

May 12, 1999

SECY-99-130

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: FINAL RULE - REVISIONS TO REQUIREMENTS OF 10 CFR PARTS 50
AND 72 CONCERNING CHANGES, TESTS, AND EXPERIMENTS

PURPOSE:

This paper requests the Commission's approval to publish a final rule that will revise 10 CFR 50.59 and related requirements in Parts 50 and 72 concerning the authority for licensees of production and utilization facilities, such as nuclear reactors and for independent spent fuel storage facilities, and for certificate holders for spent fuel storage casks, to make changes to their facilities and procedures, or to conduct tests and experiments without prior NRC approval.

SUMMARY:

The final rule will revise 10 CFR 50.59 (and related sections) to clarify which type of changes, tests, or experiments require evaluation by the licensee and to clarify the criteria that determine when NRC prior approval is needed for implementation. This paper supplements the recommendations made in SECY-99-054, dated February 22, 1999, and transmits the staff's recommendations for the final rule.

BACKGROUND:

Section 50.59 defines the conditions under which reactor licensees may make changes to their facilities or procedures, or may conduct tests or experiments without prior NRC approval. In general, such changes, tests or experiments may be carried out without prior NRC approval unless they would either involve a change to the technical specifications or an unreviewed

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safety question (as defined in § 50.59(a)(2)). Similar language exists in § 72.48 for independent spent fuel storage installations (ISFSI) or monitored retrievable storage installations (MRS) for storage of spent nuclear fuel or high-level waste.

In SECY-98-171, the staff proposed a number of changes to 10 CFR 50.59, including addition of definitions and reformatting, deletion of the term “unreviewed safety question,” revisions to criteria to allow changes involving minimal increases in probability or consequences or creation of malfunctions of a different type (but not with a different result than what was previously evaluated), to be made without prior NRC approval. In this proposed rulemaking, similar changes were proposed for those sections within Part 72 relating to change control, and also to extend the change control authority to Certificate of Compliance holders (for spent fuel storage cask designs).

The Commission approved the staff’s proposal to issue a proposed rule for public comment in its staff requirements memorandum of September 25, 1998, with a number of changes and additions. The proposed rule was published in the *Federal Register* on October 21, 1998 (63 FR 56098) for a 60 day comment period ending December 21, 1998.

DISCUSSION:

In SECY-99-054, the staff submitted draft final rule language, and recommendations for resolving certain key policy issues associated with this final rule. SECY-99-054 also included a discussion of the public comments and the staff’s proposed course for resolution of the issues raised by the public. This paper transmits the staff’s final recommendations based upon feedback from a Commission briefing on March 2, 1999, concerning SECY-99-054, and continued interactions with stakeholders to enhance the clarity of the terminology and the criteria. This paper supplements SECY-99-054 and discusses those topics for which the staff’s recommendations differ from those in SECY-99-054. The *Federal Register* (FR) notice (Attachment 1) contains the Statement of Considerations, the resolution of issues raised during the comment period, and the final rule language. Attachment 2 is the final Regulatory Analysis.

In a letter dated April 30, 1999, the Nuclear Energy Institute (NEI) provided comments on certain aspects of the rulemaking as discussed in SECY-99-054, and as reflected in public meetings held during the last few months. Some of the statements and comments in this letter are reflected in Attachment 1 based upon these interactions. However, the staff did not have sufficient time to fully review their proposals before submitting this paper. The staff will provide to the Commission its views about the NEI letter in a separate memorandum.

1. MINIMAL INCREASE IN FREQUENCY OF ACCIDENT OR LIKELIHOOD OF MALFUNCTION

As discussed in SECY-99-054, the staff recommends that the final rule state that a license amendment would be required (for a proposed change, test, or experiment) if there was more than a minimal increase in the frequency of an accident or likelihood of malfunction of structures, systems or components (SSCs) important to safety previously evaluated in the final safety analysis report (as updated). The staff had further noted that the guidance for

implementation was qualitative and more consistent with “negligible” increases. During the Commission briefing, the staff was requested to provide a clearer definition of the term “minimal.” The Statement of Considerations includes a discussion of how “minimal” should be interpreted, and provides guidance to aid in its implementation. The staff acknowledges that it would be helpful to supplement this discussion with examples, and plans to work with the industry to include examples in implementation guidance. The staff met with the Nuclear Energy Institute (NEI) on March 23, 1999, to discuss options for developing implementation guidance for the phrase “minimal increase in frequency or likelihood.” The NEI concluded that it could not offer more definitive guidance than that currently contained in NEI 96-07. However, NEI offered to continue to work with the staff during the development of the regulatory guidance to try to develop better examples in this area.

2. REPLACEMENT CRITERIA FOR THE CRITERION OF “MARGIN OF SAFETY AS DEFINED IN THE BASIS FOR ANY TECHNICAL SPECIFICATION IS REDUCED”

The staff had proposed a criterion in SECY-99-054 to replace the existing criterion on “margin of safety.” The staff considered adopting rule language proposed by NEI in its comments on the proposed rule but was concerned that that language could be interpreted too narrowly. Therefore, the staff proposed criteria in SECY-99-054 that would encompass mitigation and support systems as part of the process. Since that time, the staff has obtained a better understanding of the implementation process described by NEI in its comment letter of December 21, 1998, and the staff agrees that with certain restrictions, the process NEI proposed would appropriately address how changes to system performance are evaluated with respect to fission product barriers. Thus, the approach presented in the final rule is a combination of the NEI proposal contained in its comment letter and the staff’s proposal contained in SECY-99-054.

This final rule eliminates the existing criterion on reduction in margin of safety. In its place, the rule adds two new criteria. New criterion (vii) will require 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) pertaining to the use and control of evaluation methods.

NEW CRITERION (vii)

Criterion (vii) will require a prior NRC review of any change that would “result in a design basis limit for a fission product barrier being exceeded or altered.” The staff defines a “design basis limit” for a fission product barrier as being the controlling numerical value for a parameter established during the licensing review as presented in the FSAR for any parameter(s) used to determine the integrity of the barrier. Typically the controlling value for a parameter is set at a point that is far enough away from failure as to provide confidence in the capability of the barrier. The staff used the term “fission product barrier” so that the rule language would be appropriate for all Part 50 facilities (including nonpower reactors, and reactors undergoing decommissioning). The more general terminology is also appropriate for the Part 72 facilities. For operating power reactors, the fission product barriers will generally be limited to the fuel cladding, the reactor coolant system pressure boundary (including piping and emergency core

cooling system alignments), and containment. For a reactor undergoing decommissioning, the barrier(s) would be the fuel cladding. For Part 72 facilities, the barriers would be, as applicable to the design, the fuel cladding and the confinement structure of the cask.

To satisfy new criterion (vii), the staff believes that licensees will need to determine if the change being made can ultimately affect any of the design basis limits for a fission product barrier. The effects of a change are not limited to the specific system in which the change is being made or to parameters that are only directly linked to the actual fission product barrier. Rather, the evaluation must include an assessment of all effects of the change, including effects on mitigation and support systems. The effects of the change can then be judged in terms of whether the parameters that are design basis limits would be exceeded or altered. In determining whether approval is required under this criterion, the parameters are measured against criteria to: determine whether the parameters have values established in the FSAR, or whether the parameters are controlling parameters that are reference bounds for the design. Finally, if the specific parameter values are already subject to controls established by the technical specifications or other rules or regulations, those processes are to be followed.

After a licensee assesses the information previously discussed, it must 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 the licensee may make the change to the facility without prior NRC review. The rule language that provides that a design basis limit may not be exceeded or altered provides important and needed assurance. Changes that involve alteration of the design basis limit for the fission product barriers involve such a fundamental alteration to the facility design that a change even in the conservative direction must receive prior NRC review.

NEW CRITERION (viii)

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.” The control of methods is essential in assuring a consistent application of the change review process, especially in light of the flexibility being afforded elsewhere by the final rule, such as criterion (vii) that uses design basis limits as the point at which NRC review is required.

For the purposes of this rule, a departure from a method of evaluation means (1) changing any of the elements of the method described in the FSAR (as updated) unless the results of the revised method are conservative or essentially the same, or (2) changing from a method described in the FSAR (as updated) to another method unless that method has been approved by the NRC for the intended application. A change is not conservative when a new method predicts a response that is further from a required limit than that predicted by the old method, for the same situation being analyzed. This can be determined by benchmarking (new vs. old method), or may be apparent from the nature of the changes between the methods. Results are essentially the same, even if tending slightly in the nonconservative direction if the variations are explained by routine analysis sensitivities and the differences are not a factor in

determining whether or not any of the criteria are exceeded.

“Design bases” as used in criterion (viii) for determining which evaluation methods are subject to this criterion, is that information meeting the definition contained in § 50.2 for controlling values for SSC. Safety analyses are those evaluations that demonstrate that facility response to or capability to withstand postulated events meets the applicable acceptance criteria.

To assure consistent implementation of criterion (viii), it is important to clearly distinguish between methods of evaluation and input parameters to the methods. The staff defines *methods of evaluation* to mean the calculational framework for evaluating behavior or response, as for the reactor or any SSC. Input parameters are defined as those values derived directly from the physical characteristics of SSC or processes in the facility. Changes to input parameters (described in the FSAR) are to be evaluated as facility changes, and criterion (viii) would not be applicable. Further, the staff plans to develop additional 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 staff intends to work closely with the NEI and other stakeholders to revise the existing guidance related to implementation of § 50.59 to reflect these definitions.

