the exposure and frequency of this varietal designation will also increase. Since the purpose of these standards is to expedite the marketing of agricultural commodities, not changing this reference could result in confusion in terms of the proper application of the U.S. grade standards.

This proposed action will make the standards more consistent and uniform with marketing trends and commodity characteristics. This proposed action will not impose any additional reporting or recordkeeping requirements on either small or large grape producers, handlers, or importers. In addition, other than discussed above, the Department has not identified any Federal rules that duplicate, overlap, or conflict with this rule. Accordingly, AMS proposes to amend the United States Standards for Grades of Table Grapes (European or Vinifera Type) as follows.

List of Subjects in 7 CFR Part 51

Agricultural commodities, Food grades and standards, Fruits, Nuts, Reporting and recordkeeping requirements, Trees, Vegetables.

For reasons set forth in the preamble, 7 CFR Part 51 is proposed to be amended as follows:

PART 51—[AMENDED]

1. The authority citation for part 51 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

§ 51.882 [Amended]

2. In part 51, § 51.882 (i)(1)(ii) is amended by removing the words ''Superior Seedless'' and adding in their place the word ''Sugraone.''

§ 51.884 [Amended]

3. Section 51.884 (i)(1)(i) is amended by removing the words ''Superior Seedless'' and adding in their place ''Sugraone.''

§ 51.885 [Amended]

4. Section 51.885 (h)(1)(i) is amended by removing the words ''Superior Seedless'' and adding in their place ''Sugraone.''

§ 51.888 [Amended]

5. In § 51.888, paragraph (a)(2), the words ''February 28, 1992'' are revised to read ''November 16, 1996.''

Dated: October 15, 1998.

Robert C. Keeney,

Deputy Administrator, Fruit and Vegetable Programs.

[FR Doc. 98–28238 Filed 10–20–98; 8:45 am]

BILLING CODE 3410–02–P

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. The Commission is also seeking comment on several specific issues as discussed below.

DATES: Submit comments by December 21, 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, DC 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 Naiem Tanious, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001, telephone (301) 415–6103 (nst@nrc.gov).

SUPPLEMENTARY INFORMATION:

I. Background

The existing requirements governing the authority of production and utilization facility licensees to make changes to their facilities and procedures, or to conduct tests or experiments, without prior NRC approval are contained in 10 CFR 50.59. (Comparable provisions exist in 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 [1] 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-

[1] 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.

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) for production and utilization facilities licensed under part 50. Conforming changes are also

required in § 72.212(b)(4) and 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 §§ 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.'' [2]

[2] 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).

(2) Form of prior Commission approval

Existing § 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 licensee 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 as 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[3] 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

[3] 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.

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 to 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 conservatisms 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.

Need for Definition of Accident

In determining whether a proposed change requires prior NRC approval under § 50.59, the rule refers to whether ''accidents'' previously evaluated in the SAR are impacted, or whether an accident of a different type may be created (see also § 50.92 criteria for ''no significant hazards consideration)''. Those accidents evaluated in the SAR, that is, those events that a plant must show that it can withstand, are derived from a number of regulatory requirements, and the safety analyses are included in the FSAR.

The regulations and NRC guidance documents, refer to ''a design basis accident'' (§ 50.36), to design basis events (§ 50.49), to loss-of-coolant accidents (Appendix A), to anticipated operational occurrences (Appendix A) and to accidents that could result in release of significant quantities of radioactive fission products (part 100). The PSAR, and by extension the FSAR, pursuant to § 50.34, is to contain ''analysis and evaluation of the design and performance of SSC of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of (i) the margins of safety during normal operations and transient conditions anticipated during the life of the facility and (ii) the adequacy of SSC provided for the prevention of accidents and the mitigation of the consequences of accidents.'' RG 1.70 states that the FSAR is to include postulated anticipated operational occurrences; postulated off-design transients that induce fuel failures above those expected for normal operational experience, and design basis accidents. The Standard Review Plan for Chapter 15, refers to anticipated operational occurrences and to postulated accidents, and also to ''transients and accidents'' (the SRP notes that other events, such as response to external phenomena, are covered in other chapters).

