NEI

NUCLEAR ENERGY INSTITUTE

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December 20, 1999

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

PROJECT NUMBER: 689

Dear Mr. Matthews:

Enclosed for NRC review and comment is draft NEI 96-07, Revision 1C, *Guidelines for 10 CFR 50.59 Evaluations*. The revised guidance in Enclosure 1 reflects consideration of industry and NRC comments received on the September 17 draft of the document. Enclosure 2 is a table that indicates the disposition of the NRC's November 3 comments.

In addition to numerous clarifications and refinements to the September 17 draft, the enclosed Revision 1C includes the following new material:

- Section 4.3.8 has been revised to reflect the discussions during our November 2 public meeting on the meaning of *approved by the NRC for the intended application* as that phrase is used in the rule definition of *departure from a method of evaluation described in the FSAR (as updated)*.

- Sections 3.3 and 4.1.2 have been clarified to reflect that risk impacts of temporary changes used to support maintenance activities are assessed and managed under the Section a(4) of the Maintenance Rule, and as such, 10 CFR 50.59 does not apply to such changes.

- Consistent with new 10 CFR 50.59(c)(3) and associated statements of consideration, Section 1.2.1 has been revised and new Section 4.1.5 has been added to reflect that fire protection-related changes should be evaluated under the fire protection license condition established by licensees based on Generic Letter 86-10. Fire protection changes would not also be subject to 10 CFR 50.59 unless the changes effect non-fire protection design functions of SSCs.

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10 CFR 50.59(c)(3) and this guidance are expected to clarify longstanding confusion concerning overlapping change control criteria in the fire protection area. In public comments on DG-1094, "*Fire Protection for Operating Nuclear Power Plants*" (due to NRC by January 7, 2000), NEI intends to propose guidance for licensee evaluation of fire protection changes that is consistent with GL 86-10 and the clarified scope of 10 CFR 50.59.

We look forward to discussing the revised guidance with you in a public meeting in early January. Following that interaction, we plan to make final adjustments to the guidance as necessary and forward the final draft of NEI 96-07, Revision 1, to you for NRC endorsement.

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

Sincerely

Anthony R. Pietrangelo

Enclosures

c: Eileen McKenna

Resolution Status of NRC Nov. 3 Comments on Draft NEI 96-07, Rev. 1

NRC Comment	Resolution
1. The second bullet in Figure 1 on page 4 should be modified to read, "Is the Activity Controlled by Another Regulation ~~or~~ that contains a Change Process?" The rule only allows exclusion when another regulation contains a change process. The ensuing reference to 10 CFR 50.65 also needs to be removed because it does not contain a change process. Conforming changes need to be made in section 4.1.2. Contemplating adding new loads on a safety bus without performing a 50.59 evaluation by considering it maintenance on a bus is not acceptable. Similarly, contemplating new reactor fuel without performing a 50.59 evaluation by considering it maintenance on the core is also not acceptable.	Changed top box of Fig. 1 to say "Proposed Activity" to encompass changes, tests, experiments and maintenance activities. No changes to 2nd decision block or reference to 10 CFR 50.65. Section 4.1.2 modified to clarify the limitations on what can be considered maintenance. Adding new loads on a safety bus or adopting a new fuel design would not be considered maintenance.
2. It would be helpful to clarify the definition of "design function" to explain how redundancy, diversity and defense-in-depth are captured (pg 11).	In Section 3.3, added "single failure" to the conditions under which design functions may be required to be performed. Added screening consideration to Section 4.2:1: • Does the activity reduce the existing SSC redundancy, diversity or defense-in-depth?
3. Item (c)(2) in section 4.3.2 is not clear. What is meant by increasing challenges such that performance is degraded below some point? It would be helpful for this to be clarified.	Section 4.3:2 (c)(2) truncated to read, "Increasing challenges to safety systems assumed to function in the safety analyses."
4. It would be helpful to clarify the definition of "essentially the same." The last sentence provides examples that may confuse users because it states "examples of departures that would be considered 'essentially the same.'" It is important to stress the essentially the same standard is applied to the results of a method not to the departure from a method itself. Although we would expect the results of these examples to be essentially the same the guidance may be interpreted to imply that for these types of changes the "essentially the same" standard does not need to be demonstrated on the results. It may be helpful to provide examples that apply the definition "within the margin of error for the type of analysis being performed....." For example a method is applied using a different computational platform (mainframe vs workstation) however when cases were run on the two systems the difference in the results was always less than 1%. This is less than the margin of error for this type of calculation and the results are essentially the same (pg. 13). Conforming changes also need to be made in section 4.3.8.2.	Last sentence of the Section 3.4 discussion of "essentially the same" modified to read, "Variation in results due to routine analysis sensitivities or calculational differences (e.g., rounding errors and use of different computational platforms) <u>would typically be within the analysis margin of error and thus considered "essentially the same."</u> The suggested example will be added to Section 4.3.8.2 as follows: 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.

5.	The definition for "approved by NRC for the intended application" and the related guidance in section 4.3.8 need to be supported by additional guidance that indicates that a licensee should have established a program that conforms with the guidelines in GL 83-11, as well as further information to assist licensees with how they would determine that a particular application of a different method is technically appropriate for the intended application, and within the bounds of what has been found acceptable by NRC.	Section 4.3.8 modified to address the NRC comment. See in particular 4.3.8.2.
6.	On the bottom of page 32 of the guidance, the sentence, "This is not to say that if plant-specific accident frequency calculation or PRA can be used to evaluate a proposed activity in a quantitative sense, it should not be used." is unclear and is unnecessarily negative. Suggest deletion in favor of the clearer statement in the first complete paragraph on page 33.	Sentence modified to read, "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...."
7.	With regard to the increases in the likelihood of SSC malfunctions, a factor of 2 was proposed as the criterion. Although this criterion is reasonable (on a component level), the guidance needs to be clear at what level this criterion should be applied. For example, a change is being contemplated to a breaker associated with a diesel, should the factor of 2 increase be applied to the breaker, the diesel, the safety train, the onsite electrical power system, or the electrical power system? The guidance states that the evaluation be performed at the same level as the failure modes and effects analysis, however, this is not always clear. Please provide a clear discussion of the level at which the factor of 2 should be applied and provide a rationale for its use.	The following guidance was added to Section 4.3.2.b: The factor of two guideline should be applied based on the nature of the change, e.g., at the component level if the change affects a component or at the system train level if the change affects redundant trains of a system.
8.	In the discussion of direct vs. indirect effects, it would be helpful to describe the extent to which indirect effects need to be considered. For example, a change being contemplated to a cooling water system. Should the effect of the change be evaluated on the cooling water system alone or should it extend to the systems the cooling water systems support? Please clarify the extent to which indirect effects need to considered and provide the rationale.	NEI 96-07, R1, Section 4.2.1.1 says, "Another important consideration is that a change to non safety-related equipment not described in the UFSAR can indirectly affect the capability of SSCs described in the UFSAR to perform their intended design function(s). For example, increasing the heat load on a non safety-related heat exchanger such that the cooling system's ability to cool safety-related equipment is compromised. Section 4.3.2 says, "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." The guidance is considered adequate.

9. The discussion on screening changes to methods of evaluation in section 4.2.1.3 needs to be modified. The position that a method referenced, but not described, in the FSAR does not require a 50.59 evaluation is not acceptable. Similarly, if a change to an element of a method is being considered, and the method is described in the FSAR, a 50.59 evaluation needs to be performed, regardless of whether the element (of the method) is described in the FSAR. The position that a departure can be screened out without a 50.59 "provided the changes do not affect the UFSAR description" of the method is not acceptable, because the FSAR descriptions of the methods are generally not comprehensive descriptions of the methods. Additionally, the guidance should be clear that any changes to methods that are referenced by another method subject to 50.59 need to be changed in accordance with 50.59. For example, a topical for a non-LOCA transient analysis is referenced in the FSAR. The topical describes the use of a system transient code as the basis for the topical. Changes to the system code that affect the non-LOCA transient analysis need to be evaluated under 50.59. Conforming changes also need to be made in section 4.3.8.1.	2nd paragraph and 2nd bullet of Section 4.2.1.3 modified to read as follows: If the method used for performing specific analyses is identified or described in the UFSAR, that method is considered to be described in the UFSAR for purposes of 10 CFR 50.59. Methods of evaluation that may be discussed in references listed at the end of UFSAR sections or chapters are not considered to be described in the UFSAR 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 described in the UFSAR do not require evaluation under 10 CFR 50.59 if the changes are within the constraints and limitations associated with use of the method, e.g., identified in a topical report and/or SER. The following examples illustrate the screening of changes to methods of evaluation: • The UFSAR references the name of the computer code used for performing some particular type of analyses, with no further discussion of the methods employed within the code for performing those analyses. Changes to the computer code may be screened out provided that the changes are within the constraints and limitations identified in the associated topical report and SER. A change that goes beyond restrictions on the use of the method should be evaluated under 10 CFR 50.59(c)(2)(viii) to determine if prior NRC approval is required.
10. The manner that redundancy, diversity, and separation are discussed in sections 4.3.2 and 4.3.6 for the different criteria in the rule should be clarified. It appears, through the examples that a reduction in the level of independence would not be permitted by one criterion but may be permitted by another. It may be helpful to provide an example how a reduction in the level of redundancy, diversity or independence would be treated by the guidance as a whole.	Section 4.3.2 has been modified to conform to Section 4.3.6.
11. The guidance on identifying the design basis limits in section 4.3.7 is not consistent with the rule SOC in SECY-99-130. The test of whether the "parameter is crucial to the barrier integrity," or if exceeding the limit "alone would be sufficient for the barriers integrity to be questioned" is too narrow and somewhat subjective. The SOC for the rule defines "design basis limit for a fission product barrier" as "any parameter used to measure the integrity of a barrier." This is a simpler definition that is much less subjective and should be used in the guidance. Additionally, the list of	The SOC for the rule defines "design basis limit for a fission product barrier" as "any parameter used to <u>determine</u> (not measure) the integrity of a barrier." Not all parameters associated with fission product barriers are design bases parameters for purposes of Section 4.3.7. For clarity the sentence containing "alone would be sufficient for the barriers integrity to be questioned," has been deleted. The guidance is consistent with the SOC. For example, exceeding limits for fuel burn-up (not a design bases parameter) would affect fuel internal gas pressure, which <u>is</u> a design bases

example parameters should be expanded to include fuel rod linear heat rate, fuel burn-up limits, RCSection heat-up and cool-down limits, RCSection usage factors, and containment temperature to have a more complete set of parameters.	limit for the integrity of the fuel cladding. For similar reasoning, linear heat rate and RCS usage factor are likewise not design bases parameters. Because some licensees may consider limits on RCS heat-up and cool-down as design bases limits, these will be added to the table in Section 4.3.7 (with an asterisk indicating that these parameters are typically controlled by technical specifications limits). For clarification, the first bullet under "Identification of affected design basis limits for fission product barriers" has been revised as follows: • **The parameter is fundamental to the barrier's integrity.** Design basis limits for fission product barriers establish the boundaries, or limits of the design bases 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 should be distinguished from other parameters that—while they may affect fission product barrier performance—are of secondary importance. For example, a change to fuel burn-up limits would be evaluated for its effect on clad strain to determine if it caused the limiting value for fuel internal gas pressure to be exceeded. Thus fuel internal gas pressure is a fundamental design bases limit for fuel cladding integrity, and fuel burn-up is a secondary/subordinate parameter/limit. Similarly, linear heat rate and RCS usage factor limits affect the fuel cladding and RCS boundary but are subordinate, respectively, to the design bases limits for fuel temperature and RCS stresses. In the context of containment barrier integrity, containment temperature is not a design bases parameter. It is a function of containment pressure which is the parameter of principal interest with respect to retaining fission product materials. Containment temperature is significant to environmental qualification, which is considered elsewhere in the 10 CFR 50.59 evaluation.
12. The second bullet describing conditions not considered departures is not clear (pg 53) because terms like "fundamental assumptions" are not well understood, in all cases. Additionally, the description does not appear to be consistent with the rule definition of departure, because it implies that certain changes can be considered not departures, even if they are not NRC approved and not essentially the same (or conservative).	The bullet in question has been deleted.