Specific examples of implementation of criteria (vii) and (viii) are presented in the Statement of Considerations to aid in understanding.

3.0 OTHER REGULATIONS

3.1 PART 52 CHANGES

In SECY-99-054, the staff included draft final rule revisions to Appendices A and B to Part 52 (Design Certification Rules for the ABWR and CE System 80+ designs, respectively). In SECY-99-101, dated March 31, 1999, the staff forwarded the proposed rule for Appendix C to Part 52 for the AP600 design, which did not include these proposed changes. Further, the staff stated in SECY-99-101 that Appendix C should emulate the existing versions of Appendices A and B to Part 52. In addition, the staff notes that a rulemaking is currently planned to examine Part 52 for areas of improvement (see SECY-98-282). The staff will consider the final revisions to § 50.59 within the context of the goals and objectives of Part 52 during the future rulemaking to update 10 CFR Part 52. Therefore, consideration of the changes to Appendices A and B to Part 52 are being deferred to a later date and they have been removed from this final rule.

3.2 IMPLICATIONS FOR PART 54

In preparing the final rule on § 50.59, the staff considered the relationship between § 50.59 and the license renewal rule, Part 54. Specifically, § 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, and §54.37(b) requires the FSAR supplement to include any newly-identified SSC that would be subject to an aging management review or evaluation of

time-limited aging analysis. As discussed in the Statement of Considerations for the final Part 54, including the program descriptions in the FSAR provides the appropriate regulatory oversight such that subsequent changes are controlled by § 50.59. The staff concludes that the definition proposed for “facility” is such that these summary descriptions fall within the definition and thus that changes that affect this information require evaluation under § 50.59. Furthermore, the staff regards the evaluations and analyses required by §§ 54.21(d) and 54.37(b) as needing evaluation under criterion (viii), to the extent that evaluation methods are described in the FSAR for such evaluations. The Statement of Considerations specifically notes this relationship and further notes the staff’s intention to provide further information in implementation guidance.

3.3 PART 71 AND 72 CHANGES

In SECY-99-054, the staff noted that it may be necessary to issue a supplemental notice for proposed rule changes to Part 72 to respond to certain issues raised by the commenters. The staff has concluded that this supplemental notice is not necessary to implement the final rule change for Part 72 included in the attached notice. In addition, the rule changes for Part 72 respond to a petition for rulemaking (PRM 72-3), submitted by Ms. Fawn Shillinglaw, concerning final safety analysis updates for cask certificate holders. This petition is being closed out in this final rulemaking notice. A letter to the petitioner closing out the petition will be signed by the Executive Director for Operations upon approval of the final rule. A copy of this letter is attached (Attachment 3).

In SECY-99-054, the staff noted that it planned a supplemental rulemaking to revise Part 71 to provide a “71.48” change control process for spent fuel transportation packages used in domestic commerce only. In lieu of providing this supplemental rule for Commission consideration, the staff now will include a new § 71.48 as part of the already budgeted and planned revision to 10 CFR Part 71, to take advantage of rulemaking process and staff efficiencies. Under the schedule for the update to Part 71 to make NRC transportation regulations compatible with the most recent International Atomic Energy Agency (IAEA) transportation standards (1996), the staff proposes issuance of a final rule by December 2001. Thus, the new § 71.48 would be issued after the revised § 72.48 is issued. This interim period would provide time for the staff to develop regulatory guidance for the Part 71 changes, which will facilitate immediate implementation after final rule issuance. The guidance would be based upon the §§ 50.59 and 72.48 guidance being developed during this same time period. Further, it would allow time for appropriate coordination of proposed changes with the U.S. Department of Transportation.

Neither the IAEA transportation standards nor the international transportation practices include a §71.48-type provision. Therefore, the staff currently intends to focus the proposed new § 71.48 only on domestic transportation for spent nuclear fuel. The broader Part 71 rulemaking will also allow the staff to address the issue of whether a “71.48-type” process is appropriate for any other Part 71 transportation packages in the Part 71 rulemaking plan. The new section would incorporate a process similar to that described in the revised § 72.48 that would enable a licensee or certificate of compliance holder to perform changes, tests, and experiments relative to transportation package designs without prior NRC approval if specified criteria are met.

4.0 BACKFITTING

The backfitting discussion for the proposed rule acknowledged that the proposed definitions of “change,” “facility as described,” and the proposed change to the “reductions in margin of safety” criterion could represent backfits, and the staff prepared a backfit analysis which set forth a basis for determining that the proposed changes represented a “substantial increase” in protection to public health and safety whose costs are justified in view of the increase. Although NEI did not file any backfitting comments, the law firm of Winston and Strawn, on behalf of the Nuclear Backfitting and Reform Group (NUBARG), filed significant comments on backfitting. In addition, the staff has modified somewhat the final rule in response to public comments by inclusion of criteria (vii) and (viii) as a substitute for the “margin of safety” criterion. NUBARG stated that the rule should be made prospective only, and that the proposed backfit analysis was “very weak” since it failed to identify all new positions, together with a detailed discussion of the costs and benefits of the proposed positions, and made no finding with respect to the “substantial increase” standard in § 50.109.

The staff believes that there are several alternatives for addressing the requirements of §§ 50.109 and 72.62 for this rulemaking. Upon consideration, the staff recommends that the Commission determine that this rulemaking does not involve backfitting as defined in §§50.109(a)(1) or 72.62(a), on the basis that the final rule’s provisions constitute permissive relaxations, and clarifications and codifications of existing NRC interpretations and practices. The statement of considerations for the final rule has been modified to reflect this recommendation.

5.0 ENFORCEMENT POLICY CLARIFICATION

In SECY-99-054, the staff recommended that until the revised rules were implemented, some enforcement discretion should continue to be exercised. SECY-99-054 then detailed five graded approaches to dispositioning violations of §§ 50.59 and 72.48. The staff recommends some clarifications to approaches 1 and 3 (renumbered below to 2), as shown in the following bolded text, and deletion of approaches 2, 4 and 5 as discussed below.

(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 for the violation within a reasonable time frame commensurate with safety significance.

(2) A failure to submit an amendment as required would be considered a Severity Level

III violation if either (1) a substantial review (***based on the merits of the technical issues***) is needed by the NRC before it could conclude the licensee's actions were acceptable, or (2) the NRC would not have found the licensee's actions acceptable.

Approach 1 addresses the transition period until the rule is implemented, when, absent an exemption, licensees will need to comply with the existing rule. To avoid the potential for a willful violation, licensees will need to initiate corrective action even if the violation would not constitute a violation under the new rule. (The staff recognizes that given the limited safety significance of such violations, a schedule for corrective action commensurate with safety may extend past the effective date of the new rule in which case corrective actions would not need to be completed.) Enforcement actions could be taken between the publication date for the rule and the effective date of the revised rule for these violations of the old rule. However, the staff does not believe that is an effective use of staff resources in light of the criteria of what changes the agency now believes is appropriate to approve. Therefore, the staff is proposing to exercise discretion and not make citations for violations of the old rule that would not be violations of the new rule once the final rule is published in the FR.

Approach 2 establishes a two part test for significance. This approach will be used for violations resulting from failure to submit an amendment as required, due to a failure to perform evaluations or for inadequate evaluations. In assessing the severity level for a failure to submit a required license amendment, the staff believes it is appropriate to consider the impact of the failure to submit the change, i.e., whether the staff would have approved it, and the importance of preserving the agency's ability to review changes that meet the thresholds of the rule. The staff will focus on the complexity and technical substance of the change. If a substantial review is needed before being in a position to approve the change, then the failure to submit the change should be considered to have had a significant impact on our ability to oversee the activities of licensees. A substantial review is one where a reasonable staff reviewer familiar with the subject matter of the change concludes that the acceptability of the change is not obvious such that a technical review of the merits is needed. On the other hand, if the knowledgeable reviewer concludes at the outset that it is likely that the change would be acceptable and it was, the failure to submit the amendment would be considered a Severity Level IV violation. As with any severity decision, the staff recognizes that there is subjectivity involved. However, the use of the §50.59 oversight panel should provide for a consistent approach to these decisions.

The staff proposes to delete Approaches 2 and 4 as presented in SECY-99-054 as not being needed as specific guidance for §§ 50.59 and 72.48 as these statements are in accordance with the NRC Enforcement Policy. Approach 5 is being deleted based on the conclusion that it does not add any additional guidance that Approach 2 above does not already provide. Further, the staff believes it unlikely that there will be violations of §§ 50.59 or 72.48 that will reach to Severity Level II, absent other more risk-significant violations occurring as a result of the §§ 50.59 or 72.48 problems. In these cases, the staff would propose to cite licensees for the more risk significant violations, rather than for violations of either §§ 50.59 or 72.48. The staff has included a section discussing enforcement policy in the Statement of Considerations in Attachment 1.

The staff will submit proposed changes to NUREG-1600, Rev.1, General Statement of Policy and Procedures for NRC Enforcement Actions (Enforcement Policy), within 60 days of Commission approval of this paper. Included will be changes to the Enforcement Policy Supplements to delete Severity Level examples which are inconsistent with the approach described herein.

