NUCLEAR ENERGY INSTITUTE

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November 17, 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:

We are pleased that the Commission has approved Regulatory Guide 1.187 which endorses NEI 96-07, Revision 1, *Guidelines for10 CFR 50.59 Implementation,* without exception. The Commission action marks achievement of our shared goal to provide licensees with consensus guidelines for implementing 10 CFR 50.59 and thus restore regulatory stability in this important area. We commend the Commission and the NRC staff for their efforts in this regard.

The final NEI 96-07, Revision 1, dated November 2000, is attached. The final guideline includes two additional sentences in Section 4.1.5 on evaluation of fire protection program changes in accordance with the standard license condition. Also, the Foreword and Section 1.4 have been clarified to reflect that when completed, 10 CFR 72.48 guidance will become Appendix B of NEI 96-07, Revision 1. An electronic copy is being provided separately to Eileen McKenna.

We intend to monitor licensee implementation of the revised 10 CFR 50.59 rule and guidance. Please contact Russ Bell at 202-739-8087 regarding any significant implementation questions that may arise.

Sincerely,

Anthony R. Pietrangelo

Enclosure

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

NEI 96-07, Revision 1

Nuclear Energy Institute

# GUIDELINES FOR 10 CFR 50.59 IMPLEMENTATION

November 2000

## 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 long standing 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 who 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.

# 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 more than 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 has been used as the basis for guidance on implementing 10 CFR 72.48. When completed, 10 CFR 72.48 guidance will become Appendix B to NEI 96-07, Revision 1.

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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 that 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 are 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. The technical specifications bases are an example of documentation that may be outside the UFSAR but that is controlled via 10 CFR 50.59 by many licensees.

### 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 actions that address degraded and nonconforming 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 and 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.

