without prior NRC approval under the revised rule?

A. Licensees may modify or withdraw pending LARs at any time.

T.3. If new or unexpected information is discovered after the revised rule takes effect that necessitates revision of a completed 10 CFR 50.59 evaluation based on the existing/old rule, should the new/revised or the existing/old 10 CFR 50.59 rule be used to revise the evaluation?

A. The evaluation may be revised based on either the new/revised 10 CFR 50.59 or the existing/old rule, at the discretion of the licensee. However, the new/revised rule and guidance should be applied in the following cases:

- If the required revision reflects an increase in the effect of the change such that one or more criteria of the new/revised rule are met. (In this case the licensee should, of course, seek a license amendment for the change).
- If the new information necessitates a change to the previously evaluated activity that is significant to the evaluation

Whichever version of 10 CFR 50.59 is used to revise the evaluation, only the portion affected by the new information (e.g., the consequence evaluation) need be revised. Re-evaluation to the new criteria of the unaffected portions of the 10 CFR 50.59 evaluation is at the licensee's discretion.

T.4. Licensees typically schedule training of personnel so as not to compete with planned outages. Based on the March 13, 2001, effective date of the rule, and

the large number of plant staff that require training, 10 CFR 50.59 training would have to take place during outages for many plants. To ease transition to the new 10 CFR 50.59 rule, can a licensee opt to continue to use the (more conservative) existing/old rule for a period of time until procedures and training are completed on the new rule? Would an exemption request be required?

A. As identified by NRC at the April 10-11 Licensing Issues Workshop, licensees can continue to follow the "old" rule for a transitional period of time beyond the March 13, 2001, effective date of the new rule to complete procedure revision and training (if the 90 days proves to be insufficient). No exemption request is needed.

It is recommended that licensee keep the appropriate NRC staff informed of their implementation status to avoid misunderstandings.

Similarly, the implementation schedule for 10 CFR 72.48 lags that for 10 CFR 50.59 by at least two months. To avoid having to use both the old and new change processes for this period, can a licensee opt to continue to use the (more conservative) existing/old 10 CFR 50.59 and 10 CFR 72.48 until both revised rules are in effect?

A. Yes. See above.

T.5. The revised maintenance rule, including the new a(4) provision, went into effect before the revised 10 CFR 50.59 rule. During the period between the effective dates of the two rules, are licensees required to perform both a(4) assessments and 10 CFR 50.59 reviews for plant alterations to support maintenance?

A. No. Both the revised maintenance rule a(4) guidance and that contained in NEI 96-07 for 10 CFR 50.59 reflect that maintenance activities, including associated plant alterations lasting 90 days or less, are to be assessed and managed under the a(4) provision (no 10 CFR 50.59 review required). In approving the maintenance rule a(4) guidance (RG 1.182), the Commission noted in their May 1, 2000, SRM on SECY-00-0074 that, "Until the revised 10 CFR 50.59 rule becomes effective, performing a 50.65(a)(4) assessment in lieu of a 10 CFR 50.59 review may result in literal noncompliance with the existing 10 CFR 50.59 rule." They directed that, "Should this occur, the [NRC] staff should continue its policy of exercising enforcement discretion for violations of the existing rule that would not be violations of the revised 10 CFR 50.59 rule." Thus, licensees may at any time begin using a(4) instead of 10 CFR 50.59 to assess plant alterations (lasting <90 days) that support maintenance activities. Similarly, licensees may stop performing 10 CFR 50.59 reviews for maintenance procedure changes, consistent with forthcoming guidance on 10 CFR 50.59 and applicability of Part 50, Appendix B, criteria to control of such changes.

General/Miscellaneous

G.1. Appendix A of NEI 98-03, *Guidelines for Updating FSARs*, provides for removal of excessive detail from UFSARs. Rather than apply 10 CFR 50.59 to a given change affecting such UFSAR information, can licensees remove the information in accordance with NEI 98-03 and proceed with the change?

A. Regardless of whether a proposed change affects information contained in the UFSAR, changes that are not controlled by another regulation must, at a minimum, undergo 10 CFR 50.59 screening. Removing affected information from the UFSAR may be appropriate based on the guidance contained in NEI 98-03, however, doing so does not lessen the applicability of 10 CFR 50.59 to the change. That said, a change that affects only UFSAR details that are considered excessive with respect to providing an understanding of the safety analyses and design bases (NEI 98-03 criteria) would most likely not meet the 10 CFR 50.59 definition of "change," and thus screen out.

G.2. When does a UFSAR change become part of the UFSAR? Is it when the change is implemented? Or when the associated UFSAR update is approved?

