7R 2950017

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D.C. 20555-0001

September 5, 2000

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: John T. Larkins, Executive Director
Advisory Committee on Reactor Safeguards

SUBJECT: FINAL REGULATORY GUIDE 1.18x ON 10 CFR 50.59, CHANGES, TESTS, AND EXPERIMENTS

During the 471st meeting of the Advisory Committee on Reactor Safeguards, April 5-7, 2000, the Committee discussed draft Regulatory Guide (DG-1095), "Guidance for Implementation of 10 CFR 50.59 (Changes, Tests, and Experiments)," that endorses, with clarifications, NEI document 96-07, "Guidelines for 10 CFR 50.59 Evaluation."

During the 475th meeting, August 29- September 1, 2000, the Committee decided not to review the subject final Regulatory Guide that endorses (without exception) NEI 96-07, Revision 1.

References:

1. U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, Regulatory Guide 1.18x, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," dated September 2000.

2. Nuclear Energy Institute, NEI 96-07, Revision 1 (Pre-Publication Draft), "Guidelines for 10 CFR 50.59 Evaluations," dated July 12, 2000.

cc: A. Vietti-Cook, SECY
J. Craig, OEDO
G. Millman, OEDO
S. Collins, NRR
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E. McKenna, NRR

FR 295

DOCUMENT NAME: G:ACRSLTRS:475.Larkins1

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FINAL RG FOR 10 CFR 50.59

August 22, 2000

Eileen M. McKenna

Office of Nuclear Reactor Regulation

CRGR Briefing

Attachment 2 – Presentation Material

Timeline

- SECY-00-0071 dated March 24, 2000, forwarded draft RG to Commission for information
- Draft RG issued for public comment (FR notice, web site posting, mailing) on April 25
- 45 day comment period ended June 9
- Final RG (reflecting resolution of comments) due to Commission in September 2000
- Upon approval by Commission (and FR notice), rule becomes effective in 90 days - estimated to be February 2001
- Section 72.48 effective date is April 5, 2001

Draft Regulatory Guide Contents

DG-1095 proposed to endorse NEI 96-07 with the following clarifications and additions

- **Screening on (adversely) affects design function**
  - understanding of design function definition
  - screen on "affect" not on whether a design function if function is in FSAR
  - relocation of text on "adversely" affect under 4.2.1.1
  - evaluation not screening if new analyses needed

- **Relationship to Maintenance assessments**
  - activity must be needed to support maintenance
  - discussion about how requirements apply to modifications

Draft Regulatory Guide Contents (continued)

- Guidance on increases in likelihood of malfunction
  - factor of 2 at component level

- Methods
  - clarifications that when using a plant-specific "approvals" as the basis, relevant plant differences and slight modifications need to be assessed on the basis of "essentially the same"

- License renewal coverage

- Section 72.48 Applicability

Comments on DG-1095

- 21 Sets of comments sent by NEI, utilities endorsing those comments and from a few individuals

- Issues
  - Screening (functions in SAR not "design functions")
  - Engineering assessments for screenings (not evaluations)
  - Methods
  - Fire protection
  - Human actions

- Transition questions

Resolution of Comments

- NEI-Proposed changes to NEI 96-07 (as result of DG process)
  - meaning of design function (using DG discussion)
  - guidance on adverse effects (covering all types of changes)
  - discussion about need for information basis on plant-specific approval method use
  - clarifications about human actions

- Fire Protection DPV - under evaluation

- Discuss transition topics in Regulatory Issue Summary

Transition Topics

- Timing of licensee Implementation
  - what happens if programs and training not complete in 90 days? (Revised rule is relaxation)
  - exemption not required if implementation is delayed

- Evaluations in progress
  - at what point in process is revised rule to be used

- Applicability to evaluations performed in the past

- Maintenance rule implementation coordination
  - see SRM on maintenance rule RG

- Other questions (e.g., applicability of other NRC documents)

Implementation

- New baseline inspection program includes procedure to inspect sample of 50.59 evaluations

- Part 9900 inspection guidance (used for reference), will be issued shortly after issuance of final RG

- Training for NRC staff will be conducted on the revisions to the rule and what the guidance contains

- Enforcement policy discussed in May 2000 Federal Register Notice of revised policy

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REGULATORY RESEARCH

September 2000

REGULATORY GUIDE 1.18x

(Draft was issued as DG-1095)

GUIDANCE FOR IMPLEMENTATION OF 10 CFR 50.59, CHANGES, TESTS, AND EXPERIMENTS

A. INTRODUCTION

In 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Section 50.59, "Changes, Tests and Experiments," contains requirements for the process by which licensees may make changes to their facilities and procedures as described in the safety analysis report, without prior NRC approval, under certain conditions. The rule was promulgated in 1962 and revised in 1968.

As a result of lessons learned from operating experience and other initiatives related to control of conformance of 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 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 to clarify the requirements and to allow changes involving only "minimal increases" in probability or consequences to be made without prior NRC approval.

[1]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 or (800)397-4209; fax (202)634-3343; email <PDR@NRC.GOV>.

The proposed rule was published for comment in October 1998. Following consideration of public comments, the NRC issued a final rule on October 4, 1999 (64 FR 53582) revising 10 CFR 50.59 that becomes effective 90 days after approval of regulatory guidance, which is contained in this Regulatory Guide. The text of the revised rule is contained in Appendix A to this regulatory guide for convenience.

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 objectives of 10 CFR 50.59 are to ensure that licensees (1) evaluate proposed changes to their facilities for their effects on the licensing basis of the plant, 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 operating license. This regulatory guide, through its endorsement of a guideline document for licensees, provides guidance on complying with the revised requirements of 10 CFR 50.59.

DEVELOPMENT OF INDUSTRY GUIDELINE, NEI 96-07

Following publication of the revised rule, NEI submitted a guidance document for the implementation of 10 CFR 50.59 and requested NRC endorsement through a regulatory guide. Following a series of meetings between NEI and the NRC, a revised version of the guidance document was submitted by NEI on February 22, 2000. The NRC published a draft regulatory guide, DG-1095, which endorsed with certain clarifications, Revision 1 of NEI 96-07. As part of their comments in response to the draft RG, NEI proposed revisions to NEI 96-07 to respond to the issues raised by the NRC staff in its draft RG. Subsequently, NEI submitted a revised version of NEI 96-07, dated JULY 12, 2000 for endorsement.

C. REGULATORY POSITION

1. NEI 96-07

Revision 1 of NEI 96-07, "Guidelines for 10 CFR 50.59 Evaluations,"[2] dated JULY 2000, provides methods that are acceptable to the NRC staff for complying with the provisions of 10 CFR 50.59.

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[2]Copies of 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 xxxx . 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 or (800)397-4209; fax (202)634-3343; email <PDR@NRC.GOV>.

2. OTHER DOCUMENTS REFERENCED IN NEI 96-07

NEI 96-07 (Revision 1) references other documents, but NRC's endorsement of NEI 96-07 (Revision 1) should not be considered an endorsement of the referenced documents.

3. USE OF EXAMPLES IN NEI 96-07

Revision 1 to NEI 96-07 includes examples to supplement the guidance. While appropriate for illustrating and reinforcing the guidance in NEI 96-07, Revision1, the NRC's endorsement of NEI 96-07 (Revision 1) 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. GUIDANCE FOR FSAR SUPPLEMENTS FOR LICENSE RENEWAL

The guidance in NEI 96-07 and in this regulatory guide is applicable to information added to the FSAR in accordance with 10 CFR 54.21(d), that is, for summary descriptions of the programs and activities for managing the effects of aging and the evaluation of time-limited aging analyses.

5. APPLICABILITY TO NON-POWER REACTORS

While most of the examples and specific discussion focus upon power reactors, the guidance contained in Revision 1 to NEI 96-07 is also applicable to evaluations performed by licensees for non-power reactors. Certain of the provisions in the guidance that discuss the relationship of other regulatory requirements to 10 CFR 50.59 may not be fully applicable to non-power reactors because of differences in those other requirements. For example, nonpower reactors are not subject to 10 CFR 50.65, and thus, the guidance concerning use of risk assessments for temporary alterations associated with maintenance in lieu of 10 CFR 50.59 reviews would not be applicable.

6. APPLICABILITY TO 10 CFR 72.48 EVALUATIONS

The guidance contained in Revision 1 to NEI 96-07 is also generally applicable to evaluations performed by licensees of independent spent fuel storage facilities (ISFSIs) or spent fuel storage cask design certificate holders for implementation of the revised 10 CFR 72.48. The NRC plans to issue guidance that would endorse (with comment if needed), a companion industry guidance document that has adjustments to the examples and other specific aspects as they pertain to 10 CFR 72.48.

7. APPLICABILITY OF PAST NRC COMMUNICATIONS

The NRC has issued a number of communications, such as Generic Letters or Bulletins that discussed or referred to 10 CFR 50.59. In considering whether the information in those documents remains applicable, it should be noted that these documents were based upon the rule requirements that existed at the time of issuance. To the extent that the discussion therein relates to specific aspects of the rule, such as evaluation criteria, which have been revised, these past documents may no longer be fully consistent and the new rule requirements would prevail. The status of other parts of these documents that are not affected by the revisions to the rule is unchanged.

8. USE OF OTHER METHODS

Licensees may use methods other than those proposed in Revision 1 of NEI 96-07 to meet the requirements of 10 CFR 50.59. 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 and applicants regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which a 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 licensee compliance with the requirements of 10 CFR 50.59.

APPENDIX A
TEXT OF 10 CFR 50.59

§ 50.59 Changes, Tests, and Experiments.

(a) Definitions for the purposes of this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 2120 L Street NW., Washington, DC, as part of SECY-99-130, dated May 12, 1999. The PDR may be reached by telephone at (202)634-3273 or fax at (202)634-3343.

ADAMS Accession Number of
NEI 96-07 --

NUCLEAR ENERGY INSTITUTE

Anthony R. Pietrangelo
DIRECTOR, LICENSING
NUCLEAR GENERATION DIVISION

July 12, 2000

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

PROJECT NUMBER: 689

Dear Mr. Matthews:

Enclosed for NRC endorsement is pre-publication draft NEI 96-07, Revision 1, *Guidelines for10 CFR 50.59 Evaluations.* The enclosure incorporates the clarifications identified in our June 8 response to DG-1095 as well as changes that address matters discussed during our June 27 public meeting. In the areas of "mission doses" and maintenance rule vs. 10 CFR 50.59, the June 8 clarifications were modified based on the June 27 discussions.

In addition to substantive changes from our February 22 final draft, we have made numerous editorial and conforming changes throughout the document. As such, we have also enclosed a red-line version that identifies all changes from the earlier draft.

We understand that the staff will complete internal reviews in August and forward the final regulatory guide endorsing the industry guidance to the Commission in September. In parallel, we will complete our final editorial reviews in preparation for issuing NEI 96-07, Revision 1, for industrywide use.

As discussed with the NRC staff on June 27, we also understand that the NRC will address two implementation issues in connection with issuance of the final regulatory guide: transition from the existing rule and guidance to the new; and superceding of past NRC guidance/documents that address 10 CFR 50.59 implementation.

Attachment 4 – NEI 96-07, Revision 1

The enclosure reflects extensive input by the NRC and industry and marks the culmination of intensive efforts to resolve issues and provide licensees with consensus 10 CFR 50.59 guidance. The improved understanding and focus that has resulted from the process should significantly improve the efficiency and effectiveness of the rule for both licensees and NRC.

If you have any questions concerning pre-publication draft NEI 96-07, Revision 1, please contact me at 202-739-8081, or Russ Bell at 202-739-8087.

Sincerely,

Anthony R. Pietrangelo

Anthony R. Pietrangelo

Enclosures

c: Cindy Carpenter, NRC/NRR
Steve West, NRC/NRR
Eileen McKenna, NRC/NRR

Nuclear Energy Institute

GUIDELINES FOR 10 CFR 50.59 EVALUATIONS

Pre-publication DRAFT – July 12, 2000

Nuclear Energy Institute, 1776 I Street N.W., Suite 400, Washington D.C. (202.739.8000)

ACKNOWLEDGMENTS

In 1996, NSAC-125, *Guidelines for 10 CFR 50.59 Safety Evaluations,* was transformed into NEI 96-07 with minor changes to address specific NRC concerns. Much of this longstanding industry guidance continues to underlie the revised guidance presented in this document. We appreciate EPRI allowing NEI to use NSAC-125 in this manner and we recognize the efforts of the individuals that contributed to the development of NSAC-125.

The revised guidance in this document was developed with the invaluable assistance of the 10 CFR 50.59 Task Force and the Regulatory Process Working Group.

Nuclear Energy Institute, 1776 I Street N.W., Suite 400, Washington D.C. (202.739.8000)

FOREWORD

In 1999, the NRC revised its regulation controlling changes, tests and experiments performed by nuclear plant licensees—the first changes to 10 CFR 50.59 in over 30 years. The changes were prompted by the need to resolve differences in interpretation of the rule's requirements by the industry and the NRC that came in clear focus in 1996. These differences existed despite general recognition that licensee implementation of 10 CFR 50.59 has been effective in controlling activities affecting plant design and operation. The rule changes had two principal objectives, both aimed at restoring much-needed regulatory stability to this extensively used regulation:

- Establish clear definitions to promote common understanding of the rule's requirements
- Clarify the criteria for determining when changes, tests and experiments require prior NRC approval

While effective at controlling changes, 10 CFR 50.59 was, at the same time, viewed as overly restrictive of licensee changes and unduly burdensome. License amendment requests were prepared, submitted and reviewed by the NRC for many changes having little or no impact on the plant design or operation. Indeed, some beneficial changes were withdrawn by licensees upon determination that the change would have to go through the burdensome license amendment process. Moreover, substantial resources were expended each year by licensees to process and submit to NRC lengthy evaluations for numerous insignificant changes. The changes approved by the Commission in 1999 made 10 CFR 50.59 more focused and efficient by:

- Providing greater flexibility to licensees, primarily by allowing changes that have minimal safety impact to be made without prior NRC approval
- Clarifying the threshold for "screening out" changes that do not require full evaluation under 10 CFR 50.59, primarily by adoption of key definitions

These changes will conserve both licensee and NRC resources while continuing to ensure that significant changes are thoroughly evaluated and approved by the NRC as appropriate.

This document provides guidance for implementing the revised rule. While it contains new guidance corresponding to new and revised rule criteria, overall, the document reflects a refinement of longstanding industry practice, not a radical new approach. The basic philosophy behind 10 CFR 50.59 implementation and a substantial amount of guidance reflected in this document can be traced to EPRI/NSAC-125—the original industry guidance document in this area—issued in 1989.

Other past guidance related to 10 CFR 50.59, including NRC generic communications, was also reviewed and reflected in this document as appropriate. The intent is to provide comprehensive guidance that is consistent with the 1999 changes to 10 CFR 50.59.

In parallel with the rulemaking to amend 10 CFR 50.59, the NRC made conforming changes to the analogous provision in 10 CFR Part 72 for control of changes, tests and experiments involving independent fuel storage facilities. 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. Accordingly, the guidance herein on implementing 10 CFR 50.59 may be applied to support implementation of 10 CFR 72.48.

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APPENDICES

1 INTRODUCTION

1.1 PURPOSE

10 CFR 50.59 establishes the conditions under which licensees may make changes to the facility 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 50.59 provides a threshold for regulatory review—not the final determination of safety—for proposed activities.

The purpose of this document is to provide guidance for developing effective and consistent 10 CFR 50.59 implementation processes.

1.2 RELATIONSHIP OF 10 CFR 50.59 TO OTHER REGULATORY REQUIREMENTS AND CONTROLS

As the process for controlling a range of activities affecting equipment and procedures at a nuclear power plant, implementation of 10 CFR 50.59 interfaces with many other regulatory requirements and controls. To optimize the use of 10 CFR 50.59, 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:

1.2.1 Relationship of 10 CFR 50.59 to Other Processes that Control Licensing Basis Activities

10 CFR 50.59 focuses on the effects of proposed activities on the safety analyses that are contained in the updated FSAR (UFSAR) and are a cornerstone of each plant's licensing basis. In addition to 10 CFR 50.59 control of changes affecting the safety analyses, there are several other complementary processes for controlling activities that affect other aspects of the licensing basis, including:

- Amendments to the Operating License (including the technical specifications) are sought and obtained under 10 CFR 50.90.
- Where changes to the facility or procedures are controlled by more specific regulations (e.g., quality assurance, security and emergency

preparedness program changes controlled under 10 CFR 50.54(a), (p) and (q), respectively; Off-site Dose Calculation Manual changes controlled by technical specifications), 10 CFR 50.59 states that the more specific regulation applies.

- Changes that require an exemption from a regulation are processed in accordance with 10 CFR 50.12.
- Guidance for controlling changes to licensee commitments is provided by NEI 99-04, *Guideline for Managing NRC Commitment Changes*.
- Where a licensee possesses a license condition which specifically permits changes to the NRC-approved fire protection program (i.e., has received the standard fire protection license condition contained in Generic Letter 86-10), subsequent changes to the fire protection program would be controlled under the license condition and not 10 CFR 50.59.
- Maintenance activities, including associated temporary changes, are subject to the technical specifications and are assessed and managed in accordance with the Maintenance Rule, 10 CFR 50.65; screening and evaluation under 10 CFR 50.59 is not required.

Together with 10 CFR 50.59, these processes form a framework of complementary regulatory controls over the 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 50.59 in relation to other processes, including circumstances under which different processes, e.g., 10 CFR 50.59 and 10 CFR 50.90, should be applied to different aspects of an activity.

In addition to controlling changes to the facility and procedures described in the UFSAR under 10 CFR 50.59 as required by the rule, some licensees also control changes to other licensing basis information using the 10 CFR 50.59 process. This may be in accordance with a requirement of the license or commitment to the NRC. An example of documentation that may be outside the UFSAR but that is controlled via 10 CFR 50.59 by many licensees are the Technical Specifications Bases.

1.2.2 Relationship of 10 CFR 50.59 to 10 CFR Part 50, Appendix B

Prior to the operating license, 10 CFR Part 50, Appendix B, assures that the facility design and construction meet applicable requirements, codes and standards in accordance with the safety classification of systems, structures and components (SSCs). Appendix B design control provisions ensure that all changes continue to meet applicable design and quality requirements. The design and licensing bases evolve in accordance with Appendix B requirements up to the time that an operating license is received, and 10 CFR 50.59 is not applicable until after that time. Both Appendix B and 10 CFR 50.59 apply following receipt of an operating license.

Appendix B also addresses corrective action. The application of 10 CFR 50.59 to compensatory measures that address degraded and non-conforming conditions is described in Section 4.4.

1.2.3 Relationship of 10 CFR 50.59 to the UFSAR

10 CFR 50.59 is the process that identifies when a license amendment is required prior to implementing changes to the facility 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 50.71(e). Guidance for updating UFSARs to reflect activities implemented under 10 CFR 50.59 is provided by Regulatory Guide 1.181, which endorses NEI 98-03, Revision 1.

1.2.4 Relationship of 10 CFR 50.59 to 10 CFR 50.2 Design Bases

10 CFR 50.59 controls changes to both 10 CFR 50.2 design bases and supporting design information contained in the UFSAR. In support of 10 CFR 50.59 implementation, Section 4.3.7 of this guideline defines the design basis limits for fission product barriers that are subject to control under 10 CFR 50.59(c)(2)(vii), and Section 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 50.59(c)(2)(viii). Additional guidance for identifying 10 CFR 50.2 design bases is provided in NEI 97-04, Appendix B.

As discussed in Section 3.3, "design bases functions," (defined in NEI 97-04, Appendix B) are a subset of "design functions" for purposes of 10 CFR 50.59 screening.

1.3 10 CFR 50.59 PROCESS SUMMARY:

After determining that a proposed activity is safe and effective through appropriate engineering and technical evaluations, the 10 CFR 50.59 process is applied to determine if a license amendment is required prior to implementation. This process involves the following basic steps as depicted in Figure 1:

- **Applicability and Screening:** Determine if a 10 CFR 50.59 evaluation is required.
- **Evaluation:** Apply the eight evaluation criteria of 10 CFR 50.59(c)(2) to determine if a license amendment must be obtained from the NRC.
- **Documentation & reporting:** Document and report to the NRC activities implemented under 10 CFR 50.59.

Later sections of this document discuss key definitions, provide guidance for determining applicability, screening, and performing 10 CFR 50.59 evaluations, and present examples to illustrate the application of the process.

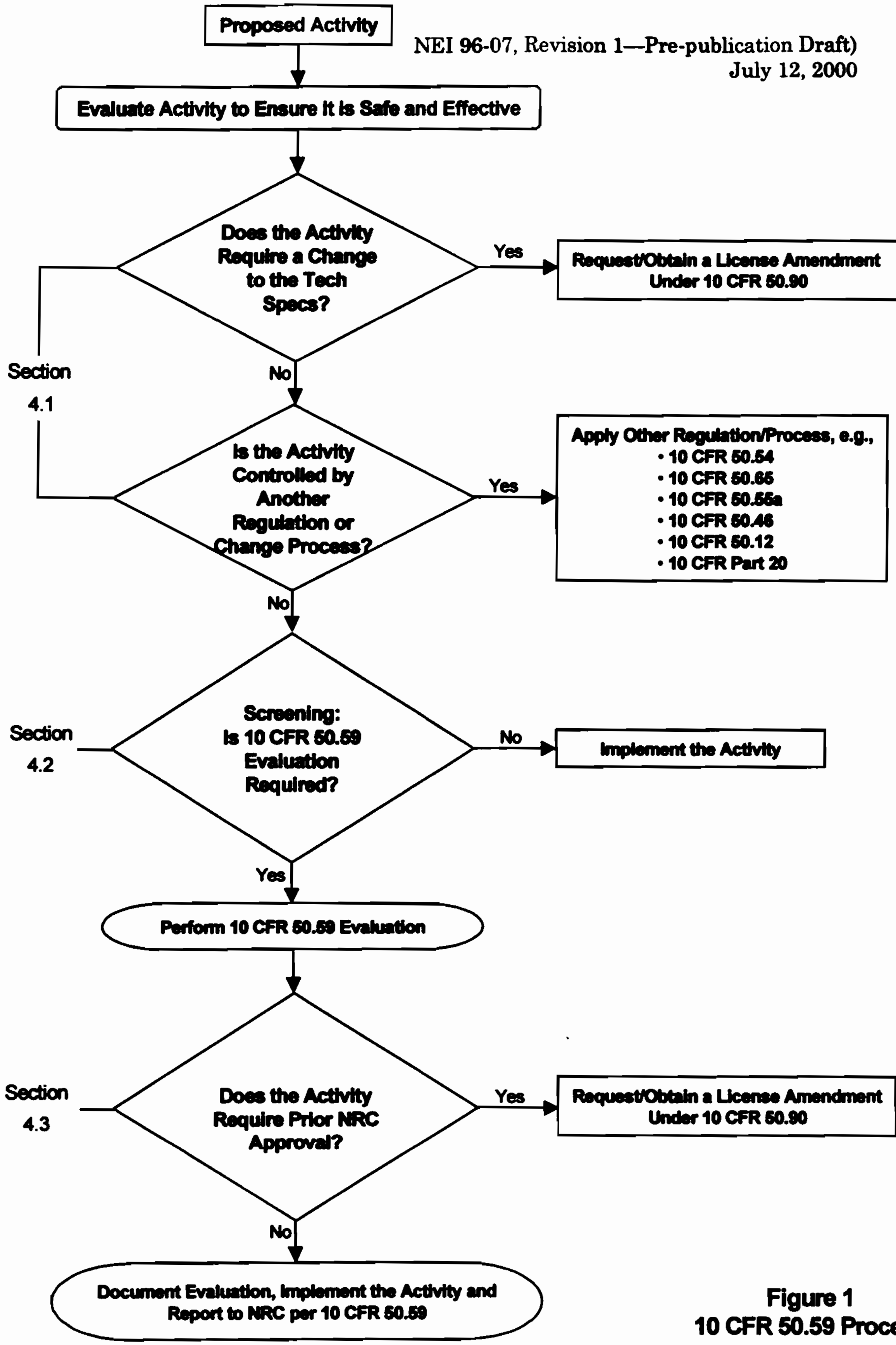

Figure 1
10 CFR 50.59 Process

1.4 APPLICABILITY TO 10 CFR 72.48

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 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. Consistent with this intent, the guidance herein on implementing 10 CFR 50.59 may be applied to support implementation of 10 CFR 72.48.

1.5 CONTENT OF THIS GUIDANCE DOCUMENT

The NRC has established requirements for nuclear plant 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 updated FSAR (UFSAR). 10 CFR 50.59 allows a licensee to make changes in the facility 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 otherwise require prior NRC approval. In order to perform 10 CFR 50.59 screenings and evaluations, an understanding of the design and licensing basis of the plant and of the specific requirements of the regulations is necessary. Individuals performing 10 CFR 50.59 screenings and evaluations should also understand the rule and concepts discussed in this guidance document.

In Section 2, the relationship between the design criteria established in 10 CFR 50, Appendix A, and 10 CFR 50.59 is discussed as background for applying the rule.

Section 3 presents definitions and discussion of key terms used in 10 CFR 50.59 and this guideline.

Section 4 discusses the application of the definitions and criteria presented in 10 CFR 50.59 to the process of changing the plant 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 50.59 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 dispositioning and documenting 10 CFR 50.59 evaluations and reporting to NRC.

Section 5 provides guidance on documenting 10 CFR 50.59 evaluations and reporting to NRC.

Appendix A provides the text of 10 CFR 50.59 as published in the *Federal Register* on October 4, 1999. Appendix B (currently under development) provides guidance and examples illustrating the application of this guidance to changes involving independent spent fuel storage installations and spent fuel storage cask designs, per 10 CFR 72.48.

2.0 DEFENSE IN DEPTH DESIGN PHILOSOPHY AND 10 CFR 50.59

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, protection of public health and safety is ensured through the design of the engineered protection of physical barriers to guard against the uncontrolled release of radioactivity. Other sources of radioactivity including radwaste systems are included. The defense-in-depth philosophy includes reliable design provisions to safely terminate accidents and provisions to mitigate the consequences of accidents. The three physical barriers that provide defense-in-depth are:

- Fuel Clad
- Reactor Coolant System Boundary
- Containment Boundary

These barriers perform a health and safety protection function. They are designed to reliably fulfill their operational function by meeting all criteria and standards applicable to mechanical components, pressure components, and civil structures. These barriers are protected extensively by inherent safety features and through the implementation of engineered safety features. 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 based on the criteria established in GDC 19 or the guidelines established in 10 CFR 100. Thus, the UFSAR analyses provide the final verification of the nuclear safety design phase by documenting plant performance in terms of public protection from uncontrolled releases of radiation. 10 CFR 50.59 addresses this aspect of design by requiring prior NRC approval of proposed activities which, although safe, require a technical specification 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 50.59, it is necessary to understand this perspective of maintaining the integrity of the physical barriers designed to contain radioactivity. 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 50.59, the term "consequences" means dose.

For many licensees, ANSI standards define categories of accidents or malfunctions. For each category a probability (frequency) and a corresponding acceptable consequence is given in terms of barrier loss and radioactivity release. Consequences resulting from accidents and malfunctions are analyzed and documented in the UFSAR and are evaluated against dose acceptance limits that vary depending on the event frequency.

The design effort and the operational controls necessary to ensure the required performance of the physical barriers during anticipated operational occurrences and postulated accidents are extensive. Because 10 CFR 50.59 provides a mechanism for determining if NRC approval is needed for activities affecting plant design and operation, it is helpful to review briefly the requirements and the objectives imposed by the CFR on plant construction and operation. The review will define more clearly the extent of applicability of 10 CFR 50.59.

Appendix A to 10 CFR Part 50 provides General Design Criteria for most nuclear power plants (for pre-Appendix A plants the criteria are in the UFSAR). Section II of Appendix A includes criteria for protection by multiple fission product barriers. The criteria establish requirements for inherent protection, instrumentation and control, reactor coolant pressure boundary and reactor coolant system design, containment design, control rooms, electric power systems, and related inspection and testing. All of these requirements concentrate on protecting fission product barriers either through inherent or mitigative means.

Section III of Appendix A establishes extensive requirements on reactor protection and reactivity control systems, the objectives again being the protection of fission product barriers. With similar intent, Sections IV, V and VI provide extensive design, inspection, testing, and operational requirements for the quality of the reactor coolant pressure boundary, and fluid systems in general, reactor containment, and fuel and radioactivity control. These requirements ensure inherent and engineered protection of the fission product barriers. Introductory statements of Appendix A address the need for consideration of a single failure criterion and redundancy, diversity and separation of mitigation and protection systems. Section I of Appendix A 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, limiting conditions for operations and limiting safety systems settings in order to prevent safety limits from being exceeded. The UFSAR presents 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 assume functioning of all the equipment (and under the conditions) specified by NRC regulations or requirements. Changes to plant design and operation and 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 50.59.

3.0 DEFINITIONS AND APPLICABILITY OF TERMS

The following definitions and terms are discussed in this section:

3.1 10 CFR 50.59 Evaluation

3.2 Accident Previously Evaluated in the FSAR (as updated)

3.3 Change

3.4 Departure from a Method of Evaluation Described in the FSAR (as updated)

3.5 Design Bases (Design Basis)

3.6 Facility as described in the FSAR (as updated)

3.7 Final Safety Analysis Report (as updated)

3.8 Input Parameters

3.9 Malfunction of an SSC Important to Safety

3.10 Methods of Evaluation

3.11 Procedures as described in the FSAR (as updated)

3.12 Safety Analyses

3.13 Screening

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

3.1 10 CFR 50.59 EVALUATION

Definition:

A 10 CFR 50.59 evaluation is the documented evaluation against the eight criteria in 10 CFR 50.59(c)(2) to determine if a proposed change, test or experiment requires prior NRC approval via license amendment under 10 CFR 50.90.

Discussion

It is important to establish common terminology for use relative to the 10 CFR 50.59 process. The definitions of *10 CFR 50.59 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 50.59(c)(2). Section 4.3 provides guidance for performing 10 CFR 50.59 evaluations. The screening process is discussed in Section 4.2.

