

July 10, 1998

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: PROPOSED RULEMAKING ON 10 CFR PARTS 50, 52 AND 72 REQUIREMENTS CONCERNING CHANGES, TESTS AND EXPERIMENTS AND STAFF RECOMMENDATIONS ON CHANGES TO OTHER REGULATIONS AND ENFORCEMENT POLICY

PURPOSE:

This paper requests Commission approval to publish, for a 90 day public comment period, a proposed rulemaking that would revise 10 CFR 50.59 and related provisions in Parts 50, 52 and 72 concerning the processes controlling licensee changes, tests and experiments for production and utilization facilities and for facilities for independent storage of spent nuclear fuel and high-level radioactive waste.

SUMMARY:

The staff is proposing rulemaking on 10 CFR 50.59 (and related sections) to clarify which changes require evaluation by the licensee and the criteria that determine when NRC approval is needed for changes. This paper discusses: (1) the background, (2) the specific areas where rulemaking is proposed and (3) other information, including (a) resolution of comments on draft NUREG-1606 (Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59), and (b) industry initiatives in this area. This paper also discusses staff recommendations for changes to other parts of the regulations, and for handling violations of 50.59 and 72.48, including staff plans for exercise of enforcement discretion, while rulemaking is underway.

BACKGROUND:

Section 50.59 of Title 10 of the *Code of Federal Regulations* (10 CFR 50.59) defines the conditions under which reactor licensees may make changes to their facilities or make changes to procedures or to conduct tests or experiments without prior NRC approval. In general, such changes, tests, or experiments may be carried out unless they would involve a change to the technical specifications or an unreviewed safety question (as defined in 50.59(a)(2)). This regulation is a regulatory threshold that determines when prior approval is needed, not a safety or acceptability determination on the merits of the change, test or experiment. Similar language exists in section 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.

CONTACTS: Eileen McKenna, NRR
(301) 415-2189
Naiem Taniouss, NMSS
(301) 415-6103

In SECY-97-035, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59," dated February 12, 1997, the staff forwarded to the Commission proposed regulatory guidance on the implementation of 10 CFR 50.59. The staff guidance was published for public comment on May 7, 1997 (62 FR 24947) as draft NUREG-1606. In this NUREG, the staff discussed its implementation positions on a number of topics related to 50.59, and how the staff's positions compare to those in industry guidance (NSAC-125, published in 1989).

In response to the *Federal Register* notice, many comments (summarized in Attachment 1 to SECY-97-205) were submitted that voiced strong opposition to the proposed staff positions. The staff has conducted a more detailed review of the comments. Attachment 1 to this paper provides a summary of the NUREG-1606 positions, the nature of the comments, and the proposed resolution; this document is being placed in the Public Document Room. The staff concludes that some issues can be resolved through guidance, while in other areas, rulemaking is the appropriate means. The staff does not plan to issue a final version of the NUREG.

In its Staff Requirements Memorandum (SRM) on SECY-97-035, the Commission also directed the staff to take other actions related to 50.59. In SECY-97-205, the staff's response to this SRM, the staff recommended rulemaking on 50.59. The Commission approved the staff recommendation to initiate rulemaking in its SRM on SECY-97-205 dated March 24, 1998. In a memorandum to the Commission dated May 27, 1998 (COMSECY-98-013), the staff provided its recommendations on certain aspects of the proposed rulemaking. The Commission also directed the staff to consider conforming changes for other parts of the regulations. This paper forwards the proposed rulemaking package which includes changes to Part 72 that parallel those for 50.59, with some additional changes that are described below. The staff recommendations concerning changes to other parts of the regulation are also included with this paper.

In SECY-97-205, the staff proposed to review the existing enforcement policy for 10 CFR 50.59 violations to determine if revisions were appropriate. The results of the staff's review on the enforcement policy are also discussed below. Finally, staff recommendations on guidance for safety analysis report updating were provided in SECY-98-087, dated April 20, 1998.

DISCUSSION:

1.0 TOPICS COVERED IN THE PROPOSED RULEMAKING

The staff recommends publishing for public comment a proposed rule that would revise certain provisions of 50.59 to clarify the circumstances under which prior approval is needed. A number of definitions would be added to the rule in a new paragraph (a) with other paragraphs renumbered, and the criteria for prior approval would be modified. In addition to changes to the process requirements of the rule, the staff is also proposing to rearrange certain provisions of the rule to create a more logical structure. The proposed rule changes are summarized in the paragraphs below. [Attachment 2](#) is the proposed *Federal Register* notice containing the Supplementary Information and the proposed rulemaking. [Attachment 3](#) is the draft regulatory analysis.

1.1. Organization of the Rule Requirements

The proposed organizational changes are as follows:

(a) Applicability

In existing Section 50.59, language concerning applicability of the rule to different facilities is contained in three different paragraphs. These facilities are: (i) production and utilization facilities (including power and non-power reactors) authorized to operate, and (ii) reactors (both power and non-power) which have permanently ceased operations. The staff recommends placing all of these provisions in one paragraph that is clearly titled "Applicability." As discussed in SECY-98-075, the staff is evaluating whether to recommend different evaluation criteria for 50.59 evaluations for reactors undergoing decommissioning.

(b) Form of prior Commission approval

Paragraph 50.59 (a) refers to the need for prior Commission approval of changes, tests, and experiments under certain conditions, but the method of receiving that approval is not discussed until paragraph (c), which states that the licensee shall submit an application for amendment under 50.90. The staff proposes to combine these two paragraphs and to revise the language to more clearly state that a licensee must apply for *and obtain* a license amendment, pursuant to 50.90, before implementing such changes, tests, or experiments.

(c) Criteria for needing approval and Unreviewed Safety Question (USQ) designation

The staff proposes to remove reference in the rule to "unreviewed safety question" and instead to refer to the need to obtain a license amendment. The staff believes that the terminology of "USQ" causes confusion about the purpose of the evaluation using the criteria in 50.59. To avoid confusion between the determination of safety from the determination of the need for approval, the staff proposes to revise 50.59 to delete use of the term "unreviewed safety question" and instead to list the criteria (in new 50.59(c)(2)) that require prior Commission approval, in the form of a license amendment. Conforming changes are proposed in other rule sections which presently use the term USQ for reactors, including 50.66, 50.71(e), the Part 52 Design Certification rule appendices, and 72.212(b)(4). As part of this change, the staff would also propose to simplify the statement of the existing criteria by breaking the present three sentences into seven. Even if the Commission decides not to delete the terminology of USQ, the staff would still recommend that the seven statements be itemized so they are more easily understood. Changes to the criteria themselves are discussed in the sections below.

The staff would simplify 50.59 by moving the provision stating: "The holder of a license... who desires (1) a change to its technical specifications... shall submit an application for amendment of his license pursuant to 50.90" from existing 50.59(c) into 50.90, which contains the requirements for applications for amendments to a license.

1.2 Change to the facility as described in the safety analysis report (SAR)

Section 50.59 states that "changes to the facility as described in the safety analysis report" must be evaluated to determine whether prior approval is needed before a change is implemented. The staff concludes that "change" should be understood to mean the modification of an existing provision (e.g., systems, structures or components (SSC), procedure, design requirement, analysis method or parameter), additions (e.g., new systems or structures, procedural steps) and removals (physical removals or non-reliance on a system to meet a requirement).

Differences in interpretation have occurred regarding whether changes that do not actually change the physical plant (the "hardware") require a 50.59 evaluation. As an example, consider a change being made to the basis (documented in the SAR) for demonstrating adequacy of the facility without a physical change to the facility. Such changes might include changes to evaluative methods, acceptance standards, procurement specifications or other information for a SSC described in the SAR. The staff believes that 50.59 applies to the requirements for design, construction and operation, and the safety analyses for the facility that are documented in the SAR. Therefore, the staff concludes that changes to this information would constitute a change to the facility as described in the SAR. Therefore, the staff recommends adding definitions to 50.59 of "change" and of "facility as described in the safety analysis report (as updated)."

1.3 Change to the procedures as described in the safety analysis report

The staff proposes to provide a definition of "Procedures as described in the final safety analysis report (as updated)." In this case, procedures would be defined to include information about how systems are operated and controlled, such as assumptions about operator action and response times, and information on conduct of operations that are encompassed by the definition. Further, the staff notes that 50.34(b) states that the final SAR is to contain the managerial and administrative controls to be used to meet Appendix B (Quality Assurance), and plans for coping with emergencies, per Appendix E. Quality assurance and emergency planning program requirements are subject to the change control provisions of 50.54(a) and

50.54(q), respectively. It could be inferred that changes to quality assurance or emergency plans would require both a 50.59 evaluation and a 50.54 [either (a) or (q)] evaluation. The staff recommends eliminating any implication that duplicative reviews are required by revising 50.59 to specifically remove changes to procedures from the scope of 50.59 when other applicable regulations establish change control processes, through clarifying language in paragraph (50.59(c)(1)).

1.4 Tests and Experiments not described in the safety analysis report

Section 50.59 also discusses the conduct of tests or experiments not described in the SAR. "Test" is subject to many meanings including both routine verifications of function, and more unusual evolutions. Therefore, the staff recommends that a definition of "tests and experiments not described in the final safety analysis report (as updated)" be provided that would allow screening (without evaluation against the review criteria) of tests and experiments that fall within the scope of what was evaluated by the final safety analysis report, even if the test itself was not actually described.

1.5 Scope (Safety Analysis Report)

One of the issues discussed in SECY-97-035 and SECY-97-205 was whether the scope of section 50.59 should be revised (e.g., by referring to "the current licensing basis" instead of to the safety analysis report). A change in scope would resolve the variance of evaluations arising from the current spectrum of quality and content of plant-specific SARs. After careful consideration, however, the staff is not proposing any change to the scope in this proposed rulemaking. The staff notes that there are actions underway that are designed to enhance the completeness and accuracy of the final safety analysis report (as updated), and to improve control of certain licensee commitments. Thus, the staff sees no current need to expand the scope of 50.59 beyond the SAR. As directed by the March 24, 1998, SRM, the staff will provide a recommendation in February 1999 on whether to revise the scope of 50.59.

In developing the proposed rule changes on "as described," however, the staff did note the variation in references to the SAR in affected sections of Part 50. To provide consistency and better understanding as to which document the requirements pertain, the staff is also proposing a definition of final safety analysis report (as updated), and consistent use of this term. The above discussed rule changes reflect this proposal.

1.6 Probability of occurrence or consequences of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report may be increased

The current rule language states that an unreviewed safety question exists when 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. Many of the commenters on the staff's proposed positions viewed the position on "may be increased" as overly restrictive. The staff concludes that in light of the qualitative consideration of probability during plant licensing, a minimal increase in probability would not impact the basis for the NRC's conclusions on acceptability. In addition, the precision of evaluation (and reporting in the SAR) of radiological consequences for accidents is such that minimal increases in consequences would also not be of concern with respect to the facility compliance with requirements to limit offsite exposures. Therefore, the staff concludes that a "minimal increase" standard will provide reasonable assurance that those changes that would affect the staff's basis for licensing are identified as requiring prior approval.

Consistent with the March 24, 1998, SRM, in the rule package, the staff proposes to revise paragraph (a)(2)(i) of the (existing) rule by rewording the criteria from "may be increased" to "would result in more than a minimal increase." The staff notes that "minimal increases" needs to be carefully distinguished from a "significant increase in probability or consequences" (the criteria in Section 50.92(c)(1) for a no significant hazards determination). Accordingly, the staff has prepared guidance to explain how "more than a minimal increase" should be applied; to the extent possible, it references industry guidance in NEI 96-07. This guidance is discussed in the FR notice, and will be included in regulatory guidance.

1.7 Possibility of an accident or malfunction of a different type from any previously evaluated in the safety analysis report may be created

The staff also proposes to modify existing paragraph 50.59 (a)(2)(ii) by replacing "may be" with "is" [created]. Therefore, the first part of the (now separate) criteria would be stated as if a change, test or experiment would "create the possibility for an accident of a different type than any evaluated previously in the final safety analysis report (as updated)." With this revised rule language, a license amendment would be needed for a change only if the licensee reasonably concluded that the possibility of an accident of a different type is created rather than under the current rule, which would require a license amendment if the licensee is uncertain or unable to reasonably conclude that a new accident of a different type is not created.

As part of this change, the staff would propose three changes to the existing 50.59(a)(2)(ii), concerning malfunctions of a different type. The first is revising "may be created" as above. The second is inserting the words "of equipment important to safety." The rule itself does not provide this characterization within paragraph (ii), but it is included in paragraph (i); it has generally been inferred that the statement in (ii) is an abbreviated version of that in (i). A review of the 1968 rulemaking that revised 50.59 did not disclose any discussion suggesting that the Commission intended to distinguish between the (a)(2)(i) and (a)(2)(ii) criteria. Therefore, the staff proposes to actually include the words to eliminate any doubt.

Finally, the staff proposes to accept one of the proposed rule language changes offered by NEI, concerning a malfunction with a different result being created. The staff recognizes that during its safety and licensing reviews, equipment malfunctions are generally postulated as potential single failures to evaluate plant performance. Thus, the focus of the NRC review was on the result, rather than the cause/type of malfunction. Unless the equipment would fail in a way not already evaluated in the safety analysis, there is no need for NRC review. The staff concludes that this proposed change is responsive to the direction provided in the March 24, 1998, SRM concerning accidents or malfunctions with minimal safety impact.

1.8 Margin of safety as defined in the basis for any technical specification is reduced

The current rule would require a licensee to conclude that prior approval is required if the 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 TS," have been the subject of differing interpretations because the rule is not clear about what constitutes (1) a margin of safety, or (2) a basis for any technical specification, in the context of 50.59. In COMSECY-98-013, the staff indicated that the proposed rule language would require licensee evaluations of whether "acceptance limits" (established during the licensing review) would be exceeded. Upon further review, the staff concluded that there is a need to first define clearly which margins were intended to be preserved by this criterion. Therefore, the staff is now recommending an alternative approach. By the specific reference to "basis for any technical specification," the staff believes that a reasonable interpretation of the rule's intent was the preservation of the margins in the analyses that established the TS requirements, *viz*, the minimum plant performance conditions and configurations (which are the TS limiting conditions for operation, limiting safety system settings and safety limits).

Because 50.59 requires prior NRC approval for a change to the TS, the staff concluded that a change that could invalidate the basis upon which the TS values were established should also receive prior approval. Accordingly, the staff recommends that the Commission adopt rule language that would state that for 50.59 reviews, a reduction in margin of safety occurs when the input assumptions (plant performance conditions and configurations), analytical methods or acceptance conditions, criteria or limits for those analyses in the final safety analysis report (as updated) that established the TS are altered in a nonconservative direction, as a result of a change, test or experiment. The staff notes that focusing on the safety analyses underlying the TS clarifies the scope of changes that would require NRC approval, and may narrow the range of such changes compared to current practice. Further, the staff believes that this approach compares favorably with the draft proposals concerning scope offered by NEI during the June 4, 1998, Commission meeting (and in the meeting with the staff summarized in the attachment to COMSECY-98-013). The staff acknowledges that it would be beneficial to have a "nonzero" increase for margins, envisioned as more comparable to "negligible" than to "minimal", to avoid the need to review truly trivial changes. The view is that this might focus on the precision of the parameters and analyses. For instance, the Commission may want to interpret "altered in a nonconservative manner" to mean "where a change in margin is so small or the uncertainties are such that it cannot be concluded reasonably that the margin actually has changed, the change need not be considered a reduction in margin of safety". However, a more substantive reduction in margin would pose great difficulties in view of the wide variety of parameters and conditions that are involved. In the FR notice, the staff is proposing to specifically seek comment on ways in which some flexibility could be provided, without affecting the integrity of the technical specifications.

1.9 Safety Evaluation

The staff proposes to delete the word "safety" in referring to the required evaluation as to whether the change requires NRC prior approval. Such changes will make it clearer that the review has a regulatory purpose, with respect to implications for the licensing basis, not for a safety determination. Conforming changes are proposed for 50.71(e), and Part 52, Appendices A and B.

1.10 Reporting and Recordkeeping Requirements

The staff is recommending a change to the record retention requirement such that records are maintained until the termination of a (renewed) license issued pursuant to 10 CFR Part 54. For reporting, the staff is proposing to revise the reporting requirement in 50.71(e), by requiring licensees to provide information to enable the staff to monitor potential cumulative impacts for "minimal" increases. Specifically, the staff proposes to define that "effects of" includes, for purposes of the FSAR update report, the effects on probabilities and consequences.

1.11 Part 72 Changes

In Part 72 the Commission is proposing to make changes to 72.48 to conform with those made to 50.59. In addition to the proposed changes to 72.48, the staff recommends changes in other sections of Part 72 to include provisions to accommodate potential amendments of Certificates of Compliance (CoC). Regulations in this area are necessary to provide requirements for certificate holders in instances where a proposed change does not meet the tests of 72.48, and an amendment to the CoC is necessary. The staff notes however, that for dual-purpose spent fuel storage casks (i.e., casks which have been issued CoCs for both transportation and storage under Part 71 and 72), no regulation equivalent to

72.48 exists in Part 71. Consequently, a certificate holder could make changes to the design of a spent fuel storage cask under the authority of 72.48 (i.e., without prior NRC approval); however, if the change also affected the transportation aspects of the cask's design, then NRC prior approval and amendment of the transportation CoC would be required before the cask could be used to transport spent fuel.

The staff proposes to revise the definition for *independent spent fuel storage installation* (ISFSI) to remove the tests for evaluation of the acceptability of sharing common utilities and services between the ISFSI and other facilities. The existing requirement in 72.24(a) would be revised to reference shared common utilities and services in the applicant's assessment of potential interactions between the ISFSI and another facility.

Changes to record keeping requirements would include the clarification that records required by 72.48 shall also include determinations that significant increases in occupational exposure or unreviewed environmental impacts did not exist, such that a license amendment would have been required. (The existing language linked the written evaluation only to the "unreviewed safety question" determination, and thus did not explicitly require record keeping for the determinations of whether the change would cause a significant increase in occupational exposure or a significant unreviewed environmental impact). Certificate holders would also be required to keep records of those changes made pursuant to 72.48.

For reporting, the staff proposes to revise 72.70 (SAR updating) to require the updates to reflect changes in procedures and to provide more guidance on the update submittal. Further, new 72.248 would establish requirements for certificate holders to submit updates to the safety analysis report for an approved cask design. Some of these changes are being proposed to conform with the proposed rulemaking sent to the Commission in SECY-98-113.

2. INDUSTRY PROPOSAL

NEI submitted proposed implementation guidance for 50.59, NEI 96-07, "Guidelines for 10 CFR 50.59 Safety Evaluations," in a letter dated October 31, 1997. In this submittal, NEI also reported that the nuclear utilities had voted to modify their existing review processes to be consistent with the NEI 96-07 guidance by June 30, 1998. The staff reviewed NEI 96-07 for adequacy with respect to existing rule language and as a guidance document to accompany the rule changes being contemplated by the staff. The revised version resolves some, but not all, of the areas where the staff and industry guidance has differed. Staff comments on NEI 96-07 were sent to NEI in a letter dated January 9, 1998.

Further, in a letter dated November 14, 1997, NEI offered proposed rule language that, if adopted, they believe would permit the NRC to endorse their guidance document. In the proposed *Federal Register* notice seeking comment on the staff's proposed rule, the staff proposes to ask for comment on their proposal as well. The proposed rule language in [Attachment 2](#) incorporates some of the changes proposed by NEI.

3. PARALLEL CHANGES TO RELATED REGULATORY REQUIREMENTS

In its SRM dated March 24, 1998, the Commission directed the staff to be cognizant of language similar to 50.59 that may appear in other parts of the regulations. The staff reviewed Parts 20, 30, 31, 33, 34, 35, 36, 39, 40, 60, 61, 71, 72 and 76, to identify those with requirements similar to 50.59, to consider whether conforming changes should be considered. The staff has identified that existing Parts 35, 36, 60, 61, 72 and 76, and proposed Parts 41, 63, and 70 have (or will have) requirements that allow licensees to make changes similar to those permitted in 50.59, although these changes vary in complexity for different licensees. At this time, the staff recommends that: (1) Part 72 be revised concurrently with the ongoing proposed 50.59 revision, (2) changes similar to 50.59 not be incorporated into other existing parts, and (3) changes similar to 50.59 will be evaluated for Parts 41 and 63. The staff recommendations are discussed in more detail in [Attachment 4](#).

4. ENFORCEMENT POLICY

As discussed in SECY-97-205, and in the March 24, 1998, SRM, changes to enforcement policy will be needed as a result of the proposed rulemaking on 50.59. The changes primarily apply to the examples of severity levels of violations that refer to unreviewed safety questions (see Supplement I - Reactor Operations, B.4, C.10-14, and E). If the changes proposed by the staff are implemented, these references would be revised to refer to need for license amendment pursuant to the criteria in 50.59(c)(2). These changes to the policy will not be made until the rulemaking is final. At present, efforts are underway to develop examples for violations of Part 72; this effort will consider 72.48.

In addition, the staff will exercise enforcement discretion, during the rulemaking period, for violations of 50.59 that are not safety significant and do not pose regulatory concerns that warrant escalated action. The staff considered exercising discretion to not take enforcement action for violations of the existing rule that would not be violations of the proposed rule. However, such an approach would in essence implement the revised rule without completing the rulemaking. Therefore, the staff intends to reduce the severity level of violations in such instances. The Commission requested specifics regarding the nature and type of situations for which discretion will be considered. The staff plans to apply the guidance described below to violations involving 50.59 (and 72.48) while the rulemaking is in progress. The staff believes that the use of this discretion is consistent with the existing enforcement policy, which recognizes the need to exercise judgment in determining severity levels and that the existing examples are not controlling. Therefore, a revision to the policy is not needed at this time.