13. Section 4.3.3 on p. 38 describes in detail current dose guidance in Parts 50 and 100 and SRPs in terms of whole body and thyroid doses. A new final rule amending Part 50 for the voluntary use of alternative source terms (in terms of TEDE dose) is expected to be approved soon. It may be helpful to reference this rule and its provisions once it is issued.	Appropriate changes to the guidance will be considered based on the forthcoming changes to Part 50 concerning alternative source terms.
14. NEI 96-07 does not provide any specific guidance regarding application of 10 CFR 50.59 for the review of digital retrofits. A large effort was undertaken by the staff, EPRI, NEI, and the utilities to establish guidance (Generic Letter 95-02) for determining which digital retrofits could or could not be implemented without NRC review under the existing rule requirements. NEI 96-07 should provide detailed guidance that is both clear and unambiguous regarding digital retrofits (which ones can and cannot be retrofitted without NRC review). Examples would be helpful in this regard.	The following changes have been made to Section 4.3.6: 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 <u>or credible common mode failure (eg. as a result of an analog-to-digital upgrade) should</u> be evaluated further to see whether new outcomes have been introduced. The following example was also added: For example, if a feedwater control system is being upgraded from an analog to a digital system, new components may be added which could obviously fail for reasons other than the components in the original design. If, however, the end <u>result</u> 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 activity or change would not be creating a "malfunction with a different result".
15. The discussion provided in Section 4.2,"SCREENING", seems to indicate that all safety related digital retrofits and non-safety related digital retrofits that impact SSC's are controlled by the 10 CFR 50.59 process. This would include new technology such as digital/software that is not an existing part of a plant's design basis. This would mean that an analysis per 10 CFR 50.59 process is required. Is this the intent of the NEI guidance? If not, there should be more detailed guidance regarding the systems and their subsequent inclusion into the 50.59 screening process. Factors that would lead to this somewhat all-inclusive screening process would be the introduction of a need for the determination of software quality, the increased susceptibility to EMI/RFI, the change in systems response times and the change in system calibration procedures including possible set point and allowable value changes due to increased accuracies. Examples in this area would be helpful for the licensee to aid in its decision making process.	The intent of the guidance is that all safety related and non-safety related tests, experiments or changes (including digital retrofits) that affect SSC's are subject to 10 CFR 50.59 screening and, if necessary, evaluation.

16. 10 CFR 50.59 Criterion 2 addresses a minimal increase in the likelihood of occurrence of a malfunction. The NEI guidance document indicates that changes in design requirements affect the likelihood of a malfunction (design requirements could include software quality, EMI/RFI, and operability characteristics). Since a digital retrofit invalidates some of the analog design requirements/characteristics, this would appear to result (according to Section 4.3.2) in more than a minimal increase in the likelihood of malfunction. System reliability when reviewed along with the UFSAR FMEA for digital retrofits leads to questions as to what the quantifiable change in reliability would be since digital system reliability is extremely difficult to quantify or even estimate. A detailed writeup using several digital retrofit examples would be beneficial.	Design requirements for digital retrofits would be consistent with and would replace – not invalidate – those of the old analog I&C. We do not agree that such a change would automatically result in more than a minimal increase in the likelihood of malfunction. This would need to be evaluated. Like other types of changes, this evaluation may be largely qualitative in nature such that the difficulty in quantifying any change in reliability is not considered an obstacle to completing the 10 CFR 50.59 evaluation. No change in the guidance is considered necessary.
17. In sections 3.11 and 4.1.4 on procedures, it may be helpful to add a short discussion that explains why procedures for work control or for conduct of operations are not included (in contrast to procedures that concern individual system operation) to assist in the screening process.	Clarifications were made to Sections 3.11 and 4.1.4 to address the NRC comment as well as industry comments
18. Page 37: In this section, the guidance gives examples of when there is **less** than a minimal increase in the likelihood of occurrence of a malfunction of a SSC important to safety (i.e., when NRC review is not required). The guidance states, "(when) the change would not cause applicable design stresses to exceed their code allowables." This example could be misleading to the reader. In many cases, a component's functionality is established by vendors at a lower stress or deformation limit than those required by a code. For example, the ASME Boiler and Pressure Vessel Code establishes stress limits for piping, pumps, valves, etc. to ensure the **pressure** integrity of the component - not necessarily the **functionality** of the component. It is not unusual for a pump vendor to specify stress limits for its casing (that are much lower than ASME Code allowable stress limits) to ensure that the pump will not bind. Similarly, NSSSection vendors often specify lower stress limits or deformation limits for certain reactor internals that are below the Code allowables to ensure the functionality of the reactor internals (e.g., rod insertion) under design basis loading conditions. As stated, the document gives the impression that there is less than a minimal increase in the likelihood of occurrence of a malfunction of a SSC as long as design stresses remain within code allowables. The NEI document should acknowledge that requirements to ensure the functional capability of SSCs might be more restrictive than code allowables.	Ex. 2 in this section modified as follows: The change would not cause applicable design stresses to exceed their ASME Code allowables or other applicable design limit (if any) for stress, deformation, etc. For example, to ensure pump functionality, vendor-specified stress limits for a pump casing may be well below the ASME Code allowable.

19. Page 46: In NEI's table, NEI provides typical design basis limits. For the RCS boundary, NEI notes that "Stresses" (as well as clad temperature and clad oxidation) are "commonly controlled by 10 CFR 50.46 and/or a specific Technical Specification and therefore would not be subject to evaluation under this criterion." RCS boundary stresses are controlled under 10 CFR 50.55a, not 50.46 or Tech Specs.	The table note will be modified to say, "These parameters are commonly controlled by 10 CFR 50.55a, 10 CFR 50.46 and/or ....
20. As discussed in Section B.2 of the SOC for 10 CFR 50.59 (64 FR 53587), supplemental guidance or examples are needed for implementation specific to 10 CFR Part 54, the license renewal rule. As required by 10 CFR 54.21(d), summary descriptions of programs for managing the effects of aging and the evaluation of time-limited aging analyses (TLAAs) must be incorporated into the FSAR. As discussed in the SOC for license renewal, [60 FR 22482], by incorporating the descriptions into the FSAR, subsequent changes are controlled by §50.59. Guidance and examples should be added (either to 1.2, 3.6, 3.11, or 4.2.1), to discuss applicability of the 50.59 process to the summary descriptions of license renewal programs and TLAAs contained in the FSAR (as updated).	We have modified Sections 3.6 and 3.11 so that the first sentence under "Discussion" of the definitions of "facility/procedures as described in the UFSAR" reads as follows: 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). This change underscores that changes affecting information contained in supplements to the UFSAR to support license renewal—like all other UFSAR information—is subject to 10 CFR 50.59, including screening and, if necessary, evaluation, to determine in prior NRC approval of the change is required. Additional guidance and examples on screening and evaluation of activities subject to 10 CFR 50.59 beyond that already presented in draft NEI 96-07, R1, is not considered necessary.
21. In section 4.1.3, the applicability guidance provides an example of FSAR changes that would not be subject to the 50.59 process, i.e., minor changes to drawings such as correcting mislabeled valves. It may be helpful to provide an example of what might be viewed as "a minor change to a drawing", but which would require further evaluation (either screening or 50.59 evaluation). For instance, consider a change to a standby lineup to reposition a valve in a safety system from the position noted on an FSAR drawing.	The draft guidance allows minor *corrections* to drawings. Changes would need to be screened and, if necessary, evaluated under 10 CFR 50.59. Corrections include resolution of inconsistencies within the UFSAR and correction of drawing information that is incidental—not material—to the UFSAR description related to the drawing. Example 5 in Section 4.2.1.2 addresses the change of a valve position indicated in the UFSAR.

22. In section 3.3, p.11, The definition of temporary change should be revised to include bypasses installed to support maintenance activities that are no longer "in progress". (This comment relates to the broader issue of when "indefinite out-for-maintenance" becomes a change).	Sections 3.3 and 4.1.2 have been revised. The revisions make clear that temporary changes are considered to be part of a maintenance activity provided they are removed at the conclusion of the activity
23. In section 3.7, p. 15, second paragraph, fourth sentence, revise to read "Therefore pending UFSAR revisions that have received final approval for incorporation..."	Sentence revised as suggested
24. It may be helpful to include a cross-reference in section 4.2.1 to the guidance on compensatory actions in section 4.4 (one can get there through the definition of change, in section 3.3, but a simpler reference is suggested).	The following will be added to Sections 4.2 and 4.3: Specific guidance for applying 10 CFR 50.59 screening (evaluation) to temporary changes proposed as compensatory measures for degraded non-conforming conditions is provided in Section 4.4.

NEI 96-07 [Draft Rev. 1C]

Nuclear Energy Institute

GUIDELINES FOR 10 CFR 50.59 EVALUATIONS

DRAFT 1C– December 20, 1999

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ACKNOWLEDGMENTS

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

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

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FOREWORD

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

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

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

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

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

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

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

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

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APPENDICES

1 INTRODUCTION

1.1 PURPOSE

10 CFR 50.59 establishes the conditions under which licensees may make changes to the facility or procedures and conduct tests or experiments without prior NRC approval. Proposed changes, tests and experiments (hereafter referred to collectively as activities) that satisfy the definitions and one or more of the criteria in the rule must be reviewed and approved by the NRC before implementation. Thus 10 CFR 50.59 provides a threshold for regulatory review—not the final determination of safety—for proposed activities.

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

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

As the process for controlling most 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:

- Amendments to the Operating License (including the technical specifications) are sought and obtained under 10 CFR 50.90.
- Where changes to the facility or procedures are controlled by more specific regulations (e.g., quality assurance, security and emergency preparedness program changes controlled under 10 CFR 50.54(a),

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

- Changes that require an exemption from a regulation are processed in accordance with 10 CFR 50.12.

- Guidance for controlling changes to licensee commitments is provided by NEI 99-04, *Guideline for Managing NRC Commitment Changes.*

- Where a licensee possesses a license condition which specifically permits changes to the NRC-approved fire protection program (i.e., has received the standard fire protection license condition contained in Generic Letter 86-10), subsequent changes to the fire protection program would be controlled under the license condition and not 10 CFR 50.59.

- Maintenance activities, including associated temporary changes, are subject to the technical specifications and are assessed and managed in accordance with the Maintenance Rule, 10 CFR 50.65; screening and evaluation under 10 CFR 50.59 is not required.

Together with 10 CFR 50.59, these processes form a framework of complementary regulatory controls over the licensing basis. To optimize the effectiveness of these controls and minimize duplication and undue burden, it is important to understand the scope of each process within the regulatory framework. This guideline discusses the scope of 10 CFR 50.59 in relation to other processes, including circumstances under which different processes, e.g., 10 CFR 50.59 and 10 CFR 50.90, should be applied to different aspects of an activity.

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

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

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

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

1.2.3 Relationship of 10 CFR 50.59 to the UFSAR

The 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 FSAR 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.

1.3 10 CFR 50.59 PROCESS SUMMARY:

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

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

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

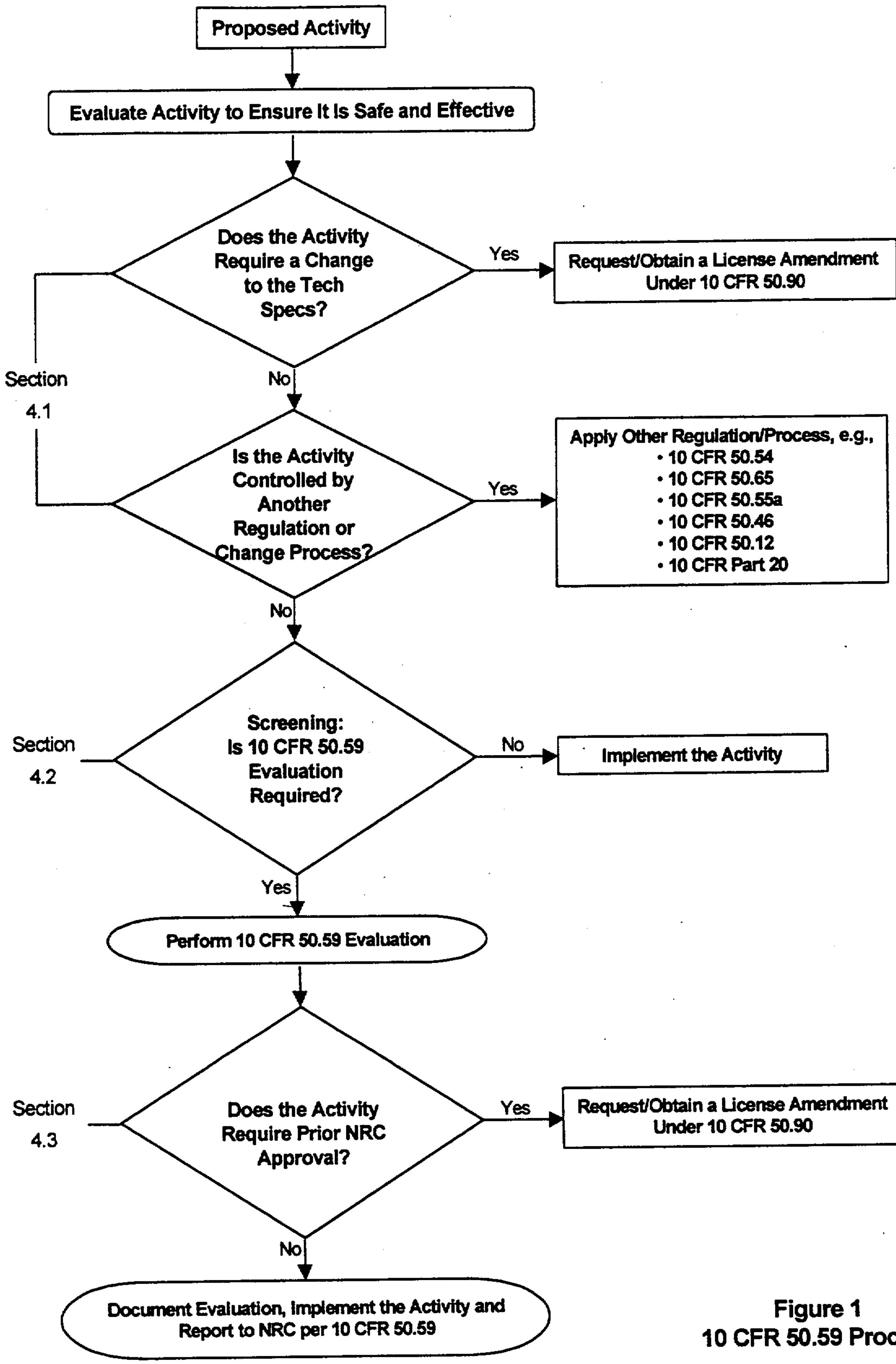

Figure 1
10 CFR 50.59 Process

1.4 APPLICABILITY TO 10 CFR 72.48

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

The intent of conforming 10 CFR 72.48 to the terms of 10 CFR 50.59 was to provide for consistent implementation of these two analogous regulations. Consistent with this intent, the guidance herein on implementing 10 CFR 50.59 may be applied to support implementation of 10 CFR 72.48.