Design basis accident(s) has been used in regulatory practice both singularly and generally. The regulations also include the concept of a design basis accident (DBA), for purposes of evaluating siting, which is an assumed fission product release, based upon a major accident that would result in potential hazards not exceeded by those from any accident considered credible. Such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products. The set of ''accidents'' that a plant must postulate for purposes of FSAR design and safety analyses, including LOCA, other pipe ruptures, rod ejection, etc., are often referred to as ''design basis accidents''.

The terms of accidents and transients are often used in regulatory documents (as for example in Chapter 15 of the Standard Review Plan), where transients are viewed as the more likely, low consequence events and accidents as more serious. In the context of probabilistic risk assessment, transients are typically viewed as initiating events, and accidents as the sequences that result from various combinations of plant and safety system response.

However, the meaning of the term ''accident'' as it is used more generally in Part 50, is somewhat obscured by the

use of the term ''design basis event.'' In § 50.49, design basis event is defined as:

> normal operations including anticipated operational occurrences, design basis accidents, external events, natural phenomena (earthquakes, tornados, hurricanes, floods, tsunami and seiches), for which the plant must be designed to ensure safety-related functions.

In view of the range of language presently used to describe the types of events evaluated as part of the licensing basis, the Commission is contemplating the need to clarify its intent as to the extent of events that are within the purview of the criteria in § 50.59 and in § 72.48). For purposes of stimulating discussion, the Commission offers two proposals. One would be to set forth a definition for the term ''accident'' as follows:

> an initiating event or combination of events and/or conditions that could occur from equipment failure, human error, natural or manmade hazards which challenges the integrity of one or more fission product barriers (fuel, reactor coolant system, release of radionuclides (confinement/containment)), required to be analyzed and/or accounted for by the Commission and addressed in the licensee's safety analysis report.

Such a definition would make it clear that the Commission's intent in referring to ''accidents'' in § 50.59 (and in § 72.48) is to refer to the design basis accidents that are addressed in the SAR. The second approach is to add the phrase ''design basis accident'' into the existing criteria. This could be done for each of the three criteria that refer to ''accident'' or just for the one on accident of a different type. Since the criteria on probability and consequences also contain language about ''previously evaluated in the SAR,'' there may be less need for a reference to ''design basis accident'' in these criteria. The proposed rule language includes use of the phrase ''design basis accident'' in the one criterion, for purposes of obtaining public comment.

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 § 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 cases, 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

Two criteria in the current regulations (§ 50.59) specifically focus upon accidents and equipment malfunction (creation, consequences and likelihood) as the measures for determining when a change requires prior NRC approval. However, the phrases ''margin of safety'' and ''as defined in the basis for any technical specification'' in the third criterion have been the subject of differing interpretations because the rule does not define what constitutes a margin of safety or a basis for any technical specification in the context of §§ 50.59 and 72.48. In addition, some have questioned the need for the third criterion on ''margin of safety.''

The Commission has under consideration a number of proposals on margin. In the proposed rule text specifically being offered for comment, one option has been inserted so that commenters can examine the

relationship of this aspect of the proposed rule to other changes being offered. This should not be viewed as meaning that this option is preferred by the Commission. The range of options under consideration is discussed in more detail below.

Questions of margin are commonly judged in terms of the degree of confidence that the response of the facility, or of particular SSC, to postulated challenges is acceptable. 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 to conditions that might be detrimental to safety is also determined by establishing acceptance criteria to be met for response to various accidents and transients. Acceptance criteria are established at a value that accounts for uncertainty about physical properties and other variability and thus provides margin to unacceptable plant conditions. Margins are built into the facility to account for routine plant fluctuations and transients. Margins are also built into the plant to establish the regulatory envelope within which a plant has demonstrated its ability to respond to a spectrum of design basis accidents. It is in this category termed the ''regulatory envelope,'' that the NRC believes that regulatory oversight of changes in margin may be needed from the standpoint of § 50.59. Thus the Commission notes that not all margins fall within the purview in which changes to the margin require prior NRC approval. As part of this rulemaking, the Commission wants to clarify which margins fall within the regulatory envelope and how possible reductions in margin resulting from facility or procedure changes, or from conduct of tests and experiments should be evaluated.

In defining in the rule a standard for NRC review and approval of changes to margins in the regulatory envelope, the Commission may want to preserve the NRC's ability to review changes when there is a potentially significant reduction in a margin of safety,[4] but clearly would not want to unduly affect licensee operations. Therefore, for this proposed rulemaking, the Commission is offering the public the opportunity to comment on a range of options for treating margin. Commenters are requested to present opinions about the merits, or concerns about the specific proposals, or both, and also to offer any other suggestions for wording.