In considering whether to exercise enforcement discretion the staff intends to weigh the following factors:

- (i) Was the safety and risk significance of the change low?
- (ii) Would the change (had it been submitted) likely have been approved by the staff without modification and with little need for clarification (e.g., because it clearly meets established NRC guidance such as contained in Standard Review Plans)?

In cases where the licensee on its own initiative identifies and appropriately corrects the 50.59 failure, which does not reflect on current performance, discretion under section VII.B.3 of the policy may be warranted. In addition, for cases where the violation of existing rule requirements would not constitute a violation under the rule were it revised as proposed (e.g., in that it involved only a minimal increase in probability or consequences), the staff will consider treating such instances as minor violations; however, they would be documented in inspection reports because the rule is still in a proposed revision stage.

In the interest of monitoring consistency of application of this guidance during the rulemaking period, the staff intends to continue using a panel made up of representatives from OE, NRR and OGC. Following the Commission approval of the staff's guidance, the staff will issue an Enforcement Guidance Memorandum.

RESOURCES:

Total resources to conduct this rulemaking and issue the guidance (3 FTE) as well as to conduct staff training (4 FTE) are budgeted and are consistent with the latest Rulemaking Activity Plan.

CONCLUSION:

The staff has prepared a proposed rulemaking package in response to Commission direction as shown in [Attachment 2](#) for which the staff requests approval to publish for public comment. Forwarding letters to Congressional committees and a draft press release are also attached to this paper. The staff plans to develop regulatory guidance that would endorse (if possible) a modified version of NEI 96-07. Inspection guidance will also be developed.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper or to the proposed rules and notice that are the subjects of this paper. OGC notes, however, that the backfit and regulatory analysis with regard to the changes to Part 72 are currently incomplete and insufficient to support the issuance of final rules to Part 72; the backfit and regulatory analyses need to be augmented and completed before issuance of any final rule involving Part 72.

The Advisory Committee on Reactor Safeguards was briefed on the proposed rule changes on July 8, 1998. The staff also briefed an ACRS subcommittee on June 19, 1998. The Committee plans to write a letter on the proposed rulemaking during its July meeting period.

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

The Office of the Chief Information Officer has reviewed the proposed rule for information technology and information management implications and concurs in it. However, the rule amends information collection requirements that must be submitted to the Office of Management and Budget no later than the date the rule is forwarded to the *Federal Register* for publication.

RECOMMENDATION:

That the Commission:

- (1) approve publication of the proposed rule for a 90 day public comment period;
- (2) note that the staff plans to use the enforcement discretion guidance in its assessment of severity levels for violations while the rulemaking is underway.

L. Joseph Callan
Executive Director for Operations

- Attachments:
1. [Resolution of Public Comments on NUREG-1606](#)
 2. [Federal Register Notice with Statement of Considerations](#)
 3. [Regulatory Analysis](#)
 4. [Recommendations concerning rulemaking for facilities governed by the regulations in parts other than Parts 50 and 72. Letters to Congressional committees](#)
 5. [Press Release](#)
 - 6.

ATTACHMENT 1

RESOLUTION OF PUBLIC COMMENTS ON NUREG-1606

On May 7, 1997, the staff of the U.S. Nuclear Regulatory Commission (NRC) published a notice in the *Federal Register* (FR) requesting public comment on a draft of NUREG-1606, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests, or Experiments)." The following discussion summarizes the staff's analysis and proposed resolution of the public comments received in response to that request. Because of the proposed rulemaking, the staff does not presently plan to issue a final version of the NUREG.

Introduction

The staff received 48 comments filed by certain organizations, including the Nuclear Energy Institute (NEI) and various law firms, on behalf of their clients or members. Letters filed by individual utilities endorsed these comments and, in some cases, provided supplemental comments in specific areas. For instance, 26 letters stated that the commenters endorsed the NEI comments; 5 letters stated that the commenters endorsed the comments filed by the law firm of Winston & Strawn, and a few letters endorsed comments filed by both the NEI and others. Further, comments filed by the law firms of Shaw, Pittman, Potts, & Trowbridge; Winston & Strawn; and Morgan, Lewis, & Bockius, LLP, stated that they represented multiple utilities. In some instances, these factors made it difficult for the staff to precisely tabulate the number of commenters for particular topics or issues, but the staff took these endorsements into account where possible.

The following sections individually address each of the topics from NUREG-1606. In each case, the discussion repeats the staff's position (as stated in NUREG-1606) in an abbreviated form, followed by the major comment(s) received on the issue, and concludes with the staff's proposed resolution for the comment(s) received.

Topic III.A: Definition of Change

Staff Position: The staff has interpreted "change" to include any modification or replacement of something, whether temporary or permanent, with something that is not identical to the original in design requirements. Additions (e.g., new systems or structures, procedural steps) and subtractions (e.g., abandoning a system or component in place) are also changes for purposes of determining whether the facility or procedures have been affected.

In deciding whether the activity being contemplated is a change, rather than maintenance or an activity already reviewed, the licensee needs to consider questions including, but not limited to the following: (a) whether components described in the SAR are removed, or their function is altered, or substitute (i.e., not identical) components are utilized, or changes are made as the result of a maintenance activity; (b) whether the activity would affect

redundancy, diversity, separation, the probability or consequences of a loss of a non-safety system, physical interactions, seismic qualification, quality classification, missile or flooding protection, fire protection, environmental qualification, high energy line break, or masonry walls; (c) whether equipment is disabled, or a system, structure or component (SSC) is removed from service for maintenance that is part of the licensing basis but that is not addressed by TS Limiting Conditions for Operation (unless the effects were previously considered in the SAR or safety evaluation report (SER)); (d) whether the change involves lifted leads, temporary lead shielding, temporary blocks or bypasses, temporary supports or other equipment used on a temporary basis, which should be evaluated if not already considered in the SAR; (e) whether the activity requires deviation from a SAR procedure or puts the plant in a condition where it functions differently from its SAR description.

Changes to SSCs not explicitly described in the SAR also need review because they have the potential for affecting the function of SSCs which are explicitly described. Changes which alter the design, function, or method of performing the function of a SSC, as described in the SAR, are within the scope of 10 CFR 50.59.

Further, when evaluating a change, the licensee must also consider not only operation of the facility after the change is in place, but also possible effects while the change is being made.

Comment 1: Several commenters stated that functionally identical replacements (that is, replacements with a component of equivalent design requirements) should not be considered a change within in the scope of 10 CFR 50.59. Another commenter noted that functional equivalence is sometimes evaluated at too high a level, and that there are different characteristics that can affect response.

Resolution: An equivalency determination would provide the basis for not requiring NRC approval of a change, but not for whether the change itself should be evaluated.

Comment 2: Most commenters stated that removal of components from service (not subject to TS LCOs) should be governed by risk assessment provisions of the Maintenance Rule, rather than a safety evaluation in accordance with 10 CFR 50.59.

Resolution: The staff generally agrees, but notes that 10 CFR 50.65 states that "risk assessment *should* be performed." Rulemaking to change this provision to "*shall*" is under development.

Comment 3: Many commenters stated that "change" is an activity that may affect the design, function, or method of performing a function of an SSC described in the SAR. These commenters further asserted that a 10 CFR 50.59 evaluation is not needed, if a licensee's screening suggests that these attributes are not affected.

Resolution: The purpose of the evaluation (whether a screening or a 10 CFR 50.59 safety evaluation) is to determine the effects of the change. An adequate "screening" could establish that the activity does not constitute a "change to the facility as described in the SAR," such that it would not be necessary to evaluate whether an unreviewed safety question (USQ) is involved.

Comment 4: For changes to SSCs that are not described in the SAR, the screening to be performed would be to determine if the changes might affect other SSCs that are described in the SAR (not just any other SSC in general).

Resolution: This is consistent with the staff's intent.

Topic III.B: Definition of Facility

Staff Position: The staff views the term "facility" to include (1) all systems, structures, and components; (2) the requirements for their design, construction, and operation; and (3) the design bases⁽¹⁾ and safety analysis information associated with those SSCs that are described in the SAR.

Comment: Some commenters thought that the guidance which included the design requirements and safety analysis, was too broad a reading of "facility."

Resolution: The staff does not agree that the definition is too broad. The staff notes that 50.34 requires the FSAR to contain a presentation of the design bases, limits on its operation, a description and analysis of the facility with emphasis upon performance requirements, and evaluations required to show that safety functions are accomplished. The original licensing decision was based upon the margins provided by this information in the SAR, that was reviewed by the staff. Therefore, the staff concludes this definition is appropriate, and as part of the rulemaking on 10 CFR 50.59, the staff plans to clarify that the rule requires evaluation of changes to analysis assumptions and design requirements that show adequacy of the "facility," as being changes to the facility as described in the SAR.

Topic III.C: Definition of Procedures

Staff Position: The staff defines "procedures" to include those procedures outlined, summarized or completely described in the SAR and also items not specifically identified as procedures, but which define or describe activities or controls over functions, plant configurations, tasks, reviews, tests, or safety review meetings. This includes procedures on initial operations, organizational information, and modes or sequences of plant operation.

The 50.59 rule would also cover parts of emergency operating procedures for which the operator actions are described in the SAR.

Specific licensee programs, such as emergency preparedness plans, security plans and quality assurance plans have change control processes explicitly established by regulation (in 10 CFR 50.54) even though the plans may also be referenced by the SAR. These specific change control processes are considered applicable to the plans rather than the 10 CFR 50.59 process because the 10 CFR 50.54 processes generally contain more restrictive reporting requirements and different criteria for determining when prior staff approval is needed.

Comment 1: Many commenters stated that system operation is governed by written procedures and, therefore, changes to valve positions from those shown on drawings should not be viewed as changes to procedures.

Resolution: The staff would agree that if procedures exist that address operation in the configurations shown on the drawing, or as revised, that a separate 50.59 evaluation is not needed for a drawing change.

Comment 2: Some commenters thought that "procedures" should not be interpreted as applying to administrative functions (such as safety review committees) because it would be difficult to determine when staff approval was needed.

Resolution: The staff's guidance on procedures was intended to reflect that the term could be viewed very narrowly to mean a specifically designated set of steps, and that the staff views "procedures" more functionally. As part of the proposed rulemaking, the staff is recommending a definition of "procedures" that would include information on conduct of operations.

Topic III.D: Definition of Tests or Experiments

Staff Position: The staff considers a test or experiment to be a special procedure for a particular purpose or an evolution performed to gather data. In order to meet the requirements of the rule, the staff position is that any tests or experiments not described in the SAR need to be evaluated to determine if a USQ (or a TS change) is involved.⁽²⁾

Comment 1: A number of commenters stated that evolutions for purposes of gathering data should not necessarily be considered tests; rather, this should be determined by whether the evolution is "non-intrusive" or would impact operation of systems and components other than as

previously conducted. Further, many commenters thought the need for evaluation should be limited to those tests or experiments that could affect a safety function of an SSC described in the SAR.

Resolution: The purpose of the review is to determine whether the test impacts the plant in some manner and thus the staff would not exclude an activity from review because it is considered, on first impression, to be "non-intrusive" There have been instances where licensees tests were conducted without first performing a 10 CFR 50.59 screening because the tests were believed to be nonintrusive, but in actuality, conduct of the test modified the system response.

Comment 2: Some commenters thought that performing a surveillance or test in a different way would fall under the "change in procedure" section of the rule.

Resolution: The staff's intent is that such actions be evaluated, the specific part of the rule that leads to this review is not important.

Topic III.E: Definition of "As Described"

Staff Position: Considering the intended function of 10 CFR 50.59, the staff now concludes that if the change affects any SSC as described in the SAR (not just the SSC that is being directly changed) such that the FSAR description is no longer accurate, then a 10 CFR 50.59 evaluation is required. .

The staff concludes, for the purposes of 10 CFR 50.59, that the information in the FSARs that presents the purpose, quality, kind, number, condition, function, operation, use, design, or material of systems, structures or components are captured by the language of the rule. The above type of information for systems, structures and components that are included in the FSAR are considered part of the design basis, and subject to evaluation, that is, they are within sections 50.2 and 50.59.

Comment: Many commenters stated that the listed types of information would not meet the definition of design bases. They also thought that a licensee should be able to screen out editorial changes to the SAR, or changes that have no impact on the design and function of the SSCs.

Resolution: The staff notes that 10 CFR 50.59 addresses changes to the facility and procedures as described in the SAR (or tests not described). Screening could eliminate the need for evaluation of editorial changes, but not those thought to have no impact on design or function of SSC. The purpose of the evaluation is to determine whether the change has an impact. With respect to the comments on design basis, the staff believes further guidance may be needed to clearly delineate what information in the SAR constitutes "design bases," but this issue is not vital for purposes of 50.59 evaluations.

Topic III.F: Definition of Final Safety Analysis Report

Staff Position: The Safety Analysis Report (SAR) as referred to in 10 CFR 50.59 is the final SAR as described in 10 CFR 50.34(b), as modified by updates in accordance with 10 CFR 50.71(e). In accordance with 10 CFR 50.34(b), the SAR is that part of the application providing technical information. The SAR contains information that describes the facility, sets forth the facility's design bases and limits on its operation, and presents a safety analysis. The SAR also includes information on site evaluation factors, information on organizational responsibilities, administrative controls, and plans for conducting normal operations and for coping with emergencies. Note that the SAR includes documents that are referenced as part of the description, but not documents merely listed as references. The SAR description includes the text, tables, figures and drawings.

The rule requires all information described in the SAR be evaluated to see if the change would make the information in the SAR no longer true or accurate and to determine whether a change in TS or a USQ is involved. A SAR may contain certain information, such as the population distribution outside of the reactor site, which may not fit under Section 50.59 or otherwise be specifically controlled under section 50.54.

Comment: A number of commenters would clarify that to be considered part of the SAR for purposes of 10 CFR 50.59, a document should be referenced

as part of the description in the SAR, and not simply cited as a reference for the chapter. This would apply to such documents as vendor topical reports, text books, and so forth.

Resolution: The staff agrees with the comments.

Topic III.G: Industry Use of a Screening Process

Staff Position: The staff believes that all proposed changes or modifications, wherever in the plant, need to be considered to determine whether a 10 CFR 50.59 evaluation is required. This does not mean all changes will require an analysis under 10 CFR 50.59. If a licensee uses a screening process, the process must be rigorous enough to actually identify those changes which will require a 10 CFR 50.59 evaluation. Screening processes should consider such factors as discussed in the sections discussing Change (Section III.A), and Test or Experiment (Section III.D), and "as described" (Section III.E).

There are no requirements in 10 CFR 50.59 to retain records of licensee evaluations performed to determine whether a "change" is within the scope of 10 CFR 50.59. While not specifically required by 10 CFR 50.59, documentation of screening evaluations might constitute records of activities affecting quality or safety and therefore fall under the documentation requirements established by 10 CFR Part 50 Appendix B.

Comment: Many commenters stated that licensees should maintain records of screening, if performed, even though rule does not require such retention. Documentation should be consistent with the requirements for the "document" (e.g., modification package, procedure, test) being screened.

Resolution: The staff notes that NEI 96-07, "Guidelines for 10 CFR 50.59 Safety Evaluations," discusses the desirability of retaining screening documentation.

Topic III.H: Definition of Accidents Previously Evaluated

Staff Position: Regarding the definition of "accidents previously evaluated," the staff position is that accidents previously evaluated in the SAR include those anticipated transients and design basis accidents evaluated in the SAR (so-called Chapter 15 events), as well as events described in the SAR which the plant is designed to endure, such as earthquakes, fire, flood, high winds, tornados, missiles, offsite hazards and high energy line breaks. This should also include events or conditions added to the design and licensing basis through regulations and orders such as anticipated transient without scram and station blackout. Further, to the extent that plant features or procedures needed for response to other conditions, such as severe accidents, fuel handling accidents or heavy loads, are described in the SAR, the accidents previously evaluated would refer to those postulated conditions which those features were intended to prevent or mitigate.

Comment: Several commenters stated that the term "accidents" should only be used with respect to those design-basis events evaluated in Chapters 2, 6, and 15 of the SAR, and the response to external events should be considered with respect to potential malfunctions of equipment. The commenters further stated that other events that the plant must withstand (such as anticipated transients without scram and station blackout) are not part of the design basis, and are not accidents, but should be covered in the SAR.

Resolution: The staff disagrees with this comment. The staff views any analyses of a new accident or safety concern such as station blackout or handling of heavy loads to be part of the design basis of the plant. The staff will provide additional clarification of this issue as part of its guidance on updating FSARs.

Topic III.I: Malfunction of Equipment Important to Safety - of a Different Type

Staff Position: The staff believes that a more complete definition of "malfunction" than what is contained in NSAC-125 is *an undesired response of equipment, for example, failure to operate, inadvertent operation, operation in an unexpected manner, operation with less than rated capacity, and failure to perform function as designed.*

Note that 10 CFR 50.59 refers to malfunction of equipment "important to safety." In the SAR, malfunctions are evaluated for equipment that can initiate accidents and transients, as well as for equipment intended to mitigate the consequences of accidents. Therefore, in considering the scope of equipment for which malfunctions should be addressed, the licensee must address not only safety-related equipment, but also other equipment that may be relied upon such that safety-related equipment performs its intended functions and equipment that can initiate accidents and transients. Generally, the equipment important to safety for a particular plant is determined as part of the licensing reviews, and the malfunctions are evaluated in the SAR to the extent that they affect plant safety.

In considering malfunctions of equipment, the staff would recommend that this be done at the component level. However, for some SSC, the evaluation of malfunctions discussed in the SAR may well have been only at the train or overall system level.

Further, in determining whether a malfunction is of a different type, the licensee needs to consider not only the effect of the malfunction on equipment or plant response but also what causes the malfunction. If the proposed activity could lead to a different initiator, or involves a failure mode of a different type than the types previously evaluated, then the failure results from a malfunction of a different type (and involves a USQ), even though the accident may be the same.

Comment 1: Many commenters disagreed with the NRC approach to categorically treat different causes of failure as failures of a different type. Commenters noted that equipment failures are often postulated in SARs for analysis purposes, without a mechanistic evaluation of how such failures might occur.

Resolution: The staff plans to respond to this topic through rulemaking on the criterion relating to malfunction of a different type, taking into account

past staff positions such as that expressed in Generic Letter (GL) 95-02.

Comment 2: Some commenters asserted that malfunctions should be evaluated on the same level used in the existing safety analysis. These commenters expressed concern that this new NRC position might result in a USQ for substitution or addition of any component or subcomponent that is different than the original component.

Resolution: See resolution to Comment 1 above.

Comment 3: One commenter disagreed with the staff's position regarding the scope of equipment for which malfunctions should be addressed. That commenter stated that unless the malfunction of the support or nonsafety equipment was previously evaluated in the SAR, it should not be included in the scope.

Resolution: The staff disagrees with this narrow interpretation of the scope of equipment for which malfunction should be addressed. In determining whether a "change" would create a different type of malfunction, licensee evaluations cannot be limited to malfunctions previously evaluated in the SAR, because a new type of malfunction may be created as a result of the "change." The staff was not intending to extend the scope of equipment beyond that already covered in the FSAR.

Topic III.J: Licensee Implementation of Modifications Associated with TS

Staff Position: The staff has not previously published guidance on this topic. Section 50.59 states that a change to the facility that would involve a change to the technical specifications requires prior approval from the NRC. Therefore, the staff concludes that where technical specifications are involved with a planned modification, such that staff review of the associated TS will be required, staff approval of the proposed modification (and TS) must occur before the ongoing modification is implemented.

Comment: The commenters generally agreed with the statement that "... staff approval of the proposed modification (and TS) must occur before the ongoing modification is implemented." However, commenters suggested that with an adequate 10 CFR 50.59 screening/evaluation and design requirements review, a modification should be allowed to be designed, planned, installed, and tested before TS approval by the NRC.

Resolution: The staff disagrees with this comment as it relates to installation or tests on installed changes. The staff position is unchanged.

Topic III.K: Need for Plant-Specific 10 CFR 50.59 Evaluation When Implementing Generic Modifications

Staff Position: The 10 CFR 50.59 process allows an individual licensee to make changes to its facility without prior approval under specified conditions. NRC involvement and approval of plant changes for other plants does not relieve a licensee of its responsibility to evaluate proposed changes for their facility in accordance with 10 CFR 50.59. An NRC safety evaluation for a facility modification proposed in response to a generic (or plant-specific) issue is not sufficient to conclude that implementation of the modification does not involve a USQ.

Comment: The staff did not receive any substantive comments regarding this topic.

Resolution: No resolution is required.

Topic III.L: Licensee Identification of TS That Are Not Adequate to Assure Compliance with the Design Bases

Staff Position: The staff position on this topic is that upon discovering such conditions, the licensee should take the appropriate action to put the plant in a safe condition (such as by imposing more conservative administrative limits), and also take action (such as requesting a license amendment) so that the TS represent the minimum requirements. The circumstances should also be reviewed for reportability under 10 CFR 50.72 and 10 CFR 50.73 with respect to operation outside the design basis. Failure to seek such approval could be considered as a failure of a licensee to take prompt corrective action and would be inconsistent with Criterion XVI (Corrective Action) of Appendix B to 10 CFR Part 50.