The phrase "change made under 10 CFR 50.59" (or equivalent) refers to changes subject to the rule (see Section 4.1) that either screened out of the 10 CFR 50.59 process or did not require prior NRC approval based on the results of a 10 CFR 50.59 evaluation. Similarly, the phrases "10 CFR 50.59 applies [to an activity]" or "[an activity] is subject to 10 CFR 50.59" mean that screening, and if necessary, evaluation is required for the activity. The "10 CFR 50.59 process" includes screening, evaluation, documentation and reporting to NRC of activities subject to the rule.

3.2 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 UFSAR including accidents, such as those typically analyzed in Chapters 6 and 15 of the UFSAR, and transients and events the facility is required to withstand such as floods, fires, earthquakes, other external hazards, anticipated transients without scram (ATWS), and station blackout (SBO).

Discussion:

The term "accidents" refers to the anticipated (or abnormal) operational transients and postulated design basis accidents that are analyzed to demonstrate that the facility can be operated without undue risk to the health and safety of the public. For purposes of 10 CFR 50.59, the term "accidents" encompasses other events for which the plant is required to cope and which are described in the UFSAR (e.g., turbine missiles, fire, earthquakes and flooding). Note that, although fire is an event for which a plant is required to cope and is described in the UFSAR (by reference to the Fire Hazards Analysis for some licensees), changes to the fire protection program are, for most licensees governed by requirements other than 10 CFR 50.59, as discussed in Section 4.1.5.

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 50.71(e), e.g., ATWS and SBO.

3.3 CHANGE

Definition:

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 function, or (3) an evaluation that demonstrates that intended functions will be accomplished.

Discussion:

Additions and removals to the facility 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 facility or procedures.

The definitions of "change...," "facility..." (see Section 3.6), and "procedures..." (see Section 3.11) make clear that 10 CFR 50.59 applies to changes to underlying analytical bases for the facility design and operation as well as for changes to SSCs and procedures. Thus 10 CFR 50.59 should be applied to a change being made to an evaluation for demonstrating adequacy of the facility even if no physical change to the facility is involved. Further discussion of the terms in this definition is provided as follows:

<u>Design functions</u> 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 SSCs that are (1) required to meet regulations, license conditions, orders or technical specifications, or (2) credited in 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 safety-related SSCs or non-safety-related SSCs and include functions that, if not performed, would initiate a transient or accident that the plant is required to withstand.

As used above, "credited in the safety analyses" means that, if the SSC were not to perform its design 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

[1] Definition of design bases function from NEI 97-04, Appendix B (endorsed by DG-1093).

whose operation or malfunction could adversely affect the performance of design bases functions (for instance, control systems and physical arrangements). Thus, both safety-related and non-safety-related 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, 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 3.10). For example, a thermodynamic calculation that demonstrates the ECCS has sufficient heat removal capacity for responding to a postulated accident.

Temporary Changes

Temporary changes to the facility or procedures, such as jumpering terminals, lifting leads, placing temporary lead shielding on pipes and equipment, removal of barriers, and use of temporary blocks, bypasses, scaffolding and supports, are made to facilitate a range of plant activities and are subject to 10 CFR 50.59 as follows:

- 10 CFR 50.59 should be applied to temporary changes proposed as compensatory measures to address degraded or non-conforming conditions as discussed in Section 4.4.
- Other temporary changes to the facility or procedures that are not associated with maintenance are subject to 10 CFR 50.59 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.

Risk impacts of temporary changes associated with maintenance activities (i.e., temporary alterations) should be assessed and managed in accordance with 10 CFR 50.65(a)(4) and associated guidance, as discussed in Section 4.1.2. Applying 10 CFR 50.59 to such activities is not required provided that temporary alterations are not in effect longer than 90 days, and affected SSCs are restored to their normal, as-designed condition at the conclusion of the maintenance activity.

3.4 DEPARTURE FROM A METHOD OF EVALUATION DESCRIBED IN THE FSAR (AS UPDATED)

Definition:

Departure from a method of evaluation described in the FSAR (as updated) 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 50.59 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 3.10. Guidance for evaluating changes in methods of evaluation under criterion 10 CFR 50.59(c)(2)(viii) is provided in Section 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 50.59. 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 containment 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 50.59(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 containment 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 plant or procedures.

"Essentially the Same"

Licensees may change one or more elements 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 satisfies applicable terms and conditions for its use. Specific guidance for making this determination is provided in Section 4.3.8.2.

3.5 DESIGN BASES (DESIGN BASIS)

Definition:

(10 CFR 50.2) Design bases means that information which identifies the specific functions to be performed by a structure, system, or component of a facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. 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.

Discussion

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.

3.6 FACILITY AS DESCRIBED IN THE FSAR (AS UPDATED)

Definition:

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

- The structures, systems, and components (SSC) that are described in the final safety analysis report (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:

The scope of information that is the focus of 10 CFR 50.59 is the information presented in the original FSAR to satisfy the requirements of 10 CFR 50.34(b), as updated per the requirements of 10 CFR 50.71(e) and as supplemented pursuant to 10 CFR 54.21(d). The definition of "facility as described in the FSAR (as updated)" follows from the requirement of 10 CFR 50.34(b) that the FSAR (and by extension, the UFSAR) contain "a description and analysis of the SSCs of the facility, with emphasis upon performance requirements, the bases, with technical justification therefore, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished."

10 CFR 50.59 screening of facility changes is discussed in Section 4.2.1.1.

3.7 FINAL SAFETY ANALYSIS REPORT (AS UPDATED)

Definition:

Final Safety Analysis Report (as updated) means the Final Safety Analysis Report (or Final Hazards Summary Report) submitted in accordance with 10 CFR 50.34, as amended and supplemented, and as updated per the requirements of 10 CFR 50.71(e) or 10 CFR 50.71(f), as applicable.

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 50.59.

Per 10 CFR 50.59(c)(4), licensees are not required to apply 10 CFR 50.59 to UFSAR information that is subject to other specific change control regulations. For example, licensee Quality Assurance Programs, Emergency Plans and Security Plans are controlled by 10 CFR 50.54(a), (p) and (q), respectively.

Per 10 CFR 50.59(c)(3), the "FSAR (as updated)," for purposes of 10 CFR 50.59, also includes UFSAR update pages approved by the licensee for incorporation in the UFSAR since the last required update was submitted per 10 CFR 50.71(e). 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 50.59 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.

Guidance on the required content of UFSAR updates is provided in Regulatory Guide 1.181 and NEI 98-03, Revision 1, *Guidelines for Updating FSARs*, June 1999.

3.8 Input Parameters

Definition:

Input parameters are those values derived directly from the physical characteristics of SSC or processes in the plant, 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 3.10) are evaluated under criterion 10 CFR 50.59(c)(2)(viii), whereas changes to input parameters described in the FSAR are considered changes to the facility that would be evaluated under the other seven criteria of 10 CFR 50.59(c)(2), but not criterion (c)(2)(viii).

If a methodology permits the licensee to establish the value of an input parameter on the basis of plant-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 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 4.2.1.3.

Section 4.3.8 provides guidance and examples to describe the specific elements of evaluation methodology that would require evaluation under 10 CFR 50.59(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 50.59(c)(2).

3.9 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 (whether or not classified as safety-related in accordance with 10 CFR 50, Appendix B).

Discussion:

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

3.10 METHODS OF EVALUATION

Definition:

Methods of evaluation means the calculational framework used for evaluating behavior or response of the facility or an SSC.

Discussion:

Examples of methods of evaluation are presented below. Changes to such methods of evaluation require evaluation under 10 CFR 50.59(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 50.59 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	■ DNBR correlations
■ Means of data reduction	■ ASME III and Appendix G methods for evaluating reactor vessel embrittlement specimens
■ Physical constants or coefficients	■ Heat transfer coefficients
■ Mathematical models	■ Decay heat models
■ Specific limitations of a computer program	■ No voiding in PWR hot legs for non-LOCA analyses
■ Specified factors to account for uncertainty in measurements or data	■ 120% of 1971 decay heat model
■ Statistical treatment of results	■ 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 50.59(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 50.59(c)(2)(vii))

- Methods of evaluation used in UFSAR safety analyses, including containment, ECCS and accident analyses typically presented in

UFSAR Chapters 6 and 15, to demonstrate that consequences of accidents do not exceed 10 CFR 100 or 10 CFR 50, Appendix A, dose limits

- Methods of evaluation used in supporting UFSAR analyses that demonstrate intended design functions will be accomplished under design basis conditions that the plant is required to withstand, including natural phenomena, environmental conditions, dynamic effects, station blackout, and ATWS

3.11 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 structures, systems, and components are operated and controlled (including assumed operator actions and response times).

Discussion:

The scope of information that is the focus of 10 CFR 50.59 is the information presented in the original FSAR to satisfy the requirements of 10 CFR 50.34(b), as updated per the requirements of 10 CFR 50.71(e) and as supplemented pursuant to 10 CFR 54.21(d).

For purposes of 10 CFR 50.59, "procedures" are not limited to plant 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 50.59.

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 50.59. Sections 4.1.2 and 4.1.4 identify examples of procedures that are not subject to 10 CFR 50.59.

10 CFR 50.59 screening of procedure changes is discussed in Section 4.2.1.2.

3.12 SAFETY ANALYSES

Definition:

Safety analyses are analyses performed pursuant to NRC requirements 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) and 10 CFR 50.71(e) and include, but are not limited to, the accident analyses typically presented in Chapter 15 of the UFSAR.

Discussion:

Safety analyses are those analyses or evaluations that demonstrate that acceptance criteria for the facility's capability to withstand or respond to postulated events are met. Containment, ECCS, and accident analyses typically presented in Chapters 6 and 15 of the UFSAR clearly fall within the meaning of "safety analyses" as defined above. Also within the meaning of this definition for purposes of 50.59 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 facility is required to withstand such as turbine missiles, fires, floods, earthquakes, station blackout, and ATWS.

Note that, although fire is an event which a plant is required to withstand and for which it has been analyzed accordingly in the UFSAR (by reference to the Fire Hazards Analysis for some licensees), changes to the fire protection program and associated analyses are (for most licensees) governed by licensee requirements other than 10 CFR 50.59, as discussed in Section 4.1.5.

3.13 Screening

Definition:

Screening is the process for determining whether a proposed activity requires a 10 CFR 50.59 evaluation to be performed.

Discussion:

Screening is that part of the 10 CFR 50.59 process that determines whether a 10 CFR 50.59 evaluation is required prior to implementing a proposed activity.

The definitions of "change," "facility as described...," "procedures as described...," and "test or experiment not described..." constitute criteria for the 10 CFR 50.59 screening process. Activities that do not meet these criteria are said to "screen out" from further review under 10 CFR 50.59, i.e., may be implemented without a 10 CFR 50.59 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 50.59 evaluation.

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

3.14 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 structure, system, or component 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 50.59 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 facility in a situation that has not previously been evaluated (e.g., unanalyzed system alignments) or that could affect the capability of SSCs to perform their intended design functions (e.g., high flow rates, high

temperatures) are evaluated before they are conducted to determine if prior NRC approval is required.

Maintenance-related testing is assessed and managed under 10 CFR 50.65(a)(4), as discussed in Section 4.1.2. 10 CFR 50.59 screening of tests and experiments unrelated to maintenance is discussed in Section 4.2.2.

4 IMPLEMENTATION GUIDANCE

Licensees may determine applicability and screen activities to determine if 10 CFR 50.59 evaluations are required as described in Sections 4.1 and 4.2, or equivalent manner.

4.1 APPLICABILITY

As stated in Section (b) of 10 CFR 50.59, the rule 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 a certification of permanent cessation of operations required under 10 CFR 50.82(a)(1) or a reactor licensee whose license has been amended to allow possession but not operation of the facility.

4.1.1 Applicability to Licensee Activities

10 CFR 50.59 is applicable to tests or experiments not described in the UFSAR and to changes to the facility 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 50.59(c)(1)(i), proposed activities that require a change to the technical specifications must be made via the license amendment process, 10 CFR 50.90. Aspects of proposed activities that are not directly related to the required technical specification change are subject to 10 CFR 50.59.
- To reduce duplication of effort, 10 CFR 50.59(c)(4) specifically excludes from the scope of 10 CFR 50.59 changes to the facility or procedures that are controlled by other more specific requirements and criteria established by regulation. For example, 10 CFR 50.54 which was promulgated after 10 CFR 50.59, specifies criteria and reporting requirements for changing quality assurance, physical security and emergency plans.

In addition to 50.90 and 50.54(a), (p) & (q), the following include change control requirements that meet the intent of 50.59(c)(4) and may take precedence over 50.59 for control of specific changes:

- 10 CFR 50.65 (Maintenance Rule) See additional discussion in Section 4.1.2.
- 10 CFR Part 50, Appendix B, (Quality Assurance Criteria) See additional discussion in Section 4.1.4
- Standard FP license condition (if applicable) See additional discussion in Section 4.1.5
- 10 CFR 50.55a (Codes and Standards)
- 10 CFR 50.46, (ECCS Rule)
- 10 CFR 50.12, (Specific Exemptions)
- 10 CFR Part 20 (Standards for Radiation Protection)

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 50.59 is not required. UFSAR changes should be identified to the NRC as part of the required UFSAR update, per 10 CFR 50.71(e). However, there may be certain activities for which a licensee would need to apply both the requirements of 10 CFR 50.59 and that of another regulation. For example, a modification to a facility involves additional components and substantial piping reconfigurations as well as changes to protection system setpoints. The protection system setpoints are contained in the facility technical specifications. Thus, a license amendment to revise the technical specifications under 10 CFR 50.90 is required to implement the new system setpoints. 10 CFR 50.59 should be applied to the balance of the modification, including impacts on required operator actions.

4.1.2 Maintenance Activities

Maintenance activities are activities that restore SSCs to their as-designed condition, including activities that implement approved design changes. Maintenance activities are not subject to 10 CFR 50.59, but are subject to the provisions of 10 CFR 50.65(a)(4) as well as technical specifications.

Maintenance activities include troubleshooting, calibration, refurbishment, maintenance-related testing, identical replacements, housekeeping, and similar activities that do not permanently alter the design or design function of SSCs. Maintenance activities also include temporary alterations to the facility 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.

Licensees should ensure operability in accordance with the technical specifications and should assess and manage the risk impact of maintenance activities per 10 CFR 50.65(a)(4) and NEI 93-01, *Industry Guidelines for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.*[2]

In addition to assessments required by 10 CFR 50.65(a)(4), 10 CFR 50.59 should also be applied in the following cases:

- A temporary alteration in support of the maintenance will be in effect during at-power operations for more than 90 days. 10 CFR 50.59 should be applied to the temporary alteration when it is recognized that the temporary alteration will be in effect longer than 90 days. This would typically be known in advance, but may not be recognized until later in the event of an unforeseen delay in completing a maintenance activity. If the temporary alteration screens in and meets any of the 10 CFR 50.59 evaluation criteria, a license amendment request should be submitted to leave the temporary alteration in effect longer than 90 days.

- The plant is not restored to its original condition upon completion of the maintenance activity (e.g., if SSCs are removed, the design, function or operation is altered, or if temporary alteration in support of the maintenance is not removed). In this case, 10 CFR 50.59 would be applied to the permanent change to the plant.

Installation and post-modification testing of approved facility changes is indistinguishable, in terms of their risk impact on the plant, from maintenance activities that restore SSCs to their as-designed condition. As such, installation and testing of approved facility changes are maintenance activities that must be assessed and managed in accordance with 10 CFR 50.65(a)(4). This contrasts with historical practice whereby 10 CFR 50.59 reviews addressed the design, installation and post-modification testing of proposed facility changes. Going forward, 10 CFR 50.59 will address the effect, following implementation, of proposed facility changes to determine if prior NRC approval is required; the risk impact of actually implementing the change will be assessed and managed per 10 CFR 50.65(a)(4).

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[2] Regulatory Guide 1.182, issued June 1, 2000, endorses the industry guidance on 10 CFR 50.65(a)(4) provided in Section 11 of NEI 93-01.

If a temporary alteration necessary to install a facility change is expected to be in effect longer than 90 days at power, the required 50.59 review of the temporary alteration may be performed as part of the 50.59 review for the facility change.

10 CFR 50.59 does not apply to changes to procedures for performing maintenance activities because such procedures do not alter the design or design function of SSCs. Changes to procedures for performing maintenance are made in accordance with applicable 10 CFR 50, Appendix B, criteria and licensee procedures. As discussed above, implementation of specific maintenance activities according to approved procedures (including consideration of actual plant conditions and concurrently scheduled activities) is assessed and managed in accordance with 10 CFR 50.65(a)(4). If a change to maintenance procedure affects information in the UFSAR (e.g., a specific test or maintenance frequency), the affected information should be updated in accordance with 10 CFR 50.71(e).

10 CFR 50.59 should be applied to temporary changes proposed as compensatory measures for degraded or non-conforming conditions, as discussed in Section 4.4.

4.1.3 UFSAR Modifications

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.

Similarly, 10 CFR 50.59 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

4.1.4 Changes to Procedures Governing the Conduct of Operations

Even if described in the UFSAR, changes to managerial and administrative procedures governing the conduct of facility operations are controlled under 10 CFR 50, Appendix B, programs and are not subject to control under 10 CFR 50.59. These include, but are not limited to, procedures in the following areas:

- Operations and work process procedures such as control of equipment status (tag outs)
- Shift staffing and personnel qualifications
- Changes to position titles when no UFSAR-described organizational responsibilities or relationships are changed
- Control of plant procedures
- Training programs
- On-site/off-site safety review committees
- Plant modification process
- Calculation process

4.1.5 Changes to Approved Fire Protection Programs

Most nuclear power plant licenses contain a section on fire protection. Originally, these fire protection license conditions varied widely in scope and content. These variations created problems for licensees and for NRC inspectors in identifying the operative and enforceable fire protection requirements at each facility.

To resolve these problems, the NRC promulgated guidance in Generic Letter 86-10, "Implementation of Fire Protection Requirements," for licensees to:

- Incorporate the fire protection program and major commitments into the FSAR for the facility, and

- Amend the operating license to substitute a standard fire protection license condition for the previous license condition(s) regarding fire protection.

Under the standard fire protection license condition, licensees may

(1) Make changes to their approved FP programs without prior NRC approval provided that the changes would not adversely affect the ability to achieve and maintain safe shutdown in the event of a fire, and

(2) Alter specific features of the approved program provided such changes do not otherwise involve a change to the license or technical specifications, or require an exemption.

Adoption of the standard fire protection license condition provided a more consistent approach to evaluating changes to the facility, including those associated with the fire protection program. Originally, changes to the FP program under the FP license condition were also subject to 10 CFR 50.59; however, this created confusion as to which regulatory requirement governed FP program changes.

10 CFR 50.59(c)(4) provides that when applicable regulations establish more specific criteria for controlling certain changes, 10 CFR 50.59 does not also apply. Consistent with this intent, the standard fire protection license condition establishes specific criteria for control of fire protection changes and falls within the scope of 10 CFR 50.59(c)(4). Thus, applying 10 CFR 50.59 to fire protection program changes is not required.

Changes to the fire protection program should be evaluated for impacts on other design functions, and 10 CFR 50.59 should be applied to the non-fire protection related effects of the change, if any.

Consistent with current practice, determinations made under the standard fire protection license condition should be based on a written evaluation that remains available for NRC review for the life of the plant. These written evaluations should provide the basis for the licensee's conclusion that changes to the fire protection program do not adversely affect the ability to achieve and maintain safe shutdown in the event of a fire.

Under the standard license condition, approved fire protection program documents (e.g., fire hazards analysis) are incorporated in the UFSAR, and as such, changes to this information are subject to 10 CFR 50.71(e) reporting requirements.

4.2 SCREENING

Once it has been determined that 10 CFR 50.59 is applicable to a proposed activity, screening is performed to determine if the activity should be evaluated against the evaluation criteria of 10 CFR 50.59(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
- A method of performing or controlling the design function, or
- An evaluation for demonstrating that intended design functions will be accomplished

Sections 4.2.1 and 4.2.2 provide guidance and examples for determining whether an activity is (1) a change to the facility 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 50.59. Activities that are screened out from further evaluation under 10 CFR 50.59 should be documented as discussed in Section 4.2.3.

Activities that screen out may nonetheless require UFSAR information to be updated. Licensees should provide updated UFSAR information to the NRC in accordance with 10 CFR50.71(e).

Specific guidance for applying 10 CFR 50.59 to temporary changes proposed as compensatory measures for degraded or non-conforming conditions is provided in Section 4.4.

4.2.1 Is the Activity a Change to the Facility or Procedures as Described in the UFSAR?

To determine whether or not a proposed change 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 affected SSCs and the proposed change is essential. A given change 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 change:

- Does the activity decrease the reliability of an SSC design function, including either functions whose failure would initiate a transient/ accident or functions that are relied upon for mitigation?

- Does the activity reduce existing redundancy, diversity or defense-in-depth?

- Does the activity add or delete an automatic or manual design function of the SSC?

- Does the activity convert a feature that was automatic to manual or vice versa?

- Does the activity introduce an unwanted or previously unreviewed system or materials 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 or environmental qualification of the SSC?

- Does the activity adversely affect other units at a multiple unit site?

- 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 electrical distribution, structural integrity, environmental conditions or other UFSAR-described design functions?

Per the definition of "change" discussed in Section 3.3, 10 CFR 50.59 is applicable to additions as well as to changes to and removals from the facility or procedures. Additions should be screened for their effects on the existing facility and procedures as described in the UFSAR and, if required, a 10 CFR 50.59 evaluation should be performed. NEI 98-03 provides guidance for determining whether additions to the facility and procedures should be reflected in the UFSAR per 10 CFR 50.71(e).

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 50.59 evaluation is required when such changes adversely affect a UFSAR-described design function, as described below.

<u>Screening for Adverse Effects</u>

A 10 CFR 50.59 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 50.59 evaluation criteria.[3]

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 effect 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 with a different result would screen in. This reflects an overlap between the technical/engineering ("safety") review of the change and the 10 CFR 50.59 evaluation. 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 50.59 evaluation may 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 50.59 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 50.59 screenings, and (2) 10 CFR 50.59 evaluations, which focus on whether changes meet any of the eight criteria in 10 CFR 50.59(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. The

[3] Note that as discussed in Section 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.

revised safety analyses may be used in support of the required 10 CFR 50.59 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. For example, a change that improves the closure time of main control room isolation dampers reduces the calculated dose to operators, and UFSAR dose consequence analyses are to be updated as a result. In this case, the dose analyses are being revised to reflect the lower dose for the main control room, not to demonstrate that GDC limits continue to be met. A change that would adversely affect the design function of the dampers (post-accident isolation of the main control room) and increase the existing calculated dose to operators would be considered adverse and would screen in. In this case, the dose analyses must be re-run to ensure that GDC limits continue to be met. The revised analyses would be used in support of the 10 CFR 50.59 evaluation to determine if the increase exceeds the minimal standard and requires prior NRC approval.

To further illustrate the distinction between 10 CFR 50.59 screening and evaluation, consider the example of a change to a diesel generator-starting relay that delays the diesel start time from 10 seconds to 12 seconds. The UFSAR-described design function credited in the ECCS analyses is for the diesel to start within 12 seconds. This change would screen out because it is apparent that the change will not adversely affect the diesel generator design function credited in the ECCS analyses (ECCS analyses remain valid).

However, a change that would delay the diesel's start time to 13 seconds would screen in because the change adversely effects the design function (to start in 12 seconds). Such a change would screen in even if technical/engineering information supporting the change includes revised safety analyses that demonstrate all required safety functions supported by the diesel, e.g., core heat removal, containment isolation, containment cooling, etc., are satisfied and that applicable dose limits continue to be met. While this change may be acceptable with respect to performance of required safety functions and meeting design requirements, the analyses necessary to demonstrate acceptability are beyond the scope/intent of 10 CFR 50.59 screening reviews. Thus a 10 CFR 50.59 evaluation would be required. The revised safety analyses would be used in support of the 10 CFR 50.59 evaluation to determine whether any of the evaluation criteria are met such that prior NRC approval is required for the change.

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

4.2.1.1 Screening of Changes to the Facility as Described in the UFSAR

Screening to determine that a 10 CFR 50.59 evaluation is required is straightforward when a change affects an SSC 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 facility also contains many SSCs not described in the UFSAR. These can be components, subcomponents of larger components or even entire systems. Changes affecting SSCs that are not explicitly described in the UFSAR can have the potential to affect SSC design functions that are described and thus may require a 10 CFR 50.59 evaluation. In such cases, the approach for determining whether a change involves a change to the facility 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 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 50.59 evaluation is required.

Another important consideration is that a change to non safety-related SSCs not described in the UFSAR can indirectly affect the capability of SSCs to perform their UFSAR-described design function(s). For example, increasing the heat load on a non safety-related heat exchanger could compromise the cooling system's ability to cool safety-related equipment.

Seismic qualification, missile protection, flooding protection, fire protection, environmental qualification, high energy line break and masonry block walls are some of the areas where changes to non safety-related SSCs, whether or not described in the UFSAR, can affect the UFSAR-described design function of SSCs through indirect or secondary effects.

Equivalent replacement is a type of change to the facility that does not alter the design functions of SSCs. Licensee equivalence assessments, e.g., consideration of performance/operating characteristics and other factors, may thus form the basis for screening determinations that no 10 CFR 50.59 evaluation is required.

As discussed in Section 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 50.59. Changes that have positive or no effect on design functions may generally be screened out. The exception to this is that any change to a design bases limit for a fission product barrier—adverse or beneficial—must be screened in. This is because 10 CFR 50.59(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 50.59 screening process as applied to proposed facility changes:

- A licensee proposes to replace a relay in the overspeed trip circuit of an emergency diesel generator with a non-equivalent relay. The relay is not described in the UFSAR, but the design functions of the overspeed trip circuit and the emergency diesel generator are. Based on engineering/technical information supporting the change, the licensee determines if replacing the relay would adversely affect the design function of either the overspeed trip circuit or EDG. If the licensee concludes that the change would not adversely affect the UFSAR-described design function of the circuit or EDG, then this determination would form the basis for screening out the change, and no 10 CFR 50.59 evaluation would be required.

- A licensee proposes a non-equivalent change to the operator on one of the safety injection accumulator isolation valves. The UFSAR describes that these isolation valves are open with their circuit breakers open during normal operation. These are motor operated, safety related valves required for pressure boundary integrity and to remain open so that flow to the RCS will occur during a LOCA as RCS pressure drops below ~600 psi. They are remotely closed during a normal shutdown so as to not inject when not required. Technical/engineering work supporting this change ensures that the replacement operator is capable of performing the functions of the existing the operator and will not adversely affect the connected Class 1E bus or diesel. This change would screen out because (1) the valve operator does not perform, support or impact the UFSAR-described design function (to ensure pressure boundary integrity and remain open when required) that supports safety injection performance credited in the safety analyses, and (2) the change does not adversely affect other SSC design functions (e.g., of the Class 1E bus).

  If the proposed change was to configure the valve as a normally closed valve that automatically opens on loss of reactor coolant system pressure, 10 CFR 50.59 evaluation would be required because the change would adversely affect the reliability of the safety injection function as credited in the safety analyses.

- A licensee proposes to replace a globe valve with a ball valve in a vent/drain application to reduce the propensity of this valve to leak. The UFSAR-described design function of this valve is to maintain the integrity of the system boundary when closed. 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 (pressure boundary integrity) that supports system performance credited in the safety analyses—and evaluation/reporting under 10 CFR 50.59 is not required. The screening determination should be documented, and the UFSAR should be updated per 10 CFR 50.71(e) to reflect the change.

- The bolts for retaining a rupture disk are being replaced with bolts of a different material and fewer threads, but equivalent load capacity and strength, such that the rupture disk will still relieve at the same pressure as before the change. Because the replacement bolts are equivalent to the original bolts, the design function of the rupture disk (to relieve at a specified pressure) is unaffected, and this activity may be screened out as an equivalent change.

4.2.1.2 Screening of Changes to Procedures as Described in the UFSAR

Changes are "screened in" (i.e., require a 10 CFR 50.59 evaluation) if they adversely affect how SSC design functions are performed or controlled (including changes to UFSAR-described procedures, assumed operator actions and response times). 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 50.59 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), analog to digital upgrades, changing a valve from "locked closed" to "administratively closed," and similar changes.

The following examples illustrate the 10 CFR 50.59 screening process as applied to proposed changes affecting how SSC design functions are performed or controlled:

- Emergency Operating Procedures include operator actions and response times associated with response to design basis events, which are described in the UFSAR, but also address operator actions for severe accident scenarios that are outside the 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 operator actions during severe accidents.

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

- The UFSAR states that a particular flow path is isolated by a locked closed valve when not in use. A procedure change would remove the lock from this valve such that it becomes a normally closed valve. In this case, the design function is to remain closed, and the method of performing the design function has fundamentally changed from locked closed to administratively closed. Thus this change would screen in and require a 10 CFR 50.59 evaluation to be performed.

- Operations proposes to revise its procedures to change from 8-hour shifts to 12-hour shifts. This change results in mid-shift rounds being conducted every 6 hours as opposed to every 4 hours. The UFSAR describes high energy line breaks including mitigation criteria. Operator action to detect and terminate the line break is described in the UFSAR which specifically states that 4 hours is assumed for the pipe break to go undetected before it would be identified during operator mid-shift rounds. The change from 4 to 6 hour rounds is a change to a procedure as described in the UFSAR that adversely affects the timing of operator actions credited in the safety analyses for limiting the effects of high energy line breaks. Therefore, this change screens in, and a 10 CFR 50.59 evaluation is required.

- The UFSAR states that the Shift Supervisor will authorize all radioactive liquid releases. Assigning this function to another individual in accordance with 10 CFR Part 50, Appendix B, and licensee procedures would not require a 10 CFR 50.59 evaluation because the change does not involve performance or control of design functions credited in the safety analyses. The licensee would be required to reflect the change in the next required update of the UFSAR, per 10 CFR 50.71(e).