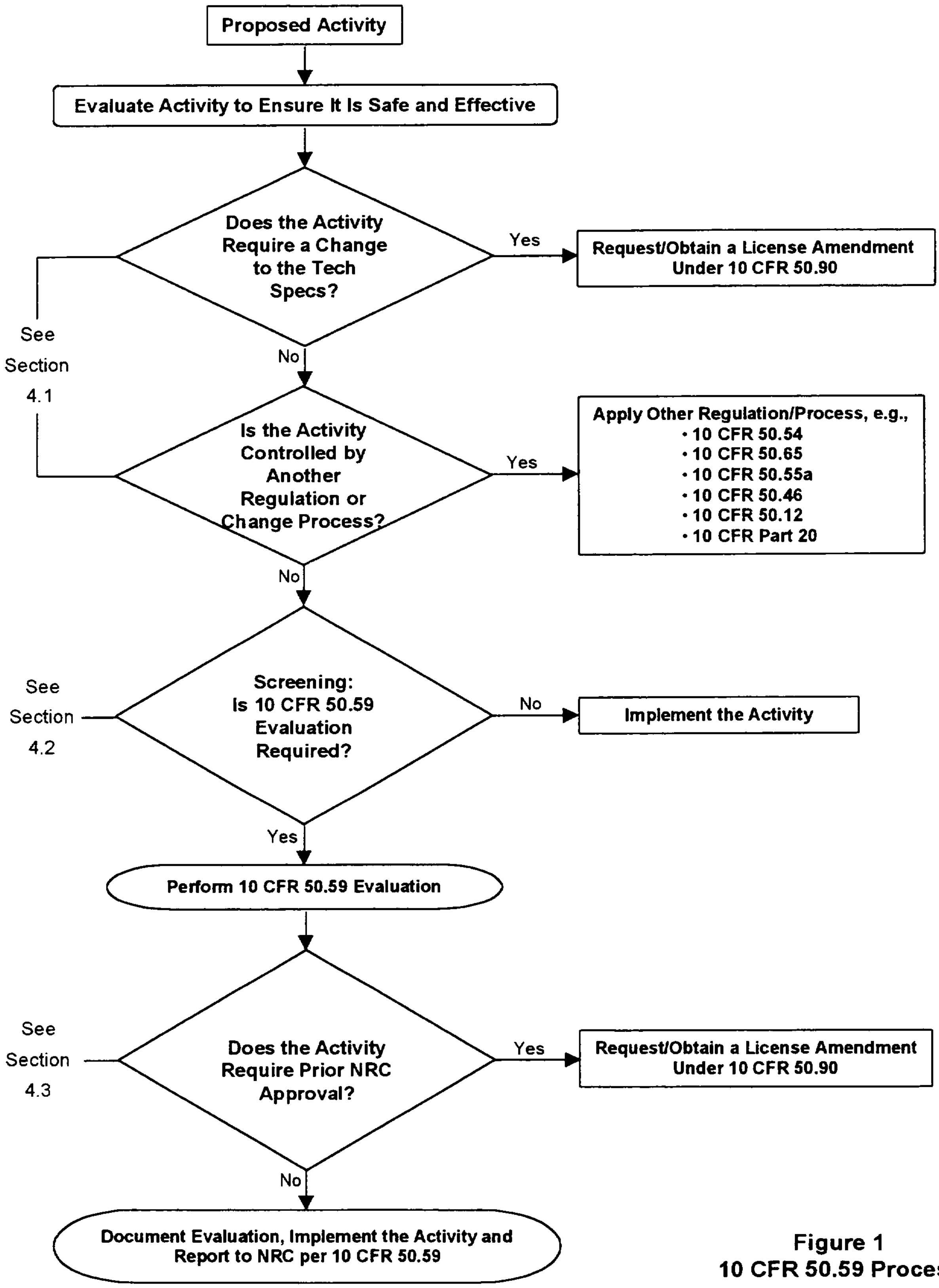


**Figure 1**
**10 CFR 50.59 Process**

## 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, make 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 has been used as the basis for guidance on implementing 10 CFR 72.48. When completed, 10 CFR 72.48 guidance will become Appendix B to NEI 96-07, Revision 1.

## 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 addressing degraded and nonconforming conditions and on dispositioning 10 CFR 50.59 evaluations.

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. When completed, Appendix B will provide 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 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 that, 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 to prevent safety limits from being exceeded. The UFSAR presents the set of limiting analyses required by NRC. The limiting analyses are used to confirm the systems and equipment design, to identify critical setpoints and operator actions, and to support the establishment of technical specifications. Therefore, the results of the UFSAR accident analyses reflect performance of equipment under the conditions specified by NRC regulations or requirements. Changes to 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 are 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 that 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 nonreliance 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:

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

Design bases functions are functions performed by systems, structures and components (SSCs) that are (1) required by, or otherwise necessary to comply with, regulations, license conditions, orders or technical specifications, or (2) credited in licensee 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 nonsafety-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 bases function in the manner described, the assumed initial conditions, mitigative actions or other information in the analyses would no longer be within the range evaluated (i.e., the analysis results would be called into question). The phrase "support or impact design bases functions" refers both to those SSCs needed to support design

[1] Definition of *design bases function* from revised Appendix B to NEI 97-04 (endorsed by Regulatory Guide 1.186).

bases functions (cooling, power, environmental control, etc.) and to SSCs whose operation or malfunction could adversely affect the performance of design bases functions (for instance, control systems and physical arrangements). Thus, both safety-related and nonsafety-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). Example: a thermodynamic calculation that demonstrates the emergency core cooling system 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 actions to address degraded or nonconforming 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 at power, 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. Nonconservative Evaluation Results

Gaining margin by revising an element of a method of evaluation is considered to be a nonconservative 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

nonconservative. 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 of a method of evaluation such that results move in the nonconservative 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) contains "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 are 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 that 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 the basis for determining if the activity screens out or requires a 10 CFR 50.59 evaluation.

Further discussion and guidance on screening are 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. Examples of tests unrelated to maintenance and thus subject to 10 CFR 50.59 include (1) most core physics testing, (2) room heat-up testing to validate a design/analysis input, and (3) testing to help determine which of two redesign alternatives to pursue.

# 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, performance requirements, operation or control 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 NUMARC 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 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.

- 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 are 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 where 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 NUMARC 93-01, Revision 3, August 2000

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 should be applied to temporary changes proposed as compensatory actions for degraded or nonconforming conditions, as discussed in Section 4.4.