Comment: Many commenters agreed that the TS should be changed, if a nonconservative TS is identified. However, the commenters asserted that there is normally no safety reason to require an immediate submittal of a license amendment request. Consequently, the commenters suggested that licensees should be allowed to implement corrective action on a schedule that is commensurate with safety. One commenter asserted that this issue is not a 10 CFR 50.59 issue at all.

Resolution: In NUREG-1606, the staff noted that this is not an issue about 10 CFR 50.59, but rather is a current staff concern. The staff is pursuing a separate generic communication regarding this topic.

Topic III.M: Role of Probabilistic Risk Assessment (PRA) in Section 50.59 Evaluations

Staff Position: In general, the staff concludes that PRA is not suitable as a decision-making tool for 10 CFR 50.59 evaluations. However, as PRA is more fully integrated into the regulatory process (i.e., through risk-informed license amendments), its role in 10 CFR 50.59 evaluations will naturally increase.

Comment: Some commenters noted that the discussion in NUREG-1606 does not acknowledge the general industry practice of maintaining living PRAs for individual plants. These commenters asserted that the NRC should not infer that PRAs cannot be used for performing 10 CFR 50.59 safety evaluations. The commenters further noted that PRA results and risk insights can play a significant role in evaluating a potential USQ. Consequently, the commenters suggested that use of a PRA should be permissible, at the option of a licensee, especially as a supplement for deterministic evaluations.

Resolution: The staff acknowledges that a PRA may provide insights about a given change, but still concludes that PRA should complement other evaluative methods, rather than providing the sole basis for the decision. This is consistent with the Commission's direction on risk-informed changes to the licensing basis, as reflected in Regulatory Guide 1.174.

Topic III.N: Licensee Practice of Deleting Information from Safety Analysis Reports

Staff Position: With respect to removal of information from the FSAR not associated with changes to the facility or procedures, the staff position is that licensees may not remove material from safety analysis reports unless the material is changed as a direct result of a change to the facility. Section 50.59 addresses the process for the licensee to make changes to the facility or procedures as described in the SAR, and 10 CFR 50.71(e) addresses FSAR updating requirements such that the updated FSAR reflects accurate information and includes the effects of changes to the plant. Together, these rules govern the process for changing the plant and then updating the FSAR description to correspond. Another way the FSAR may be changed is if a licensee revises its licensing basis ("as described in the SAR"), to accept a nonconforming condition as the new licensing basis. The SAR description must be modified as a result of the change to correspond with the change to the licensing basis that has occurred to the facility.

Comment 1: Many commenters disagreed with the staff's position of not allowing removal of information from the SAR. Their concern is that this restriction would place an unnecessary burden on licensees to conduct 10 CFR 50.59 evaluations on specified portions of the SAR that have no regulatory or safety impact. They believe that "deleting" selected information is appropriate and advisable to enhance the ease of access and the accuracy of information in the SAR. Several commenters also offered possible criteria for determining what information could be deleted from the SAR.

Resolution: Deletion of information is being addressed as part of the staff's response to the Commission on SAR updating, in particular in SECY-98-087 (Draft Generic Letter on FSAR Updating), dated April 20, 1998.

Comment 2: One commenter indicated that the term "licensing basis" is not defined and does not appear to be used consistently. That commenter recommended replacing this term with a phrase that clearly describes exactly what is referred to.

Resolution: The meaning of licensing basis has been stated in past correspondence, such as May 10, 1989 letter to NUMARC on NSAC-125.

Topic III.O: Application of 10 CFR 50.59 to the Resolution of Degraded and Nonconforming Conditions

Staff Position: To clarify the implementation of 10 CFR 50.59 as it applies to the resolution of degraded or nonconforming conditions affecting the SAR, the staff has determined that a 10 CFR 50.59 evaluation is required in the following circumstances:

(1) When a licensee plans to implement compensatory actions, such as to satisfy operability requirements, until such time as the plant can be restored to the original design bases or an alternative solution is implemented. Such compensatory actions are viewed as the licensee "making changes to the facility or procedures as described in the safety analysis report," and thus require a 10 CFR 50.59 evaluation against the FSAR-described condition before they are implemented.

(2) When a licensee intends to implement a final resolution for a degraded or nonconforming condition other than full restoration. If a licensee needs to change the design bases contained or referenced in the safety analysis report, the licensee must evaluate the final resolution against the criteria in 10 CFR 50.59 and determine if an unreviewed safety question exists.

(3) When a discovered nonconforming or degraded condition is not permanently resolved at the first available opportunity. The NRC has concluded that delay beyond the first available opportunity is in essence a de facto change to the facility that should be evaluated under 10 CFR 50.59.

The second question focuses on the course of action to follow when an existing condition, which was required to be evaluated under 10 CFR 50.59, involves a USQ. The staff position is that a plant currently operating with a condition involving a USQ would not normally be required to shutdown, provided that the licensee has determined that all necessary equipment is operable, and that the licensee expeditiously (i.e., within days) submits its application for license amendment. The staff would not allow plant startup unless the condition is first corrected or staff approval is received.

Comment 1: Many commenters believe that the NRC already has sufficient regulatory authority to deal with what is essentially an issue regarding the timeliness of corrective action via the application of Criterion XVI from Appendix B to 10 CFR Part 50. As such, the NRC does not need to create a new category of change or modification to make 10 CFR 50.59 apply to the timeliness of corrective actions. The nonconforming condition should be corrected at the first available planned maintenance opportunity with sufficient lead time and duration commensurate with prudent and practical plant schedule processes to include considerations for risk and availability. Further, the commenters asserted that following the staff's position would create significant maintenance and nonconformance program management challenges without a significant increase in safety.

Resolution: Revision 1 to GL 91-18, published on October 8, 1997, resolves the comments concerning the role of 10 CFR 50.59 for resolution of degraded or nonconforming conditions. In particular, the revision establishes that decisions regarding continued operation should be determined on the basis of operability, conformity with the license, and safety significance, not on whether a USQ has been identified. The staff would expect a licensee to perform a 10 CFR 50.59 evaluation when implementing an interim compensatory measure (the evaluation is of the measure itself, not of the nonconformance against the SAR), or when changing its licensing basis (that is, evaluating what changes the licensee is proposing on how applicable requirements are met by the revised design, method of operation, or SSC). Timely resolution of degraded or nonconforming conditions is expected, and the NRC will take enforcement measures, as appropriate, when such actions do not occur.

Comment 2: Many commenters disagreed with the staff's position on not allowing a plant to restart with a degraded condition involving a potential USQ, even when the condition is not prohibited by TS or does not involve an operability issue.

Resolution: Addressed by Generic Letter 91-18, Rev.1, see resolution to Comment 1 above.

Comment 3: One commenter asserted that the requirement to submit a license amendment request expeditiously (i.e. within days) is overly restrictive and unnecessary. That commenter recommended that the time frame be changed to "in a timely manner commensurate with safety."

Resolution: Addressed by GL 91-18 Revision 1, see resolution to Comment 1 above.

Comment 4: Another commenter indicated that circumstantial changes (such as age-related degradation mechanisms) should not require 10 CFR 50.59 evaluation. That commenter recommended that degraded and nonconforming conditions should be evaluated on the basis of an "operability" test and should not be subject to the "regulatory" test of 10 CFR 50.59 for which it is not intended.

Resolution: Addressed by Generic Letter 91-18, Revision 1, see resolution to Comment 1 above.

Topic III.P: Definition of Increase in the Probability of Occurrence

Staff Position: Section 50.59 uses the term "may be increased," and therefore, any increase, however slight, will trigger an unreviewed safety question and thus require staff review. Accordingly, the staff's position is that the language of 10 CFR 50.59 (probability may be increased) indicates that any uncertainty or doubt about whether an increase, even a negligible one, has occurred should lead to the conclusion that a USQ is involved.

Comment 1: Many commenters indicated that the NRC's position that "any" increase in probability involves a USQ is not consistent with the rule as it has historically been applied by both the NRC and licensees. The probability changes should only be a consideration if there is a definitive change in occurrence that would actually indicate a probability change. (See also comments on Topic III.M, Role of PRA in Section 50.59 Evaluations.)

Resolution: The staff is preparing a proposed rulemaking that will modify the language ("probability may be increased") to "more than a minimal increase."

Comment 2: Some commenters endorsed the concept of using "compensating measures" to deal with the issue of "probability of accidents," as discussed in the NEI "point paper" dated October 24, 1996. Others noted that the Part 9900, "Technical Guidance" of the NRC Inspection Manual discusses compensating effects that offset "negligible" increases in probability or consequences.

Resolution: The staff presently believes that compensating effects should not be allowed, and will revise the NRC Inspection guidance as part of the rulemaking. With the proposed revisions that would allow "minimal" increases in probability or consequences, there would no longer be a need for such provisions in the guidance.

Topic III.Q: Increase in Probability Still within Design Basis

Staff Position: The severity of certain design basis events that a plant must demonstrate it can withstand often have a probabilistic underpinning (for instance, the magnitude of an earthquake, wind speed, external missiles, etc.) Further, certain accidents may have been considered sufficiently unlikely that protection from their effects was not required ("outside the design basis"). In these instances, a design basis has been established for the facility which thus defines the "accidents previously evaluated." Unless the change makes this design basis event more likely (as compared to making some beyond design-basis event more likely), the change would not involve an increase in probability of an accident previously evaluated. As to creating an accident of a different type, this would arise only if the change made an accident previously considered as outside the design basis, on a probabilistic basis, now within the probability range that established the design basis. Otherwise, the staff does not believe that such changes should be determined to involve USQs if the design basis is still satisfied.

Comment 1: Many commenters agreed with this position, but stated that it was inconsistent with the position in Topic III. P, which asserts that any increase in probability of an accident or malfunction involves a USQ.

Resolution: The staff has addressed this comment through its guidance on "minimal" increases in probability of malfunction for the proposed rulemaking package on 10 CFR 50.59.

Comment 2: Some commenters stated that the staff's example about earthquake design should indicate that there was no increase in malfunction of equipment, rather than in probability of an accident.

Resolution: The staff viewed the earthquake as an initiating event that would result in an accident if equipment were not qualified; the industry comment views the earthquake as the accident, with the equipment qualification issue as possibly leading to malfunction. The result is the same and the staff has no objection to the position as stated by the commenters.

Topic III.R: Definition of Increase in Consequences

Staff Position: The language in 10 CFR 50.59, is "consequences of an accident...previously evaluated in the safety analysis report may be increased." Therefore, the staff concludes that the dose calculated in the SAR should be considered as the threshold for when an increase in consequences (and thus a USQ) results.

Comment 1: Many commenters stated that there must be a measurable (or discernable) increase in order for a USQ to exist. A few commenters believe that a small change (where there is still a lot of margin to limits) is not a USQ, but that big changes or those that approach the limits warrant formal communication with the NRC.

Resolution: The staff is proposing rulemaking that would require such approval only if the change resulted in more than a minimal increase in consequences; the previously reported value would remain as the baseline.

Comment 2: Almost all commenters believe that "consequences previously evaluated" should be interpreted to mean the acceptance limits established by the staff review (e.g., Part 100 limits, or SRP values), and that a USQ would not be involved even if a change resulted in an increase in consequences for

any accident or malfunction as long as the limit is still satisfied. Their view is that "previously evaluated" encompasses the acceptance limits that the staff used in its review; thus, if still met, the change is not "unreviewed."

Resolution: The staff disagrees that the language of the rule would permit increases in consequences up to the acceptance limits of the SRP or regulations without prior approval. Further, for radiological consequences, the staff believes that a change increasing consequences up to the limits should receive staff review. See also comment 1 above.

Comment 3: Many commenters stated that using the value reported in the SAR as the baseline for determining if a USQ is involved does not take into account that the consequences for a particular accident or malfunction may have been higher in the past, and that the SAR may have been updated to reflect more recent analyses. Therefore, using the current SAR calculation as the baseline for determining the existence of a USQ penalizes licensees who have updated their SARs to reflect the most current analysis.

Resolution: The staff concludes that it is the effect of the change being evaluated that determines whether there is a USQ. The updated SAR reflects the current configuration of the plant, and therefore, a change that has the effect of increasing consequences from the present value, as reported therein, is a USQ. There is no "penalty" because licensees are required to update their FSARs to reflect the most recent analyses; licensees who fail to do so are subject to enforcement action.

Comment 4: Many comments indicated that licensees should be permitted to use the acceptance limits and for analysis purposes, they should be allowed to use state-of-the-art methodology and standards without prior approval.

Resolution: The staff disagrees with the comment. Proposals to use acceptance limits in regulations and new methodologies, while possibly acceptable, are of sufficient significance as to require prior NRC review and approval.

Topic III.S: Definition of Reduction in Margin of Safety

Staff Position: In determining what changes represent a reduction of the margin of safety, it should be recognized that the technical specifications and the accident analyses on which they are based, provide assurance that the response of the plant to various design basis accidents and transients is acceptable.

Acceptance limits are specific values, conditions, or range of parameters within which the licensee has proposed to operate the facility and which the NRC has accepted during its review of a license application. These values are derived from the plant-specific design bases analyses reviewed by the NRC and are found in the plant-specific FSAR (unless a different value is explicitly established in the NRC safety evaluation as the acceptance limit), and may in some cases, be found in the "BASES" section for individual technical specifications.

Accordingly, for purposes of this criterion, a reduction of margin of safety as defined in the basis for any technical specification will be deemed to have occurred when an acceptance limit is no longer met as a result of a proposed change, test, or experiment. If the staff's acceptance limit in the safety evaluation is explicit, the licensees can consider the values in the staff safety evaluation as a reference for determining the "acceptance limit", rather than being limited only to values contained in the plant safety analysis report. If the staff's acceptance limit is not explicit, the "acceptance limit" is the value as reported in the SAR.

Comment 1: Most commenters stated that acceptance limits are not defined by the SAR, but are the values in the NRC's SER (generally the SRP). Some commenters stated that tying acceptance limits to SAR values penalizes licensees who have more complete SARs. Some commenters also stated that the staff's position has the effect that changes to licensee operating margins, rather than margins of safety, become subject to NRC approval.

Resolution: The Statement of Considerations for the rulemaking on 10 CFR 50.59, will clarify how acceptance limits relate to the TS, and when reductions in margin have occurred.

Comment 2: Some commenters stated that acceptance limits need to be restricted to areas directly tied to the TS, or that principally affect the fission product barriers; otherwise, every parameter in the SAR could potentially be viewed as an acceptance limit.

Resolution: The staff agrees the rule indicates that there must be a tie to a TS and that not every value stated in the SAR constitutes a basis for a margin of safety in accordance with 10 CFR 50.59.

Comment 3: A few commenters stated that more guidance is needed concerning the use of the word "explicit." Staff SERs may be worded in different ways; licensees should be able to infer acceptance limits as established in the SRP or other guidance.

Resolution: The staff believes existing guidance is sufficient.

Topic III.T: Information that Establishes the Basis for any Technical Specification

Staff Position: A USQ is involved if the margin of safety as defined in the basis for any technical specification is reduced. However, in general, the BASES sections of the TS are not written in such a manner that the safety margin is explicitly identified. The history of development of Sections 50.34 and 50.36 suggests that the SAR, as supplemented by the staff SER, is where the basis for any TS are defined, and that the BASES section of the TS is just a summary. The TS specify the equipment that must be available and initial plant conditions necessary to meet the assumptions in the safety analyses. This relationship to the safety analyses means that the basis for the TS and thus the associated margin-of-safety definitions are found in the analyses as described in the updated SAR and NRC SERs. Therefore, the BASES sections may be helpful, but should not be relied upon as the only reference in a margin-of-safety evaluation because they usually lack sufficient detail.

The staff concludes that other information, such as the SAR and supporting analyses, and the staff safety evaluation, should be reviewed in determining whether a margin of safety as defined in the basis for any TS has been reduced.

Comment: Most commenters stated that the rulemaking history does not support the interpretation that documents other than the Bases must be reviewed in determining reductions in the margins of safety. Instead, these commenters contend that this is a conservative interpretation that was taken in industry guidance.

Resolution: The staff concludes that the published position is correct, and is preparing a rulemaking package to clarify this point

Topic: III.U: Determination of Unreviewed Safety Questions when Licensees Use New Methods (Analysis Methods, Assumptions) to Evaluate Plant Changes or Conditions

Staff Position: As the knowledge base increases and computing power increases, new methods of analysis will more accurately predict the actual plant response than old methods. In making a 10 CFR 50.59 determination that a USQ is not involved as a result of a change, the results of two calculations are being compared. If the two calculations are the results of two different methodologies, the comparison is not valid. Therefore, the staff position is that a new methodology may be used for evaluating plant changes under 10 CFR 50.59 if two conditions are satisfied. First, the new methodology must be a valid methodology for the type of calculation being performed. Second, in order to judge the effect of a change, test, or experiment, the analysis must be done for the cases of before and after the change and both analyses must be performed with the same methodology. The comparison is then valid, and could be used to show that no USQ is involved and thus that the change can be done by the licensee without prior staff review.

Comment 1: Many commenters stated that since, with few exceptions, the NRC does not specifically review and approve the methodology used for analysis, licensees should be able to use a method that is standard industry practice, or has been generically approved by the NRC,

without performing 10 CFR 50.59 evaluations. The commenters agree that changes in input assumptions must be evaluated, but that this need not be a 10 CFR 50.59 evaluation, or involve a USQ if assumptions fall within acceptable ranges and results meet acceptance limits

Resolution: As discussed under Topic III.B, the staff plans rulemaking to clarify that changes to the SAR analysis are also subject to 10 CFR 50.59 review.

Comment 2: A few commenters believe that this topic is related to the issue of compensating effects, whereby licensees should be able to consider an overall change (change to facility or procedure, along with perhaps a new method), and compare the results against acceptance limits to determine if a USQ is involved.

Resolution: The staff position on the use of compensating effects has not changed. (See III.V).

Topic: III.V: Consideration of Compensating Effects When Making an Evaluation of Whether an USQ Exists

Staff Position: The current staff position is that the use of compensatory actions has no unique meaning for planned changes under 10 CFR 50.59. Licensees use compensatory measures or actions in certain situations to deal with a degraded or nonconforming condition at the plant. These measures are only of short duration and provide a licensee a basis for continued operation until such time as a licensee determines the final resolution of the degraded or nonconforming condition. However, these actions redefine the way the plant will be operated from that previously described in the plant safety analysis or other license amendment applications. Thus, such compensatory actions are viewed by the staff as a licensee "making changes to the facility or procedures," and thus require a 10 CFR 50.59 evaluation against the FSAR-described condition before they are implemented. (See Topic III.O.)

If a licensee makes a change in one component or system to offset changes made in another system or component and would attempt to consider those changes as an integrated change for the purpose of 10 CFR 50.59, the staff believes that such situations may result in enforcement action against the licensee. The effect of any change must be evaluated against each of the USQ criteria separately - that is, an increase in probability cannot be "compensated" by additional mitigation capability. There may be instances where linking elements of a change may be appropriate. A test for linking elements of proposed changes is interdependence. If a proposed change to a system or component requires a subsequent change in another system or component, the changes are linked. ("Required" should be interpreted with respect to function or performance of the system or component, not that the first change, absent the subsequent change, would involve a USQ.) However, if a change to a system or component can be made without affecting other systems or components, then the proposed changes are separate changes under 10 CFR 50.59.

Comment: Most commenters believe that more guidance is needed on interdependence, linking of changes, and how to link a plant change with an analytical change. About one-third of the commenters stated that NRC should maintain the position in Part 9900 on 10 CFR 50.59 (compensating effects allowed if "negligible" increases, and compensation clearly outweighs). Some commenters provided feedback about compensating effects with degraded or nonconforming conditions under Topic III.O. A few commenters said that the position on linking of changes will discourage improvements that have a net benefit to safety when considered on an overall basis.

Resolution: The staff agrees that further guidance is needed on this issue. The Part 9900 guidance will be modified to reflect the position in the revised rule.

Topic: IV.A: Policy Issues on Scope of Section 50.59

Staff Position and Options: In considering options on the scope, the fundamental issue is whether to change 10 CFR 50.59 to refer to something other than the SAR (such as "licensing basis"), or to change requirements such that the SAR contains all of the information over which the NRC wishes to have the controls provided by 10 CFR 50.59. Some possible approaches are listed below; options relating to the contents of the SAR and licensing basis are also discussed in the Part 2 Millstone Lessons-Learned Task Group Report.

(1) take steps to ensure that commitments which the staff considers fundamental to their regulatory approval are controlled in an appropriate process, either by requiring that such commitments be made part of the SAR (and thus controlled by 10 CFR 50.59), or by specifying other control processes. As part of the Division of Reactor Project's Process Improvement Plan, the staff has initiatives underway to accomplish this for future licensing actions.

(2) revise 10 CFR 50.59 to reference the "licensing basis" instead of "SAR", and develop a definition of licensing basis that includes all the information that the staff wishes to subject to the control of the 10 CFR 50.59 process. Such a change could bring the other information that is not presently contained in the SAR, but that is part of the licensing basis as it would be defined, within the scope of 10 CFR 50.59. If this option were followed, a definition of licensing basis, and other changes to Part 50 would be needed.

(3) take regulatory action to require that SARs be updated to correct past omissions. Under this option, licensees could be required to incorporate changes to the design bases and effects of other analyses performed since original licensing that have not been included in the updated FSAR (but which should have been as specified in 10 CFR 50.71(e)). 10 CFR 50.59 itself would not need to be changed; rather, these actions would improve the completeness and accuracy of the SAR, the document upon which 10 CFR 50.59 governs the change process.