4.2.1.3 Screening Changes to UFSAR Methods of Evaluation

As discussed in Section 3.6, methods of evaluation included in the UFSAR to demonstrate that intended SSC design functions will be accomplished are considered part of the "facility as described in the UFSAR." Thus use of new or revised methods of evaluation (as defined in Section 3.10) is considered to be a change that is controlled by 10 CFR 50.59 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 50.59(c)(2)(viii) to determine if prior NRC approval is required (see Section 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 may be screened out.

Methods of evaluation that may be identified in references listed at the end of UFSAR sections or chapters are not subject to control under 10 CFR 50.59 unless the UFSAR states they were used for specific analyses within the scope of 10 CFR 50.59(c)(2)(viii).

Changes to methods of evaluation included in the UFSAR are considered adverse and require evaluation under 10 CFR 50.59 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 50.59(c)(2)(viii).

The following examples illustrate the screening of changes to methods of evaluation:

- The UFSAR identifies the name of the computer code used for performing 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 would be considered adverse and evaluated under 10 CFR 50.59(c)(2)(viii) to determine if prior NRC approval is required.

- The UFSAR describes the methods used for atmospheric heat transfer and containment pressure response calculations contained within the CONTEMPT computer code. The code is also used for developing long term temperature profiles (post-recirculation phase of LOCA) for environmental qualification through modeling of the residual heat removal system. Neither this application of the code nor the analysis method is discussed in the UFSAR. A revision to CONTEMPT to incorporate more dynamic modeling of the residual heat removal system transfer of heat to the ultimate heat sink would screen out because this application of the code is not described in the UFSAR as being used in the safety analyses or to establish design bases. Changes to CONTEMPT that affect the atmospheric heat transfer or containment pressure predictions may not screen out (because the UFSAR describes this application in the safety analyses), and may ~~would~~ require a 10 CFR 50.59 evaluation.

- The steamline break mass and energy release calculations were originally performed at a power level of 105% of the nominal power (plus uncertainties) in order to allow margin for a future power uprate. The utility later decided that it would not pursue the power uprate and wished to use the margin to address other equipment qualification issues. The steamline break mass and energy release calculations were re-analyzed, using the same methodology, at 100% power (plus uncertainties). This change would screen out as a methodology change because the proposed activity involved a change to an input parameter (% power) and not a methodology change. This change should be screened per Section 4.2.1.1 to determine if it constitutes a change to the facility as described in the UFSAR that requires evaluation under 10 CFR 50.59(c)(2)(i-vii).

- The LOCA mass and energy release calculations were originally performed at a power level of 105% of the nominal power, plus uncertainties. Some of the assumptions in the analysis were identified as non-conservative, but the NRC concluded in the associated SER that the overall analysis was conservative because of the use of the higher initial power. The utility later decided that it would not pursue the power up-rate and wished to use the margin to address other equipment qualification issues. The LOCA break mass and energy release calculations were re-analyzed, using the same methodology, at 100% power (plus uncertainties). This change would not screen out because the proposed activity involved a change to an input parameter that was integral to the NRC approval of the methodology.

- Due to fuel management changes, core physics parameters change for a particular reload cycle. The topical report and associated SER that describe how the core physics parameters are to be calculated explicitly allow use of either 2-D or 3-D modeling for the analysis. A change to add or remove discretionary conservatism via use of 3-D methods instead of 2-D methods or vice-versa would screen out because the change is within the terms and conditions of the SER.

4.2.2 Is the Activity a Test or Experiment Not Described in the UFSAR?

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

As discussed in Section 4.1.2, testing associated with maintenance is assessed and managed under 10 CFR 50.65(a)(4) and is not subject to 10 CFR 50.59.

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 facility.

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

- For BWRs, hydrogen injection into the reactor coolant system to minimize stress corrosion cracking.
- For BWRs, zinc injection into the reactor coolant system to reduce activation.
- For PWRs, ECCS flow tests that affect the ability to remove decay heat.
- Operation with fuel demonstration assemblies.

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

- Steam generator moisture carryover tests (provided such testing is described in the UFSAR)
- Balance-of-plant heat balance test
- Information gathering that is non-intrusive to the operation or function of the associated SSC

4.2.3 Screening Documentation

10 CFR 50.59 recordkeeping requirements apply to 10 CFR 50.59 evaluations performed for activities that screened in, not to screening records for activities that screened out. However, documentation should be maintained in accordance with plant procedures of screenings that conclude a proposed activity may be screened out (i.e., that a 10 CFR 50.59 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 50.59, and thus is not subject to 10 CFR 50.59 documentation and reporting requirements. Screening records need not be retained for activities for which a 10 CFR 50.59 evaluation was performed or for activities that were never implemented.

4.3 EVALUATION PROCESS

Once it has been determined that a given activity requires a 10 CFR 50.59 evaluation, the written evaluation must address the applicable criteria of 10 CFR 50.59(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, the licensee must apply for and obtain a license amendment per 10 CFR 50.90 prior to implementing the activity. The evaluation against each criterion should be appropriately documented as discussed in Section 4.5. Subsections 4.3.1 through 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 50.59 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. For example, a pump upgrade modification may also necessitate a change to a support system, such as cooling water.

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

The effects of a proposed activity being evaluated under 10 CFR 50.59 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.

Specific guidance for applying 10 CFR 50.59 to temporary changes proposed as compensatory measures for degraded or non-conforming conditions is provided in Section 4.4.

4.3.1 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.

For most licensees, accidents and transients have been divided into categories based upon a qualitative assessment of frequency. For example, ANSI standards define the following categories for plant conditions for most PWRs as follows:

- Normal Operations - Expected frequently or regularly in the course of power operation, refueling, maintenance or maneuvering.

- Incidents of Moderate Frequency - Any one incident expected per plant during a calendar year.

- Infrequent Incidents - Any one incident expected per plant during plant lifetime.

- Limiting Faults - Not expected to occur but could release significant amounts of radioactive material thus requiring protection by design.

ANSI standards for BWRs have slightly different but equivalent definitions.

During initial plant licensing, accidents were typically assessed in relative frequencies, as described above. Minimal increases in frequency resulting from subsequent licensee activities do not significantly change the licensing basis of the facility and do not impact the conclusions reached about acceptability of the facility design.

Since accident and transient 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 plant-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 50.59 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 plant-specific and generic studies. 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 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 A to Part 50) 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 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[4] or

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

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

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.

4.3.2 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 non-safety-related and safety-related SSCs. 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 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 (e.g., a motor change on a pump). 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 in terms of malfunctions and resulting event initiators or mitigation impacts, it also needs to consider the nature of the proposed activity. Thus, for instance, if failures were previously postulated on a train level because the trains were independent, a proposed activity that introduces a cross-tie or credible common mode failure (e.g., as a result of an analog to digital upgrade) should be evaluated further to see whether the likelihood of malfunction has been increased.

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 A to Part 50) are not compatible with a "no more than minimal increase" standard.

Below are examples where there is less than a minimal increase in the likelihood of occurrence of a malfunction of a SSC important to safety:

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. For example, adding protective devices to breakers or installing an additional drain line (with appropriate isolation capability) would not cause more than a minimal increase the likelihood of malfunction.

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.

3. The change involves a new or modified operator action that supports a design function credited in safety analyses provided:

   - The action (including required completion time) is reflected in plant procedures and operator 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 plant systems

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

The following changes 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:

1. 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 for pump casings that ensure pump functionality.

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

3. The change would substitute manual action for automatic action for performing design functions.

4. 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.[5]

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

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/transient frequency under criterion 10 CFR 50.59(c)(2)(i). For example, a change that increases the likelihood of malfunction of an emergency diesel generator by a factor of two may cause more than a 10% increase in the frequency of station blackout.

4.3.3 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 50.59, it must be recognized that the objective of the regulation is the protection of public health and safety. Therefore, an increase in consequences must involve an increase in radiological doses to the public or to control room operators. Changes in barrier performance or other outcomes of the proposed activity that do not result in increased radiological dose to the public or to control room operators are addressed under Section 4.3.7, concerning integrity of fission product barriers, or the other criteria of 10 CFR 50.59(c)(2).

NRC regulates compliance with the provisions of 10 CFR 50 and 10 CFR 100 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 inside or outside the control room to mitigate the consequences of reactor accidents. For changes affecting the dose to operators performing required actions outside the control room, an increase is considered more than minimal if the resultant "mission dose" exceeds applicable GDC 19 criteria. The guidance in the remainder of this section applies to evaluation of effects of changes on main control room and off-site doses.

The consequences covered include dose resulting from any accident evaluated in the UFSAR. The accidents include those typically covered in UFSAR Chapters 6 and 15 and other events for which the plant is designed to cope and are described in the UFSAR (e.g., turbine missiles and flooding). The consequences referred to in 10 CFR 50.59 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 establishes requirements for protection against radiation during normal operations, including dose criteria relative to radioactive waste handling and effluents. 10 CFR 50.59 accident dose consequence criteria and evaluation guidance are not applicable to proposed activities governed by 10 CFR Part 20 requirements.

The dose consequences referred to in 10 CFR 50.59 are those calculated by licensees—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.

General Design Criterion 19 of Appendix A to 10 CFR 50 requires radiation protection to permit access and occupancy of the control room under accident conditions without personnel receiving radiation exposure in excess of 5 rem whole body, for the duration of the accident. 10 CFR 100 establishes requirements for exclusion area and low population zones around the reactor so that an individual located at any point on its boundary immediately following onset of the postulated fission product release would not receive a total radiation dose to the whole body in excess of 25 rem or a total radiation dose of 300 rem to the thyroid for iodine exposure. In the Standard Review Plan (SRP), NUREG-0800, the NRC established acceptance guidelines for certain events that are considered of greater likelihood than the limiting accidents. For example, for a steam generator tube rupture, the SRP acceptance guideline is that the dose be less than or equal to a small fraction (i.e., 10 percent) of the 10 CFR 100 thyroid dose value, or 30 rem.

Therefore, for a given accident, calculated or bounding dose values for that accident would be identified in the UFSAR. These dose values should be within the GDC 19 or 10 CFR 100 limits, as applicable, as modified by SRP guidelines (e.g., small fraction of 10 CFR 100), as applicable. An increase in consequences from a proposed activity is defined to be no more than minimal if the increase (1) is less than or equal to 10 percent of the difference between the current calculated dose value and the regulatory guideline value (10 CFR 100 or GDC 19, as applicable), and (2) the increased dose does not exceed the current SRP guideline value for the particular design basis event. The current calculated dose values are those documented in the most up-to-date analyses of record. This approach establishes the current SRP guideline values as a basis for minimal increases for all facilities, not just those that were specifically licensed against those guidelines[6].

For some licensees the current calculated dose consequences may already be in excess of the SRP guidelines for some events. In such cases minimal increase is defined as less than or equal to 0.1 rem.

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

[6] For licensees who adopt the alternative source term, evaluations against this criterion should be in terms of total effective dose equivalent and the limits established by 10 CFR 50.67 (effective January 24, 2000).

change in the methodology for calculating the consequences. Changes in methodology would need to be separately considered under 10 CFR 50.59(c)(2)(viii) as discussed in Section 4.3.8.

Example 1

The calculated fuel handling accident (FHA) dose is 50 rem to the thyroid at the exclusion area boundary. As a result of a proposed change, the calculated FHA dose would increase to 70 rem. Ten percent of the difference between the calculated value and the regulatory limit is 25 rem [10% of (300 rem- 50 rem)]. The SRP acceptance guideline is 75 rem. Because the calculated increase is less than 25 rem and the total is less than the SRP guideline, the increase is not more than minimal, and the licensee may make the change without prior NRC review.

Example 2

The calculated dose consequence for a particular steam generator tube rupture accident is 25 rem thyroid at the exclusion area boundary. As a result of a proposed change, the calculated dose consequence would increase to 29 rem thyroid. The increase is not more than minimal, and the change can be made without prior NRC approval because the new calculated dose does not exceed the applicable SRP guideline of 30 rem thyroid, nor does the incremental change in consequences (4 rem) exceed 10 percent of the difference between the previous calculated value and the regulatory limit of 300 rem thyroid. Ten percent of the difference between the regulatory limit (300 rem) and the calculated value (25 rem) is 27.5 rem (10% of 275). Since 4 rem is less than 27.5, this change is a minimal increase permissible under 10 CFR 50.59.

Example 3

The calculated dose consequence of a fuel handling accident is 25 rem to the thyroid at the exclusion area boundary. Because of a proposed change, the calculated dose consequence would increase to 65 rem. The SRP guideline for this accident is 75 rem and is still met. The incremental increase in dose consequence (40 rem), however, exceeds 10 percent of the difference to the regulatory limit or 27.5 rem [10% of (300 rem - 25 rem)]. Therefore, the change results in more than a minimal increase in consequences and thus requires prior NRC approval.

Example 4

The calculated dose to the control room operators following a loss of coolant accident is 4 rem whole body. A change is proposed to the control room ventilation system such that the calculated dose would increase to 4.5 rem. The regulations dictate that the control room doses are to be controlled to less than 5 rem by General Design Criterion 19. Although the new calculated dose is less than the regulatory limits, the incremental increase in dose (0.5 rem) exceeds the value of 10 percent of the difference between the previously calculated value and the regulatory value or 0.1 rem [10% of (5 rem - 4 rem)]. This change would require prior NRC review because the increase in consequences exceeds the minimal standard.

Example 5

The existing safety analysis for a fuel handling accident predicts an offsite dose to the thyroid of 77 rem. The SRP guideline for this event is 75 rem. A proposed change would result in an increase in the calculated dose from 77 to 77.1 rem. In this case, the proposed change would cause a minimal increase in consequences because the new calculated value, even though greater than the SRP value, is within the guideline limit of 0.1 rem. Thus no prior NRC approval is required.

4.3.4 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 4.3.3.

4.3.5 Does the Activity Create a Possibility for an Accident of a Different Type?

The set of accidents that a facility must postulate for purposes of UFSAR safety analyses, including LOCA, other pipe ruptures, rod ejection, etc., are often referred to as "design basis accidents." The terms accidents and transients are often used in regulatory documents (e.g., in Chapter 15 of the Standard Review Plan), where transients are viewed as the more likely, low consequence events and accidents as less likely but more serious. In the context of probabilistic risk assessment, transients are typically viewed as initiating events, and accidents as the sequences that result from various combinations of plant and safety system response. This criterion deals with creating the possibility for accidents of similar frequency and significance to those already included in the licensing basis for the 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 pipe break in a small line may not be specifically evaluated in the UFSAR because it has been determined to be less limiting than a pipe break in a larger line in the same area. Therefore, if a proposed design change would introduce a small high energy line break into this area, postulated breaks in the smaller line 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 (e.g., random single failure, loss of offsite power, etc.). 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, such as multiple steam generator tube ruptures, 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 such as a multiple steam generator tube rupture 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 plant 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 examples illustrate this point:

- If a pump is replaced with a new design, there may be a new failure mechanism introduced that would cause a failure of the pump to run. But if this effect (failure of the pump to run) was previously evaluated and bounded, then a malfunction with a different result has not been created.

- If a feedwater control system is being upgraded from an analog to a digital system, new components may be added which could fail in ways other than the components in the original design. Provided the end result of the component or subsystem failure is the same as, or is bounded by, the results of malfunctions currently described in the UFSAR (i.e., failure to maximum demand, failure to minimum demand, failure as-is, etc.), then this upgrade would not create a "malfunction with a different result."

Certain malfunctions are not explicitly described in the UFSAR because their effects are bounded by other malfunctions that are described. For example, failure of a lube oil pump to supply oil to a component may not be explicitly described because a failure of the supplied component to operate was described.

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. This evaluation should be performed consistent with any failure modes and effects analysis (FMEA) described in the UFSAR, recognizing that certain proposed activities may require a new FMEA to be performed. Attention must be given to whether the malfunction was evaluated in the accident analyses at the component level or the overall system level. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and resulting event initiators or mitigation impacts, it also needs to consider the nature of the proposed activity. Thus, for instance, if failures were previously postulated on a train level because the trains were independent, a proposed activity that introduces a cross-tie or credible common mode failure (e.g., as a result of an analog to digital upgrade) should be evaluated further to see whether new outcomes have been 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. An example that might create a malfunction with a different result could be the addition of a normally open vent line in the discharge of an emergency core cooling system pump. The different result of a malfunction could be potential voiding in the system causing it not to operate properly.

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

10 CFR 50.59 evaluation under criterion (c)(2)(vii) focuses on the fission product barriers—fuel cladding, reactor coolant system boundary, and containment—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 50.2. 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, auxiliary feedwater design flow is a subordinate parameter for purposes of this evaluation, not a design bases parameter/limit. The acceptability of a reduction in AFW design flow would be determined based on its effect on design bases limits for the RCS (e.g., RCS 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 facility'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 50.34(b), 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 50.59 applicability in Section 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	DNBR/MCPR	Value corresponding to the 95/95 DNB criterion for a given DNB correlation
	Fuel temperature	Centerline fuel melting temperature
	Linear heat rate	Peak linear heat rate (typ. in kW/ft) established to ensure clad integrity
	Fuel enthalpy	Cal/gm associated with dispersion
	Clad strain	Internal pressure associated with clad lift-off
	Fuel Burnup	Limit (typ. in MWd/ton) established to ensure clad integrity
	Clad temperature *	2200 degrees F
	Clad Oxidation *	17% local and 1 % overall
RCS Boundary	Pressure	Designated limit in safety analysis for specific accident
	Stresses *	ASME Code compliance for normal, upset, faulted, etc., as appropriate for accident
	Heat-up/Cool-down*	Applicable ASME Code stress limits
Containment	Pressure	Containment design pressure

* These parameters are commonly controlled by 10 CFR 50.55a, 10 CFR 50.46 and/or a specific Technical Specification and therefore would not be subject to evaluation under this criterion.

The list above may vary slightly for a given facility and/or fuel vendor and may include other parameters for specific accidents. For example,

- PWR licensees may utilize 100% pressurizer level as a limiting parameter to ensure RCS integrity for some accident sequences.
- A peak containment temperature may be established in the UFSAR as an independent limit for ensuring the integrity of the containment.

If a given facility has these 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 can evaluate proposed activities against this criterion are as follows. The licensee may identify all design bases parameters for fission product barriers and include them explicitly in the procedure for performing 10 CFR 50.59 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.

<u>Exceeded or altered</u>

A specific proposed activity requires a license 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 facility'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. Extending the maximum fuel burn-up limits until the fuel rod internal gas pressure exceeds the design basis limit is a direct effect that would require a license amendment. As discussed earlier, indirect effects provide for another parameter or effect to cascade from the proposed activity to the design basis limit. For example, reducing the design flow of auxiliary feedwater pumps following a loss of main feedwater could reduce the heat transferred from the RCS to the steam generators. That effect could increase the RCS temperature, which would raise RCS pressure and pressurizer level. The 10 CFR 50.59(c)(2)(vii) evaluation of this change would focus on whether the design basis limit associated with RCS pressure for that accident sequence 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 changing the DNBR value from the value corresponding to the 95/95 criterion for a given DNB correlation, perhaps as a result of a new fuel design being implemented. (A new correlation or a new value for the "95/95 DNB criterion" with the same fuel type would be evaluated under criterion (c)(2)(viii) of the rule.) Another example is redesigning portions of the RCS boundary to 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 these limits. In contrast with these examples, altering AFW design flow, or other subordinate parameter/limit, is not subject to the "may not be altered" criterion because AFW design flow is not a design bases limit for fission product barrier integrity.

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 50.59(c)(2)(vii) evaluation is required. Similarly, most parameters that require evaluation under this criterion have calculations or analyses supporting the facility's design. If an engineering evaluation demonstrates that the analysis presented in the UFSAR remains bounding, then no 10 CFR 50.59(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

It is proposed to delay the automatic start of the stand-by condensate booster pump to eliminate spurious automatic starts. The proposed change is of sufficient magnitude such that it "screens in" as affecting a UFSAR-described design function.

<u>Identification of design basis limits</u>

The direct effects of a reduction in condensate flow would be reviewed to identify potentially affected design basis parameters. In addition, the indirect effect on feedwater flow and feedwater pump NPSH of a possible transient reduction in condensate flow/pressure would be considered. Likewise, consideration of indirect effects would be extended to the reactor or steam generator (BWR or PWR, as applicable). The review concludes that no design basis limits are either directly or indirectly affected.

The change in the frequency of a reactor trip as a result of normal condensate system malfunctions would be evaluated under other 10 CFR 50.59 criteria.

Exceeded or altered

Since no design basis limits were identified, this element of the evaluation is not applicable.

Example 2

The heat transfer capability of an RHR heat exchanger tube bundle has degraded, and it is proposed to accept the condition "as-is."

Identification of design basis limits

The effects of the reduced heat transfer capability would be reviewed. The direct effect would include the increased temperature of the suppression pool or containment sump [BWR or PWR, as applicable]. The indirect effects would include increasing the peak containment post-accident pressure and increased enthalpy of ECCS flow. The increased ECCS enthalpy would also affect peak clad temperature (PCT). Thus, the proposed activity affects two design basis limits: containment pressure and PCT. In this example, the design basis limits would most likely serve as the acceptance criteria for the two parameters in the LOCA analysis described in the UFSAR. (Most licensees use containment design pressure and 2200 degrees F for those values.)

Exceeded or altered

Any increase in peak containment post-accident pressure would be compared to the design basis limit, in this case, containment design pressure. If the revised peak post-accident containment pressure exceeded the design basis limit, then a license amendment would be required.

On the other hand, PCT is governed by a more specific regulation, 10 CFR 50.46. Therefore, the evaluation under this criterion would not address the impact on this parameter. Rather, any changes or corrections to an acceptable evaluation model or application of such a model that affects the PCT calculation would be evaluated per the requirements of 10 CFR 50.46(3)(ii).

In this example, the design basis limit for containment pressure is not being altered. Therefore, this element of the review is not applicable.

Example 3

Recently identified corrosion inside the primary containment has prompted a re-evaluation of the existing containment design pressure of 55 psig. This re-evaluation has concluded that a design pressure of 48 psig is the maximum supportable. As the final resolution to the degraded containment condition, the licensee proposes to reduce the containment design pressure as reflected in UFSAR safety analyses from 55 to 48 psig.

<u>Identification of Design Basis Limit</u>

The affected parameter is post accident peak containment pressure. This parameter directly affects the containment barrier. Its design basis limit from the UFSAR is the existing containment design pressure of 55 psig.

<u>Exceeded or altered</u>

The design basis limit itself has been "altered" and thus a license amendment 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 facility's design.

4.3.8 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 nuclear power facility, including description on how regulatory requirements for design are met and how the facility responds to various design basis accidents and events. Analytical methods are a fundamental part of demonstrating how the design meets regulatory requirements and why the facility'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 facility 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 50.59 provides a process for determining if prior NRC approval is required before making changes to the facility as described in the UFSAR, changes to the methodologies described in the UFSAR also fall under the provisions of the 10 CFR 50.59 process, specifically criterion (c)(2)(viii). In general, licensees can make changes to elements of a methodology without first obtaining a license amendment if the results are essentially the same as, or more conservative than, previous results. Similarly, licensees can also use different methods without first obtaining a license 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 50.59 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 50.59 evaluation should reflect that criteria 10 CFR 50.59(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 4.2.1.3.

Next, the licensee 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 not 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 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 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 another methodology previously accepted by NRC through issuance of an SER.

Subsection 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 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 4.3.8.3.

4.3.8.1 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 50.59 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 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 50.59. 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 containment 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 containment 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 facility or procedures.

<u>"Essentially the Same"</u>

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 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 plant conditions to ensure that the results are comparable. 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.

4.3.8.2 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 50.59 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 has typically followed one of two paths. Most reactor or fuel vendors and several utilities have prepared and obtained 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 approved the use of the methodologies for a given class of power plants. In some cases, the NRC has accorded "generic" approval of analysis methodologies. Terms, conditions and limitations relating to the application of the methodologies are usually 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 has typically been part of a plant's licensing basis and limited to a given plant 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 is usually documented in the original license application or license 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 are identified below that may be applicable to determining whether new methods are technically appropriate for the intended application. The licensee should address these and similar considerations, as applicable, and document in the 10 CFR 50.59 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 should consult various sources, as appropriate. These include SERs, topical reports, licensee correspondence with the NRC, and licensee 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. Through Generic Letter 83-11, Supplement 1,[7] the NRC has established a method by which utilities can demonstrate they are generally qualified to perform safety analyses. Utilities 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. Licensees that have not satisfied the guidelines of Generic Letter 83-11, Supplement 1, may, of course, continue to seek plant-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 4.3.8.1.

<u>Considerations for Determining if New Methods are Technically Appropriate for the Intended Application</u>

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 facility's licensing basis (e.g., NUREG-0800 or other plant-specific commitments)? Will the methodology supersede a methodology addressed by other regulations such as 10 CFR 50.46, 10 CFR 50.55a or the plant Technical Specifications (Core Operating Limits Report or Pressure/Temperature Limits Report)? Is the methodology consistent with relevant industry standards?

  If application of the new methodology requires exemptions from regulations or plant-specific commitments, exceptions to relevant industry standards and guidelines, or is otherwise inconsistent with a facility's licensing basis, then prior NRC approval may be required. The applicable change process must be followed to make the plant'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 plant-specific model been adequately qualified through benchmark comparisons against test data, plant data, or approved engineering analyses? Is the application consistent with the capabilities and limitations of the

[7] Generic Letter 83-11, Supplement 1, is titled, "Licensee Qualification for Performing Safety Analyses."

computer code? Has industry experience with the computer code been appropriately considered?

The computer code installation and plant-specific model qualification is not directly transferable from one organization to another. The installation and qualification should be in accordance with the licensee's Quality Assurance program.

- Is the facility for which the methodology has been approved designed and operated in the same manner as the facility to which the methodology is to be applied? Is the relevant equipment the same? Does the equipment have the same pedigree (e.g., Class 1E, Seismic Category I, etc.)? Are the relevant failure modes and effects analyses the same? If the plant 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 plant design?
  - Can analyses be made while maintaining compliance with both the intent and literal definition of the methodology?

- Differences in the plant configurations and licensing bases could invalidate the application of a particular methodology. For example, the licensing basis of older vintage plants may not include an analysis of the feedwater line break event that is required in later vintage plants. Some plants may be required to postulate a loss of offsite power or a maximum break size for certain events; other may have obtained exemptions to these requirements from the NRC. Some plants may have pressurizer power-operated relief valves that are qualified for water relief; other plants do not. Plant specific failure modes and effects analyses may reveal new potential single failure scenarios that can not be adequately assessed with the original methodology. The existence of these differences does not preclude application of a new methodology to a facility; however, differences must be identified, understood and documented. Slight modifications to the NRC approved methodology to address plant-specific features are acceptable provided the analysis results obtained are conservative or essentially the same with respect to the unmodified methodology.

4.3.8.3 EXAMPLES

The following examples illustrate the implementation of this criterion:

Example 1 - The UFSAR states that a damping value of 0.5 percent is used in the seismic analysis of safety-related piping. The licensee wishes to change this value to 2 percent to reanalyze the seismic loads for the piping. Using a higher damping value to represent the response of the piping to the acceleration from the postulated earthquake in the analysis would result in lower calculated stresses because the increased damping reduces the loads. Since this analysis was used in establishing the seismic design bases for the piping, and since this is a change to an element of the method that is not conservative and is not essentially the same, this change would require prior NRC approval under this criterion.

On the other hand, had NRC approved an alternate method of seismic analysis that allowed 2 percent damping provided certain other assumptions were made, and the licensee used the complete set of assumptions to perform its analysis, then the 2 percent damping under these circumstances would not be a departure because this method of evaluation is considered "approved by the NRC for the intended application."

Example 2 - A facility has a design basis containment pressure limit of 50 psig. The current worst-case design basis accident calculation results in a peak pressure of 45 psig within two minutes. The licensee revises the method of evaluation, and the recalculated result is 40 psig. This change would require prior NRC approval because the result of the recalculation is not conservative. If the licensee used a different method that was approved by the NRC and met all the terms and conditions of the method, a recalculated result of 40 psig would not require prior NRC approval.

Example 3 - A licensee revises the seismic analysis described in the UFSAR to include an inelastic analysis procedure. This revised method is used to demonstrate that cable trays have greater capacity than previously calculated. This change would require prior NRC approval as it would not produce results that are essentially the same.

Example 4 - Licensee X has received NRC approval for the use of a method of evaluation at Facility A for performing steamline break mass and energy release calculations for environmental qualification evaluations. The terms and conditions for the use of the method are detailed in the NRC SER. The

SER also describes limitations associated with the method. Licensee Y wants to apply the method at its Facility B. Licensee Y has satisfied the guidelines of GL 83-11, Supplement 1. After reviewing the method, approved application, SER and related documentation, to verify that applicable terms, conditions and limitations are met and to ensure the method is applicable to their type of plant, Licensee Y conducts a 10 CFR 50.59 evaluation. Licensee Y concludes that the change is not a departure from a method of evaluation because it has determined the method is appropriate for the intended application, the terms and conditions for its use as specified in the SER have been satisfied, and the method has been approved by the NRC.

<u>Example 5</u> - The NRC has approved the use of computer code and the associated analysis of a steamline break for use in the evaluation of component stresses. A licensee uses the same computer code and analysis methodology to replace their evaluation of the containment temperature response. This change would require prior NRC approval unless the methodology had been previously approved for evaluating containment temperature response.

4.4 APPLYING 10 CFR 50.59 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 50.59 must be applied, and the focus of a 10 CFR 50.59 evaluation if one is required, depends on the corrective action plan_chosen by the licensee, as discussed below:

- If the licensee intends to restore the SSC back to its as-designed condition then this corrective action should be performed in accordance with 10 CFR 50, Appendix B (i.e., in a timely manner commensurate with safety). This activity is not subject to 10 CFR 50.59.

- If an interim compensatory action is taken to address the condition and involves a temporary procedure or facility change, 10 CFR 50.59 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 facility or procedures described in the UFSAR. In considering whether a temporary change impacts other aspects of the facility, a licensee 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 corrective action is either to accept the condition "as-is" resulting in something different than its as-designed condition, or to change the facility or procedures, 10 CFR 50.59 should be applied to the corrective action, unless another regulation applies, e.g., 10 CFR 50.55a. In these cases, the final corrective action becomes the proposed change that would be subject to 10 CFR 50.59.