1.5 CONTENT OF THIS GUIDANCE DOCUMENT

The NRC has established requirements for nuclear plant systems, structures and components to provide reasonable assurance of adequate protection of the public health and safety. Many of these requirements, and descriptions of how they are met, are documented in the updated FSAR (UFSAR). 10 CFR 50.59 allows a licensee to make changes in the facility or procedures as described in the UFSAR, and to conduct tests or experiments not described in the UFSAR, unless the changes require a change in the technical specifications or otherwise require prior NRC approval. In order to perform 10 CFR 50.59 screenings and evaluations, an understanding of the design and licensing basis of the plant and of the specific requirements of the regulations is necessary. Individuals performing 10 CFR 50.59 screenings and evaluations should also understand the rule and concepts discussed in this guidance document.

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

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

Section 4 discusses the application of the definitions and criteria presented in 10 CFR 50.59 to the process of changing the plant or procedures and the conduct of tests or experiments. This section includes guidance on the applicability requirements for the rule, the screening process for determining when a 10 CFR 50.59 evaluation must be performed, and the eight evaluation criteria for determining if prior NRC approval is required. Examples are provided to reinforce the guidance. Guidance is also provided on dispositioning and documenting 10 CFR 50.59 evaluations and reporting to NRC.

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

Appendix A provides the text of 10 CFR 50.59 as published in the *Federal Register* on October 4, 1999. Appendix B provides the text of revised 10 CFR 72.48 as well as examples [FUTURE] illustrating the application of this guidance to changes involving independent spent fuel storage installations and spent fuel storage cask designs.

2.0 DEFENSE IN DEPTH DESIGN PHILOSOPHY AND 10 CFR 50.59

One objective of Title 10 of the Code of Federal Regulations is to establish requirements directed toward protecting the health and safety of the public from the uncontrolled release of radioactivity. At the design stage, protection of public health and safety is ensured through the design of the engineered protection of physical barriers to guard against the uncontrolled release of radioactivity. Other sources of radioactivity including radwaste systems are included. The defense-in-depth philosophy includes reliable design provisions to safely terminate accidents and provisions to mitigate the consequences of accidents. The three physical barriers that provide defense-in-depth are:

- Fuel Clad
- Reactor Coolant System Boundary
- Containment Boundary

These barriers perform a health and safety protection function. They are designed to reliably fulfill their operational function by meeting all criteria and standards applicable to mechanical components, pressure components, and civil structures. These barriers are protected extensively by inherent safety features and through the implementation of engineered safety features. The public health and safety protection functions are analytically demonstrated and documented in the UFSAR. Analyses summarized in the UFSAR demonstrate that under the assumed accident conditions, the consequences of accidents challenging the integrity of the barriers will not exceed limits based on the criteria established in GDC 19 or the guidelines established in 10 CFR 100. Thus, the UFSAR analyses provide the final verification of the nuclear safety design phase by documenting plant performance in terms of public protection from uncontrolled releases of radiation. 10 CFR 50.59 addresses this aspect of design by requiring prior NRC approval of proposed activities which, although safe, require a technical specification change or meet specific threshold criteria for NRC review.

This protection philosophy pervades the UFSAR accident analyses and Title 10 of the CFR. To understand and apply 10 CFR 50.59, it is necessary to understand this perspective of maintaining the integrity of the physical barriers designed to contain radioactivity. This is because:

- UFSAR accidents and malfunctions are analyzed in terms of their effect on the physical barriers. There is a relationship between barrier integrity and dose.
- The principal "consequences" that the physical barriers are designed to preclude is the uncontrolled release of radioactivity. Thus for purposes of 10 CFR 50.59, the term "consequences" means dose.

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

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

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

Section III of Appendix A establishes extensive requirements on reactor protection and reactivity control systems, the objectives again being the protection of fission product barriers. With similar intent, Sections IV, V and VI provide extensive design, inspection, testing, and operational requirements for the quality of the reactor coolant pressure boundary, fluid systems in general, reactor containment, and fuel and radioactivity control. These requirements ensure inherent and engineered protection of the fission product barriers. Introductory statements of Appendix A address the need for consideration of a single failure criterion and redundancy, diversity and separation of mitigation and protection systems. Section I of Appendix A imposes requirements on the quality of implemented protection and the conditions under which these systems must function without loss of capability to perform their safety functions. These conditions include natural phenomena, fire, operational and accident generated environmental conditions.

The implementation of this design philosophy requires extensive accident analyses to define the correct relationship among nominal operating conditions, limiting conditions for operations and limiting safety systems settings in order to prevent safety limits from being exceeded. The UFSAR presents the set of limiting analyses required by NRC. The limiting analyses are utilized to confirm the systems and equipment design, to identify critical setpoints and operator actions, and to support the establishment of technical specifications. Therefore, the results of the UFSAR accident analyses assume functioning of all the equipment (and under the conditions) specified by NRC regulations or requirements. Changes to plant design and operation and conduct of new tests and experiments have the potential to affect the probability and consequences of accidents, to create new accidents and to impact the integrity of fission product barriers. Therefore, these activities are subject to 10 CFR 50.59.

3.0 DEFINITIONS AND APPLICABILITY OF TERMS

The following definitions and terms are discussed in this section:

3.1 10 CFR 50.59 Evaluation

3.2 Accident Previously Evaluated in the FSAR (as updated)

3.3 Change

3.1 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). While many plant activities are subject to a screening, only changes to the facility or procedures described in the UFSAR, and tests or experiments not described in the UFSAR, require evaluation and reporting to NRC under 10 CFR 50.59. Section 4.3 provides guidance for performing 10 CFR 50.59 evaluations. See also Section 3.13 on the definition of "screening."

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

3.2 ACCIDENT PREVIOUSLY EVALUATED IN THE FSAR (AS UPDATED)

Definition:

Accident previously evaluated in the FSAR (as updated) means a design basis accident or event described in the UFSAR including accidents, such as those typically analyzed in Chapters 6 and 15 of the UFSAR, anticipated operational 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. The term "accidents" encompasses other events for which the plant is required to cope and which are described in the UFSAR (e.g., turbine missiles, fire, earthquakes and flooding). Note that, although fire is an event for which a plant is required to cope and is described in the UFSAR (by reference to the Fire Hazards Analysis for some licensees), changes to the fire protection program are governed by licensee requirements other than 10 CFR 50.59, as discussed in Section 4.1.5.

Accidents also include new transients or postulated events added to the licensing basis based on new NRC requirements and reflected in the UFSAR pursuant to 10 CFR 50.71(e), e.g., ATWS and SBO.

3.3 CHANGE

Definition:

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

Discussion:

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

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

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

Method of performing or controlling a function means how a design function is accomplished as credited in the safety analyses, including specific operator actions, procedural step or sequence, or whether a specific function is to be initiated by manual versus automatic means. For example, substituting a manual actuation for automatic would constitute a change to the method of performing or controlling the function.

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

Temporary Changes

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

- 10 CFR 50.59 should be applied to temporary changes proposed as compensatory measures to address degraded or non-conforming conditions as discussed in Section 4.4.
- Other temporary changes to the facility or procedures, e.g., to facilitate permanent modifications, 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 to support maintenance activities are assessed and managed under Section a(4) of the Maintenance Rule as discussed in Section 4.1.2. Applying 10 CFR 50.59 to such activities is not required provided that temporary changes are removed (i.e., affected SSCs must be restored to their normal, as-designed condition) at the conclusion of the maintenance activity.

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

Definition:

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

Discussion:

The 10 CFR 50.59 definition of "departure ..." provides licensees with flexibility to make changes in methods of evaluation that are "conservative" or that are not important with respect to demonstrating that SSCs can perform their intended design functions. See also the definition and discussion of "methods of evaluation" in Section 3.10. Guidance for evaluating changes in methods of evaluation under criterion 10 CFR 50.59(c)(2)(viii) is provided in Section 4.3.8.

Conservative vs. Non-Conservative Evaluation Results

Gaining margin by revising an element of a method of evaluation is considered to be a non-conservative change and thus a departure from a method of evaluation for purposes of 10 CFR 50.59. Such departures require prior NRC approval of the revised method. In other words, analytical results obtained by changing any element of a method are "conservative" relative to the previous results, if they are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines). For example, a change in an element of a method of evaluation that changes the result of a containment peak pressure analysis from 45 psig to 48 psig (with design basis limit of 50 psig) would be considered a conservative change for purposes of 10 CFR 50.59(c)(2)(viii). This is because results closer to limiting values are considered conservative in the sense that the new analysis result provides less margin to applicable limits for making future physical or procedure changes without a license amendment.

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

"Essentially the Same"

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

"Approved by the NRC for the Intended Application"

Rather than make a minor change to an existing method of evaluation, a licensee may also adopt completely new methodology without prior NRC approval provided the new method is approved by the NRC for the intended application. As discussed in Section 4.3.8.2, 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.

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

Per revised Appendix B of NEI 97-04, *Design Bases Program Guidelines*, [Month] 2000, 10 CFR 50.2 design bases consist of the following:

- Design bases functions: Functions performed by SSCs that are (1) required to meet regulations, license conditions, orders or technical specifications, or (2) credited in safety analyses to meet NRC requirements.

- Design bases values: Values or ranges of values of controlling parameters established by NRC requirement, established or confirmed by safety analyses, or chosen by the licensee from an applicable code, standard or guidance document as reference bounds for design to meet design bases functional requirements.

The balance of Appendix B of NEI 97-04 provides further guidance and examples for identifying 10 CFR 50.2 design bases.

3.6 FACILITY AS DESCRIBED IN THE FSAR (AS UPDATED)

Definition:

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

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

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

Discussion:

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

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:

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

<u>Definition:</u>

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.

<u>Discussion:</u>

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.

Section 4.3.8 provides guidance and examples to describe the specific elements of evaluation methodology that would require evaluation under 10 CFR 50.59(c)(2)(viii) and to clearly distinguish these from specific types of input parameters that are controlled by the other seven criteria of 10 CFR 50.59(c)(2).

3.9 MALFUNCTION OF AN SSC IMPORTANT TO SAFETY

Definition:

Malfunction of SSCs important to safety means the failure of SSCs to perform their intended design functions described in the UFSAR (whether or not classified as safety-related in accordance with 10 CFR 50, Appendix B).

Discussion:

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

3.10 METHODS OF EVALUATION

Definition:

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

Discussion:

Examples of methods of evaluation are presented below. Changes to such methods of evaluation require evaluation under 10 CFR 50.59(c)(2)(viii) only for evaluations used either in UFSAR safety analyses or in establishing the design bases, and only if the methods are described, outlined or summarized in the UFSAR. Methodology changes that are subject to 10 CFR 50.59 include changes to elements of existing methods described in the UFSAR and to changes that involve replacement of existing methods of evaluation with alternative methodologies.

Elements of Methodology	Example
■ Data correlations	■ DNBR correlations
■ Means of data reduction	■ ASME III and Appendix G methods for evaluating reactor vessel embrittlement specimens
■ Physical constants or coefficients	■ Heat transfer coefficients
■ Mathematical models	■ Decay heat models
■ Specific limitations of a computer program	■ No voiding in PWR hot legs for non-LOCA analyses
■ Specified factors to account for uncertainty in measurements or data	■ 120% of 1971 decay heat model
■ Statistical treatment of results	■ Vendor-specific thermal design procedure
■ Dose conversion factors and assumed source term(s)	■ ICRP factors

Methods of evaluation described in the UFSAR subject to criterion 10 CFR 50.59(c)(2)(viii) are:

- Methods of evaluation used in analyses that demonstrate that design basis limits of fission product barriers are met (i.e., for the parameters subject to criterion 10 CFR 50.59(c)(2)(vii))

- Methods of evaluation used in UFSAR safety analyses, including containment, ECCS and accident analyses typically presented in UFSAR Chapters 6 and 15, to demonstrate that consequences of accidents do not exceed 10 CFR 100 or 10 CFR 50, Appendix A, dose limits.