(4) revise 10 CFR 50.71(e) update requirements, or develop guidance to improve future updates to specifically identify which information (to what level of detail) needs to be included and maintained in the SAR. These steps would improve the completeness of the SAR for future changes made pursuant to 10 CFR 50.59.

Comment 1: Most commenters believe that commitment management programs are sufficient to handle changes to items that may not be included within the SAR.

Resolution: The staff is performing audits of licensees' commitment management programs. Attachment 1 to SECY-97-205, "Integration and Evaluation of Results from Recent Lesson-Learned Reviews," summarizes the staff activities completed or under way to implement the short-term actions identified from these reviews.

Comment 2: Some commenters noted staff activities on placing commitments into the license and SAR, and stated concern that this was occurring without notification to the industry. Some felt that putting commitments into the SAR (which limits licensees' ability to revise the SAR without NRC approval), would have the effect of discouraging licensees from making any commitments beyond minimum regulatory requirements.

Resolution: The staff has met with NEI to discuss and plans further interactions to inform licensees about how the staff will handle commitments.

Comment 3: Most commenters agreed that updating the SARs to correct past implementation may be appropriate, but disagreed on the extent of the past omissions, or felt that the updating may need to be phased in over a period of years. Several commenters objected to the view that licensee responses to generic communications had to be reflected in the SAR; they conclude that changes to the SAR should arise from licensing-basis changes accomplished by rules, license amendments, and orders. Commenters said these matters should be handled as part of "lessons learned" (SECY-97-036) rather than as part of the implementation of 10 CFR 50.59.

Resolution: The staff prepared proposed guidance for FSAR updating in SECY-98-087. The staff is presenting working with NEI to endorse, if possible, NEI guidance on updating which will address responses to generic communications. As a result, SARs will become more complete and accurate, thereby enhancing the functioning of the 10 CFR 50.59 process.

Comment 4: A few commenters suggested that in future generic communications, the NRC should indicate what information should be added to the SAR.

Resolution: As part of efforts on commitments and SAR updates, the staff will enhance its internal administrative processes such that it is more clear what information needs to be put into the updated FSAR.

Topic: IV.B: Policy Issues on USQ Threshold

Staff Position and Options:

Probability of Occurrence

As discussed in the guidance section, the existing rule language would require that a change resulting in any increase, or even uncertainty about whether there has been an increase to be deemed to involve a USQ.

A policy option would be to revise this part of the USQ criterion from "may be increased" to "is increased", or "is more than negligibly increased". Such a revision would allow a determination that a USQ is involved as a result of an increase in probability when such an increase is discernable, not when an increase cannot absolutely be ruled out. This option would recognize that the staff's consideration of probability is largely qualitative. This approach would give more latitude to a licensee's judgment on whether a USQ is involved, which may be a potential concern in some specific situations. This approach would require rulemaking.

Increase in Consequences

As discussed in the guidance section, changes resulting in an increase in radiological consequences above the value(s) calculated in the SAR involve USQs. Industry guidance documents propose an approach similar to that discussed under margin of safety, that is, that no USQ is involved if the resulting dose remains within the staff's explicit acceptance guidelines for the plant and accident analyses involved.

There are options for rulemaking that could be explored such that certain changes involving increases in consequences could be made under 10 CFR 50.59. One option would be to revise the rule such that no USQ would be involved if the results are still within the acceptance guidelines specified by the staff and the licensee's SAR analysis has been specifically reviewed by the staff. Another option that might be considered is that the "previous

evaluation" includes the staff's analysis as documented in the SER, and therefore, that a licensee is permitted to consider the acceptance guidelines discussed in the SER as the baseline for determining if an increase in consequences has occurred, provided that they also adopt the staff analysis assumptions as part of its analysis of record; then for purposes of evaluating changes, the "no increase in consequences" could be based on the acceptance value established by the staff.

Another option with respect to consequences would be to delete the "increase in consequences" as a separate part of the definition of USQ, and define margin of safety to encompass all results of analyses, including dose calculations. If as part of this redefinition, the licensee were to be allowed to consider the acceptance values discussed in the staff SER for these analyses (as proposed for margin of safety), the above issues concerning the staff's analysis for radiological consequences would also have to be taken into account. These options would require rulemaking to implement.

Margin of Safety

The proposed staff position on margin of safety would allow consideration of the staff conclusions with respect to when a USQ is involved if the acceptance limit is clearly specified by the staff; otherwise, the value calculated in the SAR must be used as the baseline to gauge whether a reduction in margin has occurred. This position recognizes that for results of safety analyses other than radiological consequences, the staff does review the licensee's analyses and makes a determination on acceptability. Further, if the analyses were found acceptable because they met specified acceptance criteria, it could be concluded that a calculated result (arising from a change to the facility or procedures) that remains within the criteria explicitly approved by the staff already is not "unreviewed", and changes which result in reductions in margin of safety that still satisfy the explicit acceptance criteria used by the staff should not be USQs.

The staff position also recognizes that the TS BASIS sections do not consistently address margin of safety, so "as defined in the basis for any TS" is being interpreted to include consideration of the SAR information.

A policy option would be to define more specifically in the rule itself that a reduction in margin of safety has occurred if the results of any safety analyses documented in the SAR are no longer bounded by the staff acceptance criteria. Further, a rule change on the language for "margin of safety" could clarify whether "basis" should be read to mean the SAR and other information, or only the BASIS section of the TS.

Other Options

More wide ranging options would include totally revising all the criteria for USQ, including use of the term, by developing an alternative characterization of when prior staff approval of a change is needed. The term "unreviewed safety question" is sometimes confusing with respect to whether it is a test of safety or a test of the extent of review needed by NRC. Use of a different term and a definition more explicitly focused on the regulatory envelope previously reviewed could clarify the intent of the 10 CFR 50.59 evaluation process.

Other options could introduce a "risk significance" test; changes that meet the USQ definition, but that are not "risk-significant" might be allowed without prior approval subject to a more timely reporting requirement, while more risk-significant changes would continue to require prior staff approval. Similarly, with respect to margin, a change that made only a small reduction in the available margin might be allowed without prior approval, whereas changes which result in being close to the limits would require prior approval. Such options would require rulemaking and would also require development of guidelines for significance. However, these approaches would be more consistent with a performance-based, risk-informed regulatory framework.

Comment 1: Most commenters stated that rulemaking was not needed to accomplish this purpose, and the staff should simply endorse industry guidance (NEI 96-07). A few commenters stated that rulemaking would be worthwhile to clarify requirements. Most commenters also indicated that they would favor rulemaking to codify the industry practice, if the NRC will not accept such practices without rulemaking.

Resolution: The staff does not agree that the industry guidance is fully consistent with the rule.

As part of the rulemaking, the staff is proposing changes to USQ criteria.

Comment 2: Several commenters suggested that a method for notification or approval of changes involving USQs (but not of the significance of TS changes) should be developed (other than issuance of a license amendment.)

Resolution: The staff evaluated approaches other than a license amendment, but is not yet recommending any change on this aspect.

Comment 3: Some commenters supported development of a risk-significance test, such as an overall change in risk (this is related to questions about linking of changes, Topic III.V) or allowance for the use of PRA (see also Topic III.M).

Resolution: In the longer term, the staff will consider changes to 10 CFR 50.59 that are more directly determined by risk.

Comment 4: A number of commenters proposed that a term other than "unreviewed safety question" should be used and that "safety evaluation" should be changed to "10 CFR 50.59 evaluation." Commenters thought that the terms lead to confusion as to the purpose of the evaluation, and also to adverse public perception about the significance of the issues.

Resolution: As part of the rulemaking, the staff is proposing to delete the term "USQ" and instead to refer to the need to obtain a license amendment. The staff also proposes to refer to an "evaluation" instead of "safety evaluation."

NUCLEAR REGULATORY COMMISSION
10 CFR Parts 50, 52 and 72
RIN 3150-AF94
Changes, Tests, and Experiments

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations concerning the authority for licensees of production or utilization facilities, such as nuclear reactors, and independent spent fuel storage facilities, to make changes to the facility or procedures, or to conduct tests or experiments, without prior NRC approval. The proposed rule would clarify which changes, tests and experiments conducted at a licensed facility require evaluation, and the criteria that determine when NRC approval is needed before such changes to a licensed facility can be implemented. The proposed rule would also add definitions for terms that have been subject to differing interpretations, reorganize the rule language for clarity, and revise the criteria for when prior NRC approval is needed.

DATES: Submit comments by (90 days from publication), 1998. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001. ATTN: Rulemakings and Adjudications Staff.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. Federal workdays.

FOR FURTHER INFORMATION CONTACT: Eileen McKenna, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-2189. (emm@nrc.gov) or Philip Brochman, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001, telephone (301) 415-8592 (pgb@nrc.gov).

SUPPLEMENTARY INFORMATION:

I. Background

II. Proposed rule topics and issues

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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 10 CFR 72.48 for licensees of facilities for the independent storage of spent nuclear fuel and high-level radioactive waste. This proposed rulemaking affects the requirements for 10 CFR Parts 50, 52 and 72; for simplicity, the discussion will focus primarily on the language in 10 CFR 50.59). These regulations provide that licensees may make changes to the facility or procedures as described in the safety analysis report, 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 incorporated in the license or an unreviewed safety question. Section 50.59(a)(2), as currently codified, states:

"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 record keeping and reporting requirements associated with such changes, tests or experiments.

In order to understand the reasons for the provisions of the current rule, and how the Commission proposes to revise it, it is helpful to understand how this process fits within the overall requirements undergirding licensing and oversight of nuclear reactors.

Overview of Licensing Process

The application for an operating license includes the final safety analysis report (FSAR) which is to contain: a description of the facility; the design bases and limits on operation; and the safety analysis for the structures, systems, and components (SSC) and of the facility as a whole. The safety analysis emphasizes performance requirements, analytical bases and technical justifications, and evaluations that show how safety functions will be accomplished. Design bases include the specific functions that the SSC need to perform, the parameters that need to be controlled to assure the function, and the range of values for these parameters. As part of the FSAR, the applicant is required to propose, for NRC approval, Technical Specifications(TS) that will become part of the license.

The NRC issues a license after finding, among other things, that the plant has been built according to its design and can be operated within its design limits. The NRC prepares a safety evaluation report that documents the basis for its findings, including its review of the design information provided in the FSAR (and supporting documents) and the applicable acceptance criteria (established either in regulations, standards or guidance documents). In some cases, the NRC staff performs independent analyses to confirm the adequacy of the facility design to meet regulatory requirements. One example of this practice is the staff calculation of radiological consequences (doses) for design basis accidents.

The licensee is required to operate the facility in accordance with NRC regulations and with requirements contained in the license. The license describes the facility in general terms, and includes specific conditions imposed on the facility and the licensee, as well as incorporates the TS. Section 50.36 of the regulations defines for inclusion in the TS, those limits and parameters of most immediate significance for protection of public health and safety: safety limits, limiting safety system settings, limiting conditions for operation, surveillance requirements, and design features to which changes would have a significant effect on safety, and administrative controls. The TS are derived from the safety analysis, evaluations, and design bases described in the FSAR. Any changes to the TS must receive NRC review and approval before they are made.

Engineering evaluations demonstrate that the fundamental safety principles of the plant design are met. Design basis events play a central role in plant design. These are a combination of postulated challenges and failure events against which plants are designed to ensure adequate and safe plant response. Design basis events are defined as conditions of normal operation, anticipated operational occurrences and design basis accidents, external events and natural phenomena for which the plant has been designed to ensure the integrity of the pressure boundary, the capability to shutdown safely, and the capability to prevent or mitigate the consequences of accidents. For events with high frequency, NRC requires that consequences be low (such as by preventing fuel damage). For more severe, but less probable accidents, the allowable consequences are higher, but must still meet the regulatory guidelines established in 10 CFR Part 100. Adequacy of the reactor design is evaluated by consideration of postulated design basis events viewed as sufficiently credible that the facility should be designed to prevent or mitigate their effects.

During the design process, plant response is evaluated using assumptions that are intended to be conservative to account for uncertainties in analysis or

data. In the Final Safety Analysis Report (FSAR), analyses are done conservatively to account for uncertainties in the design, construction, and operation of nuclear power plants. These conservatisms are introduced into FSAR analyses in numerous ways. For example, some computer codes model systems and processes in a simplified but bounding fashion. Analysis input assumptions are typically worst case values (consistent with the design and operating limits) of instrument drift or error, temperature, pressure, fluid volume and enthalpy, flow rate, system response time, heat transfer rate and heat capacity, reactivity coefficients, power history and decay heat. An FSAR analysis also typically assumes the worst-case single-active failure of equipment.

National standards and other regulatory policies, such as defense-in-depth, constitute additional engineering considerations that influence plant design and operation. Commensurate with expected frequency and consequences of challenges to the system, defense-in-depth could require: (1) multiple means to accomplish safety functions and prevent release of radioactive material (multiple barriers); (2) reasonable balance among prevention of core damage, prevention of containment failure and consequence mitigation; (3) system redundancy; (4) independence; and (5) diversity.

Various margins exist in a facility design. These margins are based on, for example, assumptions of initial conditions, conservatisms in computer modeling and codes, allowance for instrument drift and system response time, redundancy and independence of components in safety trains, and plant response during operating transient and accident conditions. Margin is provided by meeting codes and standards or alternatives approved for use by NRC, including the safety analysis acceptance criteria in the FSAR and in supporting analyses. Not all margin that exists falls within the purview of "reduction in margin of safety⁽³⁾ as defined in the basis for any technical specification."

When a plant is licensed, the NRC states in its Safety Evaluation Report (SER) why it found each FSAR analysis acceptable. An FSAR analysis may be accepted because it was considered to be adequately conservative and because the NRC's acceptance criteria for that analysis are met. Frequently, the SER states specific conditions the NRC relied upon for concluding that the analysis was conservative. Examples of such conditions may be the use of an NRC-approved computer code, correlation, or setpoint methodology, specific limitations on one or more input assumptions, or penalties put into a calculation to account for uncertainties. In addition to being stated in a plant-specific SER, these conditions may be found in other safety evaluations such as for an analysis method proposed by a topical report.

Changes to the basis for licensing occur over the life of the plant through promulgation of new rules, plant-specific license amendments and other analyses and reviews that may be conducted, such as in response to NRC bulletins and generic letters. The NRC prepares a safety evaluation for many of these issues based upon either licensee requests for changes or licensee responses to NRC requests for information. The licensee is required to periodically update the final safety analysis report to reflect effects of these changes so that the safety analysis report (as updated) remains a complete and accurate description and analysis of the facility such that it can serve as the reference document for evaluation of changes made under 10 CFR 50.59.

10 CFR 50.59 Evaluation Process

Section 50.59 was promulgated in 1962 to allow licensees to make certain changes that affect systems, structures, components, 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 when approval was required. The intent of the 50.59 process is to permit licensees to make changes to the facility, provided the changes maintain the level of safety documented in the original licensing basis, such as in the safety analysis report. The process is 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. Margins and equipment functionality, reliability and availability also may be impacted by facility changes. Therefore, the criteria for requiring NRC approval were directly related to: (1) preserving licensing assumptions concerning initiation of design basis events by not allowing a different type of initiating event or probability of occurrence larger than previously considered; (2) preserving effectiveness (reliability) of the mitigation systems by not allowing introduction of different equipment malfunctions and by limiting increases in probability of malfunction, or reductions in the margin of safety (which reflects the capability of the system); and (3) preserving acceptability of consequences by limiting increases in consequences of the postulated design basis events.

Implementation Guidance

In 1989, an industry guidance document, NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations" was published to assist licensees in the conduct of the evaluations required under 50.59. The NRC neither endorsed nor disapproved this document. While the staff concluded that the evaluation process established in NSAC-125 was generally sound, the staff was unable to endorse the document because of some inconsistencies between the implementation guidance and the language of 50.59.

On October 31, 1997, the Nuclear Energy Institute (NEI) submitted for staff review a revised guidance document, NEI 96-07, "Guidelines for 10 CFR 50.59 Safety Evaluations." This document is an updated version of NSAC-125 that NEI modified in response to some of the staff positions, and other implementation issues arising from licensee use of the NSAC-125 guidance. Along with the submittal of the guidance document, NEI included an industry-wide initiative that would require industry adoption and implementation of the revised guidance by June 1998. The NRC provided comments to NEI concerning this guidance in a letter dated January 9, 1998. This letter noted that certain aspects of this guidance were unacceptable for implementation of 50.59 as presently written.

Staff efforts to develop guidance on implementation of 50.59 were prompted by a reassessment of the 10 CFR 50.59 evaluation process, conducted in 1995, that examined existing guidance and practice, with the goal of identifying how the process could be improved, or where additional guidance was needed. The staff provided an action plan to the Commission on April 15, 1996, outlining the actions the staff proposed to complete with respect to guidance and oversight of implementation of 50.59. The staff review identified a number of areas in which the meaning of the rule language is not clear, or where staff and industry interpretations (such as those in NSAC-125) are different. In SECY-97-035, dated February 12, 1997, the staff forwarded to the Commission proposed regulatory guidance on implementation of 50.59. In this SECY, the staff presented positions on a number of

topic areas. These positions in some cases reaffirmed existing regulatory practice or clarified staff expectations, and in other areas, established positions where guidance did not previously exist. In its proposed guidance, the staff compared its proposed regulatory guidance to industry guidance contained in NSAC-125. In accordance with a Commission Staff Requirements Memorandum dated April 25, 1997, the staff guidance was published in the Federal Register as draft NUREG-1606 (Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59), for public comment on May 7, 1997 (62 FR 24947).

In response to the *Federal Register* notice, many comments were submitted that voiced strong opposition to a number of the positions proposed by the staff. These comments were summarized in Attachment 1 to SECY-97-205, Integration and Evaluation of Results from Recent Lessons-Learned Reviews, dated September 10, 1997. Since that time, the NRC has conducted a more detailed review of the comments and concludes that some issues can be resolved through guidance, while in other areas, rulemaking is necessary to clarify the implementation issues. A copy of this analysis of comments is available for review in the NRC Public Document Room. As noted, the staff concluded that rulemaking was necessary to resolve some of the issues associated with implementation of the rule.

II. PROPOSED RULE TOPICS AND ISSUES

The NRC is proposing rulemaking on 50.59 (and 72.48) to address a number of issues concerning implementation of the current rule, and suitability of the criteria that determine when an unreviewed safety question exists. The implementation issues primarily relate to cases involving judgment as to whether a proposed change requires NRC approval before it can be implemented. The differing interpretations of the rule as it relates to an increase in probability of an accident, or an increase in consequences have contributed to disputed inspection and enforcement findings. Too stringent an interpretation of the meaning of the requirements could result in diversion of licensee and staff resources for review of inconsequential changes. Too high a threshold for NRC review could lead to erosion of safety margins without NRC review, particularly from the cumulative effect of more than one change. In developing the proposed rule, the Commission has carefully weighed these matters in trying to establish an appropriate threshold for NRC review.

Conforming changes are proposed in other portions of the rules, including 50.66,

50.71(e) and 72.212(b)(4) for production and utilization facilities licensed under Part 50. Conforming changes are also required in Appendices A and B to Part 52 (Design Certification Rules for ABWR and System 80+ respectively).

In addition, the Commission is proposing to make parallel changes applicable to facilities for independent spent fuel storage facilities licensed in accordance with Part 72. These changes are included in the sections below (in some cases, the discussion of the issue focuses on 50.59 for simplicity; except where noted, the discussion is also applicable to the changes for 72.48). As part of the proposed changes to Part 72, the Commission is also proposing to extend the change control process authority granted to ISFSI or MRS license holders (in 72.48) to holders of NRC Certificates of Compliance (CoC) for a spent fuel storage cask design.

In addition to changes to the requirements within sections 50.59 and 72.48, the Commission is also proposing to rearrange certain provisions of these rules to provide a more logical structure. These changes do not affect the substance of the requirements, but rather affect only where they are located and how they are stated. These organizational changes are discussed first, followed by discussion of each of the issues where revisions to requirements are proposed by this rulemaking. The proposed rule revisions are presented in the order that the issues currently arise in the regulations.

A. ORGANIZATION OF THE RULE REQUIREMENTS

The organizational changes being proposed include the following:

(1) Applicability

In the existing rule, language concerning applicability to different facilities is contained in three different paragraphs. These facilities are: 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 Commission proposes to place all of these provisions in one paragraph that is clearly labeled "Applicability."⁽⁴⁾

(2) Form of prior Commission approval

Existing paragraph 50.59(a) refers to the need for prior Commission approval of changes, tests, and experiments under certain conditions, but the method of receiving that approval is not discussed until paragraph (c), which states that the licensee shall submit an application for amendment under 50.90. The Commission proposes to combine these two paragraphs and to revise the regulation to state more clearly that a licensee must apply for and obtain a license amendment, pursuant to 50.90, before implementing such changes, tests, or experiments. This organizational change to the rule of combining (existing) paragraphs (a) and (c) will also facilitate some of the other proposed changes, such as the criteria for when approval is needed.

(3) Criteria for needing Commission approval of changes, tests and experiments and Unreviewed Safety Question (USQ) designation

The Commission proposes to remove the reference in the rule to the term "unreviewed safety question" and instead to refer to the need to obtain a license amendment. The Commission believes that the terminology of "USQ" has sometimes led to confusion about the purpose of the evaluation required by 50.59. Some licensees have concluded that if they determined a change was safe, there could be no need for NRC approval.