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 plant. The licensee may make mode changes, restart from outages, etc., provided that necessary SSCs are operable and the degraded condition is not in conflict with the technical specifications or the license.

The following example illustrates the process for implementing a temporary change as a compensatory action to address a degraded/non-conforming condition:

A level transmitter for one Reactor Coolant Pump (RCP) lower oil reservoir failed while at power. The transmitter provides an alarm function, but not an automatic protective action function. The transmitter and associated alarm are described in the UFSAR, as protective features for the RCPs, but no technical specification applies. Loss of the transmitter does not result in the loss of operability for any technical specification equipment. The transmitter fails in a direction resulting in a continuous alarm in the control room. The alarm circuitry provides a common alarm for both the upper and lower oil reservoir circuits, so transmitter failure causes a hanging alarm and a masking of proper operation of the remaining functional transmitter. Precautionary measures are taken to monitor lower reservoir oil level as outlined in the alarm manual using available alternate means. An interim compensatory action is proposed to lift the leads (temporary change) from the failed transmitter to restore the alarm function for the remaining functioning transmitter.

Lifting the leads is a compensatory action (temporary change) which is subject to 10 CFR 50.59. The 10 CFR 50.59 screening would be applied to the temporary change itself (lifted leads) not the degraded condition (failed transmitter), to determine its impact on other aspects of the facility described in the UFSAR. If screening determines that no other UFSAR-described SSCs would be affected by this compensatory action, the temporary change would screen out, i.e., not require a 10 CFR 50.59 evaluation.

4.5 DISPOSITION OF 10 CFR 50.59 EVALUATIONS

There are two possible conclusions to a 10 CFR 50.59 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 50.90 prior to implementation. 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 may design, plan, install, and test a modification prior to receiving the license amendment to the extent that these preliminary activities do not themselves require prior NRC approval under 10 CFR 50.59.

For example, a modification to a facility involved the replacement of a train of a safety system with one including diverse primary components (diesel-driven pump vice a motor-driven pump). The installation of the replacement train was largely in a new, separate structure. Ultimately the modification would require NRC approval because of impacts on the facility technical specifications as well as due to differences in reliability of the replacement pump in some situations. There was insufficient time to seek and gain NRC approval prior to construction. The facility prepared a 10 CFR 50.59 screening to support construction of the stand-alone facility through preliminary testing. The limited interfaces with the existing facility were assessed and determined to not affect the facility as described in the UFSAR. Upon receipt of the license amendment the final tie-in, testing and operation were fully authorized. 10 CFR 50.59 should be applied to any aspects of the activity not adequately addressed in the license amendment request and/or associated Safety Evaluation Report.

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 the it may proceed without prior NRC approval.

(3) Apply for and obtain a license amendment under 10 CFR 50.90 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 plant safety at the expense of a small adverse impact in a specific area. It is the responsibility of the utility to assure 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.

5.0 DOCUMENTATION AND REPORTING

10 CFR 50.59(d) requires the following documentation and recordkeeping:

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.

(1) 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.

(2) 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.

The documentation and reporting requirements of 10 CFR 50.59(d) apply to activities that require evaluation against the eight criteria of 10 CFR 50.59(c)(2) and are determined not to require prior NRC approval. That is, the phrase in 10 CFR 50.59(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 facility as described in the UFSAR), but not to those activities or changes that were screened out. Similarly, documentation and reporting under 10 CFR 50.59 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 50.59 Evaluations</u>

In performing a 10 CFR 50.59 evaluation of a proposed activity, the evaluator must address the eight criteria in 10 CFR 50.59(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 50.59, 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 50.59 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 50.59 evaluation is completeness, the items considered by the evaluator must be clearly stated.

Each 10 CFR 50.59 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 identified in this guidance.

When preparing 10 CFR 50.59 evaluations, licensees may combine responses to individual criteria or reference other portions of the evaluation.

As discussed in Section 4.2.3, licensees may elect to use screening criteria to limit the number of activities for which written 10 CFR 50.59 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 50.59, and thus is not subject to the recordkeeping requirements of the rule.

Reporting to NRC

A summary of 10 CFR 50.59 evaluations for activities implemented under 10 CFR 50.59 must be provided to NRC. Activities that were screened out, canceled or implemented via license amendment need not be included in this report. The 10 CFR 50.59 reporting requirement (every 24 months) is identical to that for UFSAR updates such that licensees may provide these reports to NRC on the same schedule.

APPENDIX A
TEXT OF 10 CFR 50.59

§ 50.59 Changes, tests, and experiments.

(a) Definitions for the purposes of this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) A change to the technical specifications incorporated in the license is not required, and
(ii) The change, test, or experiment does not meet any of the criteria in paragraph (c)(2) of this section.

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

(i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the final safety analysis report (as updated);
(ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the final safety analysis report (as updated);
(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the final safety analysis report (as updated);
(iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the final safety analysis report (as updated);
(v) Create a possibility for an accident of a different type than any previously evaluated in the final safety analysis report (as updated);
(vi) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the final safety analysis report (as updated);
(vii)Result in a design basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered; or
(viii) Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses

(3) In implementing this paragraph, the FSAR (as updated) is considered to include FSAR changes resulting from evaluations performed pursuant to this

section and analyses performed pursuant to § 50.90 since submittal of the last update of the final safety analysis report pursuant to § 50.71 of this part.

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

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

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

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

Appendix B

Appendix B is being developed separately to provide guidance and examples for applying 10 CFR 72.48 to changes involving independent spent fuel storage installations and spent fuel storage cask designs that is analogous to that for 10 CFR 50.59. This appendix will be the subject of a separate NRC regulatory guide.

10 CFR 50.59
CHANGES, TESTS AND EXPERIMENTS

A. PURPOSE

The purpose of this guidance is to clarify the specific 10 CFR 50.59 language relating to the type of proposed changes, tests and experiments (CTE) that require a record of the evaluation specified in Section 50.59(d)(1). The guidance also clarifies the specific review criteria which must be used to identify whether a proposed change, test or experiment requires prior NRC approval. This Part supersedes previous Part 9900 guidance on 10 CFR 50.59.

B. BACKGROUND

This revision to this CFR Discussion is a result of a rulemaking that revised Section 50.59 in its entirety. The rulemaking was conducted in order to clarify requirements and to provide some limited flexibility beyond that provided by the previous version of the rule for licensee changes without prior NRC approval. The rulemaking was issued in final form on October 4, 1999. Licensees are required to implement the revised requirements 90 days following publication of final regulatory guidance.

Most licensees use implementation guidance that is based upon an industry guidance document NEI 96-07 (Revision 1, dated July 12, 2000). The NRC has endorsed this document in Regulatory Guide RG-1.18x.

C. DISCUSSION

10 CFR 50.59 is composed of several parts:

a. Paragraph (a) provides definitions for several of the terms used in the rule.

b. Paragraph (b) summarizes applicability of the rule, specifically production and utilization facilities licensed to operate (including power reactors and nonpower reactors), and power reactors and nonpower reactors whose licenses no longer permit operation.

c. Paragraph (c)(1) is permissive in that it allows a licensee to make changes to the facility and its operation as described in the final safety analysis report (as updated) without prior NRC approval, provided a change in technical specifications (TS) incorporated into the license is not involved, and the change does not satisfy any of the criteria for prior NRC approval specified in Paragraph (c)(2). If a change to the TS is required, or if any of the criteria in paragraph (c)(2) are met, the licensee must apply for and obtain a license amendment in

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accordance with Section 50.90 prior to implementing the change, test or experiment.

d. Paragraph (c)(2) defines the criteria for prior NRC approval.

e. Paragraph (c)(3) states that for purposes of implementing section 50.59, the FSAR (as updated) also includes those FSAR changes resulting from facility or procedure changes made pursuant to sections 50.59 or 50.90 since the last FSAR update was submitted to NRC. Thus, it is not sufficient only to consider the updated FSAR as last submitted to NRC. The licensee must have some means to ensure that subsequent changes did not make the FSAR as last submitted inaccurate such that an evaluation based on that information may be inadequate.

f. Paragraph (c)(4) states that a section 50.59 evaluation is not required for changes to the facility or the procedures where other regulations specify requirements for such changes. The intent is to remove any confusion that a duplicative review is required for changes to the facility or procedure that may be described in the FSAR (as updated), but which are also subject to other change control requirements.

g. Paragraphs (d)(1) and (d)(3) require that the licensee maintain records of changes, tests and experiments made under the authority of Paragraph (c). These records must contain a written evaluation that provides the basis for the determination that prior NRC approval was not required.

h Paragraph (d)(2) requires that a report be submitted at least once every 24 months of such changes, tests and experiments. The report shall contain a brief description of the change and a summary of the evaluation. Licensees may submit reports more frequently, but cannot exceed 24 months between submittals. Summary reports may be submitted separately, or along with the FSAR update submission.

It should be noted that the evaluation required by 10 CFR 50.59 is only one of the several evaluations and reviews required by the NRC. Most Technical Specifications require that onsite review groups review proposed procedures and modifications or changes to plant equipment or components affecting safety. These review requirements are applicable whether or not the equipment or component is described in the final SAR. Also note that preparation of an adequate Section 50.59 evaluation often requires looking at licensing and design information not included in the FSAR. Important sources of such information are NRC safety evaluations, docketed correspondence, and records of safety and transient analyses.

D. DETAILED GUIDANCE

1. <u>Section 50.59 applicability determination guidance.</u>

All CTEs should be reviewed for Section 50.59 applicability. In the regulatory guidance and in this inspection guidance, this evaluation is referred to as the "Section 50.59 applicability determination." Changes that may be determined to be not applicable to further evaluation under section 50.59 include changes to procedures involved with the quality assurance plan that may be described in the FSAR, but where section 50.54(a) establishes criteria and reporting requirements for such changes. Other examples are emergency response facilities covered by section 50.54(q) and loss-of-coolant accident evaluation methods covered by section 50.46. These changes are covered by other regulatory processes, and, as stated in section 50.59(c)(4), an evaluation in accordance with section 50.59(c)(2) is not required.

Another category of changes for which a section 50.59 evaluation is not required are those associated with maintenance activities. The basis is that section 50.65(a)(4) (as well as the TS) provides the process for evaluating such "changes." Removing equipment from service (making it inoperable) for maintenance for the technical specification (TS) allowed outage time does not require a Section 50.59 evaluation. Removing non-TS equipment from service is covered by the requirements of the maintenance rule, Section 50.65, and a Section 50.59 evaluation is not required. One way to decide whether a particular activity is "maintenance" rather than a "change" is whether the plant will return to the same configuration following the activity.

The reliance upon the section 50.65(a)(4) assessment in lieu of a section 50.59 evaluation also extends to temporary alterations directly related to and required in support of specific maintenance activities. However, if the temporary alterations are not in support of maintenance, or are expected to remain in place for more than 90 days, a section 50.59 evaluation should be performed in addition to the (a)(4) assessment. Refer to the regulatory guidance for further information.

Another example of applicability concerns changes to fire protection plans. As discussed in the guidance, for those licensees with the standard license condition that allows changes provided that they do not "adversely affect the ability to achieve and maintain safe shutdown in the event of a fire," performance of an assessment demonstrating that this provision is met may be done in lieu of a section 50.59 evaluation.

2. Screening Review

If a change, test, or experiment is not covered by another change control process, a review in accordance with section 50.59 is required. The revised rule language allows for a licensee to screen changes as to whether a full evaluation with respect to the criteria in section 50.59(c)(2) is required, as discussed in more detail below. (see also NEI 96-07)

(a) Changes to the facility or procedures. The criterion for requiring a Section 50.59 evaluation is if it is a change to the facility as described in the FSAR (as updated) or a change to the procedures as described in the FSAR (as updated). The revised rule now defines "change," "facility as described in the FSAR (as updated), and "procedures as described in the FSAR (as updated)."

The intent of the definition of "change" as being those that affect design functions, method of performing or controlling functions, or method of evaluation, is to allow screening determinations to conclude that certain changes are administrative, or descriptive only, or do not (adversely) effect the functions of the SSC, such that a section 50.59 evaluation is not required. The screening review is intended to cause proposed changes that might involve any of the evaluation criteria to be subjected to the section 50.59 evaluation process (and not be "screened out").

The guidance discusses licensee determinations as to whether a proposed change has "adverse" effects upon design functions, methods of performing or controlling functions or evaluations. If a change has no effect or only beneficial effects, it would not trigger any of the evaluation criteria concerning higher likelihood of malfunction or higher consequences, etc. If the nature of the effects are inconclusive (some adverse, some not, or not comparable), an evaluation is needed.

The functions being effected by a change might be for a SSC other than the one to which the change is being made because of indirect effects. (Indirect effects include such items as environmental conditions, physical interactions, etc.) Therefore, the screening determination, if done only through a word search of the FSAR, might miss such effects. Refer to regulatory guidance for discussion about direct and indirect effects of changes.

The guidance also discusses those situations in which the existing safety analyses are not bounding and thus that those changes must be evaluated, and not screened. In contrast, if a licensee decides to include a new analysis for future reference that documents the enhanced performance of SSC after a change, the creation of such analyses does not mean that an evaluation was needed.

A change to the facility does not have to be an actual hardware change to require a Section 50.59 evaluation. Changes to information in the FSAR that provides performance or qualification requirements, or to the analyses and evaluations in the SAR that demonstrate that the facility meets requirements may also satisfy the screening criteria, as stated in the definitions.

SSC (or procedures) that are described in the FSAR but are not safety-related should not be excluded from evaluation in accordance with Section 50.59 solely on that basis. If the Section 50.59 screening criteria are satisfied, then a Section 50.59 evaluation is required.

Equivalency of components - As discussed in the regulatory guidance, equivalency determinations provide the basis for screening such that a section 50.59 evaluation is not required.

Additions to the facility or procedures must also be evaluated to determine whether there is any effect upon the facility as described in the FSAR. The next FSAR update shall reflect the effects of such additions, including, in most instances, a description of any added SSCs.

Each facility changes is to be evaluated separately, unless they are interdependent, that is, linked to each other and not separable for functional reasons. The intent is that a change that might add conservatism not be used to preclude the NRC review of another change that would satisfy the evaluation criteria absent being considered in combination with the "conservative" change.

Each criterion must be satisfied on its own, thus, a reduction in consequences cannot "offset" an increase in likelihood for a given change as a basis for meeting section 50.59. Similarly, changes to evaluation methods must be considered separately from other facility changes, using the applicable evaluation criteria for each. Changes to input parameters (i.e., to physical or operational characteristics of the facility, not otherwise limited by TS or requirements), may be adjusted in order to demonstrate that a facility change satisfies the criteria.

A temporary change to a SSC that would affect its FSAR description must be evaluated in accordance with Section 50.59, even though the change in the FSAR description would not be permanent. (see also discussion above concerning maintenance; see also guidance in RG 1.181 with respect to FSAR updating requirements).

An unintended deviation from the design of a SSC as described in the FSAR, whether in existence since initial licensing, or as the result of an error in a subsequent modification, installation, or maintenance activity, is considered a de facto design change to the facility. If the deviation is not promptly restored or if the licensee does not intend to restore the condition, plant operation with the de facto design change must be evaluated pursuant to section 50.59 to determine whether the change requires NRC approval or a change in the technical specifications. For these types of changes, the NRC approval prior to implementation refers to the approval of the corrective action (i.e. of the change to the licensing basis as described in the FSAR) before the nonconforming condition is resolved. Refer to the Part 9900 Guidance on Resolution of Degraded and Non-conforming Conditions for more information.

Changes to the FSAR itself, not associated with a change, test, or experiment, are considered part of the FSAR update process, in accordance with 10 CFR 50.71(e), and do not require a section 50.59 evaluation. However, care must be exercised in dealing with discrepancies between the FSAR descriptions and the facility, or with conflicting information within the FSAR. In some instances, the resolution is an FSAR update, but in other cases, the resolution actually involves a change to the licensing basis (by means of revision of the FSAR description). Section 50.59 is applicable to such changes.

(b) Tests or experiments. The criterion for requiring a Section 50.59 evaluation for the conduct of a test or experiment (not described in the FSAR (as updated)) is whether the test or experiment involves an activity under which any SSC is utilized in a way that it may not remain within the design bases and controlling parameters or in a way that is inconsistent with the safety analyses. If a test described in the FSAR would be done in a different way, a Section 50.59

evaluation is required.

3. Evaluation Process

Even when the screening criteria are satisfied, a Section 50.59 evaluation would not be required if the change to the facility (or procedure) would involve a change to the technical specifications. If a technical specification change is involved, the licensee must apply for and obtain a license amendment in accordance with Section 50.90 before implementing the proposed facility or procedure change. Therefore, it is not necessary for a licensee to provide answers to the eight evaluation criteria noted below, as the need for NRC approval is already decided by the need for a change to the TS. Note that the licensee should always determine the effect of a facility or procedure change on the technical specifications regardless of whether the change satisfies the Section 50.59 screening criterion (e.g., is described in the FSAR).

Each Section 50.59 evaluation should consider the following:

- systems and components affected by the change (What is the effect of the change on their capability to perform their specified or intended functions?);

- parameters of the accident analysis affected by the change (Are all the relevant design basis accidents and transients identified?); and

- potential effects of system or component failure (i.e., the question, "what would happen if..." is explored and answered in the evaluation).

- how the evaluation criteria are met;

The actual implementation of a design change at the plant is to be assessed as a maintenance activity, in accordance with section 50.65(a)(4), as discussed above under applicability. Operation of the facility following implementation of a design change is subject to review under section 50.59.

For design changes that are partially completed, either by plan (e.g., hardware installed during one outage, but electrical hookup is not scheduled until the following outage) or unforeseen circumstances, the licensee needs to review the partially completed status to determine whether an evaluation in accordance with Section 50.59 is required or a change in the technical specifications is involved. The licensee's control of the integration of the modification into interfacing systems should include positive control of system boundaries; full consideration of the effects of partial completion of the modification; and appropriate revisions to procedures.

4. Evaluation Criteria

(a) The first criterion is if the CTE would result in more than a minimal increase in the frequency of an accident previously evaluated in the FSAR (as updated). The intent of the criterion is to allow changes to be made without approval unless there is a discernible, attributable increase in frequency of an accident. There must be some reason to believe that the CTE would result in an impact upon the accident frequency (as because it affects the integrity of the reactor coolant system, or the ability of SSC to remove decay heat, or makes an initiating event more likely to occur). Specific guidance is included in NEI 96-07.

(b) The second criterion is if the CTE would result in more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC important to safety[1] previously evaluated in the FSAR (as updated). As for frequency, the intent is that there be some reason to conclude that the CTE has resulted in an increase in likelihood, rather than the licensee having to prove that it could not happen. In making these assessments, the licensee's evaluation should consider the effects of the proposed CTE on performance of all affected SSC and make a determination as to whether there has been an increase, and provide the basis for the determination.

(c) The third criterion is if the CTE would result in more than a minimal increase in consequences of an accident previously evaluated in the FSAR (as updated). Consequences refers to radiological consequences, and are with respect to offsite release, and onsite release, to the extent that onsite releases are evaluated in the FSAR for a particular accident or location (as for example, the control room). As discussed in the implementation guidance, a CTE involves no more than a minimal increase in consequences if the resulting dose is no greater than the previous value plus ten percent of the difference between the regulatory value (specified either in the regulations, e.g., GDC 19 or Part 100) and the previous value, and provided that the result does not exceed the value established in the Standard Review Plan[2] guidance for the particular design basis event if applicable. Applicability is with respect to the particular type of accident, not whether the plant was specifically licensed using the SRP. Also as noted, the intent is to require NRC review of changes with more than a minimal increase in consequences. Thus, revised analyses correcting errors or changes to the facility resulting in only small changes in predicted dose (on the order of 0.1 rem), even if the above guidelines are not met, do not require prior approval. One special case of consequences concerns doses to operators outside the control room, as assessed under the TMI action plan, where the applicable standard for "minimal" is whether the GDC 19 values would continue to be met.

(d) The fourth criterion is similar to the third, and is if the CTE would result in more than a minimal increase in consequences of a malfunction of an SSC important to safety previously evaluated in the FSAR (as updated). The above discussion as to understanding of "minimal" also applies to consequences of malfunctions.

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[1] The criteria refer to SSC important to safety previously evaluated. There is no established definition of "important to safety", but this should not impair the ability to implement the criteria because the SSC are already described in the FSAR to the extent of consideration of their functions and requirements thereto with respect to whether they are important to safety.

[2] The use of the SRP guidance is for purposes of implementing the section 50.59 criteria with respect to the need for NRC approval of a particular change with respect to "minimal increases in consequences." For some plants or accidents, the NRC may already have reviewed and accepted consequences that do not fully conform with the SRP criteria. These previous reviews are unaffected by this guidance, but the overall impact would be that a change that result in any increase(beyond the de minimis value) would require prior NRC approval.

(e) The fifth criterion is if the CTE would create the possibility of an accident of a different type from any previously evaluated in the FSAR (as updated). The intent of this criterion is to require review of changes that would create conditions that would have been viewed as design basis events had the possibility existed before. Thus, the assumptions typically used for design basis events, such as no credit for non-safety-related systems, postulated loss of offsite power, single failure, etc. are applicable. On the other hand, accidents that may be theoretically possible once the CTE is made if multiple independent failures were postulated would not be viewed as creation of an accident of a different type.

(f) The sixth criterion is if the CTE would create the possibility of a malfunction of an SSC important to safety with a different result from any previously evaluated in the FSAR (as updated). This criterion focuses upon the "effect" of the CTE, and whether the result of any malfunctions that might have been created by the CTE has already been analyzed or bounded by the FSAR analysis. Only if the effect is different from those already considered would this criterion require prior NRC approval for a CTE involving a new type of malfunction. Note that the likelihood of malfunction may be increased if new failure modes are introduced (even if the effects have been previously evaluated in the FSAR), and this situation would have to be evaluated under criterion (ii).

(g) The seventh criterion is if the CTE would result in a design basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered. As discussed in the implementation guidance, the determination of the need for NRC review is based upon whether the CTE results in exceeding or altering one of the design basis limits, established in the FSAR, for maintaining integrity of a fission product barrier. Effects of changes to SSC, including mitigation and support systems, need to be assessed with respect to whether the changes lead to exceeding or altering one of these limits. Depending upon the type of facility and its operational status, the particular fission product barriers and design basis limits may vary, but should be evident from the safety analyses presented in the FSAR (as updated). For operating power reactors, the barriers are the fuel clad, reactor coolant system boundary, and containment, and the design basis limits are the values for such parameters as DNB ratio, RCS design pressure, or containment design pressure. The parameters applicable to a specific facility should be ascertainable from review of the FSAR. Facility changes are judged in terms of whether the analysis results meet the criteria, such as not exceeding a design basis limit for any fission product barrier (effects are to be judged using the FSAR-described methods; methodology changes are evaluated using criterion (viii)).

(h) The final evaluation criterion is if the CTE would involve a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses. Unlike the other seven criteria for evaluating CTE, this criterion is specifically directed at changes to evaluation methods. The implementation guidance discusses the meaning of "evaluation method," and notes that the FSAR (or documents incorporated by reference), must describe the method, and the change must affect this description, to require evaluation. Then, in accordance with criterion (viii), if the method is used in establishing the design bases, or in the safety analyses, prior NRC approval is required if there is a departure from the method as described in the FSAR. A departure occurs if some part of the method is changed, such that the result of the analysis using that method is not conservative or essentially the same. The "essentially the same" language is intended to allow licensees to benchmark revisions to methods for use without prior NRC review even if the results are not "conservative" when the changes are small, would have no effect upon the acceptability of the analysis, and the amount of change in the results is not used to justify that limits and requirements are met. "Conservative" is to be judged with respect to the results obtained from the method. If the result from the revised method is further from the established limit than under the previous method, the revised method is in the nonconservative direction. When judging conservatism of a change in methods, a predicted result closer to an established limit is conservative, in that there is less opportunity for other changes without triggering the need for NRC review and approval. (In contrast, a facility change, which when evaluated (with no change in methods) results in a predicted value further from the limit, is a "conservative" facility change).

It is also not a departure if the licensee uses a different method that has already been reviewed and approved by NRC for the intended application, if used in accordance with the conditions and limitations specified in the approval. A different method must be used in its entirety to fall under this provision of the rule; changes to parts of methods are covered by the "essentially the same" standard noted above. Additional guidance for assessing whether a change to an evaluation method is a "departure" as defined in the rule is provided in the NEI 96-07 guidance.

The elements of the evaluation method include such items as treatment of uncertainties, correlations, and representations of phenomena. In contrast, items such as flows, temperatures, pressures, equipment response times that are physical characteristics of the facility are viewed either as facility changes or input parameters that are to be evaluated using the other criteria, not as "methods of evaluation." Changes to input parameters that are described in the FSAR, are to be evaluated as changes to the facility, and could be made without NRC approval as long as criteria (i) through (vii) and the TS are met.

Further, any changes to analyses and methods are also subject to design control process requirements in accordance with 10 CFR Part 50, Appendix B.

In sum, criterion (viii) is intended to preserve the basic assumptions of the evaluation method that provide the confidence that the analysis results are appropriately conservative, even if the results of the analysis are at the applicable limits or requirements. Use of different methods without specific NRC review is acceptable only if those methods have been previously found acceptable by NRC for the intended application, or the results are conservative or essentially the same.

5 .Documentation, Records and Reports

Section 50.59(d)(1) requires licensees to maintain records of CTEs made in accordance with Section 50.59 without NRC approval. It also requires that these records include a written evaluation that provides the basis for the determination that the CTE did not require prior NRC approval (i.e., the Section 50.59 evaluation). While the rule language was revised, this was for simplicity, there is no change in the requirement that evaluations be done for those situations that satisfy the applicability and screening review criteria.

Section 50.59 evaluations must be in writing and include the bases for the determination that the CTE did not require prior NRC approval. The NRC does not consider a checklist to be sufficient to meet the requirement for a written evaluation. However, depending upon the significance of the change, the Section 50.59 evaluation may be quite brief.

Each evaluation should be documented in accordance with the licensee's procedural requirements. As a minimum, the documentation should be sufficiently detailed with the conclusions logically supported so that independent review by persons designated in the licensee's procedures is possible without extensive reference to other documents and consultation with the preparer. The documentation should identify the scope of the review (what documents were looked at), responses to the items noted in 03.03.a.1 of this procedure, and any assumptions, engineering analyses or judgment, etc., that were used. In cases where the evaluation relies on the associated engineering safety analysis, the inspector should review that analysis and other relevant documents in the associated design change package.

The documentation of evaluations for temporary modifications(for which section 50.59 applies) should meet the same criteria regarding reviewability as for permanent changes. Summaries of evaluations for temporary modifications should be included in the periodic report to the NRC in accordance with Section 50.59(d)(2).

Although Section 50.59 does not specifically require that Section 50.59 screening determinations be documented with written bases for the determination that a Section 50.59 evaluation was not required, the licensee should maintain a record of these determinations in accordance with its NRC-approved operational quality assurance program. This record is needed because determining whether a Section 50.59 evaluation is needed for a CTE is an activity affecting quality covered by Criterion V of Appendix B to 10 CFR Part 50. As part of the process for design control (Criterion III, Design Control, of Appendix B to 10 CFR Part 50), the implementation of Section 50.59 requirements is an activity affecting quality.

Section 50.59(d)(3) requires that records of changes to the facility be maintained until the date of termination of the license (either the Part 50 license, or any license issued under Part 54), and that records of changes to the procedures and records of tests and experiments be maintained for a period of 5 years. The administrative controls section of the technical specifications for some plants may contain additional requirements for record keeping.

Section 50.59(d)(2) requires that the licensee submit a report containing a brief description of each CTE, including a summary of its supporting evaluation, implemented without prior NRC approval in accordance with Section 50.59. The reporting frequency has been revised to 24 months, but reports may be filed more frequently if a licensee so chooses. Reports are required only for those changes, tests and experiments for which evaluations against the criteria were required, not for CTEs screened out.

The Technical Specifications for some plants may contain references to terminology such as "unreviewed safety question" that is no longer used in the revised section 50.59. These requirements may be for TS Bases Control Programs, safety review committee responsibilities, or record retention requirements. While the explicit language of the TS may not conform with the revised rule language, this is an administrative situation only with no substantive effect. As noted in the Statement of Considerations for the rulemaking, licensees are requested to include changes to these sections as part of another license amendment they might be requesting at a convenient opportunity. There is no obligation on the licensee to do so.

GUIDANCE FOR TRANSITION FROM EXISTING 10 CFR 50.59 REQUIREMENTS
TO REVISED 10 CFR 50.59 REQUIREMENTS

Background

On October 4, 1999 (64 FR 53582), the NRC published a final rule revising 10 CFR 50.59 (and related requirements in Part 50 and in Part 72). The Part 50 requirements were to become effective 90 days after approval of regulatory guidance. During development of the industry guidance document that NRC is endorsing through a regulatory guide, certain questions arose concerning how the transition from the "old" rule to the "new" rule were to be accomplished. This document sets forth these issues and the applicable guidance.

Discussion of Issues

A. Which version of 10 CFR 50.59 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?

Response: Implementation of the 10 CFR 50.59 requirements occurs at the time that the licensee completes the evaluation (in whatever form that the licensee concludes that an evaluation is complete, as for example, when approved by the safety review committee). Thus, it is at this time that the requirements of whichever rule is currently in effect should be met (see also question B below). The actual date of implementation of the change does not play a role in this determination.

B. Due to the expected timing of the 90 day implementation period, it may be difficult to schedule procedure revisions and training for all affected personnel in light of planned refueling outages or other activities. To ease transition to the new 10 CFR 50.59 rule, may a licensee opt to continue using the "old" rule for a period of time longer than the 90 days until the training can be completed? As another example, could a licensee arrange implementation such that the effective date for the revision to section 50.59 coincides with implementation of the revised section 72.48 (April 5, 2001). What licensee actions are needed to allow this?