Option 1: Control Inputs to Analyses and Methods that Establish TS

The Commission believes it is reasonable to interpret the specific reference to ''basis for any technical specification'' in the 1968 rulemaking that added the ''margin of safety'' criterion as preserving the margins in the analyses that established the TS requirements. For instance, the minimum plant performance conditions and configurations stated in the TS are the limiting conditions for operation, limiting safety system settings, and safety limits. Margins of safety exist within the safety analyses as a result of the specific input assumptions, methods, or other limits that were used. These parameters and methods were proposed by the licensee and reviewed by NRC to account for uncertainties, instrumentation response, and ranges of possible operating conditions. 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. In accordance with this interpretation, changes that invalidate these specific conditions described in the FSAR for analyses that established the TS requirement (such as a limiting condition of operation, or a limiting safety system setting) would reduce the margin of safety associated with the TS.

Under this option, the Commission would conclude that the analyses and information in the FSAR establish the basis for the margins of safety for the TS. Thus, the Commission would propose to add a definition for ''reduction in margin of safety associated with any technical specification'' and to conform the criterion for needing a license amendment in new § 50.59(c)(2). The existing terminology of ''basis for any TS'' would be replaced by ''associated with any TS.''

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.

Although this option would maintain the safety analyses that underlie the TS, this approach would also have the effect of giving input values and assumptions the weight of TS, which is inconsistent with the philosophy in § 50.36 of establishing TS only on those values of most immediate safety importance. In many instances, changes to inputs can be accommodated by other available margins so that the licensing envelope is preserved.

Option 2: Delete ''margin of safety'' as a Criterion.

Under this option, the Commission would delete any criterion focusing upon margins. Instead, the Commission would rely upon the other criteria in § 50.59, as well as the regulatory requirement that all changes to TS be reviewed and approved by the NRC, to assure that there are no significant adverse changes to margins in design and operation. The Commission would argue that there is no need for prior review of changes that do not satisfy any of the other evaluation criteria in view of ''risk-informed'' insights and greater understanding of the margins that exist through meeting the body of regulatory requirements. The Commission seeks comment on whether any of the other evaluation criteria should be revised were this approach to be adopted.

Option 3: Control margins associated with results of analyses

Instead of focusing on the inputs to safety analyses, another interpretation would be to examine the results of the safety analyses, and to determine whether changes to operational characteristics or other information described in the FSAR (as updated) would reduce the level of protection afforded by the TS (i.e., by the limiting safety system settings and limiting conditions of operation), as reflected in the results of safety analyses.

As part of the licensing review for a facility, the NRC established a level of required performance (which will be referred to in this discussion as acceptance criteria) for certain physical parameters, such as those that define the integrity of the fission product barriers (fuel cladding, reactor coolant system boundary and containment). Satisfying these acceptance criteria (or regulatory limits) produces a margin of safety to loss of barrier integrity. The safety analyses presented in the FSAR (as updated) demonstrate that the response of the barriers to the postulated accidents, transients, and malfunctions meets the acceptance criteria. For

[4] In accordance with 10 CFR 50.92(c)(3), license amendments involving a significant reduction in a margin of safety do not meet the criteria for a ''no significant hazards consideration'' determination; thus, changes involving a significant reduction in a margin of safety are not to be performed under 10 CFR 50.59.

certain of these parameters, TS safety limits have been established; these safety limits are limits upon important process variables that are found necessary to reasonably protect the integrity of physical barriers that guard against the uncontrolled release of radioactivity.

However, for other parameters, a licensee must determine the licensing basis of the parameter in question by reviewing the plant-specific safety analyses. The acceptance criterion is that value approved by the NRC for a particular parameter or process variable (e.g., ASME Code stress limits, a departure from nucleate boiling ratio limit or maximum critical power ratio limit or containment design pressure). These acceptance criteria may be stated in the FSAR, may be in NRC regulations, or may be presented in the NRC Standard Review Plan. (Note: This approach may require some licensees to revise their FSAR to accurately describe the regulatory values for the set of critical parameters. For example, licensees would need to identify the expected operating or design values and then specify the minimum performance capabilities for the related parameters, which cannot be modified with