The Commission notes that the purpose of performing evaluations against the criteria specified in 50.59 is to identify possible changes that might affect the basis for licensing of the facility so that any changes that might pose a safety concern are either reviewed by the NRC or not implemented by the licensee. This evaluation process will thus distinguish those changes which by their nature do not raise safety concerns and therefore do not require

prior NRC approval to confirm their safety, from those that must be reviewed by the NRC to independently confirm their safety before implementation. To avoid confusion between a determination of safety and a determination of the need for NRC approval, the Commission proposes to revise

50.59 to delete use of the term "unreviewed safety question" and instead to list the criteria (in new 50.59(c)(2)) that require prior Commission approval, in the form of a license amendment. It is also noted that many facility technical specifications refer to unreviewed safety question determinations and such TS should ultimately be revised in accordance with the final wording of 50.59. The deletion of reference to USQ also requires a number of conforming changes to other parts of the regulations, including Part 52 (Appendices A and B), in which the term is presently used.

This proposed rule would revise the existing compound statements contained with the evaluation criteria to state each specific criterion individually. This will make the regulation more consistent with how it is generally implemented by licensees. Changes to the criteria are discussed in the sections below.

Finally, the Commission would simplify existing 50.59(c) by removing the following statement: "The holder of a license...who desires (1) a change to its technical specifications... shall submit an application for amendment of his license pursuant to 50.90." This statement refers to changes to the TS not associated with a change, test or experiment. The Commission concludes that a more suitable place for this provision is within 50.90, and therefore as part of this rulemaking, proposes to modify 50.90 to state that if a license wishes to amend its license (including the TS incorporated into it), the licensee must file an application as specified in 50.90. Revised 50.59(c)(i) would be revised to state that if a proposed change, test, or experiment would involve a TS change, the 50.90 process must be followed in order to change the technical specification such that the proposed change, test or experiment may be implemented.

B. CHANGE TO THE FACILITY AS DESCRIBED IN THE SAFETY ANALYSIS REPORT

Section 50.59 states that "changes to the facility as described in the safety analysis report" must be evaluated to determine whether prior approval is needed before implementation. As discussed in NUREG-1606 and in the comment discussions, a common understanding between the NRC and the industry on what constitutes a "change to the facility as described in the safety analysis report" is necessary for effective functioning of the review process. Guidance on preparation of 50.59 evaluations provides the means for review of the effects of changes, but these reviews are not conducted if the activity is not considered to be a "change..." The Commission concludes that modification of an existing provision (e.g., SSC, design requirement, analysis method or parameter), additions, and removals (physical removals or non-reliance on a system to meet a requirement) are all changes to the facility as described in the final safety analysis. The Commission believes that additions to the facility which were not previously evaluated, could adversely impact facility performance and the bases upon which the NRC previously determined the acceptability of the design as described in the SAR. Accordingly, the Commission concludes that additions should be considered "changes to the facility as described in the SAR" in order to assure that such changes are subject to evaluation using the 50.59 criteria for determining whether prior NRC review and approval are necessary.

Differences in interpretation have occurred about whether changes that do not actually change the physical plant (the "hardware") require a 50.59 evaluation. As an example, consider a change being made to the basis (documented in the SAR) for demonstrating adequacy of the facility without a physical change to the facility. Such changes might include changes to evaluative methods, acceptance standards, procurement specifications, or other information for SSC described in the FSAR. The Commission believes that 50.59 does apply to the requirements for design, construction and operation, and the safety analyses for the facility that are documented in the FSAR. Section 50.34(b), "Final safety analysis report," requires the FSAR to contain a presentation of the design bases and the limits on its operation, a description and analysis of the SSC of the facility, with emphasis upon performance requirements, the bases, with technical justifications therefore, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished. The original licensing decision was based in part upon the margins provided by performance requirements, analysis methods and assumptions described in the SAR, and reviewed by the staff in the SER. Therefore, the Commission concludes that changes to such information (e.g., 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 SAR" in order to assure that such changes are subject to evaluation using the 50.59 criteria for determining whether prior NRC review and approval are necessary..

If changes to methods and assumptions were not controlled, a licensee might revise its analyses and then subsequently conclude that a later facility change did not require NRC approval because the results of the (new) analysis with this change were bounded by the previous analysis. This proposed rulemaking would add definitions in 50.59 of "change" and of "facility as described in the final safety analysis report(as updated)" to more explicitly establish that evaluation is required for changes to the analyses and bases for the facility as well for physical or hardware changes to the facility.

Accordingly, the Commission proposes to add the following as definitions in section 50.59:

Change means a modification, addition, or removal.

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 (as updated), (ii) design or performance requirements or methods of operation for such SSC required to be included or described in the final safety analysis report (as updated), and (iii) evaluations or methods of evaluation required to be included in the FSAR (as updated) for such SSC that demonstrate that their intended functions will be accomplished or that their design bases can be met.

The Commission endorses the staff's previously stated position (in draft NUREG-1606) about what constitutes a single change, as compared to packaging of several changes with offsetting effects. Interdependent changes (i.e., where a second change is caused by the first, with respect to function or performance), can be treated as a single change, whereas treating as one change the combination of changes (whether to the facility directly or to the safety analysis) to offset one that would otherwise require prior approval is not an appropriate application of 50.59.

C. CHANGE TO THE PROCEDURES AS DESCRIBED IN THE SAFETY ANALYSIS REPORT

The Commission proposes to provide 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 would include the evaluations demonstrating that requirements are met, such as assumed operator actions and response times.

The Commission also notes that 50.34(b) states that the final SAR is to contain the managerial and administrative controls to be used to meet Appendix B (Quality Assurance), and plans for coping with emergencies, per Appendix E. Section 50.59 applies to changes to procedures as described in the SAR. Quality assurance and emergency planning program requirements are subject to the change control provisions of 50.54(a) and 50.54(q) respectively. Based on this set of rule provisions, it could be inferred that changes to quality assurance or emergency plans would require both a 50.59 evaluation and a 50.54 [either (a) or (q)] evaluation. The 50.54⁽⁵⁾ regulations provide criteria and reporting requirements specific to the plans and which were promulgated after 50.59. To reduce duplication of effort, the Commission proposes that changes to these programs be governed by 50.54 requirements, and that a 50.59 evaluation would not be required unless other information described in the FSAR is also being changed. The proposed rule would add language to specifically exclude from the scope of 50.59 changes to procedures where other more specific requirements and criteria have been established by regulation for controlling these changes (e.g., for information required by 50.34(b)(6)(ii) and (v)), through a provision in the 50.59(c)(1) of the proposed rule.

The proposed definition for "procedures as described in the final safety analysis report(as updated)" is as follows:

Procedures as described in the final safety analysis report (as updated) means information in the final safety analysis report (as updated) regarding how systems, structures and components are operated and controlled (including assumed operator actions and response times), including assumed operator actions and response times, and information on conduct of operations.

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

Section 50.59 also discusses the conduct of tests or experiments not described in the safety analysis report. "Test" is, of course, subject to many meanings including both routine verifications of function, and also more unusual evolutions. In the former category, there are many tests that are conducted that are not explicitly described in the SAR. For example, a licensee conducts tests of component and system performance that verify the SSCs perform the functions as described or required. (Performance of tests is typically controlled by procedure.) However, there also may be tests of new materials or means of plant operation that may put the plant in a situation that has not been previously evaluated and that could affect the capability of SSC to perform their required functions. The existing rule was designed to ensure that the latter type of tests would be reviewed before they were conducted. Therefore, to assure that there is clear definition with respect to the tests that are subject to prior NRC review and approval before they are conducted, the Commission proposes that a definition of "tests and experiments not described in the safety analysis report" be provided in 50.59 as follows:

Tests or experiments not described in the final safety analysis report (as updated) means any activity where the reactor or any of its systems, structures, or components are used or controlled in a manner which cannot be shown to be within (i) the controlling parameters of their design bases as described in the final safety analysis report (as updated) or (ii) consistent with the analyses in the final safety analysis report (as updated).

E. SAFETY ANALYSIS REPORT

In developing the proposed rule changes, the Commission noted the varying references to the safety analysis report within related sections of Part 50. For example, in 50.59, the phrase used is "safety analysis report," in 50.66, the reference is to the "updated final safety analysis report;" and 50.71(e) refers to the updated FSAR. (Other sections and parts generally refer to the final safety analysis report (e.g. Part 55), but this is not universally true (e.g. 50.54(a)). For purposes of 50.59, "safety analysis report" refers to the current revision of the FSAR, so that the changes are evaluated against the most complete and accurate description of the facility. When performing evaluations, a licensee needs to consider changes already made for which the FSAR update has not yet been submitted to the NRC. The Commission emphasizes the need for as current a reference base as possible for 50.59 evaluations, in order that the evaluations appropriately consider other changes already made that may have impacted the facility or procedures. However, a licensee is not required to submit an update its FSAR in the form specified by 50.71(e) except at the required frequency. To enhance consistency, the Commission is proposing to revise the rule language in these sections 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. The Commission did not use "Updated FSAR" for this purpose in order to take into account two special circumstances: (1) nonpower reactors, who are not required to submit updates to the FSAR, although they still need to consider other changes previously made when performing 50.59 evaluations, and (2) a plant licensed to operate, during the period between initial licensing and the first update. This revision is reflected in the definitions in the earlier sections and in the following sections. The definition also refers to "Final Hazards Summary Report," which is the applicable document for some early plants whose application was submitted before the regulatory term "safety analysis report" was adopted.

The proposed definition is as follows:

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 modified as a result of changes made pursuant to 50.59 and 50.90, and, as applicable, 50.71(e) and (f).

F. PROBABILITY OF OCCURRENCE OR CONSEQUENCES OF AN ACCIDENT OR MALFUNCTION OF EQUIPMENT IMPORTANT TO SAFETY PREVIOUSLY EVALUATED IN THE SAFETY ANALYSIS REPORT MAY BE INCREASED

The current language of the rule states that an unreviewed safety question exists when the probability of occurrence or consequences of an accident or malfunction of equipment important to safety previously evaluated *may be* increased [emphasis added]. Many of the concerns with current implementation relate to the appropriate interpretation of the words "probability of occurrence... or consequences... may be increased." In the draft NUREG-1606, the NRC staff stated that the plain reading of the words would mean that uncertainty about whether there has been an increase must lead to the conclusion that the criterion is met. As a result of trying to deal with the question of uncertainty, licensees were placed in the position of having to

prove there could not be an increase, even when there was no reason to believe that the proposed change, test or experiment would have that effect. A similar problem was experienced in considering whether the possibility of an accident or malfunction of a different type *may be* created.

Many of the commenters on the staff's proposed positions viewed this as overly restrictive and stated that it would result in many changes requiring prior NRC approval that are below the level of significance warranting such review. The position espoused in the revised industry guidance document (NEI 96-07) is that an increase in probability or consequences must be discernable in order for approval to be needed. The Commission concludes that the plain reading of the existing rule language is not consistent with this interpretation.

Although the current rule language would not permit discernable increases in probability or consequences, the Commission has concluded that at minimum, this would be a reasonable standard for requiring prior approval of changes, tests or experiment for increases in probability of occurrence of an accident or malfunction. The existing rule language dates from early in the development of reactor regulation, where with the knowledge base at the time, the then-AEC found it appropriate to set a very low threshold for changes. Over the last thirty years, the Commission has garnered experience with implementation of 50.59 and insights from probabilistic risk assessments, both of which indicate that this threshold can be adjusted without adversely impacting safety. Further, the analytical capabilities to calculate probabilities have greatly advanced, such that the effect of even minor changes on probabilities can be evaluated. Therefore, the Commission proposes to revise existing paragraph 50.59(a)(2)(i) of the rule by replacing "may be increased" with "would result in more than a minimal increase," in order to provide that there must be a clearly discernable change to require approval, the "minimal increase" concept is described in the next section. As noted above, the (a)(2) paragraph would be broken into four statements and renumbered as (c)(2)(i) through (iv).

G. MORE THAN A MINIMAL INCREASE IN PROBABILITY OR CONSEQUENCES

The Commission notes that 50.59 permits changes that do not otherwise require approval (such as would be the case if the provisions being changed are in TS or license, quality assurance or emergency plans, or inservice inspection and testing programs). Because the information being revised is of less immediate importance to public health and safety, and in consideration of the conservatism in NRC design and analysis requirements, acceptance criteria, and the precision with which safety analyses are performed, "minimal" variations in probability of occurrence or consequences of accidents and malfunctions should not affect the basis for the licensing decision. This conclusion is based upon the qualitative consideration of probability during plant licensing; accident probabilities were assessed in relative frequencies; equipment failures were generally postulated to gauge the robustness of the design, without estimating their likelihood of occurrence. Therefore, minimal increases in probability could not even have been identifiable, and could not impact the conclusions reached about acceptability of the facility design. Radiological consequences for accidents are calculated and reported at a level of precision such that minimal increases also would not impact the safety determination. The Commission therefore concludes 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 revised criteria would also 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 involves a "significant hazards considerations;" any hearing for an amendment constituting a "significant hazards consideration" must be completed prior to the grant of the amendment.) The standard in the proposed rule is qualitative (probability or consequences no more than minimally increased). The intent of this proposed rule is to allow changes that are small enough that they would not affect the facility's licensing basis, or adversely affect safety performance. While the proposed rule would allow minimal increases, licensee still must meet applicable regulatory limits and other acceptance criteria to which they are committed (such as contained in Regulatory Guides, etc.) Because the "more than minimal" standard allows for there to be a discernable increase, NRC needs to establish a point beyond which one would conclude that the increase is not minimal. The following guidance is offered, including values as to when the Commission would conclude that the revised criteria are not met. Quantitative calculations are not required except for those instances in which a licensee offers other than qualitative arguments as part of its evaluation.

Probability of occurrence of an accident

The current 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." The Commission believes this satisfies the proposed NRC standard.

In order to be considered as a minimal increase, the resulting probability (considering the change, test or experiment) must still satisfy the event frequency classification provided in the licensee's FSAR (as updated), e.g., for an anticipated operational occurrence (expected once a year) or for a design basis accident (not expected during life of plant, but sufficiently credible to require mitigation).

Probability of equipment malfunction

The Commission believes that the probability of malfunction is more than minimally increased if a new failure mode as likely as existing modes is introduced. The determination should be made either at the component level, or consistent with the failure modes and effects analyses, taking into account single failure assumptions, and the level of the change being made.

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." The Commission believes this satisfies this criterion.

The probability of malfunction of equipment important to safety previously evaluated in the FSAR (as updated) is no more than minimally increased if

"design bases" assumptions and requirements are still satisfied [i.e., the seismic or wind loadings, qualification specifications, procurement requirements]. As part of this guidance, note that NRC concludes that licensees can treat changes in external hazard design requirements as potentially affecting equipment malfunction probability rather than as "accident probability."

Consequences of accident or malfunction

Guidance in NEI 96-07 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." The NRC believes this satisfies the revised NRC standard.

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, NRC concludes that such a change satisfies the criteria of no more than a minimal increase in consequences.

As a quantitative measure, the Commission is considering some options. One would be to establish that a 0.5 rem increase in calculated dose as a result of the change be used to assess whether a minimal increase has occurred. This range of change would generally be in the decimal place for accident analyses where doses are reported in rem. The facility must still satisfy applicable acceptance values (e.g., the SRP) or regulatory requirements (e.g., Part 100) for the particular accident. If a licensee would need to change its design basis assumptions or analytical methods, or both, to demonstrate that the change in consequences is less than 0.5 rem, then the NRC does not view the change as minimal and would expect the licensee to submit a license amendment for such a change.

In addition, the Commission is considering a graduated approach, consistent with the concept of "minimal" being small enough so as not to impact the basis for acceptability. When the facility is far from the limit, a larger increase can be accommodated without concern about impact on the basis for acceptability. The values proposed take into account such factors as differences between licensee calculated values and staff estimation of existing performance, potential for a single change with a large increase, or for several "minimal" increases to approach the regulatory limits. The specific proposal offered for comment is:

Example using 300 rem thyroid dose as the limit

Existing calculated dose	"minimal" change	pre-change	after the change
<50% of limit	10% increase	140 rem	170 rem
80% of limit	5% increase	205 rem	220 rem
more than 80%	1% increase (NTE limit)	245 rem	248 rem

A third option under consideration, similar to option 2, would limit the fraction of remaining margin that can be consumed by a particular change. By defining "minimal" as being 10% of the remaining margin between current conditions and acceptance guidelines, the amount of change would decrease as the limit is approached, and the limit could not be exceeded.

Cumulative Effect

The Commission is concerned about the cumulative effect of minimal increases. Since some increases are allowed, the Commission believes that the proposed process 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 then becomes how the NRC can best oversee the process such that several "minimal" changes do not result in unacceptable results. The Commission has decided to require licensees to report effects of changes in a different manner to facilitate evaluation of cumulative effect, as discussed in a later section on reporting requirements, in which the Commission proposes to require that the SAR update in accordance with 50.71(e) discuss the effects of the changes upon calculated doses and other information.

H. POSSIBILITY OF AN ACCIDENT OF A DIFFERENT TYPE FROM ANY PREVIOUSLY EVALUATED IN THE SAFETY ANALYSIS REPORT MAY BE CREATED

As noted in Section F above, the uncertainty connected with demonstrating that no accident or malfunction may have been created is a major source of confusion and difficulty in implementing the existing rule; and is unnecessary for purposes of identifying when NRC review of a change is needed. Accordingly, the Commission proposes that the language in existing 50.59(a)(2)(ii) be revised as discussed below in this section and the following one. As noted earlier, the Commission is proposing to separate the requirements into distinct criteria for clarity. This criterion would now read "if a possibility for an accident of a different type from any previously evaluated in the final safety analysis report (as updated) is created." Under the proposed rule, a license amendment would be needed only if the licensee reasonably concluded that the possibility of an accident of a different type is created. This contrasts with the current rule, which would require a license amendment if the licensee is uncertain or unable to reasonably conclude that a new accident of a different type is not created. The Commission concludes that this proposed rule change will still identify those proposed changes, tests, or experiments that the NRC should review, without also including other changes of lesser significance that may be viewed as meeting the existing criteria.

I. POSSIBILITY OF A MALFUNCTION OF A DIFFERENT TYPE FROM ANY PREVIOUSLY EVALUATED IN THE SAFETY ANALYSIS REPORT MAY

BE CREATED

In a similar fashion, the Commission proposes to modify the remaining part of existing 50.59(a)(2)(ii), concerning malfunctions of a different type by creating a new criterion that would read "if 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) is created." This criterion involves three revisions to the existing rule. The first change is the use of the phrase "is created" which would require a determination that the possibility has been created, rather than uncertainty as to exclusion.

The second change is to insert the words "of equipment important to safety." The existing rule does not provide this characterization within paragraph (ii), but it is included in paragraph (i). It has generally been inferred that the statement in paragraph (ii) is an abbreviated version of that in paragraph (i). A review of the history of the 1968 rulemaking adopting revisions to Section 50.59 did not disclose any discussion suggesting that the Commission intended to distinguish between the (a)(2)(i) and the (a)(2)(ii) criteria with respect to the scope of equipment covered. Therefore, the Commission concludes that the rule was intended to apply to the same scope of equipment in each case, and therefore, proposes to include the words in this criterion to eliminate any doubt.

The final change is being proposed in response to the comments on the staff-proposed guidance (NUREG-1606) on the interpretation of malfunction (of equipment important to safety) of a different type. The commenters believe that the cause of the malfunction should be a consideration in determining whether the probability of the malfunction may have increased, and that a malfunction of a different type would only be created if the effects of the malfunction are not already bounded by the FSAR analysis. The recent industry guidance states that if a component were subject to failure from a new failure mode but the failure of the component is already considered in the safety analysis, then there would not be a failure of a different type. The Commission does not agree that the industry interpretation is consistent with the rule as written, which refers to creation or possibility of a malfunction of a different type, not of a different result. However, the Commission recognizes that in its reviews, equipment malfunctions are generally postulated as potential single failures to evaluate plant performance; thus, the focus of the NRC review was on the result, rather than the cause/type of malfunction. Unless the equipment would fail in a way not already evaluated in the safety analysis, there is no need for NRC review of the change that led to the new type of malfunction. Therefore, as the third change in 50.59(a)(2)(ii), the Commission is proposing to change the phrase "of a different type" to "with a different result". Therefore, this criterion would read: "if a possibility for a malfunction of equipment important to safety with a different result ...is created."

In implementing this position, attention must be given to whether the malfunction is evaluated at the component level or the overall system level. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and resulting event initiators or mitigation impacts, it also needs to consider the nature of the change. Thus for instance, if failures were previously postulated on a train level because the trains were independent, a change that introduces a cross-tie might need to be evaluated to see whether new outcomes have been introduced. The staff has provided guidance on this issue in Generic Letter (GL) 95-02, concerning replacement of analog systems with digital instrumentation. The GL states that in considering whether new types of failures are created, this must be done at the level of equipment being replaced -- not at the overall system level. Further, it is not sufficient for a licensee to state that since failure of a system or train was postulated in the SAR, any other equipment failure is bounded by this assumption, unless there is some assurance that the mode of failure can be detected and that there are no consequential effects (electrical interference, materials interactions, etc), such that it can be reasonably concluded that the SAR analysis was truly bounding and applicable. Otherwise, the Commission would conclude that there was increase in probability of malfunction or that a malfunction with a different result has been created.