Response: The Commission in promulgating the revision to section 50.59 noted that the revised rule provisions provide greater flexibility than the existing rule requirements for licensees to make changes without prior NRC approval. Thus, if a licensee is appropriately implementing the "old" rule, they would be complying with the "new" requirements. Therefore, there is no regulatory concern with a delay beyond 90 days in implementation of the revised rule requirements. However, to avoid confusion, it is expected that the additional implementation period would not exceed a few months (the April 2001 date would seem to be a logical break point for such implementation). While no formal notification or approval is needed for such licensee actions, it is recommended that the licensee clearly communicate with the NRC staff (in particular, the resident and regional staff) about their implementation schedule so that NRC understands what the licensee is doing.

Attachment 4

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C. If new information is discovered after the revised rule takes effect necessitates revision of a completed 10 CFR 50.59 evaluation that was completed using the "old" rule, should the "new" or the "old" rule be used to revise the evaluation?

Response: The licensee would need to comply with the rule requirements that are in effect at the time the evaluation is revised. However, as previously noted, since the new rule largely represents a relaxation from the "old" rule, if the licensee used the "old" rule requirements for purposes of completing the revision, they would be expected to also comply with the new rule. Therefore, it would be acceptable to assess the revision against the "old" rule requirements. Only the portions of the evaluation affected by the new information would need to be revised. If the effect of the new information is that one or more of the new rule criteria are met, the licensee should seek approval for the change.

D. The revised maintenance rule requirements, including implementation of new section 50.65(a)(4), go into effect on November 28, 2000, which is before the effective date of the revised section 50.59. During the period between the effective dates of the two rules, are licensees required to perform both 50.65(a)(4) assessments as well as 50.59 reviews for temporary alterations in support of maintenance?

Response: The maintenance rule guidance in RG 1.182 states that maintenance activities, including associated temporary alterations are to be assessed in accordance with 50.65(a)(4) and that a section 50.59 evaluation is not required (provided the temporary alteration is to be in effect for less than 90 days at power). This guidance is also reflected in the guidance for implementation of section 50.59. The explicit language that a section 50.59 evaluation is not needed when another regulation establishes the control process for such activities appears in the revised rule. However, the Commission, in approving the final rule revision to section 50.65, supported that licensees could begin use of the guidance in RG 1.182 before the effective date of (revised) section 50.59. Thus, if a licensee performs the assessments in accordance with section 50.65(a)(4), a section 50.59 review is not needed for such temporary alterations.

E. If an evaluation has been performed before the effective date of the revised rule, but the change has not yet been implemented, what action (if any) is required?

Response: As noted above, the rule implementation is considered to occur at the time the evaluation review process is complete. Thus, no action would be required with respect to the new rule for changes already evaluated, whether or not implemented. The licensee does have the option of performing a new evaluation under the revised rule requirements for certain changes that might have required prior approval under the "old" rule, but which would satisfy the "new" rule. Such an evaluation would then provide the basis for not seeking NRC approval for that change.

F. How should previous NRC documents that discuss 10 CFR 50.59 be viewed in light of the revised rule. In some instances, the discussion therein appears to be in conflict with the revised rule or the new regulatory guidance. Examples include GL 95-02 (on digital instrumentation) and Bulletin 96-02 (Heavy Loads).

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

GL 95-02, the part of the guidance that discusses the evaluation criterion of "malfunction of a different type" would no longer apply because that criterion has been revised to be "malfunction with a different result." However, other aspects of the guidance, as for instance how the change to the system in which the digital instrumentation is used is to be viewed in performing the evaluation, would remain applicable. In the case of the Bulletin on heavy loads, it is noted that if the heavy load were being accomplished as part of a maintenance activity, there is no section 50.59 evaluation being performed, and thus, no expectation that the heavy load lift would require prior NRC approval. The fact that the load is larger or is moving in a different load path than previously evaluated would factor into the risk assessment and thus the determination as to under what plant conditions the load lift should occur. If the heavy load lift is not maintenance-related, such that a section 50.59 evaluation is being performed, the determination as to whether prior NRC approval is needed would be made in accordance with the revised rule requirements, as for instance, whether there would be a more than minimal increase in the consequences of an accident previously evaluated (or if the change creates an accident of a different type).

LIST OF COMMENT SUBMITTALS

1.	CP&L	6/8/00	endorses NEI
2.	Duke	6/9/00	endorses NEI, interface with MR, transition (evaluations/implementation)
3.	Winston and Strawn	6/9/00	endorses NEI, esp. on screening on FSAR functions and engineering assessments
4.	E. Connell	6/9/00	fire protection
5.	Wolf Creek	6/8/00	endorses NEI
6.	Same as 2		
7.	SCE&G	6/8/00	endorses NEI, with enclosed 5/22 comments
8.	NMC	6/9/00	endorses NEI, "NRC clarifications" negate endorsement; "design function" scope, engineering assessments/bounding
9.	Entergy	6/9/00	endorses NEI, other comments on design function, engineering assessments, heavy loads, methods, transition
10	ComEd	6/9/00	endorses NEI
11	Utilities Service Alliance	6/9/00	endorses NEI
12	Southern Company	6/5/00	endorses NEI
13	Virginia Power	6/9/00	endorses NEI
14	(not used)		
15	Florida Power	6/9/00	endorses NEI
16	NEI	6/8/00	transition, "design function" definition, screening on adverse effects, other comments
17	PECO	6/9/00	endorses NEI
18	NYPA	6/14/00	endorses NEI, transition issues
19	APS	6/7/00	endorses NEI
20	Paul Sicard	6/5/00	methods (ICRP, non-fuels analyses, new conservative methods), engineering assessments, role on non-safety equipment in safety analyses, examples, heavy loads, fire protection, mission doses, risk-informed
21	TXU	6/16/00	endorses NEI

22	M. Blumberg	6/16/00	methods (approved for intended application) and related aspects
	G. Tracy	6/16/00	human actions

65 FR 24231
Apr. 25, 2000
1

RECEIVED
2000 JUN -8 PM 4: 04
RULES & DIR. BRANCH
US NRC

CP&L

Carolina Power & Light Company
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Raleigh NC 27602

Serial: PE&RAS 00-050
June 8, 2000

Chief, Rules and Directives Branch
Office of Administration
U.S. Nuclear Regulatory Commission
Washington D.C. 20555

Subject: **Draft Regulatory Guide DG-1095 - *Guidance for Implementation of 10 CFR 50.59, Changes, Tests and Experiments***
Request for Comments

Ladies and Gentlemen:

Carolina Power & Light Company's (CP&L) comments on the draft guidance have been incorporated into the industry response compiled by NEI. We endorse the NEI response and encourage NEI and the NRC to continue working towards prompt resolution of the remaining issues. The obvious NRC commitment to resolving the issues surrounding 10 CFR 50.59 is greatly appreciated.

Please contact me at (919) 546-4579 if you have questions.

Sincerely,

John R. Caves

John R. Caves
Regulatory Affairs

RGH

Template: ADM-013

E-RIDS = ADM-03
Add: E. McKenna (EMM)

WINSTON & STRAWN

Electronic Letterhead

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65FR# 24231
25 April 2000
3

WRITER'S DIRECT DIAL NUMBER
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June 9, 2000

RECEIVED
2000 JUN -9 PM 4:15
RULES & DIR. BRANCH
US NRC

Mr. David L. Meyers
Chief, Rules and Directives Branch
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Re: **Draft Regulatory Guide DG-1095, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests and Experiments'"**

Dear Mr. Meyers:

On April 25, 2000, the U.S. Nuclear Regulatory Commission published in the *Federal Register* Draft Regulatory Guide DG-1095, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests and Experiments.'" DG-1095 proposes to endorse the draft industry implementation guidance, Nuclear Energy Institute ("NEI") 96-07, Revision 1, as an acceptable means of meeting the new rule, with certain exceptions and clarifications. We submit this letter on behalf of the Licensing and Design Basis Clearinghouse ("Clearinghouse"),[1] endorsing DG-1095 and supporting the industry comments submitted by NEI.

Overall, we commend the regulatory process that has enabled the examination and resolution of several issues related to the implementation of the revised 10 C.F.R. § 50.59. Further to that process, we wish to emphasize certain points. In the draft regulatory guide, the NRC Staff is proposing clarifications in four areas: (1) the screening process on changes that affect design function; (2) the relationship between the 10 CFR § 50.59 process and the maintenance rule 10 CFR § 50.65(a)(4) assessments; (3) increases in the likelihood of malfunction of systems, structures, or components ("SSC"); and (4) licensee use of a different method and considering it as being approved by the NRC for the intended application.

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1 The Licensing and Design Basis Clearinghouse is a consortium of nuclear utility licensees representing approximately 22 nuclear power plants.

Template: ADM-013

ERIDS: ADM-03
Add- E. McKenna (EMM)

In this context, there are certain issues that we believe are particularly significant for assuring a clear and rationale application of Section 50.59, and a clear and defined licensing basis for licensees with respect to actions that warrant assessment for the applicability of or a review under Section 50.59. Accordingly, we would like to emphasize our support for certain elements of the industry comments. First, DG-1095 sections 1.1.2, 1.1.3 and 1.14 state that changes affecting any SSC function described in the Final Safety Analysis Report ("FSAR") should be "evaluated," not just screened. We agree with the industry view that this position would result in licensees performing, documenting, and reporting to NRC numerous unnecessary 10 CFR § 50.59 evaluations for changes that do not meet any of the criteria for requiring prior NRC approval.

The 10 CFR § 50.59 screening review examines the effects of the change on design functions, methods used to perform or control design functions, and evaluations that demonstrate that intended design functions will be accomplished. Not all SSCs described in the FSAR perform, support or impact functions credited in the safety analyses. Therefore, for many changes, the 10 CFR § 50.59 screening review is sufficient to determine that no prior NRC approval is required.

We also strongly support the industry position on DG-1095 section 1.1.6, which also concerns the 10 CFR § 50.59 screening process. Engineering assessments are performed for virtually all proposed changes, tests and experiments. The proposed regulatory position in section 1.1.6 would negate the screening process and require formal 10 CFR § 50.59 evaluations for nearly all activities, a significant waste of utility and Staff resources. Therefore, we support the proposed revisions to section 4.2.1 of NEI 96-07.

We appreciate the opportunity to comment on this significant regulatory guidance. If you have any questions, please feel free to contact us at (202) 371-5737 or (202) 371-5838.

Sincerely,

William A. Horin
Donald P. Ferraro
Counsel to Licensing and Design Basis
Clearinghouse

25 April 2000

4

Fire Protection

Section 4.1.5 of the February 22, 2000, draft of NEI 96-07, states that the standard license condition establishes specific criteria for control of fire protection changes and falls within the scope of 10 CFR 50.59(c)(4). This regulation states that when applicable *regulations* establish more specific criteria for controlling changes, the requirements in 10 CFR 50.59, do not apply. The statement of considerations, published with the final rule in the *Federal Register* on October 4, 1999, states that, the Commission proposed to exclude from the scope of 50.59, review, specific types of changes to procedures where other requirements and criteria have been established by *regulation*. This language refers to situations, such as 50.54(a) and 50.54(q), where the *regulations explicitly* define how changes are to be *reviewed, documented, and reported*: and thus, where a 50.59, evaluation would be duplicative. Since the standard fire protection license condition is not a regulation and *does not explicitly* define the review, documentation and reporting requirements for fire protection program changes, it is not clear how the standard license condition is duplicative or how the guidance provided in NEI 96-07, concerning the review, documentation and reporting of changes to the fire protection program is enforceable for licensee's that do not voluntarily adopt the NEI guidance. Therefore, the final version of the guide should be revised to state that changes to the fire protection program are within the scope of 10 CFR 50.59, and should be controlled accordingly.

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Template - ADM-03

E-RIDS = ADM-03
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65FR#24231
25 April 00
5

Received
3:15pm
12 June 2000

WOLF CREEK
NUCLEAR OPERATING CORPORATION

Otto L. Maynard
President and Chief Executive Officer

JUN 8 2000

WM 00-0029

Mr. David L. Meyer
Chief, Rules and Directives Branch
Division of Administrative Services
Office of Administration
Mail Stop: T-6 D59,
U. S. Nuclear Regulatory Commission
Washington, D.C., 20555-0001

Reference: Federal Register Notice, 65 FR 24231, dated April 25, 2000

Subject: Comments on Draft Regulatory Guide, DG-109, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests and Experiments"

Dear Mr. Meyer:

As noted in the referenced Federal Register Notice, the NRC published a new guide in the Regulatory Guide Series to describe methods acceptable to the NRC for complying with the NRC's revised regulation for evaluating changes, tests, and experiments that a licensee wishes to make without prior NRC approval. The regulatory guide will endorse the Nuclear Energy Institute (NEI) guidance on 10 CFR 50.59. That same notice also solicited comments from the public.

Wolf Creek Nuclear Operating Corporation (WCNOC) endorses the comments submitted by the NEI on this issue, and believes that incorporating these comments into the guidance would provide substantial improvement to both the process and its implementation. WCNOC, along with the industry, will look forward to final issuance of the regulatory guide and the NEI guidance.

If you should have any questions regarding this submittal, please contact me at (316) 364-4000, or Mr. Tony Harris at (316) 364-4038.

Very truly yours,

Otto L. Maynard

Otto L. Maynard

OLM/rlr

cc: J. N. Donohew (NRC)
W. D. Johnson (NRC)
E. W. Merschoff (NRC)
Senior Resident Inspector (NRC)
Document Control Desk (NRC)

Template: ADM-013

E-RIDS-ADM-03
Add. F McKenna (EM)

Duke Power
A Duke Energy Company

M. S. Tuckman
Executive Vice President
Nuclear Generation

65FR#24231
25April00
6

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12 June 2000

June 9, 2000

Mr. David L. Meyer, Chief
Rules and Directives Branch
Division of Administrative Services
Office of Administration
Mail Stop T-6 D59
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Subject: Comments on Draft Regulatory Guide DG-1095 "Guidance for Implementation of 10CFR 50.59, 'Changes, Tests and Experiments'" 65FR24231, dated April 25, 2000

Dear Mr. Meyer:

Duke Energy offers the attached comments relative to the solicitation for public comments regarding the Draft Regulatory Guide DG-1095, "Guidance for Implementation of 10CFR 50.59, 'Changes, Tests and Experiments'".

Please address any questions to Jeff Thomas at (704) 382-5826.

Thank you for the opportunity to provide these comments.

Very truly yours,

M.S. Tuckman
M. S. Tuckman

Template: ADM-013

E-RIDS-ADM-03
Add: E Mckenna (EMM)

Draft Regulatory Guide DG-1095
Duke Comments

1. Section C.1.2, "Interface of 10CFR50.59 With the Maintenance Rule (10CFR50.65)." It is recommended that words be added to clarify that 10CFR50.65(a)(4) and 10CFR50.59 are both applicable if the 90-day period is expected to be exceeded.

2. Duke recommends that either the Regulatory Guide or other appropriate NRC communication address the transition from the current rule (3 criteria, 7 questions) to the new rule (8 criteria, 8 questions). For example, 50.59 evaluations for activities proposed prior to implementation of the new rule do not have to be reevaluated under the new rule if implemented after the new rule becomes effective. Furthermore, in the event that a revision to an evaluation performed pursuant to the current rule is required after the new rule becomes effective, then the revision can be completed using current rule or new rule guidance.

Duke endorses the June 8, 2000 NEI industry response to DG-1095.

bxc: M. T. Cash
L. E. Nicholson
G. D. Gilbert
C. J. Thomas
D. Tower
ELL

65FR#24231
25 April 2000

7

SCE&G
A SCANA COMPANY

Received
3:20pm
12 June 2000

RC-00-0245
June 8, 2000

Rules and Directives Branch
Office of Administration
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Gentlemen:

Subject: VIRGIL C. SUMMER NUCLEAR STATION
DOCKET NO. 50/395
OPERATING LICENSE NO. NPF-12
COMMENTS ON DRAFT REGULATORY GUIDE DG-1095,
GUIDANCE FOR IMPLEMENTATION OF 10 CFR 50.59,
CHANGES, TESTS, AND EXPERIMENTS

Stephen A. Byrne
Vice President
Nuclear Operations
803.345.4622

South Carolina Electric and Gas Company (SCE&G) submits the following comments on DG-1095. SCE&G endorses the generic response prepared by the Nuclear Energy Institute (NEI) on behalf of its members.

The comments provided by the industry to NEI are exhaustive, detailed and clarified with sufficient examples.

SCE&G appreciates the opportunity to comment on this draft regulatory guide and wishes to recommend the endorsement of NEI 96-07. Should you have any questions, please call Mr. Arnie Cribb of my staff at (803) 345-4346.

South Carolina Electric & Gas Co
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Very truly yours,

Stephen A. Byrne

AJC/SAB

c: J. L. Skolds
T. G. Eppink
R. J. White
L. A. Reyes
K. R. Cotton
J. B. Knotts, Jr.
NRC Resident Inspector
NSRC
DMS (RC-00-0245)
RTS (O-L-99-0134)
File (811.05)

Template: ADM-013

E-RIDS=ADM-0

Add: E McKenna (EM

May 22, 2000
Draft Industry Response to DG-1095

DG-1095 Position 1.1, SCREENING ON WHETHER A CHANGE AFFECTS DESIGN FUNCTION

DG-1095 Position 1.1.1

To implement the rule properly, "design function," as used in screening, is broad so that changes that have the potential to meet any of the evaluation criteria are evaluated rather than screened. Since the criteria include both the initiation and response to previously postulated events (including equipment performance), as well as introduction of new events, "function" extends beyond safety-related SSC and specific mitigation systems whose performance is explicitly modeled and discussed in the safety analyses.

Industry Comment

The definition of "change" ensures that all changes that have the potential to meet one of the 10 CFR 50.59 evaluation criteria are appropriately reviewed. Indeed, any addition, modification or removal not controlled by another requirement is subject to 10 CFR 50.59, i.e., at least screened. The definition of "design function" provides the appropriate focus of these screening reviews. We agree that the definition of "design function" extends beyond safety-related SSCs and specific mitigation systems whose performance is explicitly modeled and discussed in the safety analyses. We plan to clarify the phrases "credited in the safety analyses" and "supports or impacts SSC functions" consistent with the DG-1095 Position 1.1.4. See below.

DG-1095 Positions 1.1.2, 1.1.3 and 1.1.4

(1.1.2) For SSCs that have functions described in the FSAR, changes affecting such functions should be evaluated, not excluded from further review because the described function does not fit the definition. When the change is being made to an SSC that is not itself described in the FSAR, or whose functions are not, screening with respect to whether the change affects a design function for other SSCs is appropriate, as discussed in Section 4.2.1.1, with the clarifications in 1.1.3 and 1.1.4 below.

(1.1.3) The definition for design function is modified in Section 3.3. This modification is proposed to ensure that the definition is interpreted in a comprehensive manner when deciding whether changes require further evaluation with respect to the evaluation criteria. The definition of design function is to read as follows:

functions that affect initiation as well as response to events the plant is required to withstand. For many changes, the 10 CFR 50.59 screening review is sufficient to determine that no prior NRC approval is required. This is because not all SSCs described in the UFSAR perform, support or impact functions credited in the safety analyses, i.e., not all SSCs have "design functions." Some SSCs have multiple functions, and screening may determine that the proposed change does not affect design functions. Changes have no nexus to SSCs or functions credited in the safety analyses if screening determines that they do not affect:

- design functions,
- methods used to perform or control design functions, or
- evaluations that demonstrate that intended design functions will be accomplished

Such changes cannot meet the criteria for requiring prior NRC approval and therefore do no warrant further evaluation under 10 CFR 50.59. Rather than expend resources on such changes to perform, document and report 10 CFR 50.59 evaluations to NRC, these changes should be screened out.

The NRC staff proposal to define "design function" in terms of information described in the UFSAR is helpful, and we have modified the definition in NEI 96-07, Revision 1, as indicated below. As discussed above, we have retained the focus on functions credited in the safety analyses (including those that support or impact safety analysis functions), rather than all functions that may be described in the UFSAR. The following additional changes were made to the guidance to reinforce the intended breadth of the design function definition:

- The definition was clarified to reflect that conditions under which intended functions must be performed are implicitly included within the meaning of "design function"
- Consistent with the guidance proposed in Position 1.1.4, we have added a paragraph following the definition to clarify terms used to define "design function." Rather than define the concept of "implicit credit with respect to the safety analyses" as proposed by the NRC staff, we have clarified the definition of "design function" (as discussed above) to include matters that are implicitly included within the meaning of "design function." The turbine bypass system example was not helpful in this regard[1] and was eliminated.

[1] The turbine bypass system is used to mitigate certain overpressure transients and avoid more significant transients (e.g., reactor trips, lifting of Code safety relief valves). Thus, although non-safety-related, we agree that certain functions of the turbine bypass system are "design functions" for purposes of 10 CFR 50.59 screening because they impact functions credited in the safety analyses, and a change that adversely affects these turbine bypass system design functions would screen in. However, these functions are not (as identified in DG-1095)

- Additional guidance is also provided in Section 4.2.1 that, 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 50.59 evaluation is required when such changes adversely affect a UFSAR-described design function.

In defining "design function," we have specifically avoided use of the NRC staff phraseology, "These functions include *but are not limited to....*" First, such open-ended language is not helpful or appropriate for use in defining key terms. Second, the design function definition, modified and expanded as identified below, is sufficiently broad to encompass functions that affect initiation and response to events the plant is required to withstand.

Proposed NEI 96-07, R1, Clarification

In Section 3.3, replace existing definition of "design function" with the following:

Design function for an SSC means an SSC function described in the UFSAR that is credited in the safety analyses, or that supports or impacts any credited SSC function. 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 include: (1) functions performed by safety-related SSCs or non-safety-related SSCs, and (2) functions of safety-related or non-safety-related SSCs that, if not performed, would initiate a plant transient or accident. Implicitly included within the meaning of design functions are the conditions under which intended functions are required to be performed, such as equipment response times, ~~environmental and~~ process conditions, equipment qualification, and single failure.

To be added after the definition of "design function:"

As used in this definition, "credited in the safety analyses" means that, if the SSC were not to perform its design 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 "supports or impacts SSC functions" refers both to those SSCs needed to support other SSC design functions (cooling, power, environmental control, etc.) and to SSCs whose operation or malfunction could adversely affect the performance of design functions (for instance, control systems and physical arrangements). Thus,

considered "credited" in the safety analyses. Non-safety-related systems are typically not credited in safety analyses.

both safety-related and non-safety-related SSCs may perform design functions.

DG-1095 Position 1.1.5

The discussion in Section 4.2.1, beginning with the second sentence, is to be considered under the subheading of Section 4.2.1.1. Section 4.2.1 discusses whether an activity is a "change to the facility or procedures as described in the UFSAR." The discussion begins with reference to all three parts of the rule definition of change, but then the subsequent discussion in this section (as well as in subsection 4.2.1.1) is focused only on facility changes as they relate to design functions. Other subsections (4.2.1.2 and 4.2.1.3) give further guidance on screening with respect to procedures and evaluation methods. All parts of Section 4.2.1 need to be used, as applicable. Since the noted text under Section 4.2.1 is more germane to the heading of Section 4.2.1.1, this text is to be moved.

Industry Comment:

The purpose of Section 4.2.1 (modified as indicated below) is to present guidance common to the screening of changes to the facility (discussed in Subsection 4.2.1.1), procedures (discussed in Subsection 4.2.1.2), and methods of evaluation (discussed in Subsection 4.2.1.3). These points of common guidance are:

1. In determining whether a change screens in or out, the full range of effects—direct and indirect—of the change must be considered (examples provided).

2. Additions are subject to 10 CFR 50.59 and should be screened for their effects on the existing facility as described in the UFSAR.

3. (New) Changes affecting SSCs and functions not described in the UFSAR must be screened for their effects (so-called "indirect effects") on UFSAR-described design functions.

4. Adverse changes screen in; benign and beneficial changes may generally be screened out. Expanded guidance in Section 4.2.1 for determining whether there is an adverse effect, and thus that a 10 CFR 50.59 evaluation is required, is discussed in response to DG-1095 position 1.1.6.

Proposed NEI 96-07, R1, Clarification

Section 4.2.1 to be revised as follows:

To determine whether or not a proposed change 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 affected SSCs and the proposed change is essential. A given change may have both direct and indirect effects that the screening review must consider. The following questions illustrate the range of effects that may stem from a proposed change: ~~Only proposed changes that would, based on supporting engineering and technical information, have adverse effects on SSC design functions require evaluation under 10 CFR 50.59. A determination of whether adverse effects exist should consider both direct and indirect effects of the activity. Examples of questions that could be considered include the following:~~

- Does the activity decrease the reliability of an SSC design function, including either functions whose failure would initiate a transient/ accident or functions that are relied upon for mitigation?

- Does the activity reduce existing redundancy, diversity or defense-in-depth?

- Does the activity add or delete an automatic or manual design function of the SSC?

- Does the activity convert a feature that was automatic to manual or vice versa?

- Does the activity introduce an unwanted or previously unreviewed system or materials 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 or environmental qualification of the SSC?

- Does the activity adversely affect other units at a multiple unit site?

- Does the activity use equipment/tools that interface either directly or indirectly with an operable SSC?

- Does the activity introduce intrusive test equipment into the SSC such that an SSC design function is affected?

- 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 electrical distribution, structural integrity, environmental conditions or other UFSAR-described design functions?

Per the definition of "change" discussed in Section 3.3, 10 CFR 50.59 is applicable to additions as well as to changes to and removals from the facility or procedures. Additions should be screened for their effects on the existing facility and procedures as described in the UFSAR and, if required, a 10 CFR 50.59 evaluation should be performed. NEI 98-03 provides guidance for determining whether additions to the facility and procedures should be reflected in the UFSAR per 10 CFR 50.71(e).

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 50.59 evaluation is required when such changes adversely affect a UFSAR-described design function, as described below.

> (Revised Section 4.2.1 continues with expanded guidance on "adverse effects." See response to DG-1095 Position 1.1.6.)

DG-1095 Position 1.1.6

Section 4.2.1 (relocated to Section 4.2.1.1 per Regulatory Position 1.1.5) provides guidance on whether a change may (adversely) affect a design function. Guidance is added for deciding whether a function is affected when the change is with respect to some characteristic or value (response time, capacity) of an SSC. Whether the change affects the function is determined by whether the result remains within the bounds of existing analyses or FSAR information. If the nature of the change is such that engineering assessments or revised analyses are needed to determine whether an effect is adverse, the change requires an evaluation pursuant to 10 CFR 50.59, and not a screening.

Industry Comment

Because, to some degree, engineering assessments underlie essentially all proposed changes, tests and experiments, this proposed regulatory position would negate the screening process and require 10 CFR 50.59 evaluations for nearly all activities. We do not believe the NRC staff, which has recognized the appropriateness of 10 CFR 50.59 screening, intends this.

Each proposed change is supported by technical/engineering information, that may include but is not limited to, drawings, specifications, narrative description, design evaluations, installation and testing requirements, associated procedure changes (if any), revised analyses (if any) and similar information. This information, often referred to as the design change package, demonstrates the safety and effectiveness of the change and provides the basis for management approval of its implementation. The final rule and SOC highlighted the distinction between the engineering/technical (i.e., "safety") evaluation reflected in the design change package and the 10 CFR 50.59 regulatory review that determines whether a change requires prior NRC approval. Screening determinations are based on the technical/engineering information that supports proposed changes.

Screening is the first part of the 10 CFR 50.59 regulatory review and must be based on a thorough understanding of the design function(s) of affected SSCs and the effect(s) of the proposed change. As discussed above, where screening determines that a change does not affect SSCs that perform, support or impact functions credited in the safety analyses, i.e., that changes do not affect design functions, such changes may be screened out from further 10 CFR 50.59 evaluation.

In addition to screening out changes that have no effect on design functions, certain changes can be determined during the 10 CFR 50.59 screening review to have a positive (beneficial) effect on design functions and may also be screened out. This is so for two reasons:

(1) "Design function" is defined broadly to encompass functions that affect initiation as well as response to events the plant is required to withstand.

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 a transient or accident would be considered to adversely affect a design function and would screen in. Relaxing code or quality requirements for certain SSCs are examples of changes of this type. Similarly, changes that would introduce a new type of accident or malfunction result are in this category and would screen in. This reflects an overlap between the technical/engineering ("safety") review of the change and the 10 CFR 50.59 evaluation. This overlap reflects that these considerations are important to both the safety and regulatory reviews.

and,

(2) Changes that have positive or no effect on design functions cannot increase the likelihood of malfunctions, increase consequences, create new accidents or malfunctions, or otherwise meet the 10 CFR 50.59 evaluation criteria.

Only changes that adversely affect design functions, methods of performing or controlling design functions, or evaluations that demonstrate that intended design functions will be accomplished screen in because only adverse changes have the potential to meet the 10 CFR 50.59 evaluation criteria.

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 50.59 evaluation process.

Screening determinations are made based on inspection of the engineering/technical information supporting the change. The screening focus on design functions ensures the essential distinction between 10 CFR 50.59 screenings and evaluations, which focus on whether changes meet any of the eight criteria in 10 CFR 50.59(c)(2) are met. 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 UFSAR safety analyses were, or must be, re-run to demonstrate that all required safety functions and design requirements are met (i.e., existing safety analyses are no longer bounding), the change is considered to be adverse and must be screened in. The revised safety analyses may be used to support the required 10 CFR 50.59 evaluation of such changes.

Changes that require 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 requires safety analyses to be updated. For example, a change that improves filter efficiency of the main control room ventilation system reduces the calculated dose operators and requires UFSAR dose consequence analyses to be updated. In this case, the dose analyses are being revised to reflect the lower dose for the main control room, not to demonstrate that GDC limits continue to be met. A change that would adversely affect the design function of main control room filters (to remove particulate radiation) and increase the existing calculated dose to operators would be considered adverse and would screen in. In this case, the dose analyses must be re-run to ensure that GDC limits continue to be met. The revised analyses would be used to determine if the increase exceeds the minimal standard and requires prior NRC approval.

To further illustrate the distinction between 10 CFR 50.59 screening and evaluation, consider the example of a change to a diesel generator-starting relay that delays the diesel start time from 10 seconds to 12 seconds. The UFSAR-described design function credited in the ECCS analyses is for the diesel to begin providing power at 12 seconds. This change may be screened out because it is apparent based on inspection that the change will not adversely affect the diesel generator design function credited in the ECCS analyses (ECCS analyses remain valid).