6.0 IMPLEMENTATION

In SECY-99-054, the staff recommended that the rule be implemented in 18 months to allow time for development and implementation of guidance, with the provision for earlier implementation by individual licensees if they wished. Rule text has been included that implements this position. The staff believes 18 months is sufficient time for revision of the existing guidance for licensees and NRC staff, and for all licensees to become familiar with those areas where their programs may need to be supplemented. The 18 month date is compatible with the recommendation from NEI in their April 30, 1999, memorandum, and from discussions with NEI management that supported options for individual licensees who may want to take advantage of the flexibility being offered sooner. The staff is not recommending early implementation for §72.48 since guidance is not developed. However, there are other sections in Part 72 that are being revised by this rulemaking for which guidance is not needed (for instance, the sections on amending certificates). For these sections, the staff recommends implementation in 120 days.

RESOURCES

For implementation, revision of inspection guidance, regulatory guidance and conduct of training of inspectors will be needed. Resources for these activities have been included in the budget and operating plan. No impacts on the inspection program are anticipated as a result of this rulemaking because oversight of licensee section § 50.59 (and § 72.48) processes are already part of the regular inspection program. There may be a slight reduction in license amendment submittals associated with changes of the type that would presently require approval, but that would not under the revised rule.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection to its contents.

The Advisory Committee on Reactor Safeguards was briefed on the staff's plans for the final rule (as discussed in SECY-99-054) in March 1999. In a letter dated March 22, 1999, the Committee expressed its support for completion of the rulemaking. The staff briefed the Committee on the contents of this paper on May 5, 1999.

The Committee to Review Generic Requirements was briefed on the final rule on May 6, 1999. On May 10, 1999, the Committee provided a letter recommending going forward with the amendments.

The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objection.

The Office of the Chief Information Officer has reviewed the proposed rule for information technology and information management implications and notes that the final rule amends information collection requirements. The staff had submitted its estimate of the information collection burden to the Office of Management and Budget (OMB) for the proposed rule. OMB stated that because of the probability of changes in the information collection at the final rule stage, NRC should resubmit the information collection request when it takes final action. This step will necessitate NRC's seeking OMB's approval for the information collection associated with the final rule as it is approved by the Commission before the rule can be published in the *Federal Register*.

RECOMMENDATIONS:

That the Commission:

- 1 Approve the publication of the enclosed *Federal Register* notice that promulgates the final rule;
- 2 Certify that this rule, if issued, would not have a significant economic impact on a substantial number of small entities to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).
- 3 Authorize the Executive Director for Operations to sign the attached letter (with the approved *Federal Register* notice) to Ms. Fawn Shillinglaw closing out action on PRM-72-3.
4. Note that:
 - (a) The staff plans to issue regulatory guidance and revised inspection guidance following approval of the final rule. The staff will work with the industry and other stakeholders to revise the existing NEI 96-07 to satisfy the requirements of the final rule such that it could be endorsed.
 - (b) The Regulatory Analysis (Attachment 2) will be available in the Public Document Room.
 - (c) This rule amends information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) The information collection requirements for this rulemaking will be submitted to OMB as soon as the Commission approves the final rule. Publication of the rule will proceed as expeditiously as possible once OMB approval is obtained.
 - (d) The appropriate congressional committees will be informed of this action (Attachment 4).

- (e) A press release will be issued (Attachment 5).
- (f) The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding the economic impact on small entities and the reason for it as required by the Regulatory Flexibility Act.
- (g) The NRC has determined that this action is not a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and has confirmed this determination with OMB. This determination is reflected in correspondence to the President of the Senate, the Speaker of the House, and the General Counsel of the General Accounting Office (Attachment 6).

William D. Travers
Executive Director
for Operations

- Attachments:
1. *Federal Register* notice with final rule
 2. Regulatory Analysis
 3. Letter to Ms. F. Shillinglaw
 4. Letters to congressional committees
 5. Public announcement
 6. Congressional Review Act Forms

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 72

RIN 3150-AF94

Changes, Tests, and Experiments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

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

EFFECTIVE DATE: Sections 72.3, 72.9, 72.24, 72.56, 72.70, 72.80, 72.86, 72.244, 72.246, 72.248 of this rule are effective [INSERT DATE 120 DAYS FROM DATE OF PUBLICATION] Sections 50.59, 50.66, 50.71(e), 50.90, 72.212 and 72.48 are effective [18 MONTHS FROM DATE OF PUBLICATION].

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

SUPPLEMENTARY INFORMATION:

I. Background

II. Comments and resolution on proposed rule topics

- A. Organization of the rule requirements
- B.1 Definition of change
- B.2 Definition of facility as described in the final safety analysis report
- C. Change to the procedures as described in the final safety analysis report
- D. Tests and experiments not described in the final safety analysis report
- E. Safety analysis report
- F. Minimal increase principle
- G.1 Frequency of occurrence of an accident
- G.2 Likelihood of occurrence of malfunction of structure, system, or component important to safety previously evaluated

- G.3 Consequences of an accident or malfunction of structure, system, or component important to safety previously evaluated
- H. Possibility of an accident of a different type from any previously evaluated in the final safety analysis report (as updated) is created
- I. Possibility of a malfunction of a structure, system, or component with a different result from any previously evaluated in the final safety analysis report (as updated) is created
- J. Replacement criterion for “margin of safety as defined in the basis for any technical specification is reduced”
- K. Safety evaluation
- L. Reporting and recordkeeping requirements
- .13 No significant hazards consideration determination
- N. Part 52 changes
- O.1 Part 72 changes
- O.2 Petition PRM-72-3
- O.3 Part 71 Comments
- P. Other topics discussed in the proposed rule notice
- Q Enforcement policy

III. Section by section analysis

IV Finding of no significant environmental impact

V. Paperwork Reduction Act statement

VI Regulatory analysis

VII. Regulatory Flexibility Certification

- VIII. Backfit analysis
 - IX. Small Business Regulatory Enforcement Fairness Act
 - X. National Technology Transfer and Advancement Act
 - XI. Criminal penalties
 - XII. Agreement state compatibility
- List of Subjects

I. Background

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

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

possibility for an accident or malfunction of a different type than any evaluated previously in the safety analysis report may be created; or (iii) if the margin of safety as defined in the basis for any technical specification is reduced.

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

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

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

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

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

II. Comments and Resolution on Proposed Rule Topics

The 60-day comment period for the proposed rule closed on December 21, 1998. Comments were received from 60 organizations or individuals. Copies of the comments are available for public inspection and copying for a fee at the Commission's Public Document Room, located at 2120 L Street, N.W., Washington D.C. All comments were considered in formulating the final rule. The comments were submitted by 35 utilities with power reactor facilities; 2 representatives of nonpower reactor licensees; 3 law firms representing several utilities; 2 submittals from the Nuclear Energy Institute (NEI); the U. S. Enrichment Corporation; a nuclear industry group; 6 nuclear utility vendors, service companies or consultants; 4

vendors or service companies for spent fuel storage casks; and 6 individuals. Forty commenters endorsed (sometimes with further comments) the NEI comments. NEI stated in its comment letter that it generally support 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 extended implementation period of the rule will give ample opportunity to assure that the technical specifications are appropriately modified without the need to file a separate amendment request.

(5) Implementation

As noted, the revised rule is to become effective 18 months after publication. The Commission recognizes that some licensees may wish to implement the revised requirements earlier, to take advantage of some of the flexibility, at a point where they have revised their procedures and trained their personnel. New §50.59(e) contains provisions that allow earlier

implementation on an individual licensee basis, upon documentation of the decision in the FSAR. The licensee must follow either the existing rule requirements, or fully implement the revised requirements. The noted documentation provides the record for the NRC of which set of requirements the licensee is following at any point in time. After 18 months, all licensees are to follow the revised requirements. This provision is only included in § 50.59 and not in § 72.48 because the Commission was concerned that existing guidance may not support such earlier implementation for Part 72 licensees and certificate holders.

(6) Changes in the scope of the rule

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

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

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

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

B.1 Definition of Change

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

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

(a) Screening: most of the commenters were seeking revision of the definition to allow screening of changes that would not affect design functions. For instance, some commenters, while agreeing that additions should be considered changes, also noted that additions, if not

limited by qualifiers such as “inconsistent with FSAR or changing operation”, could mean that even trivial additions to the facility or to a procedure would require evaluations. A few commenters thought that additions should instead be treated as “tests or experiments,” so that evaluations would be needed only if the additions were inconsistent with the FSAR or outside the design basis.

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

(c) Interdependent changes: A number of comments concerned “interdependent” changes, that is, under what circumstances can more than one change be considered together rather than individually. A few commenters stated that the Commission should adopt a position with respect to interdependent changes that multiple changes to the facility or its procedures may be evaluated collectively if: (1) they are interdependent as in the case where a modification to a system or component necessitates additional changes to other systems or procedures in

order for the modified system to perform its function or comply with its design or licensing basis; (2) they are performed collectively to address a design or operational issue; or, (3) they are otherwise planned as elements of a single project undertaken to restore, maintain or improve plant performance or safety. Several commenters also stated that examples would be helpful to illustrate how closely related the changes needed to be in order to be viewed as interdependent.

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

(e) De Facto Changes: One commenter stated that the NRC should modify the definition or other rule language to explicitly state that the requirements apply only to “proposed” changes and not to so-called “de facto” changes¹. Another commenter thought the rule language should explicitly codify the resolution process under Generic Letter (GL) 91-18, by including language in the rule such that the respective requirements of Appendix B, criterion 16 and § 50.59 do not interfere.

(f) Changes made in response to NRC communications: Two commenters asked if a proposed change that is the direct result of a response to issues raised in generic communications requires evaluation under § 50.59 to determine the need for NRC approval, or

¹Under 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.