Control of Maintenance Procedures

Changes to procedures for performing maintenance are made in accordance with applicable 10 CFR Part 50, Appendix B, criteria and licensee procedures. Licensee processes should ensure that changes to plant configurations called for by procedures are consistent with the technical specifications. 10 CFR 50.59 does not apply to such changes because, like the maintenance activities themselves, changes to procedures for performing maintenance do not permanently alter the design, performance requirements, operation or control of SSCs.

Certain maintenance procedures, including those for technical specification required surveillance and inspection, may contain important information concerning SSC design, performance, operation or control. Examples include acceptance criteria for valve stroke times or other SSC function, torque values, and types of materials (e.g., gaskets, elastomers, lubricants, etc.). Licensee design and/or configuration control processes should ensure that 10 CFR 50.59 is applied to changes in such information and that maintenance procedure changes do not inadvertently alter the design, performance requirements, operation or control of SSCs.

If a change to a 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).

### 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
- Administrative controls for creating or modifying procedures
- Training programs
- On-site/off-site safety review committees
- Plant modification process
- Calculation process

Example

The UFSAR states that the shift supervisor will authorize all radioactive liquid releases. This is an administrative requirement on the conduct of facility operations. Thus assigning this function to another individual would not be subject to 10 CFR 50.59 but would be done in accordance with 10 CFR Part 50, Appendix B, criteria and licensee procedures. The licensee would be required to reflect the change in the next required update of the UFSAR, per 10 CFR 50.71(e).

### 4.1.5 Changes to Approved Fire Protection Programs

Most nuclear power plant licenses contain a section on fire protection (FP). 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. An evaluation performed in accordance with the license condition should include an assessment of the impact of the change on the existing fire hazards analysis for the area, as is current practice. The assessment should address the effects on combustible loading and distribution and should consider whether circuits or components, including associated circuits, for a train of equipment needed for safe shutdown could be affected, or whether a new element could be introduced into the area.

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.

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

It is appropriate for discrete elements to be considered together if (1) they are interdependent as in the case where a modification to a system or component necessitates additional changes to other systems or procedures; or (2) they are performed collectively to address a design or operational issue. 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 that are not linked, each must be screened separately and independently of each other.

Activities that screen out may nonetheless require UFSAR information to be updated. 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 actions for degraded or nonconforming 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 activity affects a design function, method of performing or controlling a design function or an evaluation that demonstrates that design functions will be accomplished, a thorough understanding of the proposed activity is essential. A given activity may have both direct and indirect effects that the screening review must consider. The following questions illustrate a range of effects that may stem from a proposed activity:

- Does the activity decrease the reliability of 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.

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.[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 affect a design function and would screen in. In this regard, changes that would relax the manner in which Code requirements are met for certain SSCs should be screened for adverse effects on design function. Similarly, changes that would introduce a new type of accident or malfunction would screen in. This reflects an overlap between the technical/engineering ("safety") review of the change and 10 CFR 50.59. 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 should focus on the adverse effects.

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

[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.

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.

#### 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 adversely 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 adversely 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 adversely affects a UFSAR-described design function, method of performing or controlling the design function, or an evaluation demonstrating that intended design functions will be accomplished, then a 10 CFR 50.59 evaluation is required.

Another important consideration is that a change to nonsafety-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 nonsafety-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. In addition, any change to a design bases limit for a fission product barrier must be considered adverse and screened in. This is because 10 CFR 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:

<u>Example 1</u>

A licensee proposes to replace a relay in the overspeed trip circuit of an emergency diesel generator with a nonequivalent 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.

<u>Example 2</u>

A licensee proposes a nonequivalent 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 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.

Example 3

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.

Example 4

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),

changes to the man-machine interface, changing a valve from "locked closed" to "administratively closed" and similar changes.

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

Example 1

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.

Example 2

If the UFSAR description of the reactor start-up 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 start-up, the change would screen out.

Example 3

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.

Example 4

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.

#### 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:

Example 1

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.

Example 2

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 require a 10 CFR 50.59 evaluation.

Example 3

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 up-rate. 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 steamline break mass and energy release calculations were reanalyzed, 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).

Example 4

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 nonconservative, 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 reanalyzed, 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.

Example 5

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:

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

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

1. Steam generator moisture carryover tests (provided such testing is described in the UFSAR)

2. Balance-of-plant heat balance test

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

### 4.2.3 Screening Documentation

10 CFR 50.59 record-keeping 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 before 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 that are not linked, each must be evaluated separately and independently of each other.