A. A UFSAR change becomes part of the UFSAR for purposes of 10 CFR 50.59 when it is approved for incorporation in the next UFSAR update required under 10 CFR 50.71(e). This is typically after the change is implemented.

G.3. What are the implications for no significant hazards determinations under 10 CFR 50.92, which retains a criterion for "no reduction in margin of safety," now that the "margin of safety" criterion has been eliminated from 10 CFR 50.59?

A. None. The 10 CFR 50.59 rulemaking does not effect 10 CFR 50.92, or determinations of no significant hazards. While the term "margin of safety" is as subjective in the context of 10 CFR 50.92 as it was for 10 CFR 50.59, this is not considered a problem going forward. This is because required licensee submittals under 10 CFR 50.90, "no significant hazard" determinations and the ultimate approval of license amendment requests will be based on the licensee's submittal, including complete technical rationale supporting the requested action. This process will continue as it always has.

It should be noted that the existing/old 50.59 says "margin of safety as defined in the basis for any TS." Clearly, the 50.59 rulemaking has clarified the intent of that phrase by focusing on those design bases limits that ensure the integrity of fission product barriers. In contrast, 50.92 says "significant reduction in margin of safety" (without qualifying reference to technical specifications). This implies a different (broader) scope of factors relevant to the "margin of safety" criterion under 50.92 than under 10 CFR 50.59.

G.4. Technical specifications, procedures, NRC commitments, and regulatory guidance often reflect that a "10 CFR 50.59 evaluation" should be performed under certain circumstances, e.g., for compensatory action to address degraded or non-conforming conditions or when making a change to the TRM or technical specifications bases. How should this be interpreted going forward, recognizing that the 10 CFR 50.59 process has two parts: screening and evaluation?

A. References to 10 CFR 50.59 in procedures, commitments and guidance that are based on the existing/old rule should be viewed going forward as references to the complete 10 CFR 50.59 process. All activities subject to 10 CFR 50.59 should be subject to the screening provisions based on the definitions in the revised rule, and if necessary (if the activity screens in), to the evaluation provisions (and associated documentation/reporting requirements).

G.5. Are there any inconsistencies between the Statements of Consideration for the final 10 CFR 50.59 rule and final draft NEI 96-07, R1?

A. While the SOC are not part of the revised 10 CFR 50.59 regulation, NEI 96-07, R1 is largely consistent with them. Based on extensive public discussions and comment resolution between the industry and the NRC staff, two aspects of the SOC have been clarified in final draft NEI 96-07, R1. Following endorsement of NEI 96-07, R1, by the NRC, the industry guidance will take precedence over the SOC in these areas.

First, 10 CFR 54.21(d) requires that the UFSAR be supplemented for license renewal with summary descriptions of time-limited aging analyses and aging management programs. The SOC state that changes to this license renewal information require "evaluation" under 10 CFR 50.59(c)(viii). The intent of the SOC discussion was to include TLAA and (as applicable) aging management programs within the scope of "design bases and safety analyses" for purposes of criterion 8 so that if associated evaluation methods were described in the UFSAR they would fall within the definition of "methods of evaluation" and thus, the scope of 10 CFR 50.59. The industry guideline reflects that all changes subject to 10 CFR 50.59 may first be screened to determine if evaluation against the eight criteria of 10 CFR 50.59 is required. Thus, contrary to the SOC, changes to time-limited aging analyses and aging management programs for license renewal that screen out based on the definitions and guidance in NEI 96-07, R1, do not require evaluation under 10 CFR 50.59.

Second, the SOC state that licensees may adopt a new method of evaluation only if it has been specifically approved by the NRC for the intended plant/application or enjoys "generic" NRC approval. In addition to these cases, NEI 96-07, R1, provides that licensees qualified per Generic Letter 83-11, Supplement 1, to perform safety analyses may adopt methodologies approved by the NRC for other plants provided the methodology is technically appropriate for the intended application.

G.6. According to NEI 96-07, R1, I may change my 10 CFR 50.2 design bases without prior NRC approval, except those that ensure the integrity of fission product barriers, provided that the change does not meet any of the eight evaluation criteria of 10 CFR 50.59. Is that true?

A. Yes, it is true. Except for criterion 7, 10 CFR 50.59 does not treat changes to 10 CFR 50.2 design bases any differently from other changes to the facility or procedures.

Historically, NRC reporting requirements have reflected a distinction between 10 CFR 50.2 design bases and other design information. Specifically, 10 CFR 50.72 required licenses to report to NRC in 1-hour conditions "outside the design bases." Recognizing that "outside the design bases" conditions rarely imply a safety concern that must be immediately reported to the NRC, the NRC recently revised its reporting requirements to eliminate "outside the design bases" as a reporting criterion.