J. MARGIN OF SAFETY AS DEFINED IN THE BASIS FOR ANY TECHNICAL SPECIFICATION IS REDUCED

The current rule would require a licensee to conclude that an unreviewed safety question is involved if the 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..." have been the subject of differing interpretations because the rule does not define what constitutes a margin of safety or a basis for a technical specification in the context of Section 50.59.

As noted earlier, various margins exist in a facility design. These margins are based on, for example, assumptions of initial conditions, conservatism in computer modeling and codes, allowance for instrument drift and system response time, redundancy and independence of components in safety trains, and plant response during operating transient and accident conditions (sometimes referred to as implicit margins). Margin to conditions that might be detrimental to safety is also accomplished by establishing acceptance criteria to be met for response to various accidents and transients. Arguably, not all margins that exist fall within the purview of "a margin of safety as defined in the basis for any technical specification."

The Technical Specifications are provided to ensure that the plant operates in a manner that provides acceptable levels of protection for the health and safety of the public. They are not meant to be all inclusive, but are reserved for those matters where the imposition of rigid conditions or limitations upon reactor operation is deemed necessary to avoid an abnormal situation or event that gives rise to an immediate threat to public health and safety. The technical specifications specify the equipment that must be operable and the initial plant conditions necessary to meet the assumptions of the safety analyses. The relationship of the TS to the safety analyses means that the bases of the technical specifications, and thus the associated margins of safety are found in the plant's input assumptions (design inputs), analytical assumptions and safety analysis, including the acceptance conditions, criteria and limits, described in the final safety analysis report (as updated). These assumptions and inputs include such parameters as the allowable range of initial conditions (temperatures, pressures, flows, reactivity coefficients, etc.), setpoint uncertainties, penalty factors, or use of NRC-approved methodologies. NRC safety evaluation reports (SERs) will usually discuss the conditions, assumptions and margins that played a role in the staff's licensing decision. In most cases, the BASES sections of the technical specifications summarize the reasons for each specification, including the related analyzed accidents and events, and in a few cases, actually define any associated margin of safety. While, the BASES sections of TS should be helpful in determining the margin of safety, they should not be relied upon as the only reference when attempting to assess whether a margin of safety reduction has actually occurred. The wording of the existing rule has led some licensees to conclude that only margins explicitly noted in the BASES section of the TS need be considered in evaluating this criterion.

The supporting information for the 1968 rulemaking that added the "margin of safety" criteria did not state which margins were meant to be preserved

by this criterion. However, this information does reflect the understanding that the technical specifications were to be based upon the safety assessments in the SAR, and that the TS BASES were to contain a summary of the safety analyses underlying the TS. For instance, the Statement of Considerations (33 FR 18610, December 17, 1968), the Atomic Energy Commission stated:

The analyses and evaluation of the facility required under 50.34 must provide (1) the necessary information from which technical specifications will be selected, and (2) the detailed bases for the specifications derived. [AND]

Since the [rule] amendments place increased emphasis on analysis and evaluation of a facility, in order to provide a sound basis for each technical specification, the preparation of technical specifications by the applicant requires a carefully prepared safety analysis report.

By the specific reference to "basis for any technical specification," the Commission believes that a reasonable interpretation of the intent was to preserve the margins in the analyses that established the TS requirements, as for instance, in determining the minimum plant performance conditions and configurations, which are the TS limiting conditions for operation, limiting safety system settings and safety limits. Because 50.59 requires prior NRC approval for a change to the TS, a change that could invalidate the basis upon which the TS values were established should also receive prior approval. Accordingly, the Commission concludes that for 50.59 reviews, a reduction in margin of safety occurs when the input assumptions (plant performance conditions and configurations), analytical methods or acceptance conditions, criteria or limits for those analyses that established the TS are altered in a nonconservative direction. (Whether an increase or a decrease in a value is nonconservative is of course dependent on the nature of the parameter, but is generally self-evident). Changes, tests or experiments that would affect these parameters in a way that reduces safety margins (i.e., by being less conservative) must be reviewed by NRC before they are implemented.

In conclusion, the Commission concludes that the analyses and information in the FSAR establish the basis for the margins of safety for the TS. To resolve matters related to interpretation of basis for any TS, the Commission is proposing to add a definition to the new "Definitions" section, for "reduction in margin of safety associated with any technical specification" and to conform the criterion for needing a license amendment in new Section 50.59(c)(2). The confusing terminology of "basis for any TS" would be replaced by "associated with any TS⁽⁶⁾" in order to retain the emphasis upon the TS and the safety analyses (including the margins) in the FSAR(as updated).

The following definition would be added:

Reduction in margin of safety associated with any technical specification means that the input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the final safety analysis report (as updated), that established any technical specification requirement, are altered in a nonconservative manner.

In Section 50.59(c)(2), the criterion would read:

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

(i) through (vi) ...

(vii) result in a reduction in margin of safety associated with any technical specification.

K. SAFETY EVALUATION

Section 50.59(b)(1) requires licensees to maintain records that must include a written safety evaluation that provides the bases for the determination that the change, test, or experiment does not involve an unreviewed safety question. Section 50.59(b)(2) requires submittal of a report containing a brief description of any changes, tests, or experiment, including a summary of the safety evaluation of each. In the interest of emphasizing the regulatory purpose of the evaluation required under 50.59, which led the Commission to propose deletion of the term "unreviewed safety question," the Commission proposes to delete the word "safety" in referring to the required evaluation for determining whether the change, test, or experiment requires a license amendment. For purposes of the summary report of tests and experiments submitted to NRC, the staff would propose that the rule specify that a summary of the evaluation be provided (rather than a summary of the safety evaluation).

A similar change is 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 proposes to change "safety evaluation in support of license amendments" to "safety analysis in support of license amendments," to reduce confusion between the information prepared by the licensee for the amendment (safety analysis) and the NRC review (safety evaluation). The second part of this 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." (In this case, it is a licensee evaluation against the regulatory criteria in 50.59 that is being referred to). In addition, other minor wording changes are proposed such as with respect to terminology on "final safety analysis report" and "effects of" (see reporting requirements discussion below). Conforming changes in the Appendices to Part 52 and in Part 72 to revise language to refer to "evaluation" are also proposed.

L. REPORTING AND RECORDKEEPING REQUIREMENTS

In view of the "minimal increase" criteria in 50.59, the Commission concludes that the reporting requirements for the SAR update should be enhanced to enable the NRC to better understand the potential cumulative impact of changes that might have been made since the last update. Therefore, the Commission proposes to supplement the reporting requirements 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. Accordingly, the Commission proposes to revise 50.71(e) to read as follows:

"(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: (1) all changes made in the facility or procedures as described in the FSAR; (2) all safety analyses

and evaluations performed by the licensee either in support of requested 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; (3) all analyses of new safety issues performed by or on behalf of the licensee at Commission request; and (4) the net effect of all changes made since the last update on the safety analyses, including probabilities, consequences, calculated values, system or component performance, that are in the FSAR (as updated). 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."

Finally, the Commission is proposing a change to the record retention requirements in existing paragraph 50.59 (b)(3) [renumbered by this rulemaking to (c)(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 statement "or until the termination of a license issued pursuant to 10 CFR Part 54, whichever is later." This change would make more clear the requirement that records must be maintained through the life of the facility so that they will remain available until such time as they are no longer needed (that is, when the license is terminated, not just at the end of the initial licensing term).

M. PART 72 CHANGES

In Part 72 the Commission is proposing to make conforming changes to 72.48 with those made to 50.59 and to expand the scope of 72.48 so that holders of a Certificate of Compliance (CoC) are also subject to it. In addition to the proposed changes to 72.48, the Commission proposes to make changes in other sections of Part 72. When Subpart L - Approval of Spent Fuel Storage Casks, was originally added to Part 72, no provisions were included to address potential amendments of CoCs. However, regulations in this area are necessary to provide requirements for certificate holders in instances where a proposed change does not meet the tests of 72.48, and an amendment to the CoC is necessary. Therefore 72.244 and 72.246 would be added to Subpart L, to provide regulations on applying for, and approving, amendments to CoCs. Section 72.248 would also be added to provide regulations for the certificate holder submitting an updated final safety analysis report, which would document the changes it made to procedures or structures, systems, and components under the provisions of 72.48. The Commission notes that a general licensee is not precluded from loading spent fuel into an approved spent fuel storage cask during the 90-day period allowed for the certificate holder to submit a final safety analysis report. This approach is the same as that required for Part 72 license holders to update their final safety analysis report under 72.70. The Commission also notes, that for dual-purpose spent fuel casks (i.e., casks which have been issued CoCs for transportation and storage under Parts 71 and 72, respectively), no regulation equivalent to 72.48 exists in Part 71. Consequently, a certificate holder could make changes to the design of a spent fuel storage cask under the authority of 72.48 (i.e., without prior NRC approval); however, if the change also affected the transportation aspects of the cask's design and involved a modification to the Part 71 certificate, then NRC approval and amendment of the transportation CoC would be required before the cask could be used to transport spent fuel to another site. Additionally, a transportation cask CoC has a term of 5 years, compared to the 20-year term for a storage CoC. Consequently, the Commission envisions that most of this type of change would be captured during the periodic renewal of a transportation CoC and this delay would not have a significant adverse impact on a licensee's ability to transport spent fuel in a dual purpose cask.

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. The existing requirement in 72.24(a) - Contents of application: Technical Information, would be revised to reference shared common utilities and services in the applicant's assessment of potential interactions between the ISFSI and another facility. The Commission would remove the existing requirement in 72.3 for the applicant to evaluate the impact of sharing common utilities and services on the "other facility." The Commission believes that evaluation of the impact on the "other facility" should not be part of the licensing process for an ISFSI. Rather, such evaluation should be part of the license amendment process for that "other facility" and should be performed under the regulations used to license that "other facility."

Changes to 72.56 would be conforming changes to those made to 50.90. Changes to 72.70 are also conforming changes to those made to 50.71(e); additionally, requirements would be added to 72.70 on standards for submitting revised Final Safety Analysis Report (FSAR) pages. The Commission notes that the proposed 72.70 would retain the requirement that the site-specific licensee submit a final safety analysis report at least 90 days prior to the planned receipt of spent fuel or high-level waste. The Commission has not received any requests for exemption from this regulation and believes that this regulation does not impose an undue burden or schedule impact on licensees. The proposed rule also modifies the requirements for filing of updates (through reference to 72.4) to be consistent with other changes being made to Part 72. Changes to 72.216 for a general licensee are similar to the changes made to 72.70 for a site-specific licensee and are also conforming changes to those made to 50.71(e). The Commission also envisions that a general licensee who wishes to adopt a change to the design of a spent fuel storage cask it possesses--which 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. The changes to 72.9 and 72.86 are conforming changes due to the addition of new 72.244, 72.246, and 72.248.

Changes to Part 72 Record keeping requirements would include the clarification that records required by 72.48 shall also include determinations that significant increases in occupational exposure or unreviewed environmental impacts did not exist, such that a license amendment would have been required. (The existing language linked the written evaluation only to the "unreviewed safety question" determination, and thus did not explicitly require Record keeping for the determinations of whether the change would cause a significant increase in occupational exposure or a significant unreviewed environmental impact). Certificate holders would also be required to keep records of such changes as would be allowed under 72.48.

Requirements in 72.70 would be established for reporting changes to procedures. The Commission notes that 72.70 presently requires that the update include⁽⁷⁾ a description and analysis of changes in the structures, systems, and components with emphasis upon performance requirements; the bases, with technical justification therefor, upon which such requirements are based; and evaluations showing that safety functions will be accomplished. It also requires an analysis of the significance of any changes to codes, standards, regulations, or regulatory guides which the licensee has committed to meeting the requirements of which are applicable to the design, construction, or operation of the facility. 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

reporting requirements for general licensees would be added as 72.216(d), similar to existing reporting requirements for site-specific licensees in 72.70 and proposed requirements for certificate holders in 72.248.

In both of these sections, the Commission is adding a requirement that the entity making a change to the cask, either the general licensee or the certificate holder, provide a copy of the submittal to the other party for their information.

III. SECTION BY SECTION ANALYSIS

10 CFR Part 50

10 CFR 50.59

As discussed in more detail above, 50.59 would be restructured and revised to have the following components.

Paragraph (a) - This is a new paragraph that provides definitions of terms such as "change", "facility as described...", in order to specify more clearly which changes, tests and experiments require further evaluation and how reductions in margin of safety are to be determined. The references to "safety analysis report" are being revised to "final safety analysis report (as updated)" to state that the evaluations are to be performed that take into account other changes made that have affected the final safety analysis report since its original submittal.

Paragraph (b) - Relocation of existing applicability provisions.

Paragraph (c)(1) - Relocation of existing provisions establishing which changes, tests, or experiments require evaluation, using the defined terms. The terminology of "unreviewed safety question" has been replaced by referring to the need to obtain a license amendment. This paragraph also clarifies that the licensee must submit its request for license amendment, and obtain the amendment prior to implementing those changes, tests or experiments that involve TS or otherwise meet the criteria for prior NRC approval as specified in (new) paragraph (c)(2).

Paragraph (c)(2) - Reformatting of the evaluation requirements into seven distinct statements of the criteria and revision of the criteria for when prior NRC approval of a change, test or experiment is required. Specifically, language of "more than a minimal increase" was inserted in the criteria concerning increases in probability and consequences, and revisions to the rule requirements were made concerning creation of accidents of a different type and malfunctions of equipment with a different result. Clarification is also being provided that the margins of safety are those associated with TS requirements established by the FSAR analyses, and are not confined to the BASES section of the TS. 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 (d)(1) - Renumbered paragraph with record keeping requirements. Also includes change from "safety evaluation" to "evaluation."

Paragraph (d)(2) - Renumbered paragraph with reporting requirements.

Paragraph (d)(3) - Renumbered and revised paragraph on retention of records, to cover the term of any renewed license.

10 CFR 50.66

The proposed changes for 50.66 are to conform existing language referring to unreviewed safety questions, and references to updated final safety analysis report, to the language proposed in revised 50.59 for consistency.

10 CFR 50.71(e)

The proposed changes to this section are to conform language with respect to unreviewed safety question, safety evaluation, and reference to final safety analysis report (as updated), with the proposed language in 50.59, and to clarify reporting requirements relating to "effects of" changes such that cumulative effects of minimal increases in probability and consequences are included in the update to the FSAR.

10 CFR 50.90

A portion of existing 50.59(c) would be relocated into this section. This change would place the requirements for changes to technical specifications in the rule section on amendments to licenses.

10 CFR PART 52

Appendix A and Appendix B to 10 CFR Part 52

The proposed changes to these sections are to conform references to unreviewed safety question, safety evaluation and the evaluation criteria concerning when prior NRC approval is needed, to the language in the proposed revision to 50.59.

PART 72

10 CFR 72.3

The definition for *independent spent fuel storage installation* would be 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 also proposed to be revised to include this evaluation).

10 CFR 72.9

Paragraph (b) would be revised as a conforming change to include in the list of information collection requirements the new reporting requirements in 72.244 and 72.248 for reports of changes made by CoC holders and for updates to the safety analysis reports by CoC holders.

10 CFR 72.24

This section would be 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

New definitions have been added for terms such as "change" and "facility as described in the Final Safety Analysis Report (as updated)." The specific criteria in existing paragraph (a)(2) have been revised to separate out the various statements, to insert the language of "more than a minimal increase," and to modify the criterion from "malfunction of a different type" to "malfunction of a different result." The text for Record keeping requirements was revised to refer to the need for license or certificate of compliance (CoC) amendments, rather than involving an unreviewed safety question. As part of this revision, the Commission is also clarifying that the records shall also provide a basis for why a proposed change, test, or experiment did not require a license or CoC amendment with respect to significant increases in occupational exposure or significant unreviewed environmental impacts. Additionally, the term "Final Safety Analysis Report (FSAR) (as updated)" has been used to provide greater clarity and consistency with 50.59 and other sections of Part 72. The filing requirements for the summary reports are modified to be consistent with 72.4 (Communications).

10 CFR 72.56

Existing 72.48 (c)(2) is being relocated into this section. This is a parallel change to that proposed for 50.59 and 50.90, wherein the Commission would place the requirements for changes to license conditions in the rule section on amendments to licenses.

10 CFR 72.70

Paragraphs (a) and (b) would be revised to use the terms "Final Safety Analysis Report," "FSAR," and "as updated." Paragraph (b)(2) would be revised to add changes to procedures to the annual updates of the FSAR. New paragraph (c) would be added to provide requirements on submitting revisions to the FSAR.

10 CFR 72.86

Paragraph (b) currently includes those sections under which criminal sanctions are not issued. This paragraph would be revised by adding 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)(4)

The change to this section is to conform the reference to 10 CFR 50.59 provisions, specifically to change from the terminology of unreviewed safety question to referring to need for 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

New paragraph (d) provides 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 cask that are used by the general licensee. The general licensee is also required to provide a copy of its submittal to the certificate holder. This section is similar to the requirements in 72.70 and 72.248 for submission of annual updates to the FSAR associated with a site-specific Part 72 licensee or a certificate holder, respectively.

10 CFR 72.244

This new section provides requirements for a certificate holder 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 provides 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 provides requirements for submittal of annual updates to a FSAR associated with the design of a spent fuel storage cask which has been issued a CoC. This new section also provides that the changes to procedures and structures, systems, and components associated with the spent fuel storage cask and which are made pursuant to 72.48 would be included in the annual update. The proposed revisions would also require that the

certificate holder provide a copy of the FSAR submittal to each general licensee using that cask. This section is similar to the requirements in 72.70 for submission of annual updates to the FSAR associated with a site-specific Part 72 license and new section 72.216 for general licensees to provide updates to the FSAR.

IV. RULE LANGUAGE PROPOSED BY THE NUCLEAR ENERGY INSTITUTE

In a letter dated November 14, 1997, the Nuclear Energy Institute provided to the NRC suggested language for revising 10 CFR 50.59 that they believed would enable the NRC to endorse NEI 96-07. This language is included here in this Statement of Considerations so that

interested parties can offer comment on whether this language should be adopted by the NRC. The supporting information for NEI's proposal is contained in the referenced letter which is available for review in the Public Document Room.

Specifically, NEI proposed that [existing] section 50.59(a)(2) be revised to read:

(a)(2) A proposed change, test, or experiment shall be deemed to involve an unreviewed safety question: (i) if there is more than a negligible increase in the probability of occurrence of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report; or (ii) if the consequences of an accident or malfunction important to safety previously evaluated in the safety analysis report exceeds the established acceptance limit; or (iii) if a possibility for an accident of a different type or malfunction with a different result from any evaluated previously in the safety analysis report may be created; or (iv) if the margin of safety provided by any technical specification is reduced.

In this rulemaking, the Commission is proposing to adopt certain aspects of the changes offered by NEI (e.g., on malfunction with a different result). The Commission is seeking comment as to whether other aspects of this proposal should be adopted. The Commission also offers the following observations about this proposal for consideration as part of the comment process:

A. Negligible Increase in Probability of Occurrence

NEI proposes that the rule be revised to state that a change would be an USQ "if there is more than a negligible increase in the probability of occurrence of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report." As discussed above, the Commission is proposing a "more than minimally increased" criterion, which is considered comparable in overall intent to what was proposed by NEI.

B. Increase in Consequences of an Accident or Malfunction

NEI proposes that the rule be revised such that a change would be a USQ if the consequences of an accident or malfunction previously evaluated exceed the established acceptance limit. As NEI discusses further in its letter, the established acceptance limit would be the value that was previously reviewed and approved by the NRC generally as documented in the staff's safety evaluation report (SER).⁽⁸⁾

The current industry guidance, NEI 96-07, would permit, in some instances, increases in consequences up to the regulatory thresholds (such as Part 100), without review. As discussed in (draft) NUREG-1606, the staff typically performs independent evaluations of radiological consequences of accidents, rather than an in-depth review of the licensee's calculations, during licensing of the plant. As a result, the degree of conservatism in the licensee calculations differs from that used in the staff's assessments. As noted above, the Commission is proposing to revise the rule to allow "minimal" increases in consequences without prior approval, provided that the regulatory limits are still met. The Commission has some concerns about allowing licensee changes without review, which when evaluated with licensee assumptions and methods, result in doses at or very close to the regulatory guidelines (e.g., Part 100). This is because such changes, if reviewed with staff assumptions (or starting from the staff's previous estimation of the accident dose), might result in the regulatory guidelines not being met. Rather than allowing one change to result in an increase in consequences up to the guidelines, the Commission concludes that minimal increases, along with NRC oversight of cumulative effects, is the appropriate standard for review.

C. Malfunction with a Different Result

As discussed above, the Commission is proposing to adopt this particular proposed change to the rule.

D. Margin of Safety Provided by Any Technical Specification

NEI proposes to replace the existing language of "as defined in the basis for any technical specifications," with "as provided by any technical specification" with respect to reductions in the margin of safety. The proposed change is intended to clarify that the margin of safety is not necessarily limited to information in the BASES section of the technical specification. NEI 96-07 guidance notes that the SAR, staff SERs and other licensing basis documents should be reviewed to determine if a proposed change would result in a reduction in margin of safety. NEI intended to use this rule language in conjunction with guidance that the margin of safety is the range of values between the acceptance limit reviewed by the NRC (e.g., ASME code stress limits, containment design pressure, etc.) and the failure point. The Commission is proposing a definition that would accomplish the same clarification concerning BASES of the TS, but which takes a different approach concerning what constitutes the margin of safety.