The effects of a proposed activity being evaluated under 10 CFR 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. Evaluations should consider the effects of the proposed activity on operator actions.

Specific guidance for applying 10 CFR 50.59 to temporary changes proposed as compensatory actions for degraded or nonconforming 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:

Example 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 toward increasing the frequency).

Example 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.

Example 3

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

- The increase in the pre-change accident or transient frequency does not exceed 10 percent or
- The resultant frequency of occurrence remains below 1E-6 per year or applicable plant-specific threshold.

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

### 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 nonsafety-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 an 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 toward 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.

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

Example 1

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

Example 2

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

Example 3

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

Example 4

The change involves a new or modified 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.

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

Example 5

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

Example 6

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

Example 7

The change would (permanently) substitute manual action for automatic action for performing UFSAR-described design functions. (Guidance for temporary substitution of manual action for automatic action to compensate for a degraded/nonconforming condition is provided in NRC Generic Letter 91-18, Revision 1.)

Example 8

The change in likelihood of occurrence of a malfunction is calculated in support of the evaluation and increases by more than a factor of two. Note: The factor of two should be applied at the component level. Certain changes that satisfy the factor of two limit on increasing likelihood of occurrence of malfunction may meet one of the other criteria for requiring prior NRC approval, e.g., exceed the minimal increase standard for accident/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 "consequences" means dose. 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 on-site 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 toward 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[4].

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?

[4] 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).

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

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

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

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

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

The following examples illustrate the implementation of this criterion. In each example it is assumed that the calculated consequences do not include a change in the methodology for calculating the consequences. Changes in methodology would need to be separately considered under 10 CFR 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.

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 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 does not cause more than a minimal increase in consequences.

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 off-site 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 not cause more than 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.

### 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 off-site 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. Accidents of a different type are credible accidents that the proposed activity could create that are not bounded by UFSAR-evaluated accidents.

### 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 that 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."

An example of a change that would create the possibility for a malfunction with a different result is a substantial modification or upgrade to control station alarms, controls, or displays that are associated with SSCs important to safety that creates a new or common cause failure that is not bounded by previous analyses or evaluations.

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.

Identification of affected design basis limits for a fission product barrier

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 used 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 liftoff |
| | 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 10 CFR 50.59.

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 use 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 nonconservative 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.

*Identification of design basis limits*

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.

*Identification of design basis limit*

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.

*Exceeded or altered*

The design basis limit itself has been "altered" and thus a license amendment is required. The issue of conservative vs. nonconservative 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 nonconservative 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. Nonconservative Results

Gaining margin by changing one or more elements of a method of evaluation is considered to be a nonconservative 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 nonconservative 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.

"Essentially the Same"

Licensees may change one or more elements of a method of evaluation such that results move in the nonconservative 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 judgment 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 (SER), 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 users of a new methodology—even one generically approved by the NRC—to ensure they have a thorough understanding of the methodology in question, the terms of its existing application and conditions/limitations on its use. A range of considerations is identified below that may be applicable to determining whether new methods are technically appropriate for the intended application. The licensee 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,[5] the NRC has established a method by which licensees can demonstrate they are generally qualified to perform safety analyses. Licensees thus qualified can apply methods that have been reviewed and approved by the NRC, or that have been otherwise accepted as part of another plant's

[5] Generic Letter 83-11, Supplement 1, "Licensee Qualification for Performing Safety Analyses," June 24, 1999

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 May be Considered "Approved by the NRC 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 computer code? Has industry experience with the computer code been appropriately considered?

  The computer code installation and plant-specific model qualification are 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 off-site power or a maximum break size for certain events; others 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 the basis documented for concluding that the differences are not relevant to determining that the new application is technically appropriate.

### 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.

Example 5

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 its 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/nonconforming 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) that 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 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 licensee prepared a 10 CFR 50.59 screening to support construction of the separate structure through preliminary testing. The limited interfaces with the existing facility were assessed and determined to not change the facility or procedures 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 that 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.

Documenting 10 CFR 50.59 Evaluations

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 criterion 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
# GUIDELINES FOR 10 CFR 72.48 IMPLEMENTATION
# (FUTURE)

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.