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

3.11 PROCEDURES AS DESCRIBED IN THE FSAR (AS UPDATED)

Definition:

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

Discussion:

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

For purposes of 10 CFR 50.59, "procedures" are not limited to plant procedures specifically identified in the UFSAR (e.g., operating, chemistry, system, test, surveillance, 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, inspection and testing frequency, 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 for performing maintenance, work control, and administrative activities are normally outside the definition of "procedures as described in the UFSAR" because they do not typically contain information on how SSCs are operated or controlled. See Section 4.1.4 concerning the scope of procedures subject to 10 CFR 50.59. Changes to procedures identified in Appendix A of Regulatory Guide 1.33, *Quality Assurance Program Requirements*, are subject to 10 CFR 50.59. 10 CFR 50.59 screening of procedures is discussed in Section 4.2.1.2.

3.12 SAFETY ANALYSES

Definition:

Safety analyses are analyses performed pursuant to NRC requirement to demonstrate the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the guidelines in 10 CFR 50.34(a)(1) or 10 CFR 100.11. Safety analyses are required to be presented in the UFSAR per 10 CFR 50.34(b) 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 are:

- Supporting UFSAR analyses that demonstrate that SSC design functions will be accomplished as credited in the accident analyses
- UFSAR analyses of events that the facility is required to withstand such as turbine missiles, fires, floods, earthquakes, station blackout, and ATWS.

Note that, although fire is an event which a plant is required to withstand and for which it has been analyzed accordingly in the UFSAR (by reference to the Fire Hazards Analysis for some licensees), changes to the fire protection program and associated analyses are 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.

Information contained in licensee technical and engineering evaluations of the activity may be used along with other information to determine if a proposed activity screens out or requires a 10 CFR 50.59 evaluation.

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

3.14 TESTS OR EXPERIMENTS NOT DESCRIBED IN THE FSAR (AS UPDATED)

Definition:

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

- Outside the reference bounds of the design bases as described in the UFSAR, or
- Inconsistent with the analyses or descriptions in the UFSAR.

Discussion:

10 CFR 50.59 must be 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.

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

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 should be subjected 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.

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 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

In contrast to permanent changes subject to 10 CFR 50.59, maintenance activities are activities that do not permanently alter the design or design function of SSCs. Troubleshooting, calibration, refurbishment, post-maintenance testing, identical replacements, housekeeping, and similar maintenance activities are intended to restore SSCs to their normal, as-designed condition and are thus generally not subject to 10 CFR 50.59.

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

In addition to assessments required by 10 CFR 50.65(a)(4), 10 CFR 50.59 should also be applied to maintenance activities if:

- The design is not restored to its original condition as a result of the maintenance activity (e.g., if SSCs described in the UFSAR are removed; if the design, design function or operation is altered; or if a temporary change in support of the maintenance is not removed)

- Testing to support troubleshooting or other maintenance activity (e.g., post-maintenance testing) would put the facility in a condition that has not previously been evaluated or could affect the ability of operable SSCs to perform their design functions. Such testing constitutes a test or experiment that would be subject to 10 CFR 50.59.

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

<u>Equivalent Replacements</u>

Equivalent replacements may be considered maintenance activities provided that the replacement SSCs meet or exceed the functional and performance requirements of the SSCs being replaced. Considerations when making the determination that a replacement is equivalent and therefore not subject to 10 CFR 50.59 evaluation include the following:

- For instruments, are the response time, range, design pressure and temperature, and environmental qualification equivalent to those of the old instrument?
- For pumps, are the flow/head characteristics, design temperature and pressure, motor size, and controls equivalent to those of the old pump?
- For valves, are the operating time, failure position, size, design temperature and pressure, pressure drop, valve operators and controls equivalent to those of the old valves?
- For piping, are the material, design temperature and pressure, supports, insulation, and routing equivalent to those of the old piping?
- Does the activity impact other systems?
- For new electrical loads, will the diesel generator loading sequence be changed or affected, and/or will the total load be within the design capability of the diesel generator?
- Will there be an adverse effect on cable ampacity evaluations?
- Does the replacement satisfy specific commitments (if any) to ensure diversity?

As an example of an equivalent replacement, 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. Since the replacement bolts are equivalent in function to the original bolts and the rupture disk continues to meet the same functional requirements, this activity would not be subject to 10 CFR 50.59. If an equivalent replacement necessitates a change to the UFSAR, the UFSAR change should be included in the next required 10 CFR 50.71(e) update.

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, the 10 CFR 50.59 need not be applied to the following types of activities:

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

4.1.5 Changes to Approved Fire Protection Programs

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

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

- Incorporate the fire protection program and major commitments into the FSAR for the facility, and
- Amend the operating license to substitute a standard fire protection license condition for the previous license condition(s) regarding fire protection.

Under the standard fire protection license condition, licensees may

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

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

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

The focus on allowing licensees to make changes that maintain the post-fire safe shutdown capability of a FP program change is analogous to permitting changes with "minimal" effects under 10 CFR 50.59, and is consistent with the 10 CFR 50.59 rulemaking objectives to reduce regulatory burden and more effectively focus licensee and NRC resources on safety significant issues. Fire protection program changes that do not adversely affect post-fire safe shutdown capability do not warrant prior NRC review and approval. Therefore, also applying 10 CFR 50.59 to fire protection program changes is redundant and not necessary because the standard fire protection license condition establishes the appropriate regulatory framework and acceptance criteria for determining when proposed changes require prior NRC approval.

Controlling changes to the fire protection program under the standard fire protection license condition only does not alter the licensee responsibility to comply with the technical specifications and adhere to the commitments contained in licensee controlled documents. In addition, licensees should use experienced judgment when evaluating changes to the fire protection program. The person conducting the analysis of fire hazards should be thoroughly trained and experienced in the principles of industrial fire prevention and control, and in fire phenomena from fire initiation, through its development, to propagation into adjoining spaces. Evaluation of the consequences of a postulated fire on nuclear safety and safe shutdown should be performed by persons thoroughly trained and experienced in reactor safety. The evaluation of the change should consider impacts resulting from fire conditions, impacts to safe shutdown system equipment and capability, as well as impacts that may result from inadvertent operation of the fire protection systems or features. In addition, 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.

As with previous fire protection program changes made under the design and configuration control process, licensees are required to maintain, in auditable form, a current record of all such changes, including analysis of the effects of the change on the fire protection program, and shall make those records available to NRC inspectors upon request. All changes to the approved program which result in changes to the UFSAR (including the fire hazards analysis incorporated in the UFSAR) should be reported to the NRC in accordance with 10 CFR 50.71(e).

4.2 Screening

Once it has been determined that 10 CFR 50.59 is applicable to an activity, screening is performed to determine if the activity should be evaluated against the evaluation criteria of 10 CFR 50.59(c)(2).

Engineering and technical evaluations of the activity and design information concerning affected SSCs should be used to assess whether an activity is a modification, addition or removal 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. Activities that are screened out from further evaluation under 10 CFR 50.59 should be documented as discussed in Section 4.2.3.

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

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

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).

The following may be appropriate to consider, when determining based on technical/engineering evaluations, if a proposed activity is a "change to the facility or procedures as described in the UFSAR" that requires further evaluation under 10 CFR 50.59:

- Does the activity affect an SSC design function credited in the safety analyses or a supporting SSC design function?
- Does the activity affect the reliability of the SSC design function?
- 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 interaction?
- Does the activity 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 alter the seismic or environmental qualification of the SSC?

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

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

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

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

Screening to determine that a 10 CFR 50.59 evaluation is required is straightforward when a change affects an SSC design function, method of performing or controlling a design function, or evaluation that demonstrates intended design functions will be accomplished as described in the UFSAR.

However, a facility also contains many SSCs not described in the UFSAR. These can be components, subcomponents of larger components or even entire systems. Changes to SSCs that are not explicitly described in the UFSAR can have the potential to affect SSCs that are described and thus may require a 10 CFR 50.59 evaluation. In such cases, the approach for determining whether a change involves a change to the facility as described in the UFSAR, is to consider the larger, UFSAR-described SSC of which the SSC being modified is a part. If for the larger SSC, the change affects a UFSAR-described design function, method of performing or controlling the design function, or an evaluation demonstrating that intended design functions will be accomplished, then a 10 CFR 50.59 evaluation is required.

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

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

The following examples illustrate the 10 CFR 50.59 screening process as applied to proposed facility changes:

- A licensee proposes to replace a relay in the overspeed trip circuit of an emergency diesel generator with a non-equivalent relay. The relay is not described in the UFSAR, but the overspeed trip circuit and the emergency diesel generator are. The replacement of the relay could affect the overspeed trip circuit in a manner that affects the design function of the EDG as credited in the safety analyses. Thus, a specific determination of the relay's effect on the design functions of the overspeed trip circuit and the EDG is made as part of the up-front engineering/technical evaluation of the change. If the technical/engineering evaluation concludes that the change would not affect the UFSAR-described design function of the circuit or EDG, then this determination would form the basis for screening out the change, and no 10 CFR 50.59 evaluation would be required.

- A licensee proposes a non-equivalent change to the operator on one of the safety injection accumulator isolation valves. The UFSAR describes that these isolation valves are open with their circuit breakers open during normal operation. These are motor operated, safety related valves required for pressure boundary integrity and to remain open so that flow to the RCS will occur during a LOCA as pressure drops below ~600 psi. They are remotely operated so that they can be closed during a normal shutdown and not inject when not required. This change would screen out because the change affects the design of the valve—not the UFSAR-described design function (pressure boundary integrity) that supports safety injection performance credited in the safety analyses.

- A licensee proposes to replace a globe valve with a ball valve in a vent/drain application to reduce the propensity of this valve to leak. The valve is identified as normally closed in a UFSAR flow diagram. 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. Thus the proposed change affects the design of the existing vent/drain valve—not the design function that supports system performance credited in the safety analyses—and evaluation/reporting 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.

4.2.1.2 Screening of Changes to Procedures as Described in the UFSAR

Changes to procedures are "screened in" (i.e., require a 10 CFR 50.59 evaluation) if the change affects how SSC design functions are performed or controlled, as described in the UFSAR (including assumed operator actions and response times). Changes to a procedure that does not affect how SSC design functions described in the UFSAR are performed or controlled would screen out. The following examples illustrate the 10 CFR 50.59 screening process as applied to proposed procedure changes:

- Emergency Operating Procedures include operator actions and response times associated with response to design basis events, which are described in the UFSAR, but also address operator actions for severe accident scenarios that are outside the design basis and not described in the UFSAR. A change would screen out at this step if the change was to those procedures or parts of procedures dealing with operator actions during severe accidents.

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

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

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

- The UFSAR states that station batteries are tested in accordance with IEEE 450-1995, describes the testing frequency, and lists the title and designation of the plant surveillance procedure. Battery test method and frequency is thus a procedure described in the UFSAR related to the design function of station batteries to supply power to SSCs upon loss of AC power. Revisions to the battery test procedure could affect the reliability of station batteries to perform their design function. Changes that deviate from the existing test frequency or IEEE 450-1995 methods would require evaluation under 10 CFR 50.59. Listing of the procedure title and designation does not mean that all revisions to the procedure are "changes to procedures described in the UFSAR."

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

4.2.1.3 Screening Changes to UFSAR Methods of Evaluation

As discussed in section 3.6, methods of evaluation included in the UFSAR to demonstrate that intended SSC design functions will be accomplished are considered part of the "facility as described in the UFSAR." Thus use of new or revised methods of evaluation (as defined in Section 3.10) is considered to be a change that is controlled by 10 CFR 50.59 and needs to be considered as part of this screening step. Changing 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 described in the UFSAR or to methodologies included in the UFSAR that are not used in the safety analyses or to establish design bases would screen out at this step.

Methods of evaluation that may be identified in references listed at the end of UFSAR sections or chapters are not considered to be described in the UFSAR for purposes of 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 described in the UFSAR do not require evaluation under 10 CFR 50.59 if the changes are within the constraints and limitations associated with use of the method, e.g., identified in a topical report and/or SER.

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

- The UFSAR identifies the name of the computer code used for performing containment performance analyses, with no further discussion of the methods employed within the code for performing those analyses. Changes to the computer code may be screened out provided that the changes are within the constraints and limitations identified in the associated topical report and SER. A change that goes beyond restrictions on the use of the method should be evaluated under 10 CFR 50.59(c)(2)(viii) to determine if prior NRC approval is required.

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

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

10 CFR 50.59(c)(2)(i-vii).

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

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.

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.