G.7. NEI 96-07, R1, says that 10 CFR 50.59 should be applied to temporary changes that are not related to maintenance and maintenance-related plant alterations lasting >90 days. Do these have to be reported to the NRC?

A. If the temporary change required a 10 CFR 50.59 evaluation (i.e., did not screen out), it must be reported to the NRC like any other activity that received a 10 CFR 50.59 evaluation.

G.8. Why were most of the considerations (from NEI 96-07, Revision 0, and early drafts of Revision 1) for determining whether there is an increase in accident frequency or malfunction likelihood removed from Section 4.3.1 and 4.3.2?

A. The considerations were removed because they would have uncertain status in a guidance document endorsed by the NRC. They may have been interpreted as criteria that, if met, would indicate prior NRC approval was required, or it could have been interpreted that 10 CFR 50.59 evaluations were considered incomplete unless each consideration was addressed. Neither of these, of course, was intended. Rather, the considerations were intended to indicate the breadth of factors that may be appropriate to consider for a given 10 CFR 50.59 evaluation. Not all considerations are relevant to all evaluations. Licensees may wish to identify such considerations in their 10 CFR 50.59 implementation materials to ensure all relevant factors are considered.

G.9. Does NEI plan to make conformance with NEI 96-07, R1, an industry initiative?

A. No. We believe the NRC endorsement of NEI 96-07, R1, obviates the need for an industry initiative and provides adequate incentive for licensees to follow the industry guidance.

G.10. Does NEI 96-07, R1, and the associated regulatory guide supercede 10 CFR 50.59-related information and guidance contained in past NRC bulletins, generic letters, etc.?

A. . NEI 96-07, R1, and the associated RG reflect the revised 10 CFR 50.59 rule that will apply to licensees going forward. Conforming changes to NRC inspection guidance are in progress. However, past NRC bulletins and generic letters containing guidance related to 10 CFR 50.59 are not being updated and their applicability should be assessed on a case-by-case basis. Where NEI 96-07, R1, includes 10 CFR 50.59 implementation guidance in an area that was addressed by a prior NRC generic communication, the revised guidance and RG take precedence. It should be recognized that 10 CFR 50.59 implementation may have only been one aspect of the information presented in an earlier NRCB or GL, and other information presented might still be valid.

Where the revised guidance cannot be directly applied to a situation addressed previously by the NRC, the licensee should assess the prior information in the context of the revised rule and guidance and proceed accordingly.

The examples below illustrate the applicability of prior NRC guidance concerning 10 CFR 50.59 implementation in light of the new rule and NEI 96-07, R1. These example can be used as a guide for assessing the applicability of other past NRC guidance related to 10 CFR 50.59:

- NRC Bulletin 80-10 addresses actions to be taken when it is discovered that previously uncontaminated systems have become contaminated. The Bulletin requires a licensee to "perform an immediate safety evaluation of the operation of a previously non-contaminated system as a contaminated system." This requirement is no longer appropriate or applicable. Based on current guidance, these "discovered" situations should be treated as a degraded /nonconforming condition in accordance with the licensee's corrective action program. In addition, the licensee should perform an operability assessment in accordance with NRC Generic Letter 91-18. If the "discovered" situation will be accepted "as is," then 10 CFR 50.59 should be applied to this final corrective action.

- NRC IE Circular 80-18 identifies review criteria of radwaste system design changes. These criteria pertain to the technical/engineering evaluation that demonstrates that the change is safe, effective and meets all applicable codes and standards. This is no different than any other change that has to be determined to be technically appropriate prior to applying 50.59. Thus the criteria identified in IEC 80-18 for radwaste design changes would be addressed as part of the up-front technical/engineering evaluation. The 50.59 screening, and, if necessary, evaluation for such changes should be based on the technical/engineering information supporting the change.

- NRC Generic Letter 93-08 (and associated Information Notice 97-28) deals with the relocation of certain instrument response time limits from the Tech Specs to the UFSAR to allow licensees to control changes to these limits under 10 CFR 50.59 and not require a license amendment request. The requirements and guidance in this GL and related IN remain valid under the new rule.

- That portion of Generic Letter 91-18, Revision 1, dealing with 10 CFR 50.59 review of compensatory measures to address degraded/nonconforming conditions was essentially incorporated into NEI 96-07, R1. Thus the revised guidance has no effect on the prior NRC guidance, and GL-91-18, R1, remains valid.