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 could affect the functions or performance requirements of other SSC. Depending upon the level of detail contained in the FSAR, the particular component being changed may not be explicitly described. If a modification to that (non-described) component could affect any SSC design function or performance requirements that are described, that modification affects the design function, and thus is a change as defined by § 50.59(a) and thus requires evaluation under §50.59. For example, the bearings on a pump may not be specifically mentioned or described in the FSAR. However, the pump function and performance requirement is described. A change being made to the bearings would need to be evaluated to determine if it affects the function or performance requirements of the pump, and if so, whether the criteria in 50.59 (c) are met.

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

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

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

The Commission could not identify any regulations that provide change control processes for the plant (facility); therefore, the proposed rule language was retained but moved to new §50.59 (c)(4). This language refers to situations, such as §§ 50.54(a) and 50.54(q),

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

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

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

to provide additional clarification as the processes for control of most of these documents are already defined.

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

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

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

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

safety analysis report (as updated)” which has minor changes from the definition offered in the proposed rule.

E. Safety Analysis Report

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

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

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

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

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

FSAR. Rather, the intent of the requirement is that the changes that were the subject of these evaluations be considered in the process of determining what the “facility as described” now is such that the reference for subsequent evaluations is complete and accurate.

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

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

F. Minimal Increase Principle

Strict interpretation of the existing rule language related to the probability of an accident or a malfunction has led 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 of less direct importance to public health and safety. In consideration of the conservatism 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). 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 values² 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

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

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 regulatory requirements³ (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

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

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

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

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

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

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

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

As an example of the “calculational error” concept, suppose the existing approved analysis for a fuel handling accident at a plant predicts an offsite dose to the thyroid of 77 rem. The SRP acceptance guideline for this event is 75 rem. The change that a licensee wishes to

make would predict an increase in the calculated dose from 77 to 77.1 rem. In this case, the proposed change could be made under § 50.59 because the calculated value, even though greater than the SRP value, is satisfied within the level of uncertainty specified above.

However, for this example, the Commission notes that increases in consequences that would increase the calculated consequences to 77.2 rem would require prior NRC review before the specific change could be implemented.

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

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

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

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

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

The Commission has concluded that use of the modifier “design basis” with respect to accidents of a different type in the rule language may be confusing because, by the terms of the rule, accidents of a different type are distinct from those (design basis) accidents evaluated in the FSAR. Therefore, in the final rule, the Commission removed the phrase “design basis.”

The Commission agrees that the accident must be credible in the sense noted above, of having been created within the range of assumptions previously considered (e.g., random single failure, loss of offsite power, no reliance on non-safety-grade equipment, etc.), and that a new initiator of the same accident is not a “different type” (but may affect the frequency of that accident under § 50.59(c)(2)(i)).

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

Need for definition of accident

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

Several comments were received on the proposed definition of accident. Most commenters felt that a definition in the rule was not necessary, and most also disagreed with the specific definition offered in some respect. Commenters generally agreed that accidents include design basis accidents (typically analyzed in Chapters 6 and 15 of the FSAR), anticipated occupational occurrences, external events that the plant is required to withstand and other special events that are analyzed to demonstrate safety. Included within the set of accidents are those scenarios for which requirements have been established for the facility either to withstand or cope with the event. Notable examples include pressurized thermal shock

events (§50.61), anticipated transient without scram (§50.62) and station blackout (§50.63). Commenters also noted that external events, such as earthquakes, high winds, floods, and missiles can be treated as causes of malfunctions of SSC, rather than accidents. Some suggested that examples or a list of accidents could be presented in the implementation guidance.

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

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

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

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

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

Guidance for malfunction with a different result

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

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

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

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

interest, and the nature of the change in margin for which prior NRC review and approval would be required.

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

Option 1 in Proposed Rule

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

Option 2 in Proposed Rule

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

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

Option 3 in Proposed Rule

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

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

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

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

Commission asked in the proposed rule whether changes to evaluation methods should also be controlled.

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

For the question as to when NRC approval is needed, comments can be grouped into two main themes: those that are supporting the position currently included in NEI 96-07 related to acceptance limits as being the point of departure for reduction in margin, and those supporting a new proposal from NEI. No commenters supported either a “no reduction in results” or a “minimal” standard, or any type of graduated approach such as that discussed earlier for consequences. As part of its comments on the proposed rule, the NEI proposed to replace the existing margin of safety criterion with one that states that a change requires prior NRC approval if it would result in a design basis limit directly related to integrity of the fuel

cladding, the reactor coolant system boundary, or the containment boundary being exceeded or altered. Their proposal is similar in several respects to the guidance offered in NEI 96-07, with respect to using “limits” as the point at which a reduction in margin occurs, and in focusing on parameters for fission product barriers as being the instances where there is margin to protect. The difference is the concept of “design basis limits” as represented in the FSAR instead of acceptance limits that might be found in other documents. Further, NEI suggested that as part of the rule changes to adopt this criterion, the NRC should also delete the third criterion in § 50.92, which states that a determination of “no significant hazards consideration” cannot be made for amendments that would involve a significant reduction in a margin of safety.

Resolution

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

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

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

Therefore, the approach contained in the final rule is a combination of the NEI proposal contained in its comment letter and the staff proposal contained in SECY-99-054. In the final rule, the Commission is eliminating the existing criterion on reduction of margin of safety. In its place, the Commission is adding a new criterion (vii) that requires prior NRC review of changes

that result in a design basis limit related to the integrity of the fission product barriers being exceeded or altered.

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

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

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

Final Rule Language

New Criterion (vii)

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

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

New criterion (vii) narrows the focus for when prior NRC approval is required to those changes which result in the specific limits that relate directly to the performance of fission

product barriers being exceeded or altered. For power reactors, these barriers are generally limited to the fuel cladding, the reactor coolant system pressure boundary (including piping and ECCS alignments), and containment. (The ECCS alignments are those configurations of engineered safety features equipment that form the reactor coolant pressure boundary under design-basis accident mitigation scenarios.) 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 breach of these barriers is the subject of criteria (iii) and (iv), rather than criterion (vii).

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

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

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

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

Guidance for Implementation

To satisfy new criterion (vii), licensees must determine the parameters that would be affected by the proposed change. The affected parameters are not limited to the specific parameters in the system in which the change is being made or to parameters that are only directly linked to the actual fission product barrier. Rather, the design parameters must include an assessment of all affected parameters, including design parameters of mitigation and support systems. Once the parameters are identified, the licensee must establish whether the parameters have values established in the FSAR, whether the parameters are controlling

parameters that are reference bounds for the design, and whether the parameter has the potential to affect the performance of the fission product barrier. If the specific parameter values are already subject to controls established by the TS or other rules or regulation, those requirements shall be followed.

After a licensee assesses the information discussed above, it would need to identify the specific design basis limits that could be affected for each of the identified parameters. After the licensee completes its assessment of the change against each design basis limit, if no design basis limit is altered or exceeded, criterion (vii) is satisfied, and a licensee may make the change to the plant 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).

Example 4: A licensee is considering removal of thermal relief valves on a ASME Code Class 2 piping system that is part of the reactor coolant pressure boundary during a design basis accident. For many plants, ASME Code Class 2 and 3 rules are not requirements in accordance with § 50.55a, but are instead specified in the FSARs for these facilities as the basis for determining acceptability of the piping design. The licensee evaluation shows that stress limits contained in the FSAR would be exceeded if the relief valves are removed. This is another case where NRC approval would be required for the change because the design basis limit for a fission product barrier would be exceeded (exceeding design stress limits would also be considered more than a minimal increase in either the frequency of an accident or the likelihood of malfunction(depending upon the function of the system). f

Example 5: As a variant on the above example, had the licensee wished to install relief valves with smaller capacity, for which piping stresses still satisfied the Code limit, this change would satisfy criterion (vii). (The licensee would also have to determine whether the other criteria of § 50.59, as well as TS requirements, are satisfied in order to make that change without approval).

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. The submittal must describe the effects¹ of all changes made in the facility or procedures as described in the FSAR; all safety analyses and evaluations performed by the licensee either in support of approved license amendments, or in support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2) of this part; and all analyses of new safety issues performed by or on behalf of

the licensee at Commission request. The updated information shall be appropriately located within the update to the FSAR.

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

M. No Significant Hazards Consideration Determinations

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

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

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

- (2) Create the possibility of a new or different kind of accident from any accident previously considered;
- or
- (3) Involve a significant reduction in a margin of safety.

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

The Commission has also evaluated whether changes to the NSHC criteria to conform more closely to the revised § 50.59 would facilitate implementation of the revisions to § 50.59, even if changes to the NSHC criteria are not required by the AEA. There are three areas where the current NSHC criteria diverge from the revised § 50.59 criteria: (i) the current NSHC criteria do not include the “malfunction of components” criterion in the revised Section §50.59; (ii) the NSHC criteria retains a “significant reduction in margin of safety” criterion, which is no longer part of the revised § 50.59; and (iii) the NSHC criteria do not include the revised § 50.59 criteria (vii) and (viii) concerning changes to fission barrier design basis limits, and changes to and departures from evaluation methods. Although there may be some conceptual tidiness in utilizing the same evaluation factors for changes under § 50.59 and NSHC determinations under § 50.92, nothing in the AEA or the legislative history requires that the criteria be identical.