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

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

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

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

4.2.3 Screening Documentation

10 CFR 50.59 recordkeeping requirements apply to 10 CFR 50.59 evaluations performed for activities that screened in, not to screening records for activities that screened out. However, documentation should be maintained in accordance with plant procedures of screenings that conclude a proposed activity 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. 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. If any of these criteria are met, the licensee must apply for and obtain a license amendment per 10 CFR 50.90 prior to implementing the activity. The evaluation against each criterion should be appropriately documented as discussed in Section 4.5. Subsections 4.3.1 through 4.3.8 provide guidance and examples for evaluating proposed activities against the eight criteria.

Each element of a proposed activity must undergo a 10 CFR 50.59 evaluation, except in instances where linking elements of an activity is appropriate, in which case the linked elements can be evaluated together. A test for linking elements of proposed changes is interdependence.

It is appropriate for discrete elements to be evaluated together if (1) they are interdependent as in the case where a modification to a system or component necessitates additional changes to other systems or procedures; or (2) they are performed collectively to address a design or operational issue. For example, a pump upgrade modification may also necessitate a change to a support system, such as cooling water.

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

The effects of a proposed activity being evaluated under 10 CFR 50.59 should be assessed against each of the evaluation criteria separately. For example, an increase in frequency/likelihood of occurrence cannot be compensated for by additional mitigation of consequences.

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

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

In answering this question, the first step is to identify the accidents that have been evaluated in the UFSAR that are affected by the proposed activity. Then a determination should be made as to whether the frequency of these accidents occurring would be more than minimally increased.

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:

- <u>Normal Operations</u> - Expected frequently or regularly in the course of power operation, refueling, maintenance or maneuvering.
- <u>Incidents of Moderate Frequency</u> - Any one incident expected per plant during a calendar year.
- <u>Infrequent Incidents</u> - Any one incident expected per plant during plant lifetime.
- <u>Limiting Faults</u> - 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 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 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 impact of proposed activities, and their use is not required to perform 10 CFR 50.59 evaluations. In general, frequencies of accidents considered to be credible are nominally greater than 1E-7 per year of reactor operation (e.g., tornado-generated missiles, aircraft hazards, etc.). In the event that the change in frequency of an accident is calculated, the result is considered to be not more than a minimal increase in the frequency of occurrence as long as (1) the increase in the pre-change accident or transient frequency is less than 10 percent,[1] or (2) the resultant frequency of occurrence remains below 10E-6 or applicable regulatory threshold.

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. A proposed

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

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

The following considerations may be useful in making this determination:

a) Will the proposed activity meet the design, material, and construction standards applicable to the SSC being modified? If the answer is "yes", this aspect of the proposed activity is judged not to be more than a minimal increase in the frequency of occurrence of an accident. If the answer is "no" to any of the items, then either a justification for saying there is not more than a minimal increase in the frequency of an accident occurring will need to be developed or it should be concluded that the frequency of an accident occurring would more than minimally increase.

b) Will the proposed activity affect overall system performance in a manner that could more than minimally increase the frequency of occurrence of an accident? Typical considerations include:

    (1) Will the proposed activity use instrumentation with accuracies or response characteristics that are different than existing instrumentation such that an accident is more likely to occur?

    (2) Will the proposed activity cause systems to be operated outside of their current design or testing limits (e.g., imposing additional loads on electrical systems, operating a piping system at higher than normal pressure, operating a motor outside of its rated voltage and amperage, etc.)?

    (3) Will the proposed activity cause system vibration or water hammer, fatigue, corrosion, thermal cycling or degradation of the environment of equipment important to safety that would exceed the design limits?

    (4) Will the proposed activity cause a change to any system interface in a way that would increase the frequency of an accident?

If the proposed activity affects the overall system performance in a manner that could cause an accident previously evaluated to shift to a higher frequency category, or result in a calculated frequency increase to be 10% or greater (unless the resultant frequency of occurrence remains below 10E-6 or applicable regulatory threshold), then the proposed activity would more than minimally increase the frequency of occurrence of an accident previously evaluated in the UFSAR.

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 external event frequencies were established as part of initial licensing and are not expected to change, changes in design requirements for external hazards (e.g., earthquakes, tornadoes, etc.) should be treated as potentially affecting the likelihood of a malfunction rather than the frequency of occurrence of an accident.

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

The term "malfunction of an SSC important to safety" refers to the failure of structures, systems and components (SSCs) to perform their intended design functions—including both non-safety-related and safety-related SSCs. The cause and mode of a malfunction should be considered in determining whether there is a change in the likelihood of a malfunction. The effect or result of a malfunction should be considered in determining whether a malfunction with a different result is involved per Section 4.3.6.

In determining whether there is more than a minimal increase in the likelihood of occurrence of a malfunction of a SSC to perform its design function as described in the UFSAR, the first step is to determine what SSCs could be impacted 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 affect 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 may be using to determine if there is more than a minimal increase in the likelihood of occurrence of a malfunction. An appropriate calculation can be used to demonstrate the change in likelihood in a quantitative sense, if available and practical. The effect of a proposed activity on the likelihood of malfunction must be discernable and attributable to the proposed activity in order to exceed the more than minimal increase standard. A proposed activity is considered to have a negligible effect on the likelihood of a malfunction when a change in likelihood is so small or the uncertainties in determining whether a change in likelihood has occurred are such that it cannot be reasonably concluded that the likelihood has actually changed (i.e., there is no clear trend towards increasing the likelihood). A proposed activity that has a negligible effect satisfies the minimal increase standard.

Evaluations of a proposed activity for its effect on likelihood of a malfunction would be performed at level of detail that is described in the UFSAR. The determination of whether the likelihood of malfunction is more than minimally increased is made at a level consistent with existing UFSAR-described failure modes and effects analyses. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and resulting event initiators or mitigation impacts, it also needs to consider the nature of the proposed activity. Thus, for instance, if failures were previously postulated on a train level because the trains were independent, a proposed activity that introduces a cross-tie or credible common mode failure (e.g., as a result of an analog to digital upgrade) should be evaluated further to see whether the likelihood of malfunction has been increased.

The following considerations, as applicable, may be useful in determining if an activity involves more than a minimal increase in likelihood of malfunction:

a. Will the proposed activity meet the design requirements for material and construction practices considering:

1. Does the proposed activity satisfy applicable design bases (e.g., seismic or wind loadings, etc.)?

2. Does the change cause applicable design stresses to exceed their code allowables or other applicable stress or deformation limit (if any), recognizing that, to ensure pump functionality, vendor-specified stress limits for a pump casing may be well below the ASME Code allowable.

3. Are the seismic specifications met (such as use of proper supports, proper lugging at terminals, and isolation of lifted leads)?

4. Are separation criteria met (such as minimum distance between circuits in separate divisions, channels in the same division, and jumpers run in conduit)?

5. Are the environmental qualification criteria met (such as use of materials qualified for the environment, e.g., radiation, chemical, thermal, etc., in which they will be used)?

b. Will the proposed activity adversely affect the safety analyses by:

   1. Degrading the performance of a safety system assumed to function in the safety analyses below the level of performance assumed in the safety analysis?

   2. Increasing challenges to safety systems assumed to function in the safety analyses.

c. Will the proposed activity degrade SSC reliability below the assumed level of performance by:

   1. Imposing additional loads not analyzed in the design requirements?

   2. Deleting or modifying system/equipment protection features?

   3. Downgrading the support system performance necessary for reliable operation of the important to safety equipment?

   4. Reducing system/equipment redundancy, diversity or independence?

   5. Increasing the frequency of operation of important to safety SSCs?

6. Imposing increased or more severe testing requirements on important to safety SSCs?

7. Adding more components that are subject to failure?

8. **For use where the change in likelihood of a malfunction is calculated in support of the 10 CFR 50.59 evaluation:** Increasing the pre-change likelihood of occurrence of malfunction by more than a factor of two[2]? The factor of two guideline should be applied based on the nature of the change, e.g., at the component level if the change affects a component or at the system train level if the change affects redundant trains of a system. Such a quantitative calculation is intended to support—not determine—the conclusion of whether an activity would result in more than a minimal increase in the likelihood of malfunction. Thus, even if a proposed activity exceeds the factor of two guideline, a licensee may conclude that the activity involves a minimal increase in the likelihood of malfunction provided reasonable qualitative arguments and engineering judgement are applied and documented in the 10 CFR 50.59 evaluation.

Changes in design requirements for external hazards (e.g., earthquakes, tornadoes, etc.) should be treated as potentially affecting the likelihood of malfunction.

Although this criterion allows minimal increases, licensees must still meet applicable regulatory requirements and other acceptance criteria to which they are committed (such as contained in Regulatory Guides and nationally recognized industry consensus standards, e.g., the ASME B&PV Code and IEEE standards). Further, departures from the design, fabrication, construction, testing, and performance standards as outlined in the General Design Criteria (Appendix A to Part 50) are not compatible with a "no more than minimal increase" standard.

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

1. The change involves installing additional equipment or devices (e.g., cabling, manual valves, protective features) provided all applicable design, functional and quality requirements (including applicable codes, standards, etc.) continue to be met. For example, adding protective devices to breakers or installing an additional drain line

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

(with appropriate isolation capability) would not cause more than a minimal increase the likelihood of malfunction.

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

3. The change involves a new or modified operator action that supports a design function credited in safety analyses, including manual action that substitutes for automatic action, provided:

   - The action (including required completion time) is reflected in plant procedures and operator training programs
   - The licensee has demonstrated that the action can be completed in the time required considering the aggregate affects, such as workload or environmental conditions, expected to exist when the action is required
   - The evaluation of the change considers the ability to recover from credible errors in performance of manual actions and the expected time required to make such a recovery
   - The evaluation considers the effect of the change on plant systems

4.3.3 Does the Activity Result in More than a Minimal Increase in the Consequences of an Accident?

The UFSAR, based on logic similar to ANSI standards, provides an acceptance criterion and frequency relationship for "conditions for design". When determining which activities represent "more than a minimal increase in consequences" pursuant to 10 CFR 50.59, it must be recognized that the objective of the regulation is the protection of public health and safety. Therefore, an increase in consequences must involve an increase in radiological doses to the public or to control room operators. Changes in barrier performance or other outcomes of the proposed activity that do not result in increased radiological dose to the public or to control room operators are addressed under Section 4.3.7, Integrity of Fission Product Barriers, or the other criteria of 10 CFR 50.59.

NRC regulates compliance with the provisions of 10 CFR 50 and 10 CFR 100 to assure adequate protection of the public health and safety. Activities affecting onsite dose consequences that may require prior NRC approval are those that impede required actions inside or outside the control room to mitigate the consequences of reactor accidents.

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 with which the plant is designed to cope and are described in the UFSAR (e.g., turbine missiles and flooding). The consequences referred to in 10 CFR 50.59 do not apply to occupational exposures resulting from routine operations, maintenance, testing, etc. Occupational doses are controlled and maintained As Low As Reasonably Achievable (ALARA) through formal licensee programs.

10 CFR Part 20 establishes requirements for protection against radiation during normal operations, including dose criteria relative to radioactive waste handling and effluents. 10 CFR 50.59 accident dose consequence criteria and evaluation guidance are not applicable to proposed activities governed by 10 CFR Part 20 requirements.

The dose consequences referred to in 10 CFR 50.59 are those calculated by licensees—not the results of independent, confirmatory dose analyses by the NRC that may be documented in Safety Evaluation Reports.

The evaluation should determine the dose that would likely result from accidents associated with the proposed activity. If a proposed activity would result in more than a minimal increase in dose from the existing calculated dose for any accident, then the activity would require prior NRC approval. Where a change in consequences is so small or the uncertainties in determining whether a change in consequences has occurred are such that it cannot be reasonably concluded that the consequences have actually changed (i.e., there is no clear trend towards increasing the consequences), the change need not be considered an increase in consequences.

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

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

For some licensees the current calculated dose consequences may already be in excess of the SRP guidelines for some events. In such cases minimal 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 altered as a direct result of the proposed activity. Examples of questions that assist in this determination are:

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

(2) Will the proposed activity alter any 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.

<u>Example 1</u>

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. Since the calculated increase is less than 25 rem and the total is less than the SRP guideline, the licensee may make the change without prior NRC review.

<u>Example 2</u>

The calculated dose consequence for a 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 change can be made without prior NRC approval because the new calculated dose does not exceed the established SRP guideline of 30 rem thyroid nor does the incremental change in consequences (4 rem) exceed 10 percent of the difference between the previous calculated value and the regulatory limit of 300 rem thyroid. Ten percent of the difference between the regulatory limit (300 rem) and the calculated value (25 rem) is 27.5 rem (10% of 275). Since 4 rem is less than 27.5, this change is a minimal increase permissible under 10 CFR 50.59.

<u>Example 3</u>

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 as a more than minimal change in consequences.

Example 5

The existing safety analysis for a fuel handling accident predicts an offsite dose to the thyroid of 77 rem. The SRP guideline for this event is 75 rem. A proposed change would result in an increase in the calculated dose from 77 to 77.1 rem. In this case, the proposed change would be 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 offsite power, etc.). A new initiator of an accident previously evaluated in the UFSAR is not a different type of accident. Such a change or activity, however, which increases the frequency of an accident previously thought to be incredible to the point where it becomes as likely as the accidents in the UFSAR, could create the possibility of an accident of a different type. For example, there are a number of scenarios, such as multiple steam generator tube ruptures, that have been analyzed extensively. However, these scenarios are of such low probability that they may not have been considered to be part of the design basis. However, if a change or activity is proposed such that a scenario such as a multiple steam generator tube rupture becomes credible, the change or activity could create the possibility of an accident of a different type. In some instances these example accidents could already be discussed in the UFSAR.