However, a change that would delay the diesel's readiness to accept load to 13 seconds would screen in because the change adversely effects the design function (to provide emergency AC power in 12 seconds). Such a change would screen in even if technical/engineering information supporting the change includes revised safety analyses that demonstrate all required safety functions supported by the diesel, e.g., core heat removal, containment isolation, containment cooling, etc., are satisfied and that applicable dose limits continue to be met. While this change may be acceptable with respect to performance of required safety functions and meeting design requirements, the analyses necessary to demonstrate acceptability are beyond the scope/intent of 10 CFR 50.59 screening reviews. Thus a 10 CFR 50.59 evaluation would be required. The revised safety analyses would be used in determining whether any of the 10 CFR 50.59 evaluation criteria are met such that prior NRC approval is required for the change.

As indicated below, much of the above discussion has been added to Section 4.2.1 to provide expanded guidance for determining if there is an adverse effect due to a facility, procedure or methodology change. Also identified are modifications to Subsections 4.2.1.1, 4.2.1.2 and 4.2.1.3 to reflect the Section 4.2.1 guidance on screening for adverse effects. Additional specific guidance on determining if there is an adverse effect due to a procedure or methodology change is provided in subsections 4.2.1.2, and 4.2.1.3, respectively.

<u>Proposed NEI 96-07, R1, Clarifications</u>

Expanded Section 4.2.1 Guidance on "Adverse Effects"

New Subheading—Screening for Adverse Effects

A 10 CFR 50.59 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 malfunctions, or otherwise meet the 10 CFR 50.59 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 a transient or accident would be considered to adversely effect a design function and would screen in. Relaxing code or quality requirements for certain SSCs are examples of changes of this type. Similarly, changes that would introduce a new type of accident or malfunction result are in this category and would screen in. This reflects an overlap between the technical/engineering ("safety") review of the change and the 10 CFR 50.59 evaluation. 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, and the 10 CFR 50.59 evaluation may 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 50.59 evaluation process.

Screening determinations are made based on inspection of the engineering/technical information supporting the change. The screening focus on design functions, etc., ensures the essential distinction between (1) 10 CFR 50.59 screenings, and (2) 10 CFR 50.59 evaluations, which focus on whether changes meet any of the eight criteria in 10 CFR

[2] The exception to this is that a change that has any effect—positive or negative—on design basis limits for fission product barriers must be screened in (see Section 4.2.1.1).

50.59(c)(2) are met. 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 UFSAR safety analyses were, or must be, re-run to demonstrate that all required safety functions and design requirements are met (i.e., existing safety analyses are no longer bounding), the change is considered to be adverse and must be screened in. The revised safety analyses may be used to support the required 10 CFR 50.59 evaluation of such changes.

Changes that require 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 requires safety analyses to be updated. For example, a change that improves filter efficiency of the main control room ventilation system reduces the calculated dose operators and requires UFSAR dose consequence analyses to be updated. In this case, the dose analyses are being revised to reflect the lower dose for the main control room, not to demonstrate that GDC limits continue to be met. A change that would adversely affect the design function of main control room filters (to remove particulate radiation) and increase the existing calculated dose to operators would be considered adverse and would screen in. In this case, the dose analyses must be re-run to ensure that GDC limits continue to be met. The revised analyses would be used to determine if the increase exceeds the minimal standard and requires prior NRC approval.

To further illustrate the distinction between 10 CFR 50.59 screening and evaluation, consider the example of a change to a diesel generator-starting relay that delays the diesel start time from 10 seconds to 12 seconds. The UFSAR-described design function credited in the ECCS analyses is for the diesel to begin providing power at 12 seconds. This change may be screened out because it is apparent based on inspection that the change will not adversely affect the diesel generator design function credited in the ECCS analyses (ECCS analyses remain valid).

However, a change that would delay the diesel's readiness to accept load to 13 seconds would screen in because the change adversely effects the design function (to provide emergency AC power in 12 seconds). Such a change would screen in even if technical/engineering information supporting the change includes revised safety analyses that demonstrate all required safety functions supported by the diesel, e.g., core heat removal, containment isolation, containment cooling, etc., are satisfied and that applicable dose limits continue to be met. While this change may be acceptable with respect to performance of required safety functions and meeting design requirements, the analyses necessary to demonstrate acceptability are beyond the scope/intent of 10 CFR 50.59 screening reviews. Thus a 10 CFR 50.59 evaluation would be required. The revised safety analyses would be used in determining whether any of the 10 CFR 50.59 evaluation criteria are met such that prior NRC approval is required for the change.

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

To be added to Section 4.2.1.1 (on screening of changes to the facility) before the paragraph introducing the examples:

As discussed in Section 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 50.59. Changes that have positive or no effect on design functions may generally be screened out. The exception to this is that any change to a design bases limit for a fission product barrier—adverse or beneficial—must be screened in. This is because 10 CFR 50.59(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.

Section 4.2.1.2 guidance on screening procedure changes to be revised as follows:

Changes to procedures are "screened in" (i.e., require a 10 CFR 50.59 evaluation) if the change adversely affects how SSC design functions are performed or controlled, as described in the UFSAR (including assumed operator actions and response times). Proposed procedure 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 50.59 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), analog to digital upgrades, changing a valve from "locked closed" to "administratively closed," and similar changes.

Section 4.2.1.3 on screening methodology changes to be revised as follows:

> As discussed in Section 3.6, methods of evaluation included in the UFSAR to demonstrate that intended SSC design functions will be accomplished are considered part of the "facility as described in the UFSAR." Thus use of new or revised methods of evaluation (as defined in Section 3.10) is considered to be a change that is controlled by 10 CFR 50.59 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 50.59(c)(2)(viii) to determine if prior NRC approval is required (see Section 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 may be screened out.
>
> Methods of evaluation that may be identified in references listed at the end of UFSAR sections or chapters are not subject to control under 10 CFR 50.59 unless the UFSAR states they were used for specific analyses within the scope of 10 CFR 50.59(c)(2)(viii).
>
> Changes to methods of evaluation included in the UFSAR are considered adverse and require evaluation under 10 CFR 50.59 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 50.59(c)(2)(viii).

DG-1095 Position 1.2, INTERFACE OF 10 CFR 50.59 WITH THE MAINTENANCE RULE (10 CFR 50.65)

Sections 1.2.1, 3.3, and 4.1.2 of the NEI guidance discuss the relationship between 10 CFR 50.59 and 50.65(a)(4) with respect to maintenance activities, including associated maintenance preparatory activities (referred to in some instances as "temporary changes or alterations"). NRC agrees with the intent of this guidance that, for activities required to support and directly related to the maintenance, 10 CFR 50.59 does not apply for the duration of the maintenance on the basis that another regulation controls such activities.

To avoid confusion about the relationship of maintenance activities (which restore the facility to its original condition) and modifications (that change in some respect the facility), Section 4.1.2 is to read as follows:

> Maintenance activities are actions that restore SSCs to their as-designed state. Maintenance activities include troubleshooting, calibration, refurbishment, post-maintenance testing, identical replacements, housekeeping, and similar activities that do not permanently alter the design or design function of SSCs. Maintenance activities, including alterations to the facility or procedures required to support and directly related to the maintenance, are not subject to 10 CFR 50.59 evaluations but are subject to the provisions of 10 CFR 50.65(a)(4) as well as technical specifications.
>
> Licensees should address operability in accordance with the technical specifications and should assess and manage the risk impact of maintenance activities per 10 CFR 50.65(a)(4) and NEI 93-01, "Industry Guidelines for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants."[1]
>
> When the facility is not restored to its original condition as a result of the "maintenance activity" (e.g., if SSCs are removed, if the design, design function, or operation is altered, or if a temporary change in support of the maintenance is not removed), both 10 CFR 50.65(a)(4) and 50.59 would apply as discussed below. In these circumstances, the activities under way are not limited to maintenance, but also involve some sort of design or licensing basis change. An assessment of the "maintenance activity" is required as well as review of the "change." This situation might occur when the original plan is to restore the facility, but during the course of the maintenance, it is determined that full restoration will not occur (at which time the applicability of 10 CFR 50.59 would arise).
>
> A design change would be subject to 10 CFR 50.59 evaluation with respect to its effect upon the facility and its operation (following installation). Further, licensees may include as part of the modification package an evaluation pursuant to 10 CFR 50.59 for the facility in various stages of implementation of a modification (as needed). The actual implementation of a design change, including associated activities, may be viewed as "maintenance" rather than a change under 10 CFR 50.59, and be assessed under 10 CFR 50.65(a)(4). Thus, in these cases, a 10 CFR 50.65(a)(4) assessment would be needed for the duration of the "maintenance activity" to implement the modification. Whether a 10 CFR 50.65(a)(4) assessment is required for the installation of a modification should be determined by the maintenance rule requirements and guidance for assessing and managing risk before maintenance activities.

In addition to assessments required by 10 CFR 50.65(a)(4), 10 CFR 50.59 should be applied to maintenance activities if a temporary change in support of maintenance is expected to be in effect during at-power operations for more than 90 days. In this case, 10 CFR 50.59 would be applied to the temporary change prior to implementation in the same manner as a permanent change.

Apply 10 CFR 50.59 to temporary changes proposed as compensatory measures for degraded or non-conforming conditions, as discussed in Section 4.4.

Proposed NEI 96-07, R1, Clarification

We agree with the intent of the proposed NRC clarification. Section 4.1.2, Maintenance Activities, to be revised as follows:

> Maintenance activities are activities that restore SSCs to their as-designed condition, including activities that implement approved design changes. Maintenance activities include troubleshooting, calibration, refurbishment, post-maintenance testing, identical replacements, housekeeping, ~~associated temporary changes,~~ and similar activities that do not permanently alter the design or design function of SSCs, and are thus not subject to 10 CFR 50.59. Maintenance activities, including alterations to the facility or procedures that directly relate to and are necessary to support the maintenance, are not subject to 10 CFR 50.59, but are subject to the provisions of 10 CFR 50.65(a)(4) as well as technical specifications. Examples of 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.
>
> Licensees should address operability in accordance with the technical specifications and should assess and manage the risk impact of maintenance activities per 10 CFR 50.65(a)(4) and NEI 93-01, *Industry Guidelines for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.*
>
> In addition to assessments required by 10 CFR 50.65(a)(4), 10 CFR 50.59 should also be applied to maintenance activities in the following cases:

- A temporary alteration in support of the maintenance is expected to be in effect during at-power operations for more than 90 days. In this case, 10 CFR 50.59 would be applied to the temporary alteration prior to implementation in the same manner as a permanent change. If the temporary alteration meets any of the 10 CFR 50.59 evaluation criteria, prior NRC approval is required to leave the temporary alteration in effect longer than 90 days.

- The plant is not restored to its original condition upon completion of the maintenance activity (e.g., if SSCs are removed, the design, ~~design~~ function or operation is altered, or if temporary alteration in support of the maintenance is not removed). In this case, 10 CFR 50.59 would be applied to the change in design.

Installation and post-modification testing of approved design changes is indistinguishable from maintenance activities that restore SSCs to their as-designed condition in terms of their risk impact on the plant. As such, installation and testing of approved design changes are maintenance activities that must be assessed and managed in accordance with 10 CFR 50.65(a)(4). This contrasts with historical practice whereby 10 CFR 50.59 reviews addressed the design, installation and post-modification testing of proposed design changes. Going forward, 10 CFR 50.59 will address the effect, following implementation, of proposed design changes to determine if prior NRC approval is required; the risk impact of actually implementing the change will be assessed and managed per 10 CFR 50.65(a)(4).

10 CFR 50.59 should be applied to temporary changes proposed as compensatory measures for degraded or non-conforming conditions, as discussed in Section 4.4.

DG-1095 Position 1.3, INCREASES IN LIKELIHOOD OF MALFUNCTION

In Section 4.3.2 of NEI 96-07, a quantitative value for "no more than a minimal increase" is a factor of 2 increase. This factor must be applied at the individual component level. If the guidance is not so limited, further guidance would be needed to limit the overall effects of the change at the system or train level. The NRC staff agrees with the NEI guidance that states that use of the factor of 2 may also be constrained by other evaluation criteria, depending upon the specific components or functions that the change involves.

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25 Apr 00
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NMC
Committed to Nuclear Excellence

Nuclear Management Company, LLC

Michael D. Wadley
Chief Nuclear Officer

June 9, 2000

Received
13June2000
9:30am

David L. Meyer
Chief, Rules & Directives Branch
Office of Administration
Mail Stop T-6 D59
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Comments on Draft Regulatory Guide DG-1095, "Guidance for Implementation of 10CFR 50.59, Changes, Tests and Experiments."

Dear Mr. Meyer:

NMC is the operating company representing the following five nuclear plants. These comments are based on feedback received from:

Duane Arnold Energy Center, Palo, IA

Kewaunee Nuclear Power Plant, Kewaunee, WI

Monticello Nuclear Generating Plant, Monticello, MN

Point Beach Nuclear Plant, Two Rivers, WI

Prairie Island Nuclear Generating Station, Welch, MN

NMC Comments: NMC endorses the Nuclear Energy Institute's comments on DG-1095 and their proposed changes to NEI 96-07, and provides the following amplifying comments:

Template: ADM-013

700 First Street • Hudson, Wisconsin 54016
Telephone: 715.377.3303 • Fax: 715.377.3355 • Toll-Free: 800.701.4941
mdwadley@nmcco.com

E-RIDS=ADM-03
Add-E McKenna EMM

1. Section 1 of DG-1095 states that NEI 96-07 is acceptable to the NRC with clarifications. "To clarify" means to make clear or understandable. This implies that the Staff agrees with the intent of NEI 96-07, but feels it could be made clearer. However, some of the "clarifications" offered by the Staff in DG-1095 differ so much from NEI 96-07 that the DG can hardly be considered an endorsement. As discussed in the following comments, the cumulative effect of the positions taken in DG-1095 would be to negate the screening process and require a 10CFR 50.59 evaluation for nearly all activities.

2. Section 1.1.1 of DG-1095 states that the term "design function" as used in screening should be broadly defined so that changes which have the potential to meet any of the evaluation criteria should be evaluated rather than screened. By creating this surprising link between the screening criteria of 10CFR 50.59(c)(1) and the evaluation criteria of 10CFR 50.59(c)(2), the Staff is proposing to widen the scope of 10CFR 50.59 to an unprecedented extent. Linking the screening criteria to the evaluation criteria in this way negates the screening process created by 10CFR 50.59(c)(1), as supported by the 10CFR 50.59(a) definitions, and in doing so appears to be inconsistent with the Rule itself.

   A more reasonable approach would be to align the definition of "design function" to the definition of "design basis" or "design basis function" as used in 10CFR 50.2 and defined in NEI 97-04 Appendix B, which was endorsed by the NRC in DG-1093.

3. DG-1095 section 1.1.4 effectively expands the definition of structures, systems and components (SSC) "credited in the safety analyses" to include SSC that are not explicitly credited in the safety analysis, but which perform the same or a related function. This new definition and the accompanying example (turbine bypass system) unreasonably broaden the scope of 10CFR 50.59 to include non-safety-related SSC which are implicitly assumed by the safety analysis to **not** function. NMC agrees that the indirect effects of non-safety-related SSC and SSC not described in the UFSAR should be considered, but only when they have an adverse effect on a function which is explicitly credited in the UFSAR safety analysis.

4. DG-1095 section 1.1.6 takes the position that a 50.59 evaluation would be required whenever an engineering assessment or revised analysis is needed to determine whether an effect of a proposed activity is adverse. Since many proposed activities, especially modifications, involve some type of engineering analysis, this requirement would negate the screening criteria and require an evaluation of many activities which would not otherwise meet the criteria of 10CFR 50.59(c)(1). Any activity which has been shown to be bounded by the existing UFSAR design basis and Chapter 14/15 safety analyses cannot, by definition, possibly meet any of the eight evaluation criteria. Requiring an evaluation under these circumstances would be pointless.

   It should be noted that analyses related to safety related equipment are already required to be retained by the Licensee in accordance with 10CFR 50 Appendix B.

Serious consideration of all of NEI's comments, especially those discussed above, is respectfully requested.

Please contact Matthew Petitclair (763-295-1689) if you have any questions related to these comments.

Sincerely,

Michael D Wadley

Michael D. Wadley
Chief Nuclear Officer
Nuclear Management Company

cc:
Eilene M. McKenna, NRC
NMC Site VP/GMs
NMC Site Licensing Managers
William J. Hill, NMCHQ
Doug F. Johnson, NMCHQ
NMC 50.59 Working Group
Anthony R. Pietrangelo, NEI

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Entergy

Entergy Operations, Inc.

Michael A. Krupa

Received
15 June00
10:30am

June 9, 2000

Rules and Directives Branch
Office of Administration
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Comments on Draft Regulatory Guide DG-1095, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, and Experiments'"

CNRO-2000/00018

Ladies and Gentlemen:

Entergy Operations, Inc. (Entergy) appreciates the opportunity to comment on proposed Draft Regulatory Guide DG-1095, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, and Experiments,'" as noted in the Federal Register, April 25, 2000, Volume 65, Number 80. Specific comments are provided in the accompanying attachment. Entergy also endorses the comments submitted to the NRC by the Nuclear Energy Institute (NEI).

Again, thank you for the opportunity to provide our comments.

Sincerely,

M. A Krupa

MAK/GHD/baa
attachment
cc: Mr. C. G. Anderson (ANO)
Mr. C. M. Dugger (W3)
Mr. W. A. Eaton (GGNS)
Mr. R. K. Edington (RBS)
Mr. G. J. Taylor (ECH)
Mr. T. W. Alexion, NRC Project Manager (ANO-2)
Mr. D. H. Jaffe, NRC Project Manager (RBS)
Mr. N. Kalyanam, NRC Project Manager (W3)
Mr. M. C. Nolan, NRC Project Manager (ANO-1)
Mr. S. P. Sekerak, NRC Project Manager (GGNS)

Template: ADM-013

E-RIDS = ADM-03
Add: E McKenna (EMM)

COMMENTS ON
DRAFT REGULATORY GUIDE DG-1095

DG Section	Comment
C 1.1.1	Regarding the definition of "design function," please clarify the thought process regarding a system whose design function is described in the SAR only in terms of at-power conditions, and how using that system under plant shutdown conditions involves a change of "design function." There should be no change in design function in such a case provided there is no adverse impact upon the system in question.
C 1.1.3	With this clarification, the NRC is broadening the scope of "design function" to encompass anything for which the SSC may be used. This definition is too inclusive.
C 1.1.4	1. Please clarify the expectations regarding non-safety equipment in safety analyses. Specifically consider non-safety equipment (e.g., feedwater pumps) that is running at the start of an analyzed transient, which does not involve the loss of offsite power. Address the acceptability of assuming that such equipment continues to run in the same manner as it was before the start of the transient, with no response of that equipment to changing conditions (unless that response would exacerbate the transient). 2. Section 1.1.4 states the response of non-safety equipment (e.g., turbine bypass valves) is implicitly credited in safety analyses. This is incorrect. While such non-safety equipment, if described in the SAR, is part of the plant design, it is disingenuous to state that such equipment is implicitly credited in the safety analyses when the results of the analyses reported in the SAR are unchanged because that equipment is explicitly not included in the analysis.
C 1.1.6	Section C 1.1.6 states, "If the nature of the change is such that an engineering assessment or revised analyses is needed to determine whether an effect is adverse, the staff concludes that a 10CFR50.59 evaluation is required rather than a screening." This position detracts from the goal of regulatory stability implicit in the revised rule. Concerns with this statement include the fact that many engineering assessments, evaluations, or calculations are performed to document, rather than to determine, whether an adverse affect exists. Thus, vagueness would be introduced into the rule by relying on whether or not an engineering assessment was performed in support of the change. It is also the case that plants, which have previously performed sensitivity

	studies, would be able to reference those pre-existing analyses to determine that there is no adverse affect. Thus, the change could be supported without a full 50.59 evaluation. However, plants that have not performed such sensitivity studies would require a full 50.59 evaluation under the NRC guidance of SECY-00-0071. This is inconsistent. Also, to what extent would credit be allowed for analyses of similar plants when addressing the whether or not an engineering assessment is needed to determine if an affect is adverse? Past experience of the analysts, including service at other plants, would have a great impact on whether or not an engineering assessment is required to determine no adverse impact (vice an engineering assessment which is performed to document that there is no adverse impact). Consider a plant which has an analysis performed with a relatively old, outdated computer code, albeit one used to generate the results reviewed by the NRC during the original plant licensing process. For example, a containment analysis code may have been written with a binary switch to control the deposition of heat transferred via revaporization in an older code rather than have a physically realistic model. However, this is the type of intricate detail in the code which is not explicitly discussed in topical reports or NUREGs documenting the code or which is documented or mentioned in facility SARs. Consider that the plant in question has conducted detailed benchmark studies comparing the results with this old code to results with a newer, more physically accurate code, and has obtained a thorough understanding of the biases between the codes. For example, assume a utility has clearly determined there is a bias that is no greater than 1.5 psi between the results obtained by the two different codes. If, for business reasons or for improved user interface purposes, the plant desires to use the newer code instead of the older, there is a clear technical and logical basis to use the newer code in conjunction with an applied bias in place of the older code. NEI 96-07 and DG-1095 should recognize this situation is not a change in methodology since applying the bias ensures the newer method does not result in a non-conservative change in the results and, thus, is not a departure from approved methods.
C 1.2	Since the Maintenance Rule and its required risk screenings will be relied upon to assess the impact of short-term maintenance or construction instead of 50.59, does this mean that Maintenance Rule risk screenings will be performed in lieu of 50.59 reviews for Heavy Load Lifts? Is the new regulatory guidance in conflict with the guidance of Bulletin 96-02, which declared that all heavy load lifts over fuel or safety related equipment not previously analyzed is a Unreviewed Safety Question? Please clarify the requirements for Heavy Load Lifts under the revised 10CFR50.59 and the revised 10CFR50.65.

C 1.4	1. NEI 96-07 Section 4.3.8.2 discusses considerations for determining if new methods are technically appropriate for the intended application. The NRC should clarify that this discussion reflects that certain types of analyses (e.g., shielding, high-energy line break compartment thermal-hydraulic analyses, offsite dose analyses) are independent of plant design. For example, the use of ICRP30 dose conversion factors is an item that has been generically approved by the NRC by virtue of incorporating it into the basis of 10CFR21. Such factors are independent of plant design. Thus, any licensee should be able to adopt the ICRP30 dose conversion factors with a 10CFR50.59 Evaluation and should not have to obtain NRC approval to adopt this generically approved methodology. 2. The NRC should also clarify that many methodologies used in safety analyses (e.g., dose analyses, HELB, shielding, systems analyses) are not approved by the NRC and do not require approval by the NRC. NEI 96-07 Section 4.3.8.2 does not currently reflect this.
C 1.4.1	The NRC should delete Section 1.4.1. In this section, NRC questions whether licensees are able to determine if differences in configuration or licensing basis would have impacted whether the NRC would have approved an evaluation method at one plant for another plant. The basis for such a determination needs to be in the NRC SER. Due to greater familiarity with its own design, analyses, and licensing basis, a licensee is as able to make this determination to the same level of quality as the NRC would. This section should be deleted from DG-1095.
C 3	In Section 3.0, the NRC should either endorse the NEI examples, identify the examples it disagrees with and why, or provide its own examples. To do otherwise is an abdication of responsibility and would greatly detract from the regulatory stability sought through adoption of the new 10CFR50.59 rule.
D	This section provides no implementation guidance. The NRC should provide their expectations for transitioning from the old rule to the new one. For example, changes evaluated under the old rule and determined not to require prior NRC approval need not be re-evaluated under the new rule.

Commonwealth Edison Company
1400 Opus Place
Downers Grove, IL 60515-5701

65FR#24231
25 Apr 00
(10)

Received
15 June 00
10:30am

ComEd

RS-00-19

June 9, 2000

Rules and Directives Branch
Office of Administration
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Response to Request for Comments on Draft Regulatory Guide DG-1095, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, and Experiments'"

References: (1) Volume 65, Federal Register, Page 24231 (65 FR 24231), dated April 25, 2000

(2) Nuclear Energy Institute letter, "Industry Comments on Draft Regulatory Guide 1095, Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, and Experiments,' (65 Fed. Reg. 24231 – April 25, 2000)," dated June 8, 2000

Commonwealth Edison (ComEd) Company appreciates the opportunity to comment on the NRC's proposed draft Regulatory Guide DG-1095, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments." This letter provides our comments in response to Reference 1. ComEd has been actively involved with the Nuclear Energy Institute (NEI) on this issue and fully endorses the industry comments submitted by the NEI in Reference 2.

If you have any questions or require additional information please contact me at (630) 663-7330.

Respectfully,

K. A. Ainger for

R. M. Krich
Vice President - Regulatory Services

Template: ADM-013

E-RIDS= ADM-03
Add: E McKenna (EMM1)

★USA

Utilities Service Alliance, Inc.

A Not-for-Profit Membership Corporation
Working Together For Mutual Success

65FR#24231
25Apr00
11

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Received
15 June 2000
2:50pm

June 9, 2000
NANL-00-0105

Mr. David L. Meyer
Chief, Rules and Directives Branch
Division of Administrative Services
Office of Administration
Mail Stop: T-6 D59,
U. S. Nuclear Regulatory Commission
Washington, D.C., 20555-0001

Reference: Federal Register Notice, 65 FR 24231, dated April 25, 2000

Subject: **Comments on Draft Regulatory Guide, DG-1095, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests and Experiments"**

Dear Mr. Meyer:

The Utilities Service Alliance (USA) appreciates the opportunity to comment on Draft Regulatory Guide, DG-1095. The guidance in NEI 96-07 is being used by the fourteen utilities participating in the USA 50.59 Project. The USA objective is to develop standardized procedures, forms, guidance and training programs. Endorsement of NEI 96-07 by this Regulatory Guide, therefore, is clearly a very important milestone in the implementation process.

The products described above that are being developed by USA will be revised as necessary to reflect changes resulting from comments on the Draft Regulatory Guide. As described at the NEI Licensing Issues Workshop in April, the USA developed procedures, forms and resource manual are being made available to all licensees via the NEI web site in order to promote consistent understanding and implementation of 10CFR50.59.

Template: ADM-013

E-RIDS = ADM-03
Add: E-Mckenna (EMM)

The Utilities Service Alliance (USA) endorses the comments submitted on this issue by NEI's letter dated June 8, 2000. USA believes that incorporating these comments into the guidance will provide important additional clarification and result in a significant improvement.

If you should have any questions regarding this submittal or the details of the USA Project described above, please contact me at (734) 586-4211.

Very truly yours,

Robert A. Newkirk
Chairman,
USA 50.59 Project

cc: Document Control Desk (USNRC)
Carl Parry, USA
A. Pietrangelo, NEI
D. Gipson
W. O'Connor
N. Peterson
Correspondence File 140 NOC

Dave Morey
Vice President
Farley Project

Southern Nuclear Operating Company
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65FR#24231
25Apr00
12

Received
16 June 2000
9:00 am

SOUTHERN COMPANY
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NEL-00-0152

June 5, 2000

Rules and Directives Branch
Office of Administration
U. S. Nuclear Regulatory Commission
Washington, DC 20555 - 0001

Comments on
"Draft Regulatory Guide 1095, Guidance for Implementation of
10CFR50.59, Changes, Tests and Experiments"
(65 Federal Register 24231 dated April 25, 2000)

Ladies and Gentlemen:

Southern Nuclear Operating Company (SNC), the licensed operator for the Joseph M. Farley Nuclear Plant, the Edwin I. Hatch Nuclear Plant and the Vogtle Electric Generating Plant, has reviewed the request for public comment, "Draft Regulatory Guide 1095, Guidance for Implementation of 10CFR50.59," published in the Federal Register on April 25, 2000. In response to this request, SNC is in agreement with the comments that are to be provided to the NRC by the Nuclear Energy Institute.

If there are any questions, please advise.

Respectfully submitted,

DJ Morey

Dave Morey

TMM/maf: 5059endor.doc

Template= ADM-013

ERIDS= ADM-03
Add: F McKenna (FMM)

65FR#24231
25 Apr 00
13

VIRGINIA POWER

June 9, 2000

Received
19 June 2000
3:10pm

Rules and Directives Branch
Office of Administration
U.S. Nuclear Regulatory Commission
Washington D.C. 20555-0001

Serial No. GL00-027

Gentlemen:

COMMENTS ON DRAFT REGULATORY GUIDE DG-1095, "GUIDANCE FOR IMPLEMENTATION OF 10 CFR 50.59, CHANGES, TESTS AND EXPERIMENTS"

Virginia Power appreciates the opportunity to comment on the Draft Regulatory Guide DG-1095, "Guidance for Implementation of 10 CFR 50.59 Changes, Tests and Experiments" published in the Federal Register on April 25, 2000. NRC endorsement of the guidance contained in the Nuclear Energy Institute's document, NEI 96-07, Revision 1, "Guidelines For 10 CFR 50.59 Evaluations" governing proposed changes to nuclear facilities, will result in increased regulatory stability. This regulatory guidance is expected to clarify the requirements and provide licensees with reasonable latitude in implementing the changes of the Final Rule on 10 CFR 50.59 published on October 4, 1999, and continue to provide reasonable assurance of public health and safety as licensees implement changes at their facilities.

Comments on the Draft Regulatory Guide have been prepared and submitted separately by NEI on behalf of the nuclear industry. We have reviewed the NEI comments and endorse them.

If you have any questions, please contact Mr. Joe Hegner at (804) 273-2770 or Ms. Gwen Newman at (804) 273-4255.

Sincerely,

FOR:

J. H. McCarthy, Manager
Nuclear Licensing & Operations Support

Template- ADM-013

ERD- ADM-03
ADD- E. McKenna (EMM)

Florida Power
CORPORATION
Crystal River Unit 3
Docket No. 50-302
Operating License No. DPR-72

Received
19 June 2000
3:18 pm

65FR#24231
25Apr00
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June 9, 2000
3F0600-12

Rules and Directives Branch
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Comments on Draft Regulatory Guide (DG)-1095, "Guidance for Implementation of 10 CFR 50.59" (65 FR 24231-24232)

Dear Sir:

Florida Power Corporation (FPC) appreciates the opportunity to comment on Draft Regulatory Guide (DG)-1095, "Guidance for Implementation of 10 CFR 50.59." FPC endorses, in its entirety, the industry comments provided by the Nuclear Energy Institute (NEI), by letter dated June 9, 2000.