Furthermore, the Commission notes that § 50.59 and NSHC address issues which are fundamentally different in purpose. Section 50.59 is focused upon the NRC's regulatory needs with respect to its review and approval of licensee-initiated changes, tests and experiments. By contrast, the NSHC determination is directed at determining what license amendments will require the Congressionally-mandated 30-day notice in the Federal Register and completion of any hearing granted pursuant to the Congressionally-mandated opportunity for hearing in Section 189.a. In the Commission's view, the existing NSHC criteria have been demonstrated through years of application to provide a workable standard for determining the potential safety significance of a proposed amendment for the purposes of determining whether issuance of a license amendment must await notice in the Federal Register and completion of any requested hearing. On balance, the Commission believes that no changes to the existing NSHC criteria are necessary in order to implement the revised change criteria in the revised § 50.59.

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

license amendments necessitated by the “malfunction of equipment” provision in the existing § 50.59(a)(2)(ii).

N. Part 52 Changes

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

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

O.1. Part 72 Changes

This section first discusses the changes offered in the proposed rule on Part 72, then discusses the comments received and the resolution and final rule language. The comments and rule language are discussed under subheadings relating to the specific requirements, such as for evaluation of changes, FSAR updating, and other conforming changes. A discussion of

petition for rulemaking (PRM 72-3), submitted by Ms. Fawn Shillinglaw, and how it relates to the changes to Part 72 is contained in section O.2.

Changes presented in the Proposed Rule

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

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

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

In § 72.3 the definition for *independent spent fuel storage installation* (ISFSI) would be revised to remove the tests for evaluation of the acceptability of sharing common utilities and services between the ISFSI and other facilities; and the existing requirement in § 72.24(a)

revised to reference shared common utilities and services in the applicant's assessment of potential interactions between the ISFSI and another facility. Proposed changes to § 72.56 would be conforming changes to those made to § 50.90. Changes to §§ 72.9 and 72.86 are conforming changes due to the proposed addition of new §§ 72.244, 72.246, and 72.248. The change to § 72.212(b)(4) would be a conforming change necessitated directly by the change to § 50.59, as this section in Part 72 refers to § 50.59 with respect to evaluations for the reactor facility at which site the ISFSI is located.

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

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

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

1. Overall Changes to Part 72

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

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

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

The ten commenters suggested that the tests in § 72.48 should be same as are used in § 50.59; in particular, five commenters said that the significant increase in occupational

exposure and significant unreviewed environmental impact tests were unnecessary and therefore should be removed. One commenter indicated the unreviewed environmental impact test should be retained, but only for specific licensees.

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

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

The Commission disagrees with these comments. The term SSCs provides a better description than equipment and is consistent with other regulations in both Parts 50 and 72 (as noted earlier, the Commission is revising § 50.59 to refer to SSC instead of to equipment). The

scope of these § 72.48 evaluations should include all SSCs described in the FSAR, not just those that are important to safety. The current regulations in § 72.48 require a scope that includes all structures, systems, and components described in the FSAR not just those “important to safety.” The Commission continues to believe that this approach is necessary to insure that changes to SSCs considered “not important to safety” do not have a negative impact on SSCs considered important to safety due to interactions and interfaces, and do not cause any adverse impact on public health and safety. The term “evaluations and methods of evaluation” is necessary for the reasons previously discussed for § 50.59 changes, and is retained in final § 72.48(a)(2)(iii).

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

The Commission has revised §§ 72.48, 72.70 and 72.248 in response to these comments. These changes have clarified the use of the term FSAR to avoid the interpretation that multiple staff reviews of this document will be required. The FSAR being submitted 90 days

after license issuance precludes both a hold point and an additional staff review. Further the Commission agrees that providing a periodic FSAR update every 6 months and a final one 90 days prior to fuel load was an unnecessary burden, which does not exist in § 50.71(e), and these requirements have been eliminated. The Commission agrees that language was needed to indicate that the facility or design can be changed using the new process in § 72.48 after a license is issued and prior to issuing the FSAR and that has been reflected in the final rule. Paragraphs 72.48 a(2) and a(3) have been reversed in order and the phrase “required to be included” has been deleted for clarity and for consistency with § 50.59.

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

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

One commenter suggested that licensees and certificate holders should inform each other of changes implemented under § 72.48 that affect a particular cask design, through the summary reports rather than through the FSAR update, as was stated in the proposed rule.

One commenter also suggested that guidance on the timeliness of the review to be performed upon receipt of such changes be provided.

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

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

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

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

Several commenters suggested that the language in §§ 72.70, 72.216, and 72.248 on updating the FSAR conform to the language in § 50.71(e). Specific changes requested included requiring a 24-month reporting period, adding a 6-month cutoff for reporting changes, clarifying requirements for the initial submittal of the FSAR, and how no changes to the FSAR are to be reported by stating that there are no changes. One commenter felt that requiring a general

licensee to maintain its own FSAR (i.e., potentially separate and distinct from the certificate holder) was unnecessary and would cause confusion. One commenter felt that the process for revising the FSAR for a general licensee was confusing.

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

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

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

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

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

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

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

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

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

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

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

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

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

O.2 PETITION FOR RULEMAKING (PRM-72-3)

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

Specifically, the petitioner requested that the NRC amend those regulations which govern independent storage of spent nuclear fuel in dry storage casks to require that: (1) the safety analysis report (SAR) for a dry storage cask design fully conforms with the associated NRC safety evaluation report (SER) and Certificate of Compliance (CoC) before NRC certification

(i.e., approval) of the dry storage cask design; (2) the revision date and number of an SAR be specified whenever that report is referenced in documents; (3) the NRC clarify the process for modification of an SAR after a cask has been certified; and (4) the NRC make available to the public, the licensees' unloading procedures. In her supplemental letter, the petitioner recommended that to eliminate confusion, the term "CSAR" (i.e., cask safety analysis report) be used when referring to the SAR for any dry storage cask design which has been approved by the NRC and issued a CoC.

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

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

Issue (1):

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

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

Resolution of Issue (1):

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

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

The Commission agrees with the petitioner that the FSAR should be fully conformed (i.e., consistent) with the operating limits contained in the CoC, because the FSAR contains the

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

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

The Commission also disagrees with the petitioner's supplemental information to use the term "cask safety analysis report (CSAR)" when referring to the SAR submitted after the NRC

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

Issue (2):

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

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

Resolution of Issue (2):

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

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

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

Issue (3):

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

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

Resolution of Issue (3):

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

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

The Commission is seeking to reduce any unnecessary regulatory burden placed on its licensees and certificate holders without compromising safety. The dry storage cask design review process and the analysis acceptance criteria are defined in the NRC's standard review plans. This final rule allows licensees and certificate holders to make changes to the cask design, without obtaining prior NRC approval, for changes which do not significantly impact the ability of the cask to perform its intended functions. The impact of these changes are then incorporated into an updated FSAR, which is submitted to the NRC. Requiring that all changes to a cask design or changes to a FSAR be reviewed and approved by the NRC through the

rulemaking amendment process, including either a public comment period or a public hearing, defeats these efforts with no discernable increase in safety. Further, while rulemaking is currently utilized to amend a CoC, the Commission is presently re-examining the appropriateness of this procedure. Therefore, the Commission has granted petitioner's request to clarify the process for modification of an FSAR after the NRC has approved the cask design and issued the CoC, but has rejected the request to require all changes to a cask design, or the FSAR, be made via a rulemaking amendment process.

Issue (4):

The NRC should make cask unloading procedures publicly available.

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

Resolution of Issue (4):

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

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

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

Furthermore, requiring Part 72 licensees to submit their implementing procedures to the NRC (i.e., operating procedures such as loading and unloading procedures, maintenance procedures, surveillance procedures, radiation protection procedures, security procedures, emergency procedures, and administrative procedures), as well as any revisions to these

procedures, would impose a huge paperwork burden on both the licensee and on NRC staff without a corresponding safety benefit. Therefore, Issue (4) is denied.

Additional Public Comments on the Petition

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

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

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

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

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

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

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

Comment: One commenter requested that the NRC prohibit general licensees from using § 72.48 and only permit cask design changes via rulemaking. One commenter recommended that any identification of an unresolved 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.

.16 OTHER TOPICS DISCUSSED IN THE NOTICE AND COMMENTS NOT RELATED TO PRECEDING TOPIC AREAS

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

Guidance

Many comments were received on the subject of guidance. Many suggested that NEI and NRC work together to develop guidance, and that the guidance be endorsed before the revised rule becomes effective. Commenters also requested examples of such matters as

interdependent changes, minimal increases, and screening of changes (as discussed in Sections B and G).

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

Fuel Burnup limits

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

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

Alternative Criteria

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

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

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

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

Regulatory Analysis

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

Need for Further Notice and Comment

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

Different Process for non-TS Issues

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

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

Other Definitions

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

The Commission notes that § 50.2 does define design bases, but also notes that efforts are underway within the agency to enhance understanding of what constitutes design basis

information, through possible development of criteria and examples. Concerning “important to safety,” the Commission does not believe that a definition is critical to implementation of the rule, since the set of SSCs viewed as important to safety was arrived at during the license review and are described in the FSAR. Thus, lack of an established definition is not an impediment to implementation of the rule (the Commission notes that for Part 72, a definition is provided for SSC important to safety).