- NRC Bulletin 95-02 addressed when an analog to digital upgrade may be made under 10 CFR 50.59 (i.e., without prior NRC approval) based on the old 10 CFR 50.59 rule. The need for prior NRC approval for future A/D upgrades should be based on evaluation under the revised 10 CFR 50.59 criteria, including the minimal increase standard. Also, the most relevant criterion for A/D upgrades is now whether the change would cause a malfunction with a different result—not whether there would be a malfunction of a different type.

- NRC Bulletin 96-02 addressed NRC concerns regarding movement of heavy loads over safety-related equipment, and when NRC approval is required prior to such movements. Movement of heavy loads is typically a part of a maintenance activity that, going forward, will be assessed and managed under 10 CFR 50.65(a)(4). Together with 10 CFR 50.59(c)(4), which provides that if more specific requirements apply to control of an activity, 10 CFR 50.59 need not also be applied, these new requirements supercede the conclusion of NRCB-96-02 that such activities constitute "unreviewed safety questions" under 10 CFR 50.59 and therefore a license amendment request must be submitted.

  Nonetheless, NRCB-96-02 contains useful information and considerations for licensees contemplating movements of heavy loads and thus the bulletin continues to be valid in that respect.

When implementing the revised 10 CFR 50.59 rule and guidance, licensees should also be mindful of commitments made to NRC in response to generic or plant-specific communications such as NRCB-96-02. It may be necessary/appropriate in accordance with licensee procedures to notify NRC that a prior commitment has been changed in light of revised 10 CFR 50.59 rule and guidance.

G.11 Regarding the 10 CFR 50.59 review of temporary facility/procedure changes to compensate for degraded or nonconforming conditions, Section 4.4 of NEI 96-07, R1, states, "The intent is to determine whether the temporary change (not the degraded condition) impacts other aspects of the facility or procedures described in the UFSAR." What is the intent of this guidance, and how does this differ from 10 CFR 50.59 screening/evaluation of permanent changes?

A. Degraded and non-conforming (D/NC) conditions typically affect design functions such that they are no longer "as-designed" or "as-described in the UFSAR." This situation makes it problematic to apply 10 CFR 50.59 to the temporary change/compensatory action because it is difficult to distinguish between the D/NC condition and the proposed compensatory action. Section 4.4 provides specific guidance for applying 10 CFR 50.59 to a temporary facility/procedure change proposed as a compensatory action for a D/NC condition.

It is <u>not</u> intended that 10 CFR 50.59 be applied to the D/NC condition. (Per Generic Letter 91-18, the affected SSCs must be determined to be operable, and per 10 CFR Part 50, Appendix B, the D/NC condition must be corrected in a timely manner commensurate with safety.) Rather, the intent of the Section 4.4 guidance is that the temporary change/compensatory action should be screened under 10 CFR 50.59 for adverse effects on UFSAR-described design functions, etc., <u>other than</u> those that are degraded/nonconforming. This guidance differs from that for permanent changes in Section 4.2, which prescribes screening for adverse effects on all design functions, etc., <u>including</u> the design function directly affected by the change.

If a temporary change/compensatory action "screens in" (i.e., there would be adverse effects on other SSC design functions), Section 4.3 guidance for the required 10 CFR 50.59 evaluation should be applied. The focus of the evaluation in such cases is on the adverse effects on these other design functions.

G.12 GL 91-18, R1 (Inspection Manual Part 9900 - Operability) provides that in certain cases, a temporary procedure change that substitutes manual action for automatic action may be acceptable, from an operability perspective, to compensate for a D/NC condition. How should 50.59 be applied to such a temporary procedure change?

A. Provided that performance of the proposed manual action would not adversely effect design functions, etc., other than those that are already degraded or nonconforming, the proposed temporary procedure change (manual action) would "screen out." If the procedure change/manual action has adverse effects on design functions, etc., other than those that are degraded/ nonconforming, a 50.59 evaluation would be performed to determine if a license amendment request must be submitted for the temporary change.

G.13 10 CFR 50.59(c)(3) provides that the UFSAR is considered to include pending UFSAR changes resulting from activities implemented under 10 CFR 50.59 since submittal of the last required UFSAR update. Does this include temporary alterations reviewed under 10 CFR 50.59, e.g, maintenance temp alts in effect more than 90 days at power and temp alts to compensate for a degraded or nonconforming condition?

A. Generally not. According to NEI 98-03, only temporary changes that are expected to be in place throughout the next required periodic UFSAR update cycle (i.e., last more than 12-24 months) would be reflected in the UFSAR and subject to 10 CFR 50.59(c)(3). Most maintenance temp alts and compensatory actions are relatively short-term in nature and thus do not trigger a UFSAR update.

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(7-94)
NRCMD 3.57

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