If you have any questions regarding this submittal, please contact Mr. Sid Powell, Manager, Nuclear Licensing at (352) 563-4883.

Sincerely,

Sherry Bernhoft

S. L. Bernhoft
Director, Nuclear Regulatory Affairs

SLB/pei

xc: Regional Administrator, Region II
Senior Resident Inspector
NRR Project Manager
NRC Document Control Desk

Template-ADM-013

E-RIDS = ADM-03
Add: E. McKenna (EMM

CRYSTAL RIVER ENERGY COMPLEX: 15760 W. Power Line Street • Crystal River, Florida 34428-6708 • (352) 795-6486
A Florida Progress Company

NEI

NUCLEAR ENERGY INSTITUTE

65FR#24231
25Apr00
16

Anthony R. Pietrangelo
DIRECTOR LICENSING
NUCLEAR GENERATION

Received
19 June 2000
3:14 pm

June 8, 2000

Rules and Directives Branch
Office of Administration
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555-0001

SUBJECT: Industry Comments on Draft Regulatory Guide 1095, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, and Experiments'" (65 Fed. Reg. 24231 – April 25, 2000)

PROJECT NUMBER: 689

The Nuclear Energy Institute[1] offers the enclosed comments in response to the subject *Federal Register* notice soliciting public comments on Draft Regulatory Guide 1095.

The preliminary NRC endorsement of NEI 96-07, R1, *Guidelines for 10 CFR 50.59 Evaluations*, reflects the intensive efforts by industry and NRC staff to resolve issues and develop effective guidance for implementing the revised 10 CFR 50.59. We look forward to meeting with the staff later this month to discuss the enclosed comments as well as other public comments submitted in response to the subject FRN.

The enclosure addresses several clarifications proposed by the NRC staff in DG-1095, responds to specific NRC requests for comment, and identifies associated changes to the industry guidance. The enclosure also identifies proposed changes to other aspects of NEI 96-07, R1, that reflect industry comments received during and after NEI's April 10-11 workshop.

In addition to comments on DG-1095 and NEI 96-07, R1, we continue to receive numerous questions concerning the transition to the revised 10 CFR 50.59, e.g.,

- Which rule applies to changes evaluated, but not implemented, by the effective date of the rule?

Template: ADM-013

E-RIDS=ADM-03
ADD: E. McKenna(EMM)

[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including regulatory aspects of generic operational and technical issues. NEI members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

- Which rule applies when revising, after the effective date of the rule, an evaluation based on the old rule?

Additional transition issues are identified in "Draft Questions and Answers on 10 CFR 50.59 and NEI 96-07, R1,"(dated April 4) which has been provided to the NRC staff. We appreciate that the staff addressed these issues to some extent at the April workshop. However, we request that the NRC address these and related transition issues more formally in the final regulatory guide.

If you have any questions concerning the enclosed comments, please contact me at 202-739-8081, or Russ Bell at 202-739-8087.

Sincerely,

Anthony R. Pietrangelo

Anthony R. Pietrangelo

Enclosure

c: Eileen McKenna, NRC/NRR

Enclosure
June 8, 2000
Industry Response to DG-1095

DG-1095 Position 1.1, SCREENING ON WHETHER A CHANGE AFFECTS DESIGN FUNCTION

DG-1095 Position 1.1.1

To implement the rule properly, "design function," as used in screening, is broad so that changes that have the potential to meet any of the evaluation criteria are evaluated rather than screened. Since the criteria include both the initiation and response to previously postulated events (including equipment performance), as well as introduction of new events, "function" extends beyond safety-related SSC and specific mitigation systems whose performance is explicitly modeled and discussed in the safety analyses.

Industry Comment

The definition of "change" ensures that all changes that have the potential to meet one of the 10 CFR 50.59 evaluation criteria are appropriately reviewed. Indeed, any addition, modification or removal not controlled by another requirement is subject to 10 CFR 50.59, i.e., at least screened. The definition of "design function" provides the appropriate focus of these screening reviews. We agree that the definition of "design function" extends beyond safety-related SSCs and specific mitigation systems whose performance is explicitly modeled and discussed in the safety analyses. We plan to clarify the phrases "credited in the safety analyses" and "supports or impacts SSC functions" consistent with the DG-1095 Position 1.1.4. See below.

DG-1095 Positions 1.1.2, 1.1.3 and 1.1.4

(1.1.2) For SSCs that have functions described in the FSAR, changes affecting such functions should be evaluated, not excluded from further review because the described function does not fit the definition. When the change is being made to an SSC that is not itself described in the FSAR, or whose functions are not, screening with respect to whether the change affects a design function for other SSCs is appropriate, as discussed in Section 4.2.1.1, with the clarifications in 1.1.3 and 1.1.4 below.

(1.1.3) The definition for design function is modified in Section 3.3. This modification is proposed to ensure that the definition is interpreted in a comprehensive manner when deciding whether changes require further evaluation with respect to the evaluation criteria. The definition of design function is to read as follows:

> "Design Function" for an SSC is the information in the Final Safety Analysis Report (as updated) that describes what the SSC is intended to do, when it is to perform the function (e.g., modes of operation, conditions), and how it is supposed to perform. These functions include but are not limited to: (1) SSCs and their functions that are credited in safety analyses or required by regulation, (2) functions of SSCs that support or impact any credited SSC functions, or (3) functions of non-safety-related SSCs that, if not performed, would initiate a plant transient or accident. Design functions include the conditions under which intended functions are required to be performed, such as equipment response times, environmental and process conditions, equipment qualification, and single failure.

(1.1.4) Further, the staff is adding guidance that "credited in the safety analyses" means that, if the SSC were not to perform its intended 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. The "credit" may be implicit with respect to the analysis, for example, one of the functions described in the FSAR of the non-safety turbine bypass system may be to mitigate some overpressure transients, even though the code safety valves are what are explicitly credited in the transient analysis. The phrase "supports or impacts SSC functions" refers both to those SSCs needed to support other SSCs (cooling, power, environmental control, etc.) and to SSCs whose performance or malfunction could interact with SSCs that have functions described in the FSAR (for instance, offsite power, control systems, physical arrangements). The staff notes that "Safety analysis" includes demonstration of the ability to safely shut down the reactor, accident and transient response analyses, as well as supporting analyses that demonstrate that SSC functions will be accomplished.

Industry Comment

DG-1095 positions 1.1.2, 1.1.3 and 1.1.4 reflect a view that changes affecting any SSC function described in the UFSAR should be evaluated, not just screened. As discussed below, this position would result in licensees performing, documenting and reporting to NRC numerous unnecessary 10 CFR 50.59 evaluations for changes that clearly do not meet any of the criteria for requiring prior NRC approval.

Unless wholly controlled by another requirement, any change affecting an SSC function described in the UFSAR must, at a minimum, be screened. The 10 CFR 50.59 screening review is focused on the effects of the change on UFSAR-described design functions, methods used to perform or control design functions, and evaluations that demonstrate that intended design functions will be accomplished. "Design function" is defined broadly to encompass functions that affect initiation as well as response to events the plant is required to withstand. For many changes, the 10 CFR 50.59 screening review is sufficient to determine that no prior NRC approval is required. This is because not all SSCs described in the UFSAR perform, support or impact functions credited in the safety analyses, i.e., not all SSCs have "design functions." Some SSCs have multiple functions, and screening may determine that the proposed change does not affect design functions. Changes have no nexus to SSCs or functions credited in the safety analyses if screening determines that they do not affect:

- design functions,
- methods used to perform or control design functions, or
- evaluations that demonstrate that intended design functions will be accomplished

Such changes cannot meet the criteria for requiring prior NRC approval and therefore do no warrant further evaluation under 10 CFR 50.59. Rather than expend resources on such changes to perform, document and report 10 CFR 50.59 evaluations to NRC, these changes should be screened out.

The NRC staff proposal to define "design function" in terms of information described in the UFSAR is helpful, and we have modified the definition in NEI 96-07, Revision 1, as indicated below. As discussed above, we have retained the focus on functions credited in the safety analyses (including those that support or impact safety analysis functions), rather than all functions that may be described in the UFSAR. The following additional changes were made to the guidance to reinforce the intended breadth of the design function definition:

- The definition was clarified to reflect that conditions under which intended functions must be performed are implicitly included within the meaning of "design function"

- Consistent with the guidance proposed in Position 1.1.4, we have added a paragraph following the definition to clarify terms used to define "design function." Rather than define the concept of "implicit credit with respect to the safety analyses" as proposed by the NRC staff, we have clarified the definition of "design function" (as discussed above) to include matters that are implicitly included within the meaning of "design function." The turbine bypass system example was not helpful in this regard[1] and was eliminated.

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[1] The turbine bypass system is used to mitigate certain overpressure transients and avoid more significant transients (e.g., reactor trips, lifting of Code safety relief valves). Thus, although non-safety-related, we agree that certain functions of the turbine bypass system would be "design

- Additional guidance is also provided in Section 4.2.1 that, 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 50.59 evaluation is required when such changes adversely affect a UFSAR-described design function.

In defining "design function," we have specifically avoided use of the NRC staff phraseology, "These functions include *but are not limited to….*" First, such open-ended language is not helpful or appropriate for use in defining key terms. Second, the design function definition, modified and expanded as identified below, is sufficiently broad to encompass functions that affect initiation and response to events the plant is required to withstand.

Proposed NEI 96-07, R1, Clarification

In Section 3.3, replace existing definition of "design function" with the following definition and discussion:

Design function for an SSC means an SSC function described in the UFSAR that is credited in the safety analyses, or that supports or impacts any credited SSC function.

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 ~~include: (1)~~ may be ~~functions~~ performed by safety-related SSCs or non-safety-related SSCs and include ~~(2)~~ functions ~~of non-safety-related SSCs~~ that, if not performed, would initiate a ~~plant~~ transient or accident that the plant is required to withstand. 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, ~~environmental and~~ process conditions, equipment qualification, and single failure.

As used in this definition, "credited in the safety analyses" means that, if the SSC were not to perform its design 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 "supports or impacts SSC functions" refers both to

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functions" for purposes of 10 CFR 50.59 screening if they are described in the UFSAR and impact functions credited in the safety analyses. A change that adversely affects such turbine bypass system design functions would screen in. However, these functions are not (as identified in DG-1095) considered "credited" in the safety analyses. Non-safety-related systems are typically not credited in safety analyses.

those SSCs needed to support other SSC design functions (cooling, power, environmental control, etc.) and to SSCs whose operation or malfunction could adversely affect the performance of design functions (for instance, control systems and physical arrangements). Thus, both safety-related and non-safety-related SSCs may perform design functions.

DG-1095 Position 1.1.5

The discussion in Section 4.2.1, beginning with the second sentence, is to be considered under the subheading of Section 4.2.1.1. Section 4.2.1 discusses whether an activity is a "change to the facility or procedures as described in the UFSAR." The discussion begins with reference to all three parts of the rule definition of change, but then the subsequent discussion in this section (as well as in subsection 4.2.1.1) is focused only on facility changes as they relate to design functions. Other subsections (4.2.1.2 and 4.2.1.3) give further guidance on screening with respect to procedures and evaluation methods. All parts of Section 4.2.1 need to be used, as applicable. Since the noted text under Section 4.2.1 is more germane to the heading of Section 4.2.1.1, this text is to be moved.

Industry Comment:

The purpose of Section 4.2.1 (modified as indicated below) is to present guidance common to the screening of changes to the facility (discussed in Subsection 4.2.1.1), procedures (discussed in Subsection 4.2.1.2), and methods of evaluation (discussed in Subsection 4.2.1.3). These points of common guidance are:

1. In determining whether an activity screens in or out, both direct and indirect effects of the activity must be considered (examples provided).

2. Additions are subject to 10 CFR 50.59 and should be screened for their effects on the existing facility and procedures as described in the UFSAR.

3. Proposed activities affecting SSCs and functions not described in the UFSAR must be screened for their effects (so-called "indirect effects") on UFSAR-described design functions.

4. Adverse changes screen in; benign and beneficial changes may generally be screened out. Expanded guidance in Section 4.2.1 for determining whether there is an adverse effect, and thus that a 10 CFR 50.59 evaluation is required, is discussed in response to DG-1095 position 1.1.6.

Proposed NEI 96-07, R1, Clarification

Section 4.2.1 to be revised as follows:

> To determine whether or not a proposed change 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 affected SSCs and the proposed change is essential. A given change 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 change: ~~Only proposed changes that would, based on supporting engineering and technical information, have adverse effects on SSC design functions require evaluation under 10 CFR 50.59. A determination of whether adverse effects exist should consider both direct and indirect effects of the activity. Examples of questions that could be considered include the following:~~

- Does the activity decrease the reliability of an SSC design function, including either functions whose failure would initiate a transient/ accident or functions that are relied upon for mitigation?
- Does the activity reduce existing redundancy, diversity or defense-in-depth?
- Does the activity add or delete an automatic or manual design function of the SSC?
- Does the activity convert a feature that was automatic to manual or vice versa?
- Does the activity introduce an unwanted or previously unreviewed system or materials 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 or environmental qualification of the SSC?
- Does the activity adversely affect other units at a multiple unit site?

- Does the activity use equipment/tools that interface either directly or indirectly with an operable SSC?

- Does the activity introduce intrusive test equipment into the SSC such that an SSC design function is affected?

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

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

Per the definition of "change" discussed in Section 3.3, 10 CFR 50.59 is applicable to additions as well as to changes to and removals from the facility or procedures. Additions should be screened for their effects on the existing facility and procedures as described in the UFSAR and, if required, a 10 CFR 50.59 evaluation should be performed. NEI 98-03 provides guidance for determining whether additions to the facility and procedures should be reflected in the UFSAR per 10 CFR 50.71(e).

<u>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 50.59 evaluation is required when such changes adversely affect a UFSAR-described design function, as described below.</u>

(Revised Section 4.2.1 continues with expanded guidance on "adverse effects." See response to DG-1095 Position 1.1.6.)

<u>DG-1095 Position 1.1.6</u>

Section 4.2.1 (relocated to Section 4.2.1.1 per Regulatory Position 1.1.5) provides guidance on whether a change may (adversely) affect a design function. Guidance is added for deciding whether a function is affected when the change is with respect to some characteristic or value (response time, capacity) of an SSC. Whether the change affects the function is determined by whether the result remains within the bounds of existing analyses or FSAR information. If the nature of the change is such that engineering assessments or revised analyses are needed to determine whether an effect is adverse, the change requires an evaluation pursuant to 10 CFR 50.59, and not a screening.

Industry Comment

Because, to some degree, engineering assessments underlie essentially all proposed changes, tests and experiments, this proposed regulatory position would negate the screening process and require 10 CFR 50.59 evaluations for nearly all activities. We do not believe the NRC staff, which has recognized the appropriateness of 10 CFR 50.59 screening, intends this.

Each proposed change is supported by technical/engineering information, that may include but is not limited to, drawings, specifications, narrative description, design evaluations, installation and testing requirements, associated procedure changes (if any), revised analyses (if any) and similar information. This information, often referred to as the design change package, demonstrates the safety and effectiveness of the change and provides the basis for management approval of its implementation. The final rule and SOC highlighted the distinction between the engineering/technical (i.e., "safety") evaluation reflected in the design change package and the 10 CFR 50.59 regulatory review that determines whether a change requires prior NRC approval. Screening determinations are based on the technical/engineering information that supports proposed changes.

Screening is the first part of the 10 CFR 50.59 regulatory review and must be based on a thorough understanding of the design function(s) of affected SSCs and the effect(s) of the proposed change. As discussed above, where screening determines that a change does not affect SSCs that perform, support or impact functions credited in the safety analyses, i.e., the change does not affect design functions, such changes may be screened out from further 10 CFR 50.59 review (i.e., evaluation).

In addition to screening out changes that have no effect on design functions, certain changes can be determined during the 10 CFR 50.59 screening review to have a positive (beneficial) effect on design functions and may also be screened out. This is so for two reasons:

(1) "Design function" is defined broadly to encompass functions that affect initiation as well as response to events the plant is required to withstand.

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. Relaxing code or quality requirements for certain SSCs are examples of changes of this type. Similarly, changes that would introduce a new type of accident or malfunction with a different result would screen in.

This reflects an overlap between the technical/engineering ("safety") review of the change and the 10 CFR 50.59 review. This overlap reflects that these considerations are important to both the safety and regulatory reviews.

and,

(2) Changes that have positive or no effect on design functions cannot increase the likelihood of malfunctions, increase consequences, create new accidents or malfunctions, or otherwise meet the 10 CFR 50.59 evaluation criteria.

Only changes that adversely affect design functions, methods of performing or controlling design functions, or evaluations that demonstrate that intended design functions will be accomplished screen in because only adverse changes have the potential to meet the 10 CFR 50.59 evaluation criteria.

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 50.59 evaluation process.

Screening determinations are made based on the engineering/technical information supporting the change. The screening focus on design functions ensures the essential distinction between (a) 10 CFR 50.59 screenings, and (b) 10 CFR 50.59 evaluations, which focus on whether adverse changes meet any of the eight criteria in 10 CFR 50.59(c)(2) are met. 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. The revised safety analyses may be used to support the required 10 CFR 50.59 evaluation of such changes.

Changes that entail revision 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. For example, a change that improves the closure time of main control room isolation dampers reduces the calculated dose to operators, and UFSAR dose consequence analyses are updated as a result. In this case, the dose analyses are being revised to reflect the lower dose for the main control room, not to demonstrate that GDC limits continue to be met. A change that would adversely affect the design function of the dampers (post-accident isolation of the main control room) and increase the existing calculated dose to operators would be considered adverse and would screen in. In this case, the dose analyses must be re-run to ensure that GDC limits continue to be met. The revised analyses would be used in support of the 10 CFR 50.59 evaluation to determine if the increase exceeds the minimal standard and requires prior NRC approval.

To further illustrate the distinction between 10 CFR 50.59 screening and evaluation, consider the example of a change to a diesel generator-starting relay that delays the diesel start time from 10 seconds to 12 seconds. The UFSAR-described design function credited in the ECCS analyses is for the diesel to start within 12 seconds. This change would screen out because it is apparent that the change will not adversely affect the diesel generator design function credited in the ECCS analyses (ECCS analyses remain valid).

However, a change that would delay the diesel's start time to 13 seconds would screen in because the change adversely effects the design function (to start in 12 seconds). Such a change would screen in even if technical/engineering information supporting the change includes revised safety analyses that demonstrate all required safety functions supported by the diesel, e.g., core heat removal, containment isolation, containment cooling, etc., are satisfied and that applicable dose limits continue to be met. While this change may be acceptable with respect to performance of required safety functions and meeting design requirements, the analyses necessary to demonstrate acceptability are beyond the scope/intent of 10 CFR 50.59 screening reviews. Thus a 10 CFR 50.59 evaluation would be required. The revised safety analyses would be used in support of the 10 CFR 50.59 evaluation to determine whether any of the evaluation criteria are met such that prior NRC approval is required for the change.

As indicated below, much of the above discussion has been added to Section 4.2.1 to provide expanded guidance for determining if there is an adverse effect due to a facility, procedure or methodology change. Also identified are modifications to Subsections 4.2.1.1, 4.2.1.2 and 4.2.1.3 to reflect the new Section 4.2.1 discussion and provide additional specific guidance on determining if there is an adverse effect due to a facility, procedure or methodology change, respectively.

Proposed NEI 96-07, R1, Clarifications

Expanded Section 4.2.1 Guidance on "Adverse Effects"

New Subheading—Screening for Adverse Effects

A 10 CFR 50.59 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 50.59 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 effect a design function and would screen in. Relaxing code or quality requirements for certain SSCs are examples of changes of this type. Similarly, changes that would introduce a new type of accident or malfunction with a different result would screen in. This reflects an overlap between the technical/engineering ("safety") review of the change and the 10 CFR 50.59 evaluation. 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 50.59 evaluation may 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 50.59 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 50.59 screenings, and (2) 10 CFR 50.59 evaluations, which focus on whether changes meet any of the eight criteria in 10 CFR 50.59(c)(2). Technical/ engineering information, e.g., design evaluations, etc., that demonstrates changes have no adverse effect

[2] The exception to this is that a change that has any effect—positive or negative—on design basis limits for fission product barriers must be screened in (see Section 4.2.1.1).

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. The revised safety analyses may be used in support of the required 10 CFR 50.59 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. For example, a change that improves the closure time of main control room isolation dampers reduces the calculated dose to operators, and UFSAR dose consequence analyses are to be updated as a result. In this case, the dose analyses are being revised to reflect the lower dose for the main control room, not to demonstrate that GDC limits continue to be met. A change that would adversely affect the design function of the dampers (post-accident isolation of the main control room) and increase the existing calculated dose to operators would be considered adverse and would screen in. In this case, the dose analyses must be re-run to ensure that GDC limits continue to be met. The revised analyses would be used in support of the 10 CFR 50.59 evaluation to determine if the increase exceeds the minimal standard and requires prior NRC approval.

To further illustrate the distinction between 10 CFR 50.59 screening and evaluation, consider the example of a change to a diesel generator-starting relay that delays the diesel start time from 10 seconds to 12 seconds. The UFSAR-described design function credited in the ECCS analyses is for the diesel to start within 12 seconds. This change would screen out because it is apparent that the change will not adversely affect the diesel generator design function credited in the ECCS analyses (ECCS analyses remain valid).

However, a change that would delay the diesel's start time to 13 seconds would screen in because the change adversely effects the design function (to start in 12 seconds). Such a change would screen in even if technical/engineering information supporting the change includes revised safety analyses that demonstrate all required safety functions supported by the diesel, e.g., core heat removal, containment isolation, containment cooling, etc., are satisfied and that applicable dose limits continue to be met. While this change may be acceptable with respect to performance of required safety functions and meeting design requirements, the analyses necessary to demonstrate acceptability are beyond the scope/intent of 10 CFR 50.59 screening reviews.

Thus a 10 CFR 50.59 evaluation would be required. The revised safety analyses would be used in support of the 10 CFR 50.59 evaluation to determine whether any of the evaluation criteria are met such that prior NRC approval is required for the change.

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

To be added to Section 4.2.1.1 (on screening of changes to the facility) before the paragraph introducing the examples:

As discussed in Section 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 50.59. Changes that have positive or no effect on design functions may generally be screened out. The exception to this is that any change to a design bases limit for a fission product barrier—adverse or beneficial—must be screened in. This is because 10 CFR 50.59(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.

Section 4.2.1.2 guidance on screening procedure changes to be revised as follows:

Changes affecting the way design functions are performed or controlled, including changes to procedures, are "screened in" (i.e., require a 10 CFR 50.59 evaluation) if the change adversely affects how SSC design functions are performed or controlled~~, as described in the UFSAR~~ (including assumed operator actions and response times). 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 50.59 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), analog to digital upgrades, changing a valve from "locked closed" to "administratively closed," and similar changes.

Section 4.2.1.3 on screening methodology changes to be revised as follows:

As discussed in Section 3.6, methods of evaluation included in the UFSAR to demonstrate that intended SSC design functions will be accomplished are considered part of the "facility as described in the UFSAR." Thus use of new or revised methods of evaluation (as defined in Section 3.10) is considered to be a change that is controlled by 10 CFR 50.59 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 50.59(c)(2)(viii) to determine if prior NRC approval is required (see Section 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 may be screened out.

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 50.59 unless the UFSAR states they were used for specific analyses within the scope of 10 CFR 50.59(c)(2)(viii).

Changes to methods of evaluation included in the UFSAR are considered adverse and require evaluation under 10 CFR 50.59 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 50.59(c)(2)(viii).

DG-1095 Position 1.2, INTERFACE OF 10 CFR 50.59 WITH THE MAINTENANCE RULE (10 CFR 50.65)

Sections 1.2.1, 3.3, and 4.1.2 of the NEI guidance discuss the relationship between 10 CFR 50.59 and 50.65(a)(4) with respect to maintenance activities, including associated maintenance preparatory activities (referred to in some instances as "temporary changes or alterations"). NRC agrees with the intent of this guidance that, for activities required to support and directly related to the maintenance, 10 CFR 50.59 does not apply for the duration of the maintenance on the basis that another regulation controls such activities.

To avoid confusion about the relationship of maintenance activities (which restore the facility to its original condition) and modifications (that change in some respect the facility), Section 4.1.2 is to read as follows.

> Maintenance activities are actions that restore SSCs to their as-designed state. Maintenance activities include troubleshooting, calibration, refurbishment, post-maintenance testing, identical replacements, housekeeping, and similar activities that do not permanently alter the design or design function of SSCs. Maintenance activities, including alterations to the facility or procedures required to support and directly related to the maintenance, are not subject to 10 CFR 50.59 evaluations but are subject to the provisions of 10 CFR 50.65(a)(4) as well as technical specifications.
>
> Licensees should address operability in accordance with the technical specifications and should assess and manage the risk impact of maintenance activities per 10 CFR 50.65(a)(4) and NEI 93-01, "Industry Guidelines for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants."
>
> When the facility is not restored to its original condition as a result of the "maintenance activity" (e.g., if SSCs are removed, if the design, design function, or operation is altered, or if a temporary change in support of the maintenance is not removed), both 10 CFR 50.65(a)(4) and 50.59 would apply as discussed below. In these circumstances, the activities under way are not limited to maintenance, but also involve some sort of design or licensing basis change. An assessment of the "maintenance activity" is required as well as review of the "change." This situation might occur when the original plan is to restore the facility, but during the course of the maintenance, it is determined that full restoration will not occur (at which time the applicability of 10 CFR 50.59 would arise).
>
> A design change would be subject to 10 CFR 50.59 evaluation with respect to its effect upon the facility and its operation (following installation). Further, licensees may include as part of the modification package an evaluation pursuant to 10 CFR 50.59 for the facility in various stages of implementation of a modification (as needed). The actual implementation of a design change, including associated activities, may be viewed as "maintenance" rather than a change under 10 CFR 50.59, and be assessed under 10 CFR 50.65(a)(4). Thus, in these cases, a 10 CFR 50.65(a)(4) assessment would be needed for the duration of the "maintenance activity" to implement the modification. Whether a 10 CFR 50.65(a)(4) assessment is required for the installation of a modification should be determined by the maintenance rule requirements and guidance for assessing and managing risk before maintenance activities.

In addition to assessments required by 10 CFR 50.65(a)(4), 10 CFR 50.59 should be applied to maintenance activities if a temporary change in support of maintenance is expected to be in effect during at-power operations for more than 90 days. In this case, 10 CFR 50.59 would be applied to the temporary change prior to implementation in the same manner as a permanent change.

Apply 10 CFR 50.59 to temporary changes proposed as compensatory measures for degraded or non-conforming conditions, as discussed in Section 4.4.

Industry Comment

We agree with the intent of the proposed NRC clarification. See proposed NEI 96-07, R1, clarification, below.

While we have used a different approach to clarify that installation and testing of plant modifications is subject 10 CFR 50.65(a)(4) in the same way as maintenance that restores the plant to its prior condition, we note the following about the proposed NRC language:

- Where the NRC staff uses the phrase "subject to 10 CFR 50.59 evaluation" (two places), the correct language would be "subject to 10 CFR 50.59," which includes both screening and, as necessary, evaluation.

- The NRC incorrectly states that "...10 CFR 50.59 should be applied to the maintenance activities if a temporary change in support of maintenance is expected to be in effect during at-power operations for more than 90 days." The correct language would be, "10 CFR 50.59 should be applied to a temporary change in support of maintenance if the temporary change is expected to be in effect during at-power operations for more than 90 days.

Proposed NEI 96-07, R1, Clarification

Section 4.1.2, Maintenance Activities, to be revised as follows:

Maintenance activities are activities that restore SSCs to their as-designed condition, including activities that implement approved design changes. Maintenance activities are not subject to 10 CFR 50.59, but are subject to the provisions of 10 CFR 50.65(a)(4) as well as technical specifications.

Maintenance activities include troubleshooting, calibration, refurbishment, ~~post-~~maintenance-related testing, identical replacements, housekeeping,

~~associated temporary changes~~ and similar activities that do not permanently alter the design or design function of SSCs ~~and are thus not subject to 10 CFR 50.59~~. Maintenance activities also include temporary alterations to the facility 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 lead shielding on pipes and equipment, removal of barriers, and use of temporary blocks, bypasses, scaffolding and supports.

Licensees should address operability in accordance with the technical specifications and should assess and manage the risk impact of maintenance activities per 10 CFR 50.65(a)(4) and NEI 93-01, *Industry Guidelines for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.*[3]

In addition to assessments required by 10 CFR 50.65(a)(4), 10 CFR 50.59 should also be applied ~~to maintenance activities~~ in the following cases:

- A temporary alteration in support of the maintenance is expected to be in effect during at-power operations for more than 90 days. In this case, 10 CFR 50.59 would be applied to the temporary alteration prior to implementation in the same manner as a permanent change. If the temporary alteration screens in and meets any of the 10 CFR 50.59 evaluation criteria, prior NRC approval is required to leave the temporary alteration in effect longer than 90 days.

- The plant is not restored to its original condition upon completion of the maintenance activity (e.g., if SSCs are removed, the design, ~~design~~ function or operation is altered, or if temporary alteration in support of the maintenance is not removed). In this case, 10 CFR 50.59 would be applied to the permanent change to the plant.

Installation and post-modification testing of approved facility changes is indistinguishable from maintenance activities that restore SSCs to their as-designed condition in terms of their risk impact on the plant. As such, installation and testing of approved facility changes are maintenance activities that must be assessed and managed in accordance with 10 CFR 50.65(a)(4). This contrasts with historical practice whereby 10 CFR 50.59 reviews addressed the design, installation and post-modification testing of proposed facility changes. Going forward, 10 CFR 50.59 will address the effect, following implementation, of proposed facility changes to determine if

[3] Regulatory Guide 1.182, issued June 1, 2000, endorses the industry guidance on 10 CFR 50.65(a)(4).

prior NRC approval is required; the risk impact of actually implementing the change will be assessed and managed per 10 CFR 50.65(a)(4).