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

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

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

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

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

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

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

In evaluating a proposed activity against this criterion, the types and results of failure modes of SSCs that have previously been evaluated in the UFSAR and that are affected by the proposed activity should be identified. This evaluation should be performed consistent with any failure modes and effects analysis (FMEA) described in the UFSAR, recognizing that certain proposed activities may require a new FMEA to be performed. Attention must be given to whether the malfunction was evaluated in the accident analyses at the component level or the overall system level. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and resulting event initiators or mitigation impacts, it also needs to consider the nature of the proposed activity. Thus, for instance, if failures were previously postulated on a train level because the trains were independent, a proposed activity that introduces a cross-tie or credible common mode failure (e.g., as a result of an analog to digital upgrade) should be evaluated further to see whether new outcomes have been introduced.

Once the malfunctions previously evaluated in the UFSAR and the results of these malfunctions have been determined, then the types and results of failure modes that the proposed activity could create are identified. Comparing the two lists can provide the answer to the criterion question. An example that might create a malfunction with a different result could be the addition of a normally open vent line in the discharge of an emergency core cooling system pump. The different result of a malfunction could be potential voiding in the system causing it not to operate properly.

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

10 CFR 50.59 evaluation under criterion (c)(2)(vii) focuses on the fission product barriers—fuel cladding, reactor coolant system boundary, and containment—and on the critical design information that supports their continued integrity. Guidance for applying this criterion is structured around a two-step approach:

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

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

The first step is to identify the fission product barrier design basis limits, if any, that are affected by a proposed activity. Design basis limits for a fission product barrier are the controlling numerical values established during the licensing review as presented in the UFSAR for any parameter(s) used to determine the integrity of the fission product barrier. These limits have three key attributes:

- **The parameter is fundamental to the barrier's integrity.** Design basis limits for fission product barriers establish the reference bounds for design of the barriers, as defined in 10 CFR 50.2. They are the limiting values for parameters that directly determine the performance of a fission product barrier. That is, design bases limits are fundamental to barrier integrity and may be thought of as the point at which confidence in the barrier begins to decrease.

  For purposes of this evaluation, design bases parameters should be distinguished from other parameters that—while they may affect fission product barrier performance—are of secondary importance. For example, a change to fuel burn-up limits would be evaluated for its effect on clad strain to determine if it caused the limiting value for fuel internal gas pressure to be exceeded. Thus fuel internal gas pressure is a fundamental design bases limit for fuel cladding integrity, and fuel burn-up is a secondary/subordinate parameter/limit. Similarly, linear heat rate and RCS usage factor limits affect the fuel cladding and RCS boundary but are subordinate, respectively, to the design bases limits for fuel temperature and RCS stresses.

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

- **The limit is found 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 included in the UFSAR by reference.

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. Evaluations under this criterion supporting proposed changes that might directly or indirectly (see discussion below) impact a design basis limit covered by another regulation or Technical Specification need not be extended to consider those parameters.

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	95/95 DNB
	Fuel temperature	Centerline fuel melting temperature
	Fuel enthalpy	Cal/gm associated with dispersion
	Clad strain	Internal pressure associated with clad lift-off
	Clad temperature *	2200 degrees F
	Clad Oxidation *	17% local and 1 % overall
RCS Boundary	Pressure	Designated limit in safety analysis for specific accident
	Stresses *	ASME code compliance for normal, upset, faulted, etc., as appropriate for accident
	Heat-up/Cool-down*	Applicable ASME Code stress limits
Containment	Pressure	Containment design pressure

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

The list above may vary slightly for a given facility and/or fuel vendor and may include other parameters for specific accidents. For example, PWRs may utilize 100% pressurizer level as a limiting parameter to ensure RCS integrity for some accident sequences. If a given facility has that parameter incorporated into the UFSAR as a design basis limit, then changes to it should be evaluated under this criterion.

Two ways that a licensee can evaluate proposed activities against this 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.

Exceeded or altered

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. 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 such that it no longer corresponds to a 95/95 DNB, perhaps as a result of a new fuel design being implemented with the existing correlation. (A new correlation or a new value for 95/95 DNB with the same fuel type would be evaluated under criterion (c)(2)(viii) of the rule.) Another example is redesigning portions of the RCS boundary to no longer comply with the code of construction. These are infrequent activities affecting key elements of the defense-in-depth philosophy. As such, no distinction has been made between a conservative and non-conservative change in the limit.

Evaluations performed under this criterion may incorporate a number of refinements to simplify the review. For example, if an engineering evaluation demonstrates that no parameters are affected that have design basis limits for fission product barriers associated with them, no 10 CFR 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 reported in the UFSAR remains bounding, then no 10 CFR

50.59(c)(2)(vii) evaluation is required. When using these techniques, both indirect and direct effects must be considered to ensure that important interactions are not overlooked.

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

Example 1

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

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

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

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

<u>Exceeded or altered</u>

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."

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

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 limits for containment pressure or PCT are not being "exceeded or 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 situation, the licensee proposes to reduce the containment design pressure as reflected in the 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. non-conservative is not germane to requiring a submittal. That is, prior NRC approval is required regardless of direction because this is a fundamental change in the facility's design.

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

The UFSAR contains design and licensing basis information for a nuclear power facility, including description on how regulatory requirements for design are met and how the facility responds to various design basis accidents and events. Analytical methods are a fundamental part of demonstrating how the design meets regulatory requirements and why the facility's response to accidents and events is acceptable. As such, in cases where the analytical methodology was considered to be an important part of the conclusion that the facility met the required design bases, these analytical methods were described in the UFSAR and received varying levels of NRC review and approval during licensing.

Because 10 CFR 50.59 provides a process for determining if prior NRC approval is required before making changes to the facility as described in the UFSAR, changes to the methodologies described in the UFSAR also fall under the provisions of the 10 CFR 50.59 process, specifically criterion (c)(2)(viii). In general, licensees can make changes to elements of a methodology without first obtaining a license amendment if the results are essentially the same as, or more conservative than, previous results. Similarly, licensees can also use different methods without first obtaining a license amendment if those methods have been approved by the NRC for the intended application.

If the proposed activity does not involve a change to a method of evaluation, then the 10 CFR 50.59 evaluation should reflect that this criterion is not applicable. If the activity involves only a change to a method of evaluation, then the 10 CFR 50.59 evaluation should reflect that criteria 10 CFR 50.59(c)(2)(i—vii) are not applicable.

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

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

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

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

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

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

- Use of an updated or new NRC-approved methodology (e.g., 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 documentation in the licensee evaluation.

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

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

4.3.8.1 Guidance for Changing One or More Elements of a Method of Evaluation

The definition of "departure …" provides licensees with the flexibility to make changes under 10 CFR 50.59 to methods of evaluation whose results are "conservative" or that are not important with respect to the demonstrations of performance that the analyses provide. Changes to elements of analysis methods that yield conservative results, or results that are essentially the same would not be departures from approved methods.

Conservative vs. Non-Conservative Results

Gaining margin by changing one or more elements of a method of evaluation is considered to be a non-conservative change and thus a departure from a method of evaluation for purposes of 10 CFR 50.59. Such departures require prior NRC approval of the revised method. Analytical results obtained by changing any element of a method are "conservative" relative to the previous results, if they are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines). For example, a change from 45 psig to 48 psig in the result of a containment peak pressure analysis (with design basis limit of 50 psig) using a revised method of evaluation would be considered a conservative change when applying this criterion. In other words, the revised method is more conservative if it predicts more severe conditions given the same set of inputs. This is because results closer to limiting values are considered conservative in the sense that the new analysis result provides less margin to applicable limits for making potential physical or procedure changes without a license amendment.

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

"Essentially the Same"

Licensees may change one or more elements of a method of evaluation such that results move in the non-conservative direction without prior NRC approval, provided the 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. Relative to the original method, the revised method may result in differences in the details, or intermediate results, of an analysis; however, the end results of the existing and revised analyses must be essentially the same.

4.3.8.2 Guidance for Changing from One Method of Evaluation to Another

The definition of "departure ..." provides licensees with the flexibility to make changes under 10 CFR 50.59 from one method of evaluation to another provided that the new method is approved by the NRC for the intended application. A new method is approved by the NRC for intended application if it is approved for the type of analysis being conducted, and applicable terms, conditions and limitations for its use are satisfied.

NRC approval has typically followed one of two paths. Most reactor or fuel vendors and several utilities have prepared and obtained NRC approval of topical reports that describe methodologies for the performance of a given type or class of analysis. Through a Safety Evaluation Report, the NRC approved the use of the methodologies for a given class of power plants. In some cases, the NRC has accorded "generic" approval of analysis methodologies. Terms, conditions and limitations relating to the application of the methodologies are usually documented in the topical reports, the SER, and correspondence between the NRC and the methodology owner that is referenced in the SER or associated transmittal letter.

The second path is the approval of a specific analysis rather than a more generic methodology. The NRC's approval has tended to be limited to a given plant design and a given application. Again, terms, conditions and limitations relating to the application of the methodologies are usually documented in the original license amendment request, the SER, and any correspondence between the NRC and the analysis owner that is referenced in the SER or associated transmittal letter.

It is incumbent upon the user of a new methodology—even one generically approved by the NRC—to ensure that all conditions and limitations under which the method received NRC approval are identified. 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, the NRC has established a method by which utilities can demonstrate they are generally qualified to perform safety analyses. Utilities thus qualified can apply methods that have been reviewed and approved by the NRC, or that have been otherwise accepted as part of another plant's licensing basis, without requiring prior NRC approval. Licensees that have not satisfied the guidelines of Generic Letter 83-11, Supplement 1, may, of course, continue to seek plant-specific approval to use new methods of evaluation.

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

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

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

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

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

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

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

- Is the plant configuration the same as described in the methodology? If the plant configuration is similar, but not the same, the following types of considerations should be addressed to assess the applicability of the methodology:

  - How could those differences affect the methodology?

  - Are additional sensitivity studies required?

- Should additional single failure scenarios be considered?

- Are analyses of limiting scenarios, effects of equipment failures, etc., applicable for the specific plant design?

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

Differences in the plant configurations and licensing bases could invalidate the application of a particular methodology. For example, the licensing basis of older vintage plants may not include an analysis of the feedwater line break event that is required in later vintage plants. Some plants may be required to postulate a loss of offsite power or a maximum break size for certain events; other may have obtained exemptions to these requirements from the NRC. The existence of these differences does not preclude application of a new methodology to a facility; it only requires the analyst to thoroughly understand and document the effects of these differences on the application of the methodology to ensure compliance with the terms, conditions, and limitations of the NRC approval.

- 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? If the facilities are not designed and operated in the same manner, the following types of considerations should be addressed to assess the applicability of the methodology:

- Is the equipment the same? Does the equipment have the same pedigree (e.g., Class 1E, Seismic Category I, etc.)? If similar, but not the same, what additional allowances must be made? Are the relevant failure modes and effects analyses the same? If slight modifications to the methodology are required, are these within the terms, conditions, and limitations on which NRC approval of the methodology was based?

- Even if the basic facility configuration is nearly the same between two units, differences in plant specific components may make the application of a methodology to another plant inappropriate. For example, some plants may have pressurizer power-operated relief valves that are qualified for water relief; other plants do not. In addition, plant specific failure modes and effects analyses may reveal new potential single failure scenarios that were not considered in the original methodology. The existence of these differences does not preclude application of a new methodology to a facility; it only requires the analyst to thoroughly understand the effects of these differences on the application of the methodology to ensure compliance with the terms, conditions, and limitations of the NRC approval.

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. 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 their evaluation of the containment temperature response. This change would require prior NRC approval unless the methodology had been previously approved for evaluating containment temperature response.

4.4 Applying 10 CFR 50.59 to Compensatory Actions to Address Nonconforming or Degraded Conditions

Three general courses of action are available to licensees to address non-conforming and degraded conditions. Whether or not 10 CFR 50.59 must be applied, and the focus of a 10 CFR 50.59 evaluation if one is required, depends on the corrective action chosen by the licensee, as discussed below:

- If the licensee intends to restore the SSC back to its previous condition (as described in the UFSAR), 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 described in the UFSAR, or to change the facility or procedures to something different than described in the UFSAR, 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 resolution becomes the proposed change that would be subject to 10 CFR 50.59.

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

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

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

4.5 DISPOSITION OF 10 CFR 50.59 EVALUATIONS

There are two possible conclusions to a 10 CFR 50.59 evaluation:

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

(2) The proposed activity requires prior NRC approval.

Where a change to the technical specifications is required by the proposed activity, the technical specification change must be approved by the NRC 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 NRC approval of the license amendment provided (1) 10 CFR 50.59 has been applied to aspects of the modification outside the scope of the license amendment request and (2) these activities are consistent with applicable Technical Specifications.