Applicability to Part 76

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

The Commission notes that the gaseous diffusion plants (GDP) have significantly less design basis information than is currently available for reactor facilities. The lack of design detail and lack of understanding of the design basis has been documented in the Compliance Plans for the GDPs, in NRC inspection reports, and is evident in the GDP SARs. The Commission concludes that successful implementation of a change control process is dependent upon the level of knowledge about the design basis of the plant equipment or operation being changed.

At the present time, the Commission does not believe that additional flexibility is appropriate for Part 76 facilities.

Q. Enforcement Policy

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

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

(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.

(2) A failure to submit an amendment as required would be considered a Severity Level III violation if either a) a substantial review (based on the merits of the technical issues) is needed by the NRC before it could conclude that the licensee's actions were acceptable or b) NRC would not have found the licensee's actions acceptable. The determination as to whether substantial review is involved is based solely upon the complexity and significance of the technical issues, not whether the review spans an appreciable period of time due to higher-priority activities or other considerations. The substantial review standard would be applied to both violations resulting from failure to perform an evaluation, and from inadequate evaluations.

The Commission believes it is unlikely that violations of §§ 50.59 or 72.48 will reach to Severity Level II absent other more risk-significant violations occurring as a result of the §§ 50.59 or 72.48 violation. In these instances, the NRC would propose to cite these other violations rather than either §§ 50.59 or 72.48. 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. 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.

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 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.

Paragraph (e): A paragraph on Implementation was added to allow licensees to implement sooner than the 18 month effective date upon documentation by the licensee of its decision in the FSAR.

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 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 both general and site-specific licensees, including provisions for replacement pages, a cut off date for changes, time frame to file, and provisions for updating if no changes were made.

10 CFR 72.80

New paragraph (g) is being added to this section to require a specific licensee to notify the NRC at least 90 days in advance of its readiness to commence ISFSI (or MRS) operations

This requirement replaces a requirement in present 72.70(a) that an FSAR be submitted to the Commission at least 90 days prior to the planned receipt of spent fuel or high-level waste. This requirement thus ensures that the NRC is informed in advance of licensee plans to use the facility so that appropriate oversight activities can be conducted.

10 CFR 72.86

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

10 CFR 72.212(b)(2)

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

10 CFR 72.212(b)(4)

The change to this section is to conform the reference to § 50.59 provisions, specifically to change from the terminology of unreviewed safety question to referring to the need for a

license amendment for the facility (that is, the reactor facility at whose site the independent spent fuel storage installation is located).

10 CFR 72.216

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

10 CFR 72.244

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

10 CFR 72.246

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

10 CFR 72.248

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

IV. Finding of No Significant Environmental Impact

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

significant impact on the environment from this rule. This discussion constitutes the environmental assessment and finding of no significant impact for this rulemaking.

V. Paperwork Reduction Act Statement

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

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

The public reporting burden for this information collection request was estimated in the proposed rule to average 3100 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The Commission had estimated that there would be

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

Public Protection Notification

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

VI. Regulatory Analysis

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

VII. Regulatory Flexibility Certification

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

VIII. Backfit Analysis

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

Changes to Section 50.59

Section 50.59 defines the circumstances under which holders of nuclear power plant operating licenses may make changes to and conduct tests or experiments at their facilities

without prior NRC review and approval. In this rulemaking, new definitions are added to § 50.59 (e.g., the definitions for “change,” and “facility as described in the final safety analysis report (as updated)”), and the structure and language of the rule were modified (e.g., the addition of a new applicability section, and the removal of the term, “unreviewed safety question”). These changes constitute clarifications of the existing rule, and codification of existing NRC practice and interpretations of terminology which are undefined by the current rule. Clarifications and codification of existing NRC interpretation and practice do not constitute a generic backfit (although the application of the revised rule may constitute a plant-specific backfit). The new criteria in § 50.59(c)(2)(i), (ii), (iii), (iv), (v) and (vi) are being added primarily⁴ 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 relaxations⁵ from the superseded Section 50.59(a)(2)(i) and (ii) criteria. Permissive relaxations are not considered to be backfits, inasmuch as a licensee will continue to be in compliance with the final rule even if it uses its existing procedures and the superseded criteria for implementing § 50.59. The new criteria in § 50.59(c)(2)(vii) and (viii) together constitute replacements for the superseded § 50.59(a)(2)(iii) criterion on “margin of safety.” As noted in Section J, these two criteria together, in place of a criterion on margin of safety, explicitly cover those margins that the Commission believes are important to address in this evaluation process—the first being the margin that exists in the limits that are to be met, and the second being the margin that exists from the conservatism included in the methods used to demonstrate that requirements are met. The replacement criteria were thus developed to accomplish two complementary goals: (1)

⁴In 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.

defining with more precision the important safety margins which should be the focus of a § 50.59 determination, rather than the problematic term, “margin of safety as defined in the basis for any technical specification;” and (2) assuring that the relaxations embodied in the § 50.59(c)(2)(i), (ii), (iii), (iv), (v) and (vi) criteria will not result in changes approaching the adequate protection threshold without prior NRC review and approval. As such, the new criteria (vii) and (viii) are fundamentally part of the overall regulatory scheme in the revisions to § 50.59 which relax and clarify the thresholds for licensee-initiated changes and tests requiring prior NRC review and approval before their implementation. In sum, the Commission has determined that the changes to § 50.59 constitute clarifications and codifications of existing practices, or constitute permissive relaxations from the existing § 50.59 criteria, and therefore do not constitute backfits as defined in §50.109(a)(1).

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 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 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.

(e) Implementation. Licensees shall implement this section no later than [INSERT DATE 18 MONTHS AFTER PUBLICATION OF THE FINAL RULE]. Licensees may implement this section at an earlier date upon documentation of the licensee's decision in the FSAR (as updated). Until

the licensee implements the requirements of this section, the licensee shall comply with the superseded provisions of this section.

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

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

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

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

(c) ★ ★ ★

(2) If the thermal annealing was completed but the annealing was not performed in accordance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program, the licensee shall submit a summary of lack of compliance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program and a

justification for subsequent operation to the Director, Office of Nuclear Reactor Regulation. Any changes to the facility as described in the final safety analysis report (as updated) which are attributable to the noncompliances and which require a license amendment pursuant to § 50.59(c)(2) and any changes to the Technical Specifications, shall also be identified.

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

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

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

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

(B) If any changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to Technical Specifications are identified, the licensee may not restart its reactor until approval is

obtained from the Director, Office of Nuclear Reactor Regulation and the requirements of paragraph (f)(2) of this section have been met.

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

§50.71 Maintenance of records, making of reports.

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(e) Each person licensed to operate a nuclear power reactor pursuant to the provisions of § 50.21 or § 50.22 of this part shall update periodically, as provided in paragraphs (e)(3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the operating license, to assure that the information included in the report contains the latest information developed. This submittal 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 effects¹ 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.

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

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5. Section 50.90 is revised to read as follows:

§ 50.90 Application for Amendment of license or construction permit.

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

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

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

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

2229, 2230, 2232, 2241, sec. 148, Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

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

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

§ 72.3 Definitions.

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

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

§ 72.9 Information collection requirements: OMB approval.

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

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

§ 72.24 Contents of application: Technical information.

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

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10. Section 72.48 is revised to read as follows:

§ 72.48 Changes, Tests, and Experiments.

(a) Definitions for the purposes of this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) This section applies to:

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

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

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

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

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

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

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

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

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

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 effects¹ of:

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

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

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

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

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

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

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

(4) The update shall include:

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

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

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

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

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

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

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

§ 72.80 Other records and reports.

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

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

§ 72.86 Criminal penalties.

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

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

§ 72.212 Conditions of general license issued under § 72.210.

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(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 subparagraph 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.

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(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 effects¹ of:

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

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

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

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

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

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

(4) The update shall include:

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

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

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

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

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

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

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

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

Dated at Rockville, Maryland, this ____ day of _____, 1999.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

REGULATORY ANALYSIS

Revision to Title 10, Section 50.59 "Changes, Tests and Experiments" and parallel changes to 10 CFR 72.48 "Changes, Tests and Experiments" (and other related sections)

Objective and Problem:

The objective of the revisions to 10 CFR 50.59 and to 10 CFR 72.48 (along with conforming changes to other sections impacted by these proposed changes) is to clearly define those changes, tests or experiments for which prior NRC approval is required. Through this rulemaking, the NRC is ensuring that those changes which clearly could have an impact on the basis for licensing receive review while at the same time relieving both the NRC and the licensees from the need for NRC prior approval for changes that are of little regulatory or safety significance, but may be viewed as satisfying the existing criteria for such approval. This revision also clarifies areas of confusion associated with existing rule requirements.

Background:

Detailed background discussions for this issue are found in the following documents:

NUREG-1606, Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests and Experiments), Draft for comment, published for public comment in May 1997 (available in the PDR).

Public comments filed on NUREG-1606 (available in the PDR)

SECY-97-205 Integration and Evaluation of Results from Recent Lessons-learned Reviews, September 10, 1997 (available in the PDR)

SECY-98-171, Proposed Rule for 10 CFR Parts 50, 52 and 72, Changes, Tests and Experiments (published in the Federal Register on October 21, 1998, 63 FR 56098)

Public comments filed on proposed rule (available in the PDR)

SECY-99-054 Plans for Final Rule - Revisions to 10 CFR 50,52 and 72, Requirements concerning Changes, Tests, and Experiments, February 22, 1999 (available in the PDR)

As discussed in these documents, there are aspects of 10 CFR 50.59 that are subject to varying interpretations. In draft NUREG-1606, the staff published its proposed interpretation of these particular sections for public comment. Numerous comments were received stating that the implementation guidance for the existing rule posed unwarranted burden and were not necessary to ensure that changes, tests and experiments are reviewed when necessary by the NRC. The industry had previously developed implementation guidance, NSAC-125, in 1989, which contains interpretations of 10 CFR 50.59 different from the NRC's; this guidance was later issued in a revised form as NEI 96-07 on October 31, 1997.

The NRC has stated that the guidance proposed in NEI 96-07 cannot be endorsed as being consistent with existing provisions of 10 CFR 50.59 (and by similarity, of 10 CFR 72.48). Therefore, the NRC evaluated alternative approaches to resolve these differences.

NEW OR AMENDED PROVISIONS OF THE RULES

The rule changes in Parts 50⁶ and 72 that are the subject of this analysis are as follows:

Definitions: Rule previously did not contain definitions, and the appropriate interpretation of the rule language of "change," "facility as described..." and other phrases has not been stated in any

⁶The NRC had included similar revisions to Appendices A and B to Part 52 in the proposed rule. These appendices are the design certification rules for the ABWR and system 80+ standard reactor designs, respectively. In light of a rulemaking plan to review Part 52 for improvements, and the lack of current licensees who would be able to use the authority provided to make changes to a plant-specific design control document, the Commission has decided to defer any changes to Part 52. However, the discussion in this regulatory analysis is also applicable to such licensees.

NRC positions. (Some information existed in inspection manual procedures but was not comprehensive).

definition of "change" as a modification, addition or removal from the facility or procedures that affects design function, method of performing or controlling a function, or a method of evaluation that demonstrates intended functions are accomplished.

definition of "facility, as described in the final safety analysis report (as updated)" as including the structures, systems, and components, as well as design and performance requirements, evaluations or methods of evaluation which demonstrate that functions are accomplished.

Definition of "procedure as described in the FSAR (as updated)" as those procedures that contain information about how SSC are controlled or operated.

Definition of "tests or experiments not described in the final safety analysis report (as updated)" as being any activity where any SSC is used in a manner outside the reference bounds or inconsistent with the safety analyses in the FSAR.

Criteria for when prior NRC approval is needed (replacing current § 50.59(a)(2) criteria)

If Change, test, or experiment would:

- Result in more than a minimal increase in the frequency of an accident previously evaluated in the final safety analysis report (as updated)
- Result in more than a minimal increase in the likelihood of a malfunction of a structure, system or component important to safety previously evaluated in the FSAR (as updated)
- Result in more than a minimal increase in the consequences of an accident previously evaluated in the FSAR (as updated)

- Result in more than a minimal increase in the consequences of a malfunction of a structure, system or component important to safety previously evaluated in the FSAR (as updated)
- Create the possibility of an accident of a different type from any previously evaluated in the FSAR (as updated)
- Create the possibility of a malfunction of an structure, system or component important to safety with a different result from any previously evaluated in the FSAR (as updated)
- Result in a design basis limit for a fission product barrier being exceeded or altered
- 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.

For facilities licensed under Part 72, the rule changes include the above revisions, as well as new requirements for Certificate of Compliance (CoC) holders that specify conditions under which certificate holders can make changes to a spent fuel storage cask design, either by seeking NRC approval, or without NRC approval if the specified criteria in § 72.48 are met. The final rule also establishes requirements for FSAR updating for CoC holders to reflect effects of changes made either under the authority of § 72.48 or for changes made under the provisions of sections §§72.244 and 72.246 for amendment of the certificate. Other clarifying and conforming changes in Parts 50 and 72 are also involved.

In addition, the final rule reduces the frequency of reporting of changes via the summary report for all facilities, and for submittal of FSAR updates for Part 72 facilities.

Alternative Approaches

The following three alternatives were evaluated:

(1) No action: Under this alternative, the NRC would not proceed with rulemaking or other action to address the problem. Existing differences in interpretations between the NRC and the industry would be resolved on a case-by-case basis. Licensees would have to follow the existing rule requirements (such as the criterion for “consequences may be increased”), which are currently viewed by the NRC and licensees as too restrictive. Thus licensees would be required to seek license amendments for changes that meet the criteria in the existing rule.

(2) Issue Guidance: Under this alternative, the NRC would issue guidance that provides its interpretation of the existing rule language, on the basis of NUREG-1606 and its resolution of public comments. This alternative would resolve the differences in interpretation, but would maintain the existing rule requirements, which are currently viewed as being too restrictive. Moreover, guidance would not have provide the level of regulatory stability as rulemaking.

(3) Rulemaking: Under this alternative, the NRC would conduct a rulemaking to modify the criteria that result in changes requiring unnecessary review and approval. As part of the rulemaking process, the NRC would also establish definitions for terms used in the rule to add clarity and provide regulatory stability. Completion of rulemaking would enable NRC to endorse (possibly with limited exceptions) industry guidance that has been widely used by licensees.

Evaluation of Values and Impacts

NO ACTION

Values

The "no action" alternative does not resolve the difference in interpretation in the existing regulations. Rather than settling issues on a generic basis, individual instances would be debated as they arise through inspection and enforcement activities. Thus, there are no "values" associated with this action.

Impacts

The impacts are the regulatory instability associated with these unresolved differences and the expenditure of NRC and licensee resources to debate the merits of these specific cases, and to process amendments for changes that meet the requirements under the existing language, but that would not under revised language. Further, the restrictive rule requirements may be inhibiting licensees from implementing changes that are overall improvements, but for which the costs associated with a license amendment lead the licensee not to implement them.

ISSUANCE OF GUIDANCE

Values

The value of issuing guidance would be to clearly establish how specific aspects of the rule should be interpreted, which should reduce the number of instances in which the licensee and the NRC staff reach different conclusions about whether changes require approval.

Impacts

The impacts of this alternative could be substantial. Reviewers of the draft NUREG commented that issuing guidance that is consistent with the existing rule language would have a large impact on implementation of the change control process. These reviewers stated that the proposed guidance would result in many changes of little safety significance being deemed to require NRC approval before implementation, so that either the licensee would not proceed with a change that might be an overall safety improvement, or that both NRC and licensee resources would be used to review changes with little significance to safety. Thus, the impacts on the NRC and licensees would be at least as great as those for “no action,” and would also involve costs for finalization of guidance as well as for revision of procedures and training (see rulemaking alternative).

RULEMAKING

Values

The values of the rulemaking are that there would be clearer and more consistent interpretation between the NRC and licensees regarding 10 CFR 50.59 (and 10 CFR 72.48). NRC and licensee resources can be directed at issues of safety significance, as represented by those that would meet the revised evaluation criteria. Further, the process would be more efficient in that only those changes with more than a minimal change in probability or consequences, or that create a malfunction with a result not previously evaluated, and thus those changes of most

potential impact on risk, would require prior NRC approval. Since changes involving more than minimal increases in probability or consequences or that exceed design basis limits for fission product barriers (or involve TS) would still require prior NRC approval, there is no adverse impact on public health and safety.

In addition, the NRC expects that the licensees will experience some cost savings as follows:

1) the greater capability to perform screenings for some changes rather than performing full evaluations. The amount of licensee resources necessary for a screening is significantly less than for a full evaluation because of the documentation and independent review requirements for evaluations.

2) the ability to implement certain changes without prior NRC approval under the final rule that they are not be able to under the existing rule requirements. Implementing changes without processing a license amendment saves licensee resources from both the costs associated with preparing the application, and the fees for the NRC review time for the amendment. In addition, the schedule for implementation is within the licensee's control, rather than subject to NRC's review schedule.

3) fewer disputed enforcement issues. There have been several cases over the last several years where the NRC has concluded that a licensee did not fully comply with the rule as written. Licensees have been required to respond to such violations, take corrective actions, or in some instances have disputed the violation. All of these actions

involve resources that may no longer need to be expended if the threshold for review are clarified and revised as in the rulemaking.

4) a reduction in the required frequency of reporting. This may be a cost savings for some licensees.

The commenters on the proposed rule were generally supportive of rulemaking to resolve the differences in interpretation between the industry guidance and the NRC views, as well as of the stated objectives of the rulemaking as allowing changes with only “minimal” increases in probability or consequences being implemented without prior approval.

Impacts

The rulemaking process requires NRC resources to conduct rulemaking activities, issue guidance (either NRC guidance or endorsement of industry guidance) and conduct staff training. This is estimated at 3 full-time equivalent staff (FTE) (for rulemaking and guidance) and 4 FTE (for training).

The NRC resources needed for oversight of licensee activities following completion of this rule change is not expected to change from the current level in the inspection program as a result of the rule change. (Inspection of licensee implementation of §50.59 and § 72.48 is already in the core inspection program. Any changes to the level of effort would be on the basis of broader decisions about the NRC inspection program, not as a result of the revisions to the rule). Some slight reduction in NRC resources may result from those license amendments that do not require

processing with the revised criteria, as well as for handling violations of the existing requirements but which are not of significance.

Continuing licensee costs would be those associated with conducting evaluations and recordkeeping and reporting, which are expected to be less than existing costs of the current rule requirements. The staff notes that the rule changes are more consistent with industry guidance that is already commonly used by licensees than are the present rule requirements. The revised criteria provide more flexibility for licensees to perform screening reviews and to make certain changes without obtaining a license amendment. These provisions apply only to changes, tests or experiments that a licensee proposes to make in the future.

There would be a one-time impact on licensees to revise their guidelines and train personnel. The staff estimates that about 100 persons per power reactor facility may need training. Costs for procedure changes and training are estimated to be \$148,000 per power reactor facility. The implementation costs for other facilities (non-power reactors, Part 72 facilities and certificate holders) are estimated as being substantially less. The impacts are expected to be smaller for the fuel storage facilities because of the simpler operations, smaller number of changes projected and fewer personnel involved (Also since the licensees of Part 72 facilities are also in most cases, also Part 50 licensees, training for both rule changes may be simplified). The impacts for non-power reactors are also expected to be less than for power reactors for similar reasons. No facility downtime is involved in order to implement the revised requirements of the rule.

BACKFIT ANALYSIS

A backfit analysis is required for agency actions that impose a backfit. Backfitting is defined in 10 CFR 50.109 as follows:

the modification of or addition to systems, structures, components, or design of a facility
... or the procedures or organization required to design, construct or operate a facility;
any of which may result from a new or amended provision in the Commission rules or the
imposition of a regulatory staff position interpreting the Commission rules that is either
new or different from a previously applicable staff position.

DISCUSSION

The NRC has evaluated the proposed changes under the backfitting requirements in § 50.109 and § 72.62. These rule changes are not regarded to be backfits as defined in Section 50.109(a)(1) and Section 72.62(a), as applicable. Accordingly, a backfit analysis applicable to these changes has not been prepared. However, the staff has prepared this 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. This analysis provides for a disciplined approach for evaluating the impacts of the proposed changes, which satisfies the underlying purposes of the backfitting requirements in §50.109 and § 72.62.

Changes to Section 50.59

Section 50.59 defines the circumstances under which holders of nuclear power plant operating licenses may make changes to and conduct tests at their facilities without prior NRC review and approval. 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 primarily⁷ for the purpose of providing additional flexibility to licensees to make changes and conduct tests without having to obtain prior NRC review and approval. Thus, the criteria allow “minimal increases” instead of being limited to “may be increased.” Another relaxation is the revision to the criteria for malfunction of a different type to malfunction with a different result, which will allow uses of new technology that might have different failure modes, as long as the effects of the failure have been previously evaluated. Each of these changes constitute permissive relaxations⁸ 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

⁷In 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.

⁸ “Permissive” relaxations are relaxations which licensees may voluntarily choose (but are not compelled) to comply.

replacements for the superseded § 50.59(a)(2)(iii) criterion on “margin of safety.” These two criteria together, in place of a criterion on “margin of safety” explicitly cover those margins that the NRC believes are important to address in the evaluation process—the first being the margins that exist in the limits to be met, and the second being the margins that exist as a result of the conservatisms in the methods use to demonstrate that requirements are met. The replacement criteria were 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 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 overall regulatory scheme in the revised §50.59 which relax and clarify the thresholds for licensee-initiated changes and tests requiring prior NRC review and approval before their implementation. In sum, the NRC 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 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 considered 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 Section § 72.62. The final rule requirements for records, reports, and SAR updating would not impose any burden unless the CoC holder exercised the authority to make changes under either §§ 72.48 or 72.244 and 72.246. In sum, the NRC has determined that the changes to Part 72 constitute permissive relaxations to existing criteria in §72.48, or are changes that are not subject to backfitting considerations under § 72.62.

Information Collection Requirements

As discussed in detail in the NRC's supporting statement for this rulemaking as submitted to the Office of Management and Budget (and available at the NRC's public document room or through the NRC's web site), the NRC concludes that there will be at most a slight increase in recordkeeping and reporting requirements associated with the rule changes. The change in information collection burden is associated with a one-time change to procedures and training on

the aspects of the rule that are being revised. Certain other aspects of the rulemaking will result in a reduction in recordkeeping and reporting requirements on a continuing basis.

Decision Rationale

The NRC plans to proceed with the rulemaking on the basis of consideration of the alternatives, the value/impact analysis, the estimated costs and projected burden reduction, the small change in information collection requirements, as well as the public comments received that were supportive of rulemaking along the lines outlined in the proposed rule.

In summary, NRC concludes that the rule language as written poses unnecessary burden by requiring licensees to seek license amendments for certain changes with extremely low potential to impact plant safety. In addition, the rule is not consistent with certain interpretations that the industry has been following (e.g., for discernable increases in consequences), and thus, disagreements have arisen in inspection and enforcement of particular changes that a licensee may have made. In view of the implementation problems and licensee burden associated with existing rule language of "may be increased," the staff proposes to proceed with the rulemaking to establish "minimal increase" criteria. The other rule changes provide additional clarification on the criteria and definitions to ensure that potential changes affecting the design bases and safety analyses are reviewed by the NRC, and that the NRC can continue effective oversight of changes that a licensee may make without NRC approval.

The other alternatives (no action, issue guidance) would not achieve the objectives of consistency between implementation guidance and rule requirements, and of reducing the

burden associated with unnecessarily obtaining prior NRC approval for changes that do not warrant such review.

Ms. Fawn Shillinglaw

1952 Palisades Drive

Appleton, Wisconsin 54915

SUBJECT: FINAL NRC ACTION ON PETITION FOR RULEMAKING PRM-72-3

Dear Ms. Shillinglaw:

In your letters addressed to Chairman Jackson dated December 9 and 29, 1995, you filed a petition for rulemaking requesting the Nuclear Regulatory Commission (NRC) to amend its regulations regarding the control and use of safety analysis reports for spent fuel dry storage casks under 10 CFR Part 72. On March 14, 1996, the petition was docketed by the NRC as PRM-72-3. In addition, in a letter dated April 15, 1996, you provided supplemental information on your petition. On May 14, 1996, the NRC published in the Federal Register a notice of receipt of your petition (61 FR 24249).

Specifically, you requested the NRC to amend its regulations which govern independent storage of spent nuclear fuel in dry storage casks to require that: (1) the safety analysis report (SAR) for a cask design fully conform 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 must 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. Your supplemental letter 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 has considered the issues you raised in your petition and has determined that issues (1), (2), and (3) above are being granted in part, and issue (4) is being denied. Each of the issues raised in your petition is addressed in a final rule amending 10 CFR Parts 50 and 72, "Changes, Tests, and Experiments." The enclosed Federal Register Notice on this final rule

Ms. Shillinglaw

-3-

contains a discussion of the issues raised in your petition and the Commission's resolution of each of those issues (see subheading 0.2 "Petition for Rulemaking (PRM-72-3)"). This notice constitutes the Commission's final action on your petition

Sincerely,

William D. Travers

Executive Director for Operations

U. S. Nuclear Regulatory Commission

Docket: PRM-72-3

Enclosure: Federal Register Notice

Ms. Shillinglaw

-4-

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Sincerely,

William D. Travers

Executive Director for Operations

U. S. Nuclear Regulatory Commission

Docket: PRM-72-3

Enclosure: Federal Register Notice

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The Honorable Joe Barton
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington D.C. 20515

Dear Mr. Chairman:

In the near future, the Nuclear Regulatory Commission (NRC) intends to publish in the *Federal Register* the enclosed final amendments to the Commission's rules in 10 CFR 50 and 72. This final rule amends the NRC's regulations relating to the authority for licensees of production or utilization facilities, such as nuclear reactors, and for independent spent fuel storage facilities, to make changes to these facilities, or to procedures, and to conduct tests and experiments, without prior NRC approval, when certain conditions are met. The rule amendments clarify which changes, tests, or experiments require evaluation, and revise the criteria that determine when NRC approval is needed before such changes can be implemented. The final rule amendments also add definitions for terms used in the rule that have been subject to differing interpretations. Changes in other parts of the regulations that use the same criteria and terminology for these types of facilities are also included.

Sincerely,

-2-

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:

Federal Register Notice

cc: Representative Ralph Hall

The Honorable Joe Barton
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington D.C. 20515

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The Honorable James M. Inhofe, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

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-7-

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:

Federal Register Notice

cc: Senator Robert Graham

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Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:

Federal Register Notice

cc: Senator Robert Graham

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***NRC REVISES ITS REGULATIONS
FOR MAKING CHANGES TO LICENSED FACILITIES***

The Nuclear Regulatory Commission is amending several sections of its rules that define the conditions under which nuclear power plants and facilities for independent storage of spent nuclear fuel and high-level radioactive waste may make changes to their facilities or procedures, or conduct tests and experiments without prior NRC approval.

Current NRC regulations (Parts 50.59 and 72.48 of Title 10 of the Code of Federal Regulations) permit such licensees to make these changes and to conduct such tests if they do not present what the regulations call an "unreviewed safety question" or require a change in the technical specifications of the facility's license.

The rule change came about as the result of an NRC staff review of existing regulatory processes, directed by the Commission because of concerns about so-called "50.59" changes at some plants. The staff concluded from this review that, although existing regulations have generally given licensees needed flexibility, problems have arisen from differing rule interpretations by the NRC staff and the nuclear industry.

In drafting the changes, the NRC staff has considered public comments received in response to a proposed rule published last October. The amendments will clarify specifically which changes, tests or experiments require evaluation, and revise the criteria that determine when NRC approval is needed before such changes can be made. The rule also adds definitions for terms that have been subject to differing interpretations.

The new rule will become effective 18 months from the date of publication for Part 50 licensees and for Part 72 facilities and certificate holders. A copy of the rule will be posted on the NRC Homepage at: www.nrc.gov/NRC/rule.html.

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