If a temporary alteration necessary to install a design change is expected to be in effect longer than 90 days at power, the required 50.59 review of the temporary alteration may be performed as part of the 50.59 review for the design change.

10 CFR 50.59 should be applied to temporary changes proposed as compensatory measures for degraded or non-conforming conditions, as discussed in Section 4.4.

DG-1095 Position 1.3, INCREASES IN LIKELIHOOD OF MALFUNCTION

In Section 4.3.2 of NEI 96-07, a quantitative value for "no more than a minimal increase" is a factor of 2 increase. This factor must be applied at the individual component level. If the guidance is not so limited, further guidance would be needed to limit the overall effects of the change at the system or train level. The NRC staff agrees with the NEI guidance that states that use of the factor of 2 may also be constrained by other evaluation criteria, depending upon the specific components or functions that the change involves.

Proposed NEI 96-07, R1, Clarification

Item 3 on page 42 (Section 4.3.2) is revised as follows:

3. 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 ~~based on the nature of the activity, e.g.,~~ at the component level ~~for component changes~~. ~~System/functional 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/transient frequency under criterion 10 CFR 50.59(c)(2)(i). For example, a change that increases the likelihood of malfunction of the Emergency AC system or Reactor Protection System by a factor of two would likely cause more than a 10% increase in the frequency of station blackout or ATWS, respectively.

DG-1095 Position 1.4, METHODS APPROVED BY NRC FOR THE INTENDED APPLICATION

DG-1095 Position 1.4.1 and 1.4.2

(1.4.1) NEI 96-07 refers to whether differences in plant configuration or licensing basis are "material to the NRC approval basis" in concluding whether the NRC approval of an evaluation method (reviewed for a plant-specific application) is still valid for use at another facility. The NRC staff believes that it will be difficult for a licensee to determine whether the differences meet this criterion; as for plant-specific reviews, the staff's evaluation may not discuss all aspects of the approval basis. Instead, the NRC staff has concluded the decision should be based upon whether the differences are relevant to the results obtained. If such relevant differences exist, the method is not "approved" and any modifications to NRC-approved methodologies should be evaluated using the "conservative or essentially the same" criteria in the definition of "departure."

(1.4.2) Section 4.3.8.2 states "slight modifications to the [NRC approved] methodology can be made and the methodology can still be considered approved for the intended application." The basis for acceptability of modifications to approved methods that is acceptable to the NRC staff is using the "conservative or essentially the same" criteria.

Industry Comment

We concur with the staff's conclusion that the decision as to whether a methodology approved for use at Plant A can be applied to Plant B should be based on the relevance of plant differences to the results obtained. It is important to note that adjustment of analysis input parameters is typically necessary to reflect plant differences, but such input differences (provided they are within the range of values for which the methodology is valid) do not affect the application of the methodology. It is incumbent upon the GL 83-11 qualified licensee to assess plant differences in an appropriate manner.

The staff proposal to use the "conservative or essentially the same" criterion to determine the acceptability of slight modifications to an NRC approved methodology that may be necessary is helpful and is reflected in the revised industry guidance below (last sentence).

Proposed NEI 96-07, R1, Clarification

The last two (full) bullets in Section 4.3.8.2 have been reorganized and condensed as follows:

- Is the facility for which the methodology has been approved designed and operated in the same manner as the facility to which the methodology is to be applied? Is the relevant equipment the same? Does the equipment have the same pedigree (e.g., Class 1E, Seismic Category I, etc.)? Are the relevant failure modes and effects analyses the same? If the plant 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 plant design?
  - Can analyses be made while maintaining compliance with both the intent and literal definition of the methodology?

- Differences in the plant configurations and licensing bases could invalidate the application of a particular methodology. For example, the licensing basis of older vintage plants may not include an analysis of the feedwater line break event that is required in later vintage plants. Some plants may be required to postulate a loss of offsite power or a maximum break size for certain events; other may have obtained exemptions to these requirements from the NRC. Some plants may have pressurizer power-operated relief valves that are qualified for water relief; other plants do not. Plant specific failure modes and effects analyses may reveal new potential single failure scenarios that can not be adequately assessed with the original methodology. The existence of these differences does not preclude application of a new methodology to a facility; however, differences must be identified, understood and documented. Slight modifications to the NRC approved methodology to address plant-specific features are acceptable provided the analysis results obtained are conservative or essentially the same with respect to the unmodified methodology.

DG-1095 GUIDANCE ON USE OF EXAMPLES

Revision 1 to NEI 96-07 includes examples to supplement the guidance. These examples are illustrative only, and the NRC's endorsement of NEI 96-07 (Revision 1) 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.

Industry Comment

As important as the examples are, their appropriateness for purposes of illustrating and reinforcing the NEI 96-07, R1, guidance should be acknowledged in the final regulatory guide as indicated below:

> Revision 1 to NEI 96-07 includes examples to supplement the guidance. While appropriate for illustrating and reinforcing the guidance in NEI 96-07, R1, ~~These examples are illustrative only, and~~ the NRC's endorsement of NEI 96-07 (Revision 1) 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.

DG-1095 GUIDANCE FOR FSAR SUPPLEMENTS FOR LICENSE RENEWAL

The guidance in NEI 96-07 and in this regulatory guide is applicable to information added to the FSAR in accordance with 10 CFR 54.21(d), that is, for summary descriptions of the programs and activities for managing the effects of aging and the evaluation of time-limited aging analyses. If necessary, the staff may provide further guidance or examples for use with respect to such programs and evaluations at a later date.

Industry Comment

We do not believe additional guidance is necessary with respect to applicability of 10 CFR 50.59 to supplemental license renewal information added to the UFSAR. If the NRC decides to provide further guidance or examples for use with respect to such information, we request the NRC provide opportunity for public comment on the proposed additional guidance.

Specific feedback requested by NRC

1. The NRC specifically seeks comment on the impact of not allowing screening of changes that affect functions that do not meet the definition of design function. In particular, examples of functions that might be described in the FSAR, but for which an evaluation under 10 CFR 50.59 would not be needed if that function were affected, would be helpful.

   Industry Comment

   See responses to DG-1095 Positions 1.1.1 – 1.1.6.

2. The NRC staff has proposed that NEI supplement the guidance with a few examples that are subjected to the entire evaluation process, including all of the eight evaluation criteria, to show some of the interrelationships. Commenters are invited to suggest examples of changes that would best demonstrate functioning of the overall process.

   Industry Comment

   Upon closure of DG-1095 issues[4], we will consider the need for including one or more comprehensive examples in the final guidance. It should be recognized that because criterion c(2)(viii) applies to methodology changes only, it is unlikely that any single change would be subject to all eight evaluation criteria.

3. Finally, the NRC is interested in the issue of documentation. The guidance notes the need for records of evaluations and for documentation of screening. The NRC staff believes that the guidance could be improved by direction about the level of detail to be documented about the considerations and questions contained in the NEI guidance. This is particularly true with respect to criteria 10 CFR 50.59(c)(2)(vii) and (viii). Comments on this subject are also requested.

   Industry Comment

   We have added the underlined sentence to Section 4.2.3, Screening Documentation:

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[4] Consideration of additional examples would also be subject to disposition of the industry comment above concerning DG-1095 Guidance on Use of Examples.

Revised Section 4.2.3

> 10 CFR 50.59 recordkeeping requirements apply to 10 CFR 50.59 evaluations performed for activities that screened in, not to screening records for activities that screened out. However, documentation should be maintained in accordance with plant procedures of screenings that conclude a proposed activity screened out (i.e., that a 10 CFR 50.59 evaluation was not required). The basis for the conclusion should be documented to a degree commensurate with the safety significance of the change. <u>For changes, the documentation should include the basis for determining that there would be no adverse effect on design functions, etc.</u> 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 50.59, and thus is not subject to 10 CFR 50.59 documentation and reporting requirements. Screening records need not be retained for activities for which a 10 CFR 50.59 evaluation was performed or for activities that were never implemented.

Concerning documentation of 10 CFR 50.59 evaluations, Section 5.0 of NEI 96-07, R1, currently includes the following guidance:

> Each 10 CFR 50.59 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.

Of the two new criteria, documentation of c(vii) evaluations is expected to be rather straightforward due to the objective nature of the criterion. As for c(viii), the following Question and Answer (E.14) was provided as a supplement to the guidance in NEI 96-07, R1:

> Q. 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.

Q&A E.14 is among approximately 50 questions and answers provided to attendees (including NRC staff)of the April 10-11 NEI workshop. These Q&A are being maintained on NEI's member-only website and will be updated as necessary to supplement and clarify the industry guidance.

We believe the available guidance is adequate and appropriate with respect to documentation of 10 CFR 50.59 evaluations, particularly in light of the long industry experience in implementing 10 CFR 50.59. However, we will consider further guidance based on public comments received on this subject and further discussion with the NRC staff.

Additional Changes to NEI 96-07, R1

In addition to the changes identified above, we are incorporating the following changes into NEI 96-07, R1, based on industry comments received during and after our April 10-11 workshop:

1. Section 4.3.3 (2d paragraph) to be revised as follows:

   NRC regulates compliance with the provisions of 10 CFR 50 and 10 CFR 100 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 inside ~~or outside~~ the control room to mitigate the consequences of reactor accidents. Changes affecting dose consequences to operators performing required actions outside the control room should be evaluated in accordance with applicable TMI Action Items; 10 CFR 50.59 need not be applied to such changes.

2. To be consistent with Section 4.1.2 guidance identifying that 10 CFR 50.65(a)(4) is the primary mechanism for control of maintenance-related activities, we have modified the last two paragraphs of Section 3.14 (Discussion of Tests or Experiments definition) as follows.

~~Post-modification testing should be evaluated as a test under 10 CFR 50.59 only if an abnormal mode of operation is proposed that is not described in the UFSAR. Post-modification testing may be considered as part of the 10 CFR 50.59 evaluation for the modification itself.~~

~~10 CFR 50.59 screening of tests and experiments is discussed in Section 4.2.2.~~

Maintenance-related testing is assessed and managed under 10 CFR 50.65(a)(4), as discussed in Section 4.1.2. 10 CFR 50.59 screening of tests and experiments unrelated to maintenance is discussed in Section 4.2.2.

[Section 4.2.2 will also be modified to reflect this guidance.]

3. We have clarified the Section 3.2 definition of "accident previously evaluated in the FSAR (as updated)" as indicated below so it is clear that not all transients need be considered "accidents" for purposes of 10 CFR 50.59.

Accident previously evaluated in the FSAR (as updated) means a design basis accident or event described in the UFSAR including accidents, such as those typically analyzed in Chapters 6 and 15 of the UFSAR, ~~anticipated operational~~ <u>and</u> transients and events the facility is required to withstand such as floods, fires, earthquakes, other external hazards, anticipated transients without scram (ATWS), and station blackout (SBO).

Station Support Department

65FR# 24231
25 Apr 00
(17)

PECO NUCLEAR

A Unit of PECO Energy

Received
19 June 2000
3:14 pm

PECO Energy Company
965 Chesterbrook Boulevard
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June 9, 2000

Chief, Rules and Directives Branch,
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Comments Concerning Draft Guide DG-1095 "Guidance for Implementation of 10 CFR 50.59, Changes, Tests and Experiments." (65FR24231, dated April 25, 2000)

Dear Sir/Madam:

This letter is being submitted in response to the Nuclear Regulatory Commission's (NRC) request for comments concerning Draft Guide DG-1095 "Guidance for Implementation of 10 CFR 50.59, Changes, Tests and Experiments," which was published in the Federal Register (i.e., 65FR24231, dated April 25, 2000). The guide is being developed to describe methods acceptable to the NRC staff for complying with the NRC's regulations with regard to the process for evaluating changes, tests, and experiments that a licensee wishes to make without prior NRC approval. The guide proposes to endorse, with some clarifications, a Nuclear Energy Institute (NEI) document, Revision 1 of NEI 96-07, "Guidelines for 10 CFR 50.59 Evaluations."

PECO Energy appreciates the opportunity to comment on Draft Guide DG-1095 "Guidance for Implementation of 10 CFR 50.59, Changes, Tests and Experiments." PECO Energy endorses the comments on DG-1095 being provided through NEI.

If you have any questions, please do not hesitate to contact us.

Sincerely,

James A. Hutton, Jr.
Director - Licensing

Template: ADM-013

E-RIDS= ADM-03
ADD: E McKenna (EMM

1. In NEI 96-07, Section 4.3.8.2, Considerations for Determining if New Methods are Technically Appropriate for the Intended Application are discussed. This discussion should reflect the fact certain types of analyses (e.g., shielding, high energy line break compartment thermal-hydraulic analyses, offsite dose analyses) are independent of plant design. Specifically, use of ICRP30 dose conversion factors is an item which has been generically approved by the NRC by virtue of incorporation into the basis of 10CFR21 and which are independent of plant design. Thus, any licensee should be able to adopt the ICRP30 dose conversion factors with a 10CFR50.59 Evaluation and should not require NRC approval to adopt this generically approved methodology. An example to this effect should be added to Section 4.3.8.3 of NEI 96-07.

2. NEI 96-07 Section 4.3.8.2 needs to reflect the fact that many methodologies used in safety analyses (e.g., dose analyses, HELB, shielding, systems analyses) are not approved by the NRC and do not require approval by the NRC. This section is too focussed on fuels-type analyses (e.g., Chapter 15 transient event analyses) which do require explicit NRC code approval. Similarly, Generic Letter 83-11 Supplement 1 is overly focussed on high level Chapter 15 style safety analysis codes and can be overly burdensome when applied to codes which do not require the same level of NRC approval. As the NRC has pointed out numerous times, SER review of analyses performed using a specific code is not the same as NRC review and approval of the code itself.

Specifically, the second bullet of two on page 57 of NEI 96-07 needs to be revised to reflect that not all methods of evaluation documented in a SAR were approved by the NRC.

Also, the term "or new NRC-approved methodology" in the second bullet of 3 on page 57 should be replaced with "or (for methodologies previous approved by the NRC or otherwise requiring NRC approval) new NRC-approved methodology)".

Use of a qualified bias term to demonstrate conservative results should be a recognized option as part of the third of 3 bullets on page 57 of NEI 96-07.

3. The NRC comments in SECY-00-0071 Section A that "If the nature of the change is such that an engineering assessment or revised analyses is needed to determine whether an effect is adverse, the staff concludes that a 10CFR50.59 evaluation is required rather than a screening." would detract from the goal of regulatory stability implicit in the revised rule.

Concerns with this statement include the fact that many engineering assessments, evaluations, or calculations are performed to <u>document</u>, rather than to determine, whether an adverse affect exists. Thus, vagueness would be introduced into the rule by the reliance on whether or not an engineering assessment was performed in support of the change.

It is also the case that plant which had previously performed sensitivity studies would be able to reference those pre-existing analyses to determine that there is no adverse affect, thus the change could be supported without a full 50.59 evaluation. However, plants that had not performed such sensitivity studies would require a full 50.59 evaluation under the NRC guidance of SECY-00-0071, which is inconsistent. Also, to what extent would analyses for similar plants be able to be credited in addressing the question of if an engineering assessment is needed to determine if an affect is adverse? Past experience of the analysts, including service at other plants, would have a great impact in whether or not an engineering assessment is required to determine there is no adverse impact (vice an engineering assessment which is performed to document that there is no adverse impact).

Is the acceptance criteria for Vital Area Access doses based on the full GDC19 limits (5 rem whole body, 30 rem thyroid)?

Or are the acceptance criteria (to be able to implement under 50.59 without NRC approval) based on 10% of the remaining margin?

In this case, if the full GDC19 limits do not apply, would the remaining margin assume an initial dose of 0 rem whole body and 0 rem thyroid?

16. It is unfortunately that risk insights have not been fully applied in the development of the revised 50.59 rule. A prime example is the change in the regulation to allow minimal increases in consequences or probability of an event, instead of the use of a consistent and clear figure of merit (i.e., SRP acceptance criteria) for all plants. The final proposed rule, while workable, is similar to enforcing a different speed limit for different vehicles on a highway. Also, since the acceptance criteria is now based on the documented analysis results in the SAR, those licensees who have made the attempt to maximize the value of the SAR by having up to date and detailed information in it, beyond the basic requirements, are those who will have the greatest burden placed upon them by this non-risk informed approach. Even the NRC, in its December 17, 1998, White Paper, "Options for Incorporating Risk Insights into 10CFR50.59 Processes," concluded that there was no impact on risk associated with the use of SRP acceptance criteria for consequences vice values as documented in licensee SAR's.

17. In any eventual movement to a risk-informed 50.59 rule, the industry and the NRC need to recognize the limitations of the PRA metrics of CDF and LERF in evaluating changes to plants or plant procedures. PRA analyses are focussed upon severe accidents, vice upon transients which could occur with greater frequency but have far less severe consequences. Since Risk is generally regarded as the product of Frequency * Consequences, the 50.59 rule may also need to consider metrics which are appropriate to higher frequency, lower consequence events, such as the various non-accident events documented in SAR Chapter 15 which have the potential to result in puff releases to the environment without any core damage. If such transients were to be considered, for example, the risk importance of diesel generators would tend to increase and that of service water or cooling water systems would tend to decrease, since these are short-term transients. In approving the staff's proposal for 50.59 rulemaking of SECY-98-171, former NRC Chairman Jackson provided some detailed comments under "Giving Definition to Minimal" concerning a tiered approach toward risk-informing the 50.59 rule. Chairman Jackson's discussion should be revisted in any large scale effort to risk-inform the rule; the philosophy (if not the detailed approach) in the ACRS proposal she references to create frequency-consequence curves for various class transients should also be considered. Such approaches would provide a more robust means of capturing risk and providing defense-in-depth by not solely focussing upon severe accident risks.

Received
21 June 2000
3:15 pm

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Ref: DG-1095

65FR# 24231
25 Apr 00

21

CPSES # 200001482
Log # TXX-00125
File # 883

June 16, 2000

Mr. David L. Meyer
Chief, Rules and Directives Branch
Office of Administration
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555-0001

SUBJECT: COMANCHE PEAK STEAM ELECTRIC STATION (CPSES) ENDORSEMENT OF NEI COMMENT LETTER ON DRAFT REGULATORY GUIDE DG-1095, "GUIDANCE FOR IMPLEMENTATION OF10 CFR 50.59, 'CHANGES, TESTS, AND EXPERIMENTS'"

REF: 1) 65 Federal Register 24231, April 25, 2000

2) Nuclear Energy Institute (NEI) letter addressed to Chief,Rules and Directives Branch, U. S. Nuclear Regulatory Commission, dated June 8, 2000

Dear Mr. Meyer:

This letter is in response to the request for comment (Reference 1) on the subject Draft Regulatory Guide DG-1095, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, and Experiments'".

TXU Electric has reviewed DG-1095. TXU Electric endorses the NEI comment letter (Reference 2). TXU Electric agrees with the NEI discussed issues, responses and rationale.

Template: ADM-013

E-RIDS= ADM-03
Add- E. McKenna (EMM)

From: <Mslbdose@aol.com>
To: TWFN_DO.twf4_po(DLM1)
Date: Fri, Jun 16, 2000 3:55 PM
Subject: Comments on DG-1095

Process as a comment on Draft Guide - 1095

65 FR # 24231
25 Apr 00

22

Please find my comments on the proposed subject guide. If you have any questions I can be reached at 301-415-1083 or wmb1@nrc.gov.

Mark Blumberg

CC: OWFN_DO.owf2_po(EMM,WMB1)

Template: ADM-013

E-RIDS = ADM-03
Add: E. McKenna (EMM)

Pg 13, 3.4. The sentence "changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application," is a statement that is open to many various interpretations. The regulatory guide does not appear to do an adequate job of providing sufficient guidance on interpreting this statement. While the guide seems to be adequate, from a practical standpoint, there are many questions it does not answer. Some of the key questions that the Regulatory Guide does not seem to address are given below :

A) The definition on page 14 of "Approved for the NRC intended application," is entirely subjective. From a practical standpoint it is subject to abuse for many reasons.

1) An NRC reviewer can not predict every application for which a method may be used. What is good for application X may not be good for application Y. In the past NRC reviewers did not consider these impacts. They only evaluated the method for the proposed change. Nor did they document all the considerations of approving a method. A licensee can not possibly understand all the considerations made by a reviewer when they approve a method because there is no requirement for a reviewer to document all these considerations.

2) Reviewers do not have the time to check every aspect of proposed change. Many do not perform confirmatory calculations, nor does a licensee provide every change in methodology in every license amendment. Typically, the license amendment only describes a cursory amount of detail and the conclusions.

3) Some methods in the UFSAR were obtained by default and not by NRC review of the method. The NRC's view of approving amendments has changed over the years. At one time the NRC approved amendments based upon the NRC's independent calculations. Many of these calculations did not consider the methods the licensees utilized. Typically, rather than resolve the differences between the licensees' calculations and what the NRC believed to be correct, the NRC would use its own methods to evaluate the proposed change. The NRC staff believed at that time that this independent evaluation carried some weight with respect to the licensing bases of the plant. Recently, as a result of a court ruling, this interpretation was found to be false. There is now a disjoint between what was approved by independent calculations and what is in the Safety Analysis Reports (SAR). Currently, these disjoints are limited to individual licensees, but the proposed guidance appears to allows any method in current Safety Analysis Reports to be propagated to any licensee.

With these thoughts in mind, consider the impact of freely, legally and instantaneously allowing the propagation of any methods that may have been in error or not directly reviewed, but yet appear to be "approved by the NRC." As things stand now individual reviewers have the opportunity to stop changes in methodology that may be in error. With this guidance the NRC will not have that chance, because they may not even know that these changes are occurring.

For example, two months ago a licensee proposed a change in methodology to support a change to their facility. It was a very complex method so they were asked if anyone else had ever used this method. They found another licensee that had this methodology in their Safety Analysis Report. When the project manager looked for the safety evaluation which supported that change it did not mention anything about that methodology. The reviewer did not mention it. It is not known whether the reviewer looked at it. Under the proposed 50.59 Regulatory Guidance, I do not believe that there are sufficient controls or guidance for dealing with the complexities of these common issues. In this case the guidance does not seem to provide enough detail to prevent a licensee from utilizing the proposed method. The burden of proof to prevent such improper utilization of these methods will be solely on the NRC and will be nearly impossible to identify.

The guidance needs more concrete guidance to deal with these issues.

The guidance does not seem to adequately address compensatory methods of offsetting dose margin. I believe it could be much more complete. Many dose calculations contain methods and design inputs that are not completely detailed in the SAR, but the results are presented in Design Basis Safety Analyses. It seems arbitrary to me to exclude the values and methods and inputs which support the SAR from 50.59, but are not included in the SAR.

Pg. 5, Section 1.4.1 The guidance does not seem to address the following scenario. A method is found to not be relevant to the results obtained for a particular application. Therefore, it is placed into the licensing bases. In this case the method could be a computer code with multiple options. In a future application a different combination of options in the code would produce a relevant difference in results. Because the code is in the licensing bases, this aspect is not considered to be a different methodology. The words in this section should address such common scenarios and require licensees to address different methods within the same computer code. It should be noted that a computer code is not a method, but it contains methods. I recommend that an example be generated which would describe this scenario. Furthermore, when a new code (method) is used to replace an old code (method) in the SAR, the new method should be described in the SAR in enough detail to understand what part of the code was utilized.

Pg. 14. The "Essentially the Same" definition should be more restrictive. It should be limited to rounding errors and use of different computational platforms and not to within the margin of error of the analyses. The margin of error for the analyses can be broadly interpreted and is far too liberal and not enforceable. The rounding errors and differences in computational platforms should be limited to less than 1% differences in the final (not interim) and utilized results.

Page 44. The paragraph that allows a minimal increase of 0.1 rem for those in excess of SRP limits should be removed. There is no reason for allowing someone over the SRP guidelines to continue to exceed these guidelines. This implies that if a person can break up a change into small enough doses anything is acceptable. At the very least there should be restrictions on the number of times this can be utilized.

June 16, 2000

MEMORANDUM TO:	Cynthia A. Carpenter, Chief Generic Issues, Environmental Financial and Rulemaking Branch Office of Nuclear Reactor Regulation
FROM:	Glenn M. Tracy, Chief ***Original signed by: David Trimble for:*** Operator Licensing, Human Performance and Plant Support Branch Office of Nuclear Reactor Regulation
SUBJECT:	STAFF COMMENTS ON DRAFT REGULATORY GUIDE 1095 AND NEI GUIDELINES FOR 10 CFR 50.59 EVALUATIONS (NEI-96-07, REV.1)

Staff from IOLB's Operator Licensing and Human Performance section, together with members from the Regulatory Effectiveness and Human Factors Branch, RES, and staff of BNL's Systems Engineering and Safety Analysis Group, have developed the following comments and recommendations related to Draft Regulatory Guide (DG) 1095, "Guidance for Implementation of 10CFR 50.59, Changes, Tests, and Experiments," and NEI "Guidelines for 10 CFR 50.59 Evaluations" (NEI 96-07, Rev. 1). DG-1095 proposes to endorse the NEI guideline document as an acceptable means for meeting the revised 10 CFR 50.59 rule. Both documents are currently undergoing a period of public comment.

IOLB has particular interest in the DG and NEI guidance as they relate to 10 CFR 50.59 rulemaking because adverse human performance can be a significant contributor to overall plant risk. 10 CFR 50.59 is a key regulation that establishes parameters under which licensees can make certain changes to their plants and procedures without prior NRC approval. Changes being proposed by licensees often involve crediting human actions performed by operators or other plant personnel, sometimes as substitutes for previously automated functions and other times as new or modified manual actions. Human actions can, and do, affect plant safety and risk.

The staff believes that DG-1095 and proposed NEI guidance are incomplete in their current treatment of human performance and the potential safety consequences that may result from human error, and thus do not meet the requirements of 10 CFR 50.59. The staff has identified two concerns and several additional comments and suggestions for the DG and NEI guidance, as these documents relate to human performance, are provided. It is recommended that these issues and comments be addressed before the documents are finalized. A discussion of these concerns and comments follows.

Concerns:

1. Based on NEI 96-07, section 4.3.2, it does not appear that it is necessary for licensees to submit human actions (HA's) to the NRC for review regardless of their effect on risk, on the frequency of occurrence of accidents, or on the consequences of accidents. The staff believes that NEI 96-07, section 4.3.2, does not meet the requirements of 10 CFR 50.59.

2. HAs should be evaluated at the same level as structures, systems, and components (SSCs) and thus HA's should be addressed in all of the appropriate criteria of 10 CFR 50.59 (c) (2) and, correspondingly, in NEI 96-07.

The staff proposes that both of these concerns can be addressed by either:

1. adding to DG-1095 a statement such as,

   Evaluation of Human Actions (HAs): NEI 96-07 only addresses HAs in Section 4.3.2 (and, possibly,Section 4.3.6 as it might be effected by 4.3.2) regarding SSCs. Any change in the facility involving new or modified human actions, must receive the evaluation in at least Sections 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, and 4.3.6, to satisfactorily address the criteria of 50.59 (c) (2), or,

2. Alternatively, revising NEI 96-07 in a similar manner to satisfactorily address the staff's concerns.

Justification for the Staff's Concerns:

The current guidance in NEI 96-07, Rev.1, Section 4.3.2 (page 41, item 3),appears very non-conservative and the staff has concerns regarding the technical basis. Using this guidance, it is most probable that all operator actions (including manual actions substituted for automatic actions) would be determined as creating, "less than a minimal increase in the likelihood of occurrence of a malfunction...". Therefore, there is little likelihood that any operator action would be submitted to the NRC for evaluation. As an example, one of the provisions in 4.3.2 used to determine whether an action has a less than minimal increase on the occurrence of a malfunction is if, "the licensee has demonstrated that the action can be completed in the time required..." There is no specificity in the guidance for what constitutes an acceptable method for demonstrating that the action can be successfully completed. In addition, following are examples of important operator actions that could very well be overlooked if the proposed NEI guidance is used.

Attachment A to reference 1 provides a list of generically, risk-important human actions, with 5 for BWRs and 7 for PWRs. This list was derived from NUREG-1560, "Individual Plant Examination Program: Perspectives on Reactor Safety and Plant Performance-Final Report," and has its origin from the results of individual licensee IPE's. Changes associated with these actions would be risk important and it appears they would be inappropriately "screened out" by the current NEI guidance. Twenty one actual cases of changes to operator actions submitted

References

1. "Guidance for the Review of Changes to Risk-Important Human Actions, BNL report Y6022-T2-2-1-2000, J. Higgins, J. O'Hara, & W. Stubler. April 7, 2000

2. "The Development of Guidance for the Review of Plant Modifications Involving Risk-Important Human Actions," BNL Letter Report Y6022-T2-1-1/2000, J. O'Hara, J. Higgins, and W. Stubler. April, 17, 2000.

3. NUREG-1150, "Severe Accident Risks: An Assessment for Five US Nuclear Power Plants," December, 1990.

4. NUREG-1560, "Individual Plant Examination Program: Perspectives on Reactor Safety and Plant Performance-Final Report," December, 1997.

5. NUREG-0711, :"Human Factors Engineering Program Review Model," July, 1994.

6. Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment In Risk-Informed Decisions On Plant-Specific Changes to the Licensing Basis," July, 1998.

General Comments

1. In Section 1.4 of DG-1095, NRC provides two clarifications to Section 4.3.8 of NEI 96-07. However, 4.3.8 is nine pages long. NRC should specifically state where in Section 4.3.8 these comments apply, as it is very difficult to apply Section 1.4 of the DG as written.

2. NEI 96-07: On page 39, item 3, no units are given for the frequency of occurrence.

3. NEI 96-07: On pages 38 & 39, there are three examples given for Section 4.3.1. They use double negative logic, and are confusing. As a result on page 39 item3, it is not clear wether the two items are intended to use "and" or "or" logic. The document should be reworded for clarity and should use the more straight-forward logic of 50.59 (more than a minimal increase).

4. NEI 96-07, page 63, Section 4.4, "Applying 10 CFR50.59 to Compensatory Actions to Address Nonconforming Conditions or Degraded Conditions." This section does not address the important situation where the degraded condition exceeds Technical Specification limits.

Attachment