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

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

(1) Cancel the planned change.

(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.

In resolving degraded or nonconforming conditions, the need to obtain NRC approval for a change 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.

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:

(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.

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 criteria must be addressed, the questions and considerations listed throughout this guidance document to assist evaluating the criteria are not requirements for all evaluations. Some evaluations may require that none of these questions be addressed while others will require additional considerations beyond those addressed in this guidance.

When preparing 10 CFR 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

10 CFR 50.59 Changes, tests, and experiments.

(a) Definitions for the purposes of this section:

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

(2) *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 UFSAR 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

10 CFR 72.48 Changes, tests, and experiments.

(a) Definitions for the purposes of this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) This section applies to:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

List of Subjects in 5 CFR Parts 831 and 842

Administrative practice and procedure, Air traffic controllers, Alimony, Claims, Disability benefits, Firefighters, Government employees, Income taxes, Intergovernmental relations, Law enforcement officers, Pensions, Reporting and recordkeeping requirements, Retirement.

Office of Personnel Management.

Janice R. Lachance,

Director.

Accordingly, OPM is amending parts 831 and 842 of title 5, Code of Federal Regulations, as follows:

PART 831—RETIREMENT

1. The authority citation for part 831 is revised to read as follows:

Authority: 5 U.S.C. 8347; § 831.102 also issued under 5 U.S.C. 8334; § 831.106 also issued under 5 U.S.C. 552a; § 831.114 also issued under 5 U.S.C. 8336(d)(2), Pub. L. 105–174, 112 Stat. 91; § 831.201(b)(1) also issued under 5 U.S.C. 8347(g); § 831.201(b)(6) also issued under 5 U.S.C. 7701(b)(2); § 831.201(g) also issued under sections 11202(f), 11232(e), and 11246(b) of Pub. L. 105–33, 111 Stat. 251; § 831.204 also issued under section 102(e) of Pub. L. 104–8, 109 Stat. 102, as amended by section 153 of Pub. L. 104–134, 110 Stat. 1321; § 831.303 also issued under 5 U.S.C. 8334(d)(2); § 831.502 also issued under 5 U.S.C. 8337; § 831.502 also issued under section 1(3), E.O. 11228, 3 CFR 1964–1965 Comp.; § 831.663 also issued under 5 U.S.C. 8339(j) and (k)(2); §§ 831.663 and 831.664 also issued under section 11004 (c)(2) of Pub. L. 103–66, 107 Stat. 412; § 831.682 also issued under section 201(d) of Pub. L. 99–251, 100 Stat. 23; subpart S also issued under 5 U.S.C. 8345(k); subpart V also issued under 5 U.S.C. 8343a and section 6001 of Pub. L. 100–203, 101 Stat. 1330–275, § 831.2203 also issued under section 7001(a)(4) of Pub. L. 101–508, 104 Stat. 1388–328.

Subpart A—Administration and General Provisions

§ 831.108 [Removed]

2. Section 831.108 is removed.

3. In § 831.114, paragraphs(b)(4) and (c)(2)(iii) are revised to read as follows:

§ 831.114 Early retirement-major reorganization, major reduction in force, or major transfer of function

* * * * *

(b) * * *

(4) OPM may approve an agency's request for voluntary early retirement authority to cover the entire period of the major reduction in force, major reorganization, or major transfer of function; or through the end of each fiscal year, whichever is less.

(c) * * *

(2) * * *

(iii) The time period during which voluntary early retirement will be offered. At the agency's discretion, the agency may request voluntary early retirement authority to cover the entire period of the major reduction in force, major reorganization, or major transfer of function; or through the end of the fiscal year, whichever is less.

* * * * *

PART 842—FEDERAL EMPLOYEES RETIREMENT SYSTEM—BASIC ANNUITY

4. The authority citation for part 842 is revised to read as follows:

Authority: 5 U.S.C. 8461(g); §§ 842.104 and 842.106 also issued under 5 U.S.C. 8461(n); § 842.105 also issued under 5 U.S.C. 8402(c)(1) and 7701(b)(2); § 842.106 also issued under section 102(e) of Pub. L. 104–8, 109 Stat. 102, as amended by section 153 of Pub. L. 104–134, 110 Stat. 1321; § 842.107 also issued under sections 11202(f), 11232(e), and 11246(b) of Pub. L. 105–33, 111 Stat. 251; § 842.213 also issued under 5 U.S.C. 8414(b)(1)(B), Pub. L. 105–174, 112 Stat. 91; §§ 842.604 and 842.611 also issued under 5 U.S.C. 8417; § 842.607 also issued under 5 U.S.C. 8416 and 8417; § 842.614 also issued under 5 U.S.C. 8419; § 842.615 also issued under 5 U.S.C. 8418, § 842.703 also issued under section 7001(a)(4) of Pub. L. 101–508; § 842.707 also issued under section 6001 of Pub. L. 100–203; § 842.708 also issued under section 4005 of Pub. L. 101–239 and section 7001 of Pub. L. 101–508; subpart H also issued under 5 U.S.C. 1104

Subpart B—Eligibility

§ 842.205 [Removed]

5. Section 842.205 is removed.

6. In § 842.213, paragraphs (b)(4) and (c)(2)(iii) are revised to read as follows:

§ 842.213 Early retirement-major reorganization, major reduction in force, or major transfer of function

* * * * *

(b) * * *

(4) OPM may approve an agency's request for voluntary early retirement authority to cover the entire period of the major reduction in force, major reorganization, or major transfer of function; or through the end of each fiscal year, whichever is less.

(c) * * *

(2) * * *

(iii) The time period during which voluntary early retirement will be offered. At the agency's discretion, the agency may request voluntary early retirement authority to cover the entire period of the major reduction in force, major reorganization, or major transfer of function; or through the end of the fiscal year, whichever is less.

* * * * *

[FR Doc. 99–25707 Filed 10–1–99; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 72

RIN 3150–AF94

Changes, Tests, and Experiments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

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

EFFECTIVE DATE: The amendments to sections 72.3, 72.9, 72.24, 72.56, 72.70, 72.80, 72.86, 72.244, 72.246, 72.248 of this rule are effective February 1, 2000. Sections 50.59, 50.66, 50.71(e), and 50.90 become effective 90 days after issuance of applicable regulatory guidance. The NRC will publish a document in the **Federal Register** that announces the issuance of the regulatory guidance and specifies that the final rule becomes effective in 90 days. Section 72.212 and the amendments to 72.48 are effective April 5, 2001.

FOR FURTHER INFORMATION CONTACT: Eileen McKenna, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington,

DC 20555–0001, telephone (301) 415–2189; e-mail: emm@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

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

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

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

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

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

The Commission proposed to make similar changes to appendices A and B of part 52, the standard design certifications for the ABWR and CE System 80+ designs respectively. These regulations contain a change control process similar to that in § 50.59. As noted in Section N, "Part 52 changes" below, the Commission has decided to defer consideration of any changes to part 52 until a later date.

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

II. Comments and Resolution on Proposed Rule Topics

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

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

A. Organization of the Rule Requirements

(1) Definitions

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

(2) Applicability

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

(3) Form of Prior Commission Approval

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

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

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

(4) Criteria for Needing Commission Approval of Changes, Tests, and Experiments and Unreviewed Safety Question (USQ) Designation

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

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

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

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

(5) Changes in the Scope of the Rule

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

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

B. Change to the Facility as Described in the Safety Analysis Report

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

B.1 Definition of Change

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

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

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

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

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

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

(e) De Facto Changes: One commenter stated that the NRC should modify the definition or other rule language to explicitly state that the requirements apply only to "proposed" changes and not to so-called "de facto" changes.[1] Another commenter thought the rule language should explicitly codify the resolution process under Generic Letter

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

(GL) 91–18, by including language in the rule such that the respective requirements of Appendix B, criterion 16 and § 50.59 do not interfere.

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

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

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

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

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

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

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

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

B.2 Definition of Facility

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

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

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

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

The Commission had included these words in the rule as an attempt to limit what part of the FSAR needed to be considered for purposes of § 50.59 evaluations. If information was not required to be in the FSAR, then as discussed under NEI 98–03, it could be removed from the FSAR. On the other hand, a licensee may wish to retain such information in its FSAR for purposes of completeness; then this part of the definition would allow the licensee to screen out changes to the information that does not meet the definition of facility as described. In view of the confusion surrounding this phrase, and in light of other proposed changes to these definitions, the Commission has deleted this phrase from the final rule.

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

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

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

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

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

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

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

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

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

Changes Governed by Other Regulatory Processes

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

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

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

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

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

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

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

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

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

E. Safety Analysis Report

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

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

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

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

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

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

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

F. Minimal Increase Principle

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

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

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

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

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

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

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

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

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

(i) More Than a Minimal Increase in the Frequency of Occurrence of an Accident Previously Evaluated

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

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

Guidance for Frequency of Accidents

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

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

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

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

(ii) Minimal Increase in Likelihood of Malfunction of Structures, Systems or Components

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

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

Guidance for Likelihood of Occurrence of Malfunction

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

First, the Commission noted that the existing guidance in NEI 96–07 states:

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

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

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

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

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

(iii) and (iv) Minimal Increases in Consequences of Accident or Malfunction

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

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

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

Guidance for Minimal Increase in Consequences

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

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

Third, if a licensee would need to change its design basis assumptions or analytical methods, or both, to demonstrate that the change in consequences satisfies this guidance, then the NRC does not view the change as minimal and would expect the licensee to submit a license amendment for such a change. This position is consistent with the logic presented as the basis for implementing new criterion § 50.59(c)(2)(viii), which will be discussed in greater detail below. Some commenters thought that adopting methodologies that have been approved by NRC in certain contexts (such as use of International Conference on Radiation Protection (ICRP) dose conversion factors, or credit for suppression pool scrubbing) should be allowable under § 50.59. New criterion (viii), discussed in section J below, specifies under what conditions changes to evaluation methods can be changed without prior NRC approval.

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

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

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

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

Examples

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

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

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

[2] In the Standard Review Plan, NUREG–0800, the NRC established acceptance criteria for certain events that are considered of greater likelihood than the limiting accidents as a small fraction of the part 100 guidelines. [illegible] instance, for a steam generator [illegible] the SRP guideline is that the dose be 10 percent of the part 100 value. For the postulated accident with an assumed preaccident [illegible] at the time the [illegible] the full part 100 value is the acceptance [illegible].

[3] [illegible] radiation protection [illegible] occupancy of the control room [illegible] with [illegible] personnel [illegible] in excess of 5 rem [illegible] equivalent to any part of the [illegible] duration of the accident. Part 100 [illegible] for exclusion area and low population zone [illegible] and the reactor so that an [illegible] located at any point on its boundary [illegible] the postulated [illegible] would not receive a total [illegible] the whole body in excess of 25 rem [illegible] 300 rem to the thyroid for iodine exposure. For future applications as noted in subpart B of 10 CFR part 100, the radiological consequences are to meet the criteria stated in § 50.34(a)(1) which sets a dose of 25 rem total effective dose equivalent (TEDE).

since 4 is less than 27.5, this change satisfies the criterion.

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

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

Example 4 involves a case where the calculated dose to the control room operators following a loss of coolant accident is 4 rem whole body. A change is made to the control room ventilation system such that the calculated dose increases to 4.5 rem. The regulations dictate that the control room doses are to be controlled to less than 5 rem by General Design Criterion 19. Although the new calculated doses are less than the regulatory limits for the operators, the incremental increase in dose (0.5 rem) exceeds the value of 10 percent of the difference between the previously calculated value and the regulatory value (10% of 1 rem = 0.1 rem). This change would require prior NRC review before the licensee could implement the change.

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

H. Possibility of an Accident of a Different Type From Any Previously Evaluated in the Final Safety Analysis Report (as Updated) Is Created

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

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

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

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

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

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

Need for Definition of Accident

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

Several comments were received on the proposed definition of accident. Most commenters felt that a definition in the rule was not necessary, and most also disagreed with the specific definition offered in some respect. Commenters generally agreed that accidents include design basis accidents (typically analyzed in Chapters 6 and 15 of the FSAR), anticipated occupational occurrences, external events that the plant is required to withstand and other special events that are analyzed to demonstrate safety. Included within the set of accidents are those scenarios for which requirements have been established for the facility either to withstand or cope with the event. Notable examples include pressurized thermal shock events (§ 50.61), anticipated transient without scram (§ 50.62) and station blackout (§ 50.63).

Commenters also noted that external events, such as earthquakes, high winds, floods, and missiles can be treated as causes of malfunctions of SSC, rather than accidents. Some suggested that examples or a list of accidents could be presented in the implementation guidance.