V. Request for Comment

The Commission requests comments on the proposed rule, as discussed in Section II above. The Commission is particularly interested in comments on the guidance on "minimal" increase in Section II.G, including suggested examples of changes that commenters believe should be deemed to involve only a "minimal increase" in probability or consequences. In addition to the NRC proposals in Section II and III, the Commission is also interested in receiving comments on the proposals and language suggested by NEI (Section IV). Finally, the Commission is interested in any proposals (not previously submitted) concerning margin of safety that would preserve the integrity of the TS and their underlying basis, but which might allow a limited degree of flexibility for very small changes in input parameters without the need for prior NRC review and approval.

VI. Availability of Documents and Electronic Access

Certain documents related to this rulemaking, including comments received and the regulatory analysis, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, D.C. NRC documents also may be viewed and downloaded electronically via the interactive rulemaking website established by NRC for this rulemaking.

You may also provide comments via the NRC's interactive rulemaking web site through the NRC home page (<http://www.nrc.gov>). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301) 415-6215; e-mail CAG@nrc.gov.

VII. 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, if adopted, will not have a significant impact on the environment. The proposed 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 being proposed 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 probability or consequences of accidents (still satisfying regulatory limits) would 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, or reductions in defined margins of safety require prior approval. 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, the Commission concludes that there will be no significant impact on the environment from this proposed rule. This discussion constitutes the environmental assessment and finding of no significant impact for this proposed rule.

VIII. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been 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 3150-0039.

The proposed rule changes would 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 and in 50.71(e) for submittal of updates to the FSAR, as well as record keeping requirements. To the extent that the definitions provided in the proposed revisions would require evaluations that are not presently being performed, there may be an increase in record keeping and reporting. The Commission estimates that this is a small increment over the existing burden. On the other hand, some changes might be screened out as not needing evaluation on the basis of these definitions, and thus there would overall be at most a small increase in the record keeping required.

In addition, the requirements under 72.48 are also being revised to explicitly require records of determinations concerning occupational dose and environmental impact (the existing rules required the evaluations but did not explicitly specify record retention requirements for these evaluations). The Commission does not believe this that this change will significantly impact record keeping burden because records of evaluations of changes are already required (as to whether they involve a USQ), and the evaluation itself is already required by the rule. The Part 72 burden associated with the definitions of when evaluations are required should be significantly less than for 50.59 since the number of licensees is smaller and the expected number of changes is also smaller. Further, there is a recordkeeping requirement established for CoC holders who make changes to an approved storage cask design in accordance with 72.48.

With respect to reporting requirements, the Commission is proposing to modify the FSAR update requirement to state that the updates must include specific information on the effects of changes made. This was not explicitly stated in the current rule, although it could be inferred that this was what the update rule intended, as follows. In the Statement of Considerations for 50.71(e), (45 FR 30615), the NRC commented on the relationship between changes made under 50.59 and FSAR updating, stating: "The 50.59(b) reporting may not be detailed sufficiently to be considered adequate to fulfill the FSAR updating requirement. The degree of detail required for updating the FSAR will be generally greater than a 'brief description' and a 'summary of the safety evaluation'." Thus, the Commission clearly expected the update submittal to include sufficient information to appropriately reflect the changes that were made. The burden associated with explicitly documenting in the update the effects of the changes on event probabilities and consequences is therefore small.

The public reporting burden for this information collection request is estimated 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 estimates that there is only a slight increase in burden associated with these proposed changes over the existing burden. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the collection of information contained in the proposed rule and on the following issues:

1. Is the proposed collection of information necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of the burden correct?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the collection of information be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed collection of information, including suggestions for reducing the burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0017, -0020, -0011, -0009, and -01320), Office of Management and Budget, Washington, D.C. 20503.

Comments to OMB on the collections of information or on the above issues should be submitted by (insert date 30 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the values and impacts of the alternatives considered by the Commission and includes the backfit analysis required by 50.109 (and 72.62). The alternatives considered in this analysis include no action, issuance of guidance only, or rulemaking. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, D.C. and is available through the NRC interactive rulemaking website. Single copies of the analysis may be obtained from Eileen McKenna, EMM@NRC.GOV (301) 415-2189, Mail stop O-10-H-5, U.S. Nuclear Regulatory Commission, Washington D.C. 20555.

The Commission requests public comment on the draft analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

X. 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, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing and operation and decommissioning of nuclear power plants, nonpower reactors, and independent spent fuel storage facilities. 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.

XI. Backfit Analysis

As required by 50.109 and 72.62, the Commission has completed a backfit analysis for the proposed rule, which is included within the regulatory analysis. The Commission has determined, based on this analysis, that in most respects, the proposed rule does not impose new requirements, but provides more flexibility or clarification of existing requirements. In other respects, such as the definitions of change to the facility and "reduction of margin of safety..." , some licensees may view the revised rule as imposing new requirements. Therefore, the Commission has prepared an analysis considering the factors in 50.109(c), which is included in the Regulatory Analysis.

XII. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act (AEA), the Commission is issuing the proposed rule to amend 10 CFR 50 : 50.59, : 50.66, and : 50.71; and 10 CFR 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.

XIII. 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 does not confer regulatory authority on the State.

List of Subjects

10 CFR Part 72

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

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 52

Administrative practice and procedure, Antitrust, Backfitting, Combined license, Early site permit, Emergency planning, Fees, Inspection, Limited work authorization, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Reporting and record keeping requirements, Standard design, Standard design certification.

10 CFR Part 72

Manpower training programs, Nuclear materials, Occupational safety and health, Reporting and record keeping 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. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 50, 52 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. 1244, 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 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 185, 68 Stat. 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, and 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). Section 50.37 also issued under E.O. 12829, 3 CFR 1993 Comp., P. 570; E.O. 12958, Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 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, 68 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, addition, or removal.

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

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

(ii) The design, performance requirements and methods of operation for such systems, structures and components required to be included or described in the final safety analysis report (as updated), and

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

(3) *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 modified as a result of changes made pursuant to 50.59 and 50.90, and, as applicable, 50.71(e) and (f).

(4) *Procedures as described in the final safety analysis report (as updated)* means

information in the final safety analysis report (as updated) regarding how structures, systems, and components are operated and controlled (including assumed operator actions and response times) and information describing the conduct of operations.

(5) *Reduction in margin of safety associated with any technical specification* means that the input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the final safety analysis report (as updated), that established any technical specification requirement, are altered in a nonconservative manner.

(6) *Tests or experiments not described in the final safety analysis report (as updated)* means any condition where the reactor or any of its systems, structures or components are utilized or controlled in a manner which is either:

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

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

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

(2) A licensee shall obtain an amendment to the license pursuant to 50.90 prior to

implementing a change, test or experiment if it would:

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

(ii) Result in more than a minimal increase in the probability of occurrence of a malfunction of equipment important to safety previously evaluated in either the final safety analysis report (as updated), 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;

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

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

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

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

(vii) Result in a reduction in the margin of safety associated with any Technical Specification.

(d) (1) The licensee shall maintain records of changes in the facility and of changes in procedures made pursuant to this section, to the extent that these changes constitute changes in the facility as described in the final safety analysis report (as updated) or to the extent that they constitute changes in procedures as described in the final safety analysis report (as updated). The licensee shall also maintain records of tests and experiments carried out 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. The report may be submitted annually or along with the FSAR updates as specified by 50.71(e), or at such shorter intervals as may be specified in the license.

(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 five years.

3. In 50.66, paragraphs (b), (b)(4), (c)(2), (c)(2)(i), (c)(2)(iii), (c)(3)(iii)(A) and (c)(3)(iii)(B) are revised to read as follows:

50.66 Requirements for thermal annealing of the reactor pressure vessel.

* * * * *

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

* * *

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

(c) * * *

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

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

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

(3) * * *

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

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

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

* * * * *

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

50.71 Maintenance of records, making of reports.

* * * * *

(e) Each person licensed to operate a nuclear power reactor pursuant to the provisions of 50.21 or 50.22 of this part shall update periodically, as provided in paragraphs (e)(3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the operating license, to assure that the information included in the report contains the latest information developed. This submittal must 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 submittal must include the effects¹ of: (1) all changes made in the facility or procedures as described in the FSAR; (2) all safety analyses and evaluations performed by the licensee either in support of requested 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; (3) all analyses of new safety issues performed by or on behalf of the licensee at Commission request; and (4) the net effect of all changes made since the last update on the safety analyses, including probabilities, consequences, calculated values, system or component performance, that are in the FSAR (as updated). 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."

* * * * *

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 52 - EARLY SITE PERMITS, STANDARD DESIGN CERTIFICATIONS; AND COMBINED LICENSES FOR NUCLEAR POWER PLANTS

6. The authority citation for Part 52 continues to read as follows:

AUTHORITY: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2133, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5546).

7. Appendix A to Part 52 is amended by revising Section VIII.B, paragraphs 5.a,b,d, and Section X.A.3 as follows:

Appendix A - Design Certification Rule for the U.S. Advanced Boiling Water Reactor

VIII. Processes for Changes and Departures

* * * * *

B. Tier 2 information

5. * * *

a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the technical specifications, or otherwise requires a license amendment as defined in paragraphs B.5.b and B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would---

(1) Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the probability of occurrence of a malfunction of equipment important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of equipment important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of equipment important to safety with a different result than any evaluated previously in the plant-specific DCD; or

(7) Result in a reduction in the margin of safety associated with any Technical Specification for an application or license referencing this design certification.

* * * * *

d. If a departure requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

* * * * *

X. Records and Reporting

A. Records.

* * * * *

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

8. Appendix B to Part 52 is amended by revising Section VIII.B, paragraphs 5.a,b,d, Section X.A, Paragraph 3 to read as follows:

Appendix B - Design Certification Rule for the system 80+ Design

VIII. Processes for Changes and Departures

* * * * *

B. Tier 2 information.

* * *

a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the technical specifications, or otherwise requires a license amendment as defined in paragraphs B.5.b and B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would---

(1) Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the probability of occurrence of a malfunction of equipment important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of equipment important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of equipment important to safety with a different result than any evaluated previously in the plant-specific DCD; or

(7) Result in a reduction in the margin of safety associated with any Technical Specification for an application or license referencing this design certification.

* * * * *

d. If a departure requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

* * * * *

X. Records and Reporting

A. Records.

* * * * *

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

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

9. 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).

10. Section 72.3 is revised to read as follows:

72.3 Definitions.

* * * * *

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

* * * * *

11. Section 72.9 is revised to read as follows:

72.9 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0132.

(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, 72.242, 72.244, and 72.248.

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

72.24 Contents of application: Technical information.

* * * * *

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

* * * * *

13. Section 72.48 is revised to read as follows:

72.48 Changes, Tests and Experiments.

(a) Definitions:

(1) *Change* means a modification, addition or removal.

(2) *Final Safety Analysis Report (as updated)* means: (i) for site-specific licensees, the Safety Analysis Report for a ISFSI, MRS or spent fuel storage cask, submitted in accordance with 72.24, as modified as a result of changes made pursuant to 72.48, and as updated in accordance with 72.70; (ii) for general licensees, the Safety Analysis Report for a ISFSI, MRS or spent fuel storage cask, as modified as a result of changes made pursuant to 72.48, and as updated in accordance with 72.216; and (iii) for certificate holders, the Safety Analysis Report for an approved cask, modified by as a result of changes made pursuant to 72.48 and as updated in accordance with 72.248.

(2) The ISFSI, MRS, or spent fuel storage cask as described in the Final Safety Analysis Report (as updated) means:

(i) The systems, structures, and components that are described in the Final Safety Analysis Report as updated in accordance with 72.70, 72.216 or 72.248,

(ii) The design, performance requirements and methods of operation for such systems, structures, and components required to be included or described in the Final Safety Analysis Report (as updated), and

(iii) The evaluations for such systems, structures, and components required to be included in the Final Safety Analysis Report (as updated) and which demonstrate that their intended function(s) will be accomplished.

(3) *Procedures as described in the Final Safety Analysis Report (as updated)* means

information in the Final Safety Analysis Report (as updated) regarding how structures, systems, and components are operated or controlled and information describing conduct of operations.

(3) *Reduction in margin of safety associated with any technical specification* means that the input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the Final Safety Analysis Report (as updated), that established any technical specification requirement, are altered in a nonconservative manner.

(4) *Tests or experiments not described in the Final Safety Analysis Report (as updated)* means any condition where the ISFSI, MRS or spent fuel storage cask or any of its systems, structures, or components are utilized or controlled in a manner which is either:

(i) outside the controlling parameters of the design bases as described in the Final Safety Analysis Report (as updated) or

(ii) inconsistent with the analyses in the Final Safety Analysis Report (as updated).

(b)(1) A licensee or certificate holder may make changes in the ISFSI, MRS, or spent fuel storage cask 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 either (A) a license amendment pursuant to 72.56 (for licensees), if a change in the conditions incorporated in the license is not required, and the change, test, or experiment does not meet any of the criteria in paragraph (b)(2) of this section. or (B) a Certificate of Compliance (CoC) amendment pursuant to 72.244 (for certificate holders), if a change in the terms, conditions or specifications incorporated in the CoC is not required; and the change, test, or experiment does not meet any of the criteria in paragraph (b)(2) of this section. The provisions in this section do not apply to changes in procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(2) A licensee shall obtain a license amendment pursuant to 72.56 and a certificate holder shall obtain a CoC amendment pursuant to 72.244, prior to implementing a change, test, or experiment if it would:

(i) Result in more than a minimal increase in the probability of occurrence of an accident previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to sections 72.56 or 72.244 after the last Final Safety Analysis Report was updated pursuant to sections 72.70, 72.216 or 72.248, of this part, as applicable.;

(ii) Result in more than a minimal increase in the probability of occurrence of a malfunction of structures, systems, and components important to safety which were previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to sections 72.56 or 72.244 after the last final safety analysis report was updated pursuant to sections 72.70, 72.216 or 72.248, of this part, as applicable.;

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to sections 72.56 or 72.244 after the last final safety analysis report was updated pursuant to section 72.70, 72.216 or 72.248, of this part, as applicable.;

(iv) Result in more than a minimal increase in the consequences of a malfunction of structures, systems, and components important to safety which were previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to section 72.56 or 72.244 after the last final safety analysis report was updated pursuant to section 72.70, 72.216 or 72.248, of this part, as applicable.;

(v) Create the possibility for an accident of a different type than any evaluated previously in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to sections 72.56 or 72.244 after the last final safety analysis report was updated pursuant to section 72.70, 72.216 or 72.248, of this part, as applicable.;

(vi) Create the possibility for a malfunction of structures, systems, and components important to safety with a different result than any evaluated previously in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to sections 72.56 or 72.244 after the last final safety analysis report was updated pursuant to section 72.70, 72.216 or 72.248, of this part, as applicable.;

(vii) Result in a reduction in the margin of safety associated with any technical specification;

(viii) Result in a significant increase in occupational exposure;

(ix) Result in a significant unreviewed environmental impact.

(c)(1) Each licensee or certificate holder shall maintain records of changes in the ISFSI, MRS, or spent fuel storage cask and of changes in procedures it has made pursuant to this section if these changes constitute changes in the ISFSI, MRS, or spent fuel storage cask or procedures described in the Final Safety Analysis Report (as updated). The licensee or certificate holder shall also maintain records of test and experiments carried out pursuant to paragraph (b) of this section. These records shall include a written evaluation that provides the bases for the determination that the change, test, or experiment does not require a license or CoC amendment pursuant to paragraph (b)(2). The records of changes in the ISFSI, MRS, or spent fuel storage cask and of changes in procedures and records of tests and experiments shall be maintained until spent nuclear fuel is no longer stored in the ISFSI, MRS or spent fuel storage cask, and the Commission terminates the license or CoC. For a holder of cask Certificate of Compliance who permanently ceases operation, any such records shall be provided to the new holder of cask Certificate of Compliance or to the Commission, as appropriate, in accordance with 72.234(d)(3).

(2) Annually, or at such shorter interval as may be specified in the license or CoC, each holder of a license or cask Certificate of Compliance shall submit a report containing a brief description of changes, tests and experiments made by the license or certificate holder under paragraph (b) of this section, including a summary of the evaluation of each. Licensee and certificate holders shall submit their reports in accordance with 72.4. Any report submitted by a licensee or certificate holder pursuant to this paragraph will be made a part of the public record pertaining to the license or CoC.

14. Section 72.56 is revised to read as follows:

72.56 Application for amendment of license.

Whenever a holder of a 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.

15. In 72.70, paragraphs (a) and (b) are revised to read as follows and new paragraph (c) is added to read as follows:

72.70 Safety analysis report updating

(a) The design, description of planned operations, and other information submitted in the Safety Analysis Report for an ISFSI or MRS shall be updated by the licensee and submitted to the Commission at least once every six months after issuance of the license during final design and construction, until preoperational testing is completed, with a Final Safety Analysis Report (FSAR) completed and submitted to the Commission at least 90 days prior to the planned receipt of spent fuel or high-level radioactive waste. The FSAR shall include a final analysis and evaluation of the design and performance of structures, systems, and components that are important to safety taking into account any pertinent information developed since the submittal of the license application.

(b) After the first receipt of spent fuel or high-level radioactive waste for storage, the FSAR shall be updated annually and submitted to the Commission by the licensee. This submittal shall include the following:

* * *

(2) A description and analysis of changes in procedures or in structures, systems, and components of the ISFSI or MRS, as described in the FSAR (as updated), with emphasis upon:

* * * * *

(c) The licensee shall submit revisions of the FSAR to the Commission in accordance with 72.4, on a replacement-page basis that is accompanied by a list which 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).

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

72.86 Criminal penalties.

* * * * *

(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.

17. In 72.212, subparagraph (b)(4) is revised to read as follows:

72.212 Conditions of general license issued under 72.210.

* * * * *

(b) * * *

(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.

18. In 72.216, new subparagraph (d) is added to read as follows:

72.216 Reports.

* * * * *

(d) The final safety analysis report (FSAR) for each approved cask used by the general licensee shall be updated annually and submitted to the Commission by the general licensee. The submittal shall include the following:

(1) A description and analysis of changes in procedures or in structures, systems, and components of the spent fuel storage cask, as described in the FSAR (as updated), with emphasis upon:

(i) Performance requirements,

(ii) The bases, with technical justification therefor upon which such requirements have been established, and

(iii) Evaluations showing that safety functions will be accomplished.

(2) An analysis of the significance of any changes to codes, standards, regulations, or regulatory guides which the general licensee has committed to meeting the requirements of which are applicable to the design, construction, or fabrication of the spent fuel storage cask.

(3) The general licensee shall submit revisions containing updated information to the Commission, in accordance with 72.4, on a replacement-page basis that is accompanied by a list which identifies the current pages of the FSAR following page replacement. The general licensee shall also provide a copy of the submittal to the holder of the certificate for the cask. 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). Each replacement page shall also indicate the cask FSAR, including the certificate holder's revision number, upon which the general licensee's update is based.

19. 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.

20. 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.

21. Section 72.248 is added to read as follows:

72.248 Safety analysis report updating

(a) The design, description of planned operations, and other information submitted in the Safety Analysis Report for a spent fuel storage cask shall be updated by the certificate holder and submitted to the Commission after the design of the spent fuel storage cask has been approved pursuant to 72.238. This Final Safety Analysis Report (FSAR) shall be completed and submitted to the Commission within 90 days after approval of the cask design. The FSAR shall incorporate all changes and requirements contained in the CoC and the staff's safety evaluation report (SER) associated with approval of the cask's design.

(b) The FSAR shall be updated annually and submitted to the Commission by the certificate holder. This submittal shall include the following:

(1) A description and analysis of changes in procedures or in structures, systems, and components of the spent fuel storage cask, as described in the FSAR (as updated), with emphasis upon:

(i) Performance requirements,

(ii) The bases, with technical justification therefor upon which such requirements have been established, and

(iii) Evaluations showing that safety functions will be accomplished.

(2) An analysis of the significance of any changes to codes, standards, regulations, or regulatory guides which the certificate holder has committed to meeting the requirements of which are applicable to the design, construction, or fabrication of the spent fuel storage cask.

(c) The certificate holder shall submit revisions containing updated information to the Commission, in accordance with 72.4, on a replacement-page basis that is accompanied by a list which identifies the current pages of the FSAR following page replacement. The certificate holder shall also provide a copy of the submittal to each general licensee using the spent fuel storage cask. 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).

Dated at Rockville, Maryland, this ____ day of _____, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.

Proposed Revision to Title 10, Section 50.59 "Changes, Tests and Experiments" and parallel changes to 10 CFR 72.48 "Changes, Tests and Experiments"

Objective and Problem:

The objective of the proposed 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:

- Memorandum to Chairman Jackson, April 15, 1996 (available in the NRC Public Document Room (PDR))
- SECY-97-035, Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests and Experiments), February 12, 1997 (available in the PDR)
- 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)

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.

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 would remain unresolved between the NRC and the industry.
- (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.
- (3) Rulemaking: Under this alternative, the NRC would conduct a limited rulemaking focused on the specific aspects of the criteria that are resulting 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. Completion of rulemaking would enable NRC to endorse (possibly with limited exceptions) industry guidance.

Evaluation of Values and Impacts

No Action

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. The impacts are the regulatory instability associated with these unresolved differences and the expenditure of staff and licensee resources to debate the merits of these specific cases.

Issuance of Guidance

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.

The 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. The reviewers stated that the proposed guidance would result in many changes being deemed to involve unreviewed safety questions (USQ), such that either the licensee would not proceed with a change that might be an overall safety improvement, or that both staff and licensee resources would be used to review changes with little significance to safety.