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

I. Possibility of a Malfunction of Structures, System, or Components Important to Safety With a Different Result From Any Previously Evaluated in the Final Safety Analysis Report (as Updated) is Created

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

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

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

Guidance for Malfunction With a Different Result

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

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

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

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

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

Option 1 in Proposed Rule

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

Option 2 in Proposed Rule

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

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

Option 3 in Proposed Rule

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

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

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

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

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

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

Resolution

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

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

Since the time that SECY–99–054 was submitted to the Commission, the NRC has gained a greater understanding of the NEI proposal and how it would be implemented, and, in particular, how it would be used to assess changes to mitigation systems and support systems. Although the NRC agreed that the process described in the NEI comment letter of December 21, 1998, would be sufficient to ensure that changes to other systems are appropriately examined with respect to impact upon the barriers, it was not apparent that the specific rule language suggested would require licensees to implement such a systematic approach to examination of design basis limits.

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

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

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

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

Final Rule Language

New Criterion (vii)

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

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

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

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

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

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

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

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

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

Guidance for Implementation

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

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

Examples

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

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

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

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

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

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

New Criterion (viii)—Control of Evaluation Methods

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

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

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

Final Rule Language

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

Definitions and Guidance

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

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

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

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

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

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

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

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

—Data correlations
—Means of data reduction
—Physical constants or coefficients
—Mathematical models
—Specific assumptions in a computer program
—Specified factors to account for uncertainty in measurements or data
—Statistical treatment of results
—Dose conversion factors and assumed source term(s)

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

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

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

Examples

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

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

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

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

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

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

K. Safety Evaluation

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

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

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

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

L. Reporting and Recordkeeping Requirements

Records

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

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

Summary Report

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

Updates to the Final Safety Analysis Report

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

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

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

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

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

(e) Each person licensed to operate a nuclear power reactor pursuant to the provisions of § 50.21 or § 50.22 of this part shall update periodically, as provided in paragraphs (e)(3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the operating license, to assure that the information included in the FSAR (as updated) contains the latest information developed. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the last submittal of the original FSAR, or as appropriate the last update to the FSAR under this section. The submittal shall include the effects[1] of all changes made in the facility or procedures as described in the FSAR; all safety analyses and evaluations performed by the licensee either in support of approved license amendments, or in

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

support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2) of this part; and all analyses of new safety issues performed by or on behalf of the licensee at Commission request. The updated information shall be appropriately located within the update to the FSAR.

M. No Significant Hazards Consideration Determinations

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

(c) The Commission may make a final determination * * * that a proposed amendment to an operating license * * * involves no significant hazards consideration, if operation of the facility in accordance with the proposed amendment would not:

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

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

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

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

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

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

N. Part 52 Changes

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

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

O.1. Part 72 Changes

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

Changes Presented in the Proposed Rule

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

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

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

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

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

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

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

1. Overall Changes to Part 72

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

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

2. § 72.48 Changes, Tests, and Experiments

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Issue (1): Part 72 should be amended to require that the safety analysis report (SAR) for a spent fuel dry storage cask design fully conforms with the associated NRC safety evaluation report (SER) and certificate of compliance (CoC) before NRC certification (*i.e.*, approval) of the cask design.

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

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

> Each certificate holder shall submit an original FSAR to the Commission * * * within 90 days after the spent fuel storage cask design has been approved pursuant to § 72.238. This original FSAR shall be based on the safety analysis report submitted with the application and reflect any changes and applicant commitments developed during the cask design review process. The original FSAR shall be updated to reflect any changes to requirements contained in the issued Certificate of Compliance (CoC). * * *

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

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

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

Issue (2): Part 72 should be amended to require that the revision date and number of an SAR be specified whenever that report is referenced in documents.

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

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

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

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

Issue (3): The NRC must clarify the process for modification of a safety analysis report after a cask [design] has been certified (*i.e.*, approved by the NRC).

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

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

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

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

Issue (4): The NRC should make cask unloading procedures publicly available.

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

Resolution of Issue (4): The NRC does not approve or test a licensee's loading or unloading procedures, rather the licensee is responsible for development, verification, and validation of the loading and unloading procedures. The NRC inspects the licensee's procedures (*i.e.*, reviews the procedures and observes the licensee implementing them) to determine whether the procedures will provide reasonable assurance that public health and safety will be adequately protected.

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

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

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

Additional Public Comments on the Petition

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

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

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

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

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

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

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

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

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

O.3 Part 71 (Transportation) Comments

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

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

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

Guidance

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

The NRC agrees that guidance is important, and notes that NEI has stated its willingness to revise existing guidance to conform with the final rule such that NRC could endorse it. The

NRC will work with interested stakeholders to agree upon guidance that includes consideration of these issues. Further, NRC is delaying the required implementation of the rule for several months to allow time for guidance to be revised.

Fuel Burnup Limits

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

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

Alternative Criteria

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

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

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

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

Regulatory Analysis

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

Need for Further Notice and Comment

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

Different Process for non-TS Issues

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

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

Other Definitions

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

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

Applicability to Part 76

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

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

Q. Enforcement Policy

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

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

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

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

R. Implementation

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

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

III. Section by Section Analysis

10 CFR Part 50

10 CFR 50.59

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

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

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

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

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

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

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

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

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

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

10 CFR 50.66

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

10 CFR 50.71(e)

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

10 CFR 50.90

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

10 CFR Part 72

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

10 CFR 72.3

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

10 CFR 72.9

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

10 CFR 72.24

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

10 CFR 72.48

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

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

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

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

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

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

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

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

10 CFR 72.56

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

10 CFR 72.70

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

10 CFR 72.80

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

10 CFR 72.86

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

10 CFR 72.212(b)(2)

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

10 CFR 72.212(b)(4)

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

10 CFR 72.216

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

10 CFR 72.244

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

10 CFR 72.246

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

10 CFR 72.248

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

IV. Finding of No Significant Environmental Impact

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

V. Paperwork Reduction Act Statement

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

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

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

Public Protection Notification

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

VI. Regulatory Analysis

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

VII. Regulatory Flexibility Certification

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

VIII. Backfit Analysis

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

Changes to Section 50.59

Section 50.59 defines the circumstances under which holders of nuclear power plant operating licenses may make changes to and conduct tests or experiments at their facilities without prior NRC review and approval. In this rulemaking, new definitions are added to § 50.59 (e.g., the definitions for "change," and "facility as described in the final safety analysis report (as updated)"), and the structure and language of the rule were modified (e.g., the addition of a new applicability section, and the removal of the term, "unreviewed safety question"). These changes constitute clarifications of the existing rule, and codification of existing NRC practice and interpretations of terminology which are undefined by the current rule. Clarifications and codification of existing NRC interpretation and practice do not constitute a generic backfit (although the application of the revised rule may constitute a plant-specific backfit). The new criteria in § 50.59(c)(2)(i), (ii), (iii), (iv), (v) and (vi) are being added primarily[4] for the purpose of providing additional flexibility to licensees to make changes and conduct tests without having to obtain prior NRC review and approval. Each of these changes constitute permissive relaxations[5] from the superseded § 50.59(a)(2)(i) and (ii) criteria. Permissive relaxations are not considered to be backfits, inasmuch as a licensee will continue to be in compliance with the final rule even if it uses its existing procedures and the superseded criteria for implementing § 50.59. The new criteria in § 50.59(c)(2)(vii) and (viii) together constitute replacements for the superseded § 50.59(a)(2)(iii) criterion on "margin of safety." As noted in Section J, these two criteria together, in place of a criterion on margin of safety, explicitly cover those margins that the Commission believes are important to address in this evaluation process—the first being the margin that exists in the limits that are to be met, and the second being the margin that exists from the conservatisms included in the methods used to demonstrate that requirements are met. The replacement criteria were thus developed to accomplish two complementary goals: (1) Defining with more precision the important safety margins which should be the focus of a § 50.59 determination, rather than the problematic term, "margin of safety as defined in the basis for any technical specification;" and (2) assuring that the relaxations embodied in the § 50.59(c)(2)(i), (ii), (iii), (iv), (v) and (vi) criteria will not result in changes approaching the adequate protection threshold without prior NRC review and approval. As such, the new criteria (vii) and (viii) are fundamentally part of the overall regulatory scheme in the revisions to § 50.59 which relax and clarify the thresholds for licensee-initiated changes and tests requiring

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

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

prior NRC review and approval before their implementation. In sum, the Commission has determined that the changes to § 50.59 constitute clarifications and codifications of existing practices, or constitute permissive relaxations from the existing § 50.59 criteria, and therefore do not constitute backfits as defined in § 50.109(a)(1).

Changes to Part 72

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

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

IX. Small Business Regulatory Enforcement Fairness Act

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

X. National Technology Transfer and Advancement Act

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

XI. Criminal Penalties

For the purposes of section 223 of the Atomic Energy Act (AEA), the Commission is issuing this rule to amend 10 CFR part 50:50.59, : 50.66, and :50.71; and 10 CFR part 72:72.48, : 72.70, :72.212, and :72.248, under one or more of sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

XII. Compatibility of Agreement State Regulations

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

List of Subjects

10 CFR Part 50

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

10 CFR Part 72

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

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

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

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

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

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

2. Section 50.59 is revised to read as follows:

§ 50.59 Changes, tests, and experiments.

(a) Definitions for the purposes of this section:

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

(2) *Departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses* means:

(i) Changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or

(ii) Changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

* * * * *

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

(1) * * *

(4) Identification of Changes Requiring a License Amendment. Any changes to the facility as described in the final safety analysis report (as updated) which requires a license amendment pursuant to § 50.59(c)(2) of this part, and any changes to the Technical Specifications, which are necessary to either conduct the thermal annealing or to operate the nuclear

power reactor following the annealing must be identified. The section shall demonstrate that the Commission's requirements continue to be complied with, and that there is reasonable assurance of adequate protection to the public health and safety following the changes.

(c) * * *

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

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

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

(3) * * *

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

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

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

* * * * *

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

§ 50.71 Maintenance of records, making of reports.

* * * * *

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

* * * * *

5. Section 50.90 is revised to read as follows:

§ 50.90 Application for amendment of license or construction permit.

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

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

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

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

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

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

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

§ 72.3 Definitions.

* * * * *

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

* * * * *

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

§ 72.9 Information collection requirements: OMB approval.

* * * * *

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

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

§ 72.24 Contents of application: Technical information.

* * * * *

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

* * * * *

10. Section 72.48 is revised to read as follows:

§ 72.48 Changes, tests, and experiments.

(a) Definitions for the purposes of this section:

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

(2) *Departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses* means:

(i) Changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or

(ii) Changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) This section applies to:

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

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

(c)(1) A licensee or certificate holder may make changes in the facility or spent fuel storage cask design as described in the FSAR (as updated), make changes in the procedures as described in the FSAR (as updated), and conduct tests or experiments not described in the FSAR (as updated), without obtaining either:

(i) A license amendment pursuant to § 72.56 (for specific licensees) or

(ii) A CoC amendment submitted by the certificate holder pursuant to § 72.244 (for general licensees and certificate holders) if:

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

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

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

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

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

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

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

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

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

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

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

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

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

last update of the FSAR pursuant to § 72.70, or § 72.248 of this part.

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

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

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

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

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

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

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

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

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

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

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

11. Section 72.56 is revised to read as follows:

§ 72.56 Application for amendment of license.

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

12. Section 72.70 is revised to read as follows:

§ 72.70 Safety analysis report updating.

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

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

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

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

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

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

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

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

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

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

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

(4) The update shall include:

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

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

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

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

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

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

§ 72.80 Other records and reports.

* * * * *

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

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

§ 72.86 Criminal penalties.

* * * * *

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

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

§ 72.212 Conditions of general license issued under § 72.210.

* * * * *

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

(b) * * *

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

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

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

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

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

* * * * *

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

16. Section 72.244 is added to read as follows:

§ 72.244 Application for amendment of a certificate of compliance.

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

17. Section 72.246 is added to read as follows:

§ 72.246 Issuance of amendment to a certificate of compliance.

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

18. Section 72.248 is added to read as follows:

§ 72.248 Safety analysis report updating.

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

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

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

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

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

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

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

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

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

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

(4) The update shall include:

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

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

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

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

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

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

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

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

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 99-25054 Filed 10-1-99; 8:45 am]

BILLING CODE 7590-01-P

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

FEDERAL RESERVE SYSTEM

12 CFR Part 204

[Regulation D; Docket No. R-1046]

Reserve Requirements of Depository Institutions

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is amending Regulation D, Reserve Requirements of Depository Institutions, to reflect the annual indexing of the low reserve tranche and the reserve requirement exemption for 2000, and announces the annual indexing of the deposit reporting cutoff levels that will be effective beginning in September 2000. The amendments decrease the amount of transaction accounts subject to a reserve requirement ratio of three percent in 2000, as required by section 19(b)(2)(C) of the Federal Reserve Act, from $46.5 million to $44.3 million of net transaction accounts. This adjustment is known as the low reserve tranche adjustment. The Board is increasing from $4.9 million to $5.0 million the amount of reservable liabilities of each depository institution that is subject to a reserve requirement of zero percent in 2000. This action is required by section 19(b)(11)(B) of the Federal Reserve Act, and the adjustment is known as the reservable liabilities exemption adjustment. The Board is also increasing