Rulemaking

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). Staff and licensee resources can be directed at issues of safety significance. 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, thus those changes of most potential impact on risk, would require approval.

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 net impact on the industry from the rule changes is estimated to be small. The staff notes that the proposed rule changes are more consistent with industry guidance that is already commonly used by licensees than the present rule requirements. There would be a one-time impact on licensees to revise their guidelines and train personnel. The revised criteria provide more flexibility for licensees to make changes without obtaining a license amendment. Since changes involving more than minimal increases in probability or consequences would still require prior NRC approval, there is no adverse impact on public health and safety.

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.

The proposed rule changes that are the subject of this backfit analysis are as follows:

- definition of "facility as described in the final safety analysis report (as updated)" (and of "procedure")

- definition of "change"

- definition of "tests or experiments not described..":

- criteria for when prior NRC approval is needed
 - Probability or consequences of an accident previously evaluated is more than minimally increased
 - Possibility of an accident of a different type is created
 - Possibility of a malfunction with a different result is created
 - Reduction in the margin of safety associated with any technical specification occurs

For the most part, these rule changes reduce regulatory burden by eliminating the need for evaluations against the review criteria for changes only affecting descriptive material in the safety analysis report (SAR) (i.e., those that do not meet the definitions of facility, procedure or test/experiment), and by slightly relaxing the criteria for when approval is needed. The proposed definitions of "change" in combination with the definition of "facility as described ..." and for "reduction in margin of safety..." might be considered backfits. In the proposed rule, the NRC is (1) defining "change to the facility" as including additions and other than physical changes, and (2) stating that reductions in margin of safety result when the safety analyses that established the technical specifications are altered in a nonconservative manner.

The NRC acknowledges that the implementation practices of licensees (and NRC oversight) have not always been consistent. While the NRC concludes that these proposed rule changes regarding 10 CFR 50.59 (or 10 CFR 72.48) requirements (i.e. the definitions) clarify existing requirements, some licensees might view these as imposing requirements that are different from what is currently required.

The NRC does not believe that these rule language changes reflect imposition 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 (as defined in 10 CFR 50.109(a)(1) -- see also 10 CFR 72.62) because in many respects, a regulatory staff position was never clearly established concerning appropriate interpretations of the rule. The Commission notes that exercise of the authority under 10 CFR 50.59 or 10 CFR 72.48 is at the licensee's option so no burden is imposed unless a licensee wishes to make facility or procedure changes without NRC approval. Nevertheless, because the rule changes could be viewed as imposing more restrictive requirements than what a licensee may have followed in the past when evaluating changes, the NRC has prepared an evaluation considering the following nine factors provided in 10 CFR 50.109(c).

(1) *Statement of specific objectives*

The objectives of the proposed action (specifically, a proposed rulemaking to revise certain provisions of 10 CFR 50.59 and 10 CFR 72.48) are twofold: (a) to clarify requirements for a licensee to evaluate particular changes to the facility, including supporting information in the SAR, that they wish to make without prior NRC approval, and (b) to clarify and slightly relax the criteria for when prior NRC approval is needed for such changes.

The rule changes are designed to reduce the licensee's burden associated with performing written evaluations and possibly needing to submit license amendment applications for nonsubstantive changes, by more clearly delineating those changes that require evaluation and those instances for which prior NRC review and approval are necessary.

(2) *General description of the activity that would be required of the licensee to complete the backfit*

The proposed action relates to licensee processes for evaluating future planned changes to its facility or procedures; the requirements are revisions of existing requirements. These provisions apply when a licensee chooses to exercise the authority granted under 10 CFR 50.59 (or 10 CFR 72.48) to make changes to its facility or procedures, or to conduct tests and experiments without NRC approval. Licensees will need to review their existing programs and procedures to determine whether they are fully consistent with the rule changes. In many respects, existing programs would continue to meet the requirements of the revised rule because the rule change provides greater flexibility to licensees and is more consistent with guidance commonly used by the industry. Training of licensee personnel would also be necessary.

(3) *Potential change in risk to public from accidental release of radioactive material*

The proposed action should result in no change in risk to the public from accidental release of radioactive material. The rule changes include provisions for the greater likelihood of licensee review of possible changes as to how they might impact plant design and operation, and for only minimal increases in probability or consequences of design basis events, below the level at which the license and technical specifications control the plant performance requirements. Therefore, there is no change in risk to the public from accidental release of radioactive material.

(4) *Potential impact on radiological exposure of facility employees*

There is no potential impact on radiological exposure of facility employees associated with the proposed action. The backfit only affects procedural and administrative activities for evaluating planned changes.

(5) *Installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay*

As noted above, there is a one-time cost for revisions of procedures and training. The staff estimates that about 100 persons per facility may need training. Costs for procedure changes and training are estimated to be \$100,000 per facility. Continuing costs would be those associated with licensee costs for conducting evaluations and recordkeeping and reporting, but are not expected to be significantly greater than existing costs of the current rule requirements. Further, these provisions apply only to changes, tests or experiments that a licensee proposes to make in the future. No facility downtime is involved.

(6) *The potential safety impact of changes in plant or operational complexity, including the relationship to proposed or existing requirements*

The proposed action would not impact plant or operational complexity. The rule changes are a clarification of existing requirements for licensees to evaluate facility changes before implementation.

(7) *The estimated resource burden on the NRC associated with the proposed backfit and availability of NRC resources*

Expected NRC burden is that associated with issuance of the rulemaking and associated regulatory and inspection guidance, about 3 FTE; resources are available in the NRC operating plan to complete this action. NRC staff training will also be required for around 1000 staff, estimated to use 4 FTE. The 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 (inspection of licensee implementation of 10 CFR 50.59 is already in the core inspection program).

(8) *The potential impact of differences in facility type, design or age on the relevance and practicality of the proposed backfit*

Potential impact of differences in facility age may arise because the existing rule requirements apply to information contained in each plant-specific SAR. Older facilities generally have smaller, less detailed SARs and thus the rule, on its terms, could have the effect of imposing more burden on reactors with larger SARs because of the need to perform and document more evaluations when they desire to make facility or procedure changes. These potential differences in facility design or type are present in the current rule requirements but should be lessened by the rule change that is the subject of this backfit analysis. This is because of the new definitions of what constitutes a change to the facility and the flexibility on the criteria, such that it is more likely that a change made by a licensee with the larger SAR would pose no greater burden than for a licensee with a smaller SAR.

(9) *Whether the proposed backfit is interim or final, and, if interim, the justification for imposing the proposed backfit on an interim basis.*

The proposed backfit is a final position.

Information Collection Requirements and Paperwork Reduction Act

The burden from existing recordkeeping and reporting requirements under 10 CFR 50.59, as discussed in the most recent information collection request to the Office of Management and Budget was estimated as follows:

- **Estimation of Recordkeeping Requirements** - The staff estimates that licensees for 178 facilities (109 operating power reactor licensees, 44 operating nonpower reactors, 14 permanently shutdown power reactor licensees, and 11 permanently shutdown nonpower reactor licensees) evaluate approximately 100 changes a year (per licensee). It is also estimated that approximately 16 hours of burden each is required for records associated with the analysis of each change. Thus the recordkeeping burden encompassed within [the existing] 10 CFR 50.59(b) is estimated to be 284,800 hours (1600 hours x 178 plants). Accordingly, annual record keeping cost to the industry will be (\$128 x 284,800), or \$36,454,400.

- **Estimation of Respondent Reporting Burden** - Since the report (required under 10 CFR 50.59(c) of changes, tests and experiments) may be filed annually or with the FSAR update (refueling outage basis or about every 18 months), the staff estimated that annually 135 licensees will submit a summary report of the changes that have been evaluated. It is expected that approximately 4 hours each are required to summarize and prepare reports for approximately 100 changes per year. Thus, the reporting burden for this provision of the regulation is expected to involve 54,000 hours annually (400 x 135 plants). The annual cost to the industry is, therefore, expected to be \$6,912,000 (54,000 x \$128).

- The total annual industry burden for 10 CFR 50.59 is thus 338,800 hours: total annual cost is \$43,366,400.

The burden from existing reporting requirements of 10 CFR 50.71(e), as discussed in the most recent information collection request to the Office of Management and Budget was estimated as follows:

- Since the updates for operating nuclear power reactors may be submitted annually or 6 months after each refueling outage, approximately 71 of 109 licensees will be affected by this reporting requirement annually. The average burden per licensee for the updating is estimated to be 1,000 hours. Therefore, the annual burden for licensees of operating plants is 71,000 hours.
- Since updates for nuclear power reactors that have ceased operation must be filed every 24 months, approximately 7 of 14 licensees will be affected by this reporting requirement annually. The average burden per licensee of these reactor facilities is estimated to be 250 hours. Therefore, the annual burden for licensees of permanently shutdown plants is 1750 hours.
- The total estimated burden to licensees is expected to be 72,750 hours (71,000 + 1,750 hours) at a cost of \$9,312,000 (72,750 hours x \$128).

In the Statement of Considerations for 10 CFR 50.71(e), (45 FR 30615), the NRC commented on the relationship between changes made under 10 CFR 50.59 and FSAR updating, stating: "The 50.59(b) reporting may not be detailed sufficiently to be considered adequate to fulfill the FSAR updating requirement. The degree of detail required for updating the FSAR will be generally greater than a 'brief description' and a 'summary of the safety evaluation'." Further, it said: "New analyses...which were required during consideration of unreviewed safety questions, technical specifications or other licensing questions may be incorporated as appendices or otherwise inserted within the FSAR." Thus, the Commission clearly expected the update submittal to include sufficient information to appropriately reflect the changes that were made. The burden associated with explicitly documenting in the update the effects of the changes on event probabilities and consequences is therefore small.

Note that the estimated burden for reporting and recordkeeping for Part 72 is expected to be small in comparison to that for 10 CFR 50.59. This is because the number of licensees is smaller (around 22) and the expected number and complexity of changes is less than would be expected for reactors. The staff has estimated that the burden for Part 72 would be xxxx hours at a cost of \$xx,xxx.

Decision Rationale

The NRC plans to proceed with the rulemaking on the basis of consideration of the alternatives, the value/impact analysis, the backfit analysis, and the small change in information collection requirements. 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 probability or consequences. 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.

ATTACHMENT 4

PARALLEL CHANGES TO OTHER PARTS OF NRC REGULATIONS

As directed by the SRM on SECY-97-205, the staff reviewed other parts of NRC regulations under the responsibility of the Office of Nuclear Material Safety and Safeguards (NMSS) to identify sections that contain requirements similar to 10 CFR 50.59, and candidates for changes similar to those in the proposed rule for 50.59.

The staff has reviewed the following regulations:

- (1) existing regulations in Parts 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 60, 61, 70, 71, 72, and 76,
- (2) proposed major revisions to regulations for medical use of byproduct materials and domestic licensing of special nuclear materials (Parts 35 and 70, respectively), and
- (3) proposed new parts on uranium recovery and Yucca Mountain (Parts 41 and 63, respectively).

The staff has identified that Parts 35, 36, 41, 60, 61, 63, 70, 72, and 76, and proposed revisions to Parts 41 and 63 have requirements that allow licensees to make changes similar to that permitted in 50.59, although these changes vary in complexity for different licensees.

For Independent Spent Fuel Storage Installations (ISFSI), the staff notes that the current requirements are essentially identical to 10 CFR 50.59, and that many ISFSIs licensed under Part 72 are either on the site of a nuclear power reactor operating under a Part 50 license with a Part 72 general license for storage of spent fuel in a dry cask, or are Part 72 site-specific ISFSI licensees (i.e., power reactors that have permanently ceased operations). Therefore, the staff concludes that concurrent revision of Part 72 with the 10 CFR 50.59 revision is appropriate.

The results of the staff's review for other parts are summarized below.

The staff recommends that (1) Part 72 be revised concurrently with the ongoing proposed 50.59 amendment, (2) changes similar to 50.59 not be incorporated into other existing rule parts at this time, and (3) changes similar to 50.59 be incorporated into the new Parts 41 and 63 when they are promulgated.

PART 35 -- MEDICAL USE OF BYPRODUCT MATERIAL

Existing Regulations

Section 35.31, entitled "Radiation safety program changes," allow medical use licensees to make minor changes, without Commission approval, in radiation safety procedures that are not potentially important to safety, i.e., ministerial changes, that were described in the application for license, renewal, or amendment except for those changes that require license amendment as specified in 35.13 and 35.606. Examples of such ministerial changes include: updating names or telephone numbers, adopting of model radiation safety procedures published in NRC regulatory guides, replacement of equipment, or reassignment of tasks among employees. These changes must be approved by various parties, including the Radiation Safety Officer, the affected authorized user, and the licensee management. A licensee must retain a record of each change until the license has been renewed or terminated.

Proposed Regulations:

In the proposed major revision, 35.26, entitled "Radiation protection program changes," would allow a licensee to revise its radiation protection program without Commission approval if the revisions do not reduce radiation safety, except for changes that require license amendment as specified in proposed 35.13. The revisions must be approved by the Radiation Safety Officer and the licensee management. A record of each change must be kept.

The staff does not recommend adopting a 50.59-type change process in Part 35 rulemaking for the following reasons:

- A. A licensee is allowed to make only limited changes without NRC approval. For any condition specified in 35.13, a licensee must obtain NRC approval before making changes.
- B. Most medical use licensees may not have appropriate "tools" to evaluate and measure effects of changes upon the margin of safety.

PART 36 -- LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

Existing Regulations

Paragraph (c) of 36.53, entitled "Operating and emergency procedures," allows licensees who operate irradiators to revise operating and emergency procedures without Commission approval if certain provisions are met, including that the revisions do not reduce the safety of the facility and that the users and operators must be instructed and tested on the revised procedures. The revisions must be approved by the Radiation Safety Officer. A licensee must retain a record of each change for 3 years.

Proposed Regulations:

The staff does not recommend adopting a 50.59-type change process in Part 36 for the following reasons:

- A. A licensee is allowed to make revisions only in operating and emergency procedures that are consistent with an NRC approved outline.
- B. Most irradiator licensees may not have appropriate "tools" to evaluate and measure the effects on the margin of safety for such procedural changes.

PROPOSED NEW PART 41 -- URANIUM RECOVERY

The staff is currently in the process of developing a rulemaking plan for new Part 41, which would be specific to uranium recovery. The staff proposed that Part 41 contain a section similar to 50.59. It would allow: (1) changes in the facility or process described in the application; (2) changes in the procedures presented in the application; and conduct of tests or experiments not presented in the application. If changes were made in 50.59, similar changes could be incorporated into the proposed Part 41. Therefore, the staff would address a 50.59-type of change in Part 41.

PART 60 -- DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN GEOLOGIC REPOSITORIES

Existing Regulations

Section 60.44, contains language similar to 50.59 which allow DOE to make changes in the geologic repository operations area as described in the license application, make changes in the procedure, and conduct tests or experiments without Commission approval, provided that the change, test or experiment do not involve a change in the license condition, or an unreviewed safety question. An unreviewed safety question is defined in 60.44 in a language similar to the definition in 50.59. Authorization to pursue any activity involving an unreviewed safety question requires a license amendment.

Proposed Regulations:

In response to a March 6, 1998, Staff Requirements Memorandum on SECY-97-300, the staff has decided to retain Part 60 as is and to address site-specific requirements for Yucca Mountain in a new Part 63. Consistent with the strategy in SECY-97-300, which was approved by the Commission, to adopt insofar as possible pre-closure and administrative aspects of the existing part 60 in the new site-specific regulations, initial working drafts of Part 63 contain a section that will be virtually identical to existing 60.44. If changes were made in 50.59, similar changes could be incorporated into the proposed Part 63. Therefore, since there is no immediate applicability for Part 60, the staff is not recommending adopting a 50.59-type of change in Part 60 at this time.

PART 61 -- LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE

Section 61.25 does not allow licensees to make changes in the land disposal facility or procedures described in the license application, except as provided for in specific license condition.

The existing regulations in 61.25 provide substantial amount of flexibility for applicants to propose a change process; therefore the staff recommends not making changes similar to 50.59 at this time.

PART 70 -- DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

Amendments to Part 70, currently under development, would include a new provision for making changes (based on integrated safety analysis) without Commission prior approval, that result in a minimal increase in the risk of an accident at a facility. This change process will be suitable for the level of detail that would be required by the proposed amendment to Part 70. Therefore, the staff does not recommend adopting further 50.59-type change process in the planned Part 70 amendment.

PART 76 -- CERTIFICATION OF GASEOUS DIFFUSION PLANTS

Section 76.68 allows the corporation to make changes to the plant or to the plant's operations as described in the safety analysis report without prior Commission approval provided certain provisions specified in this section are met. The staff concludes, based on its review of this part, that 76.68 contains an acceptable process for the degree of design detail that is currently available. Therefore, the staff does not recommend adopting a change similar to the one proposed for 50.59.

ATTACHMENT 5

The Honorable Dan Schaefer, Chairman
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 proposed amendment to the Commission's rules in 10 CFR Parts 50, 52 and 72. This proposed rule would amend 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 proposed rule would 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 proposed rule would 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 proposed.

The Commission is issuing the proposed rule for public comment.

Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: Federal Register Notice

cc: Representative Ralph Hall

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
Dear Mr. Chairman:

In the near future, the Nuclear Regulatory Commission (NRC) intends to publish in the *Federal Register* the enclosed proposed amendment to the Commission's rules in 10 CFR Parts 50, 52 and 72. This proposed rule would amend 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 proposed rule would 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 proposed rule would 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 proposed.

The Commission is issuing the proposed rule for public comment.

Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: Federal Register Notice

cc: Senator Bob Graham

ATTACHMENT 6

***NRC PROPOSES REVISIONS TO ITS REGULATIONS
FOR MAKING CHANGES TO LICENSED FACILITIES***

The Nuclear Regulatory Commission is proposing to revise several sections of its rules that define the conditions under which nuclear power plants and spent fuel storage facility licensees may make changes in their facilities or conduct tests and experiments without prior NRC approval.

Current NRC regulations (Parts 50, 52 and 72 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 now under consideration 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 proposed rule, the NRC staff has considered public comments received last year after draft regulatory guidance was published on this subject. As a result, the amendments would 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 proposed rule would also add definitions for terms that have been subject to differing interpretations.

The proposed rule will be published in an upcoming issue of the *Federal Register* for public comment and is also available on the NRC Homepage at: <http://www.nrc.gov/about-nrc/regulatory/rulemaking.html>.

Comments should be filed within 90 days after publication. They should be sent to: Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001. ATTN: Rulemakings and Adjudications Staff. Comments may also be filed electronically as described in the *Federal Register* notice.

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1. In section 50.2, Design Bases is defined as that information which identifies the specific functions to be performed by a structure, system or component of a facility, and the specific range of values chosen for controlling parameters as reference bounds for design. These values may be (1) restraints derived from generally accepted "state of the art" practices for achieving functional goals, or (2) requirements derived from analysis (based on calculation and/or experiments) of the effects of a postulated accident for which a structure, system or component must meet its functional goals.

2. In 50.34(a)(4) and (b)(4), it is noted that the FSAR is to include analysis and evaluation of design and performance of SSCs with the objective of assessing risk to public health and safety resulting from operation of the facility and determination of the margins of safety during normal operations, and the adequacy of SSCs for prevention of accidents and mitigation of consequences. Therefore, an inadequate evaluation of such a test or experiment would be a violation of more than minor severity if the test or experiment as conducted affected these factors.

3. Margin of safety is not defined in the regulations, although it is mentioned in 50.34(a) ["the margins of safety during normal operations and transient conditions anticipated during the life of the facility"]; 50.92(c) ["No significant hazards considerations if the proposed amendment would not involve a significant reduction in a margin of safety"] as well as 50.59.

4. Section 50.59(a) refers to holders of a license authorizing operation of a production or utilization facility. Section 50.59(d) explicitly refers to power reactor licensees who have submitted certification of permanent cessation of operation required under 50.82(a)(1)(i). As noted in 50.82(a)(iii), for power reactors whose licenses were modified to allow possession but not operation, before the effective date of this rule [that is of 50.82], the certification of

50.82(a)(1)(i) shall be deemed to have been submitted. Section 50.59(e) refers to non-power reactors whose license no longer authorizes operation. The net effect is that 50.59 applies to both power and nonpower reactors, whether authorized to operate or no longer authorized to operate (and to other production or utilization facilities).

5. Section 50.54(p) establishes change control requirements for safeguards contingency plans. While these plans are part of the application submitted pursuant to 50.34, they are not part of the FSAR, and thus 50.59 would not apply to these plans.

6. The staff paper sending the proposed rule to the AEC (p.10 of AEC-R 2/50, dated June 30, 1966), characterized the added USQ criterion on margin of safety, as "this definition has been extended to cover instances in which a change results in a reduction of the margin of safety associated with any technical specification."

7. The similarity in the language between 72.24 and 50.34(a) and between 72.70 and 50.34(b)(2) is noteworthy.

8. Attempting to use values from the staff's SER as acceptance limits would be difficult since SERs were not written for the purpose of establishing such limits. In a literal sense, neither the SAR nor the SER set an "acceptance limit." Rather, the SAR documents an applicant's/licensee's analytically derived conclusion that a given event has a certain consequence which is within the regulatory bounds set by NRC regulations. The SER is intended only to confirm or modify that conclusion. The SAR value as modified through the staff's review and approval then becomes the baseline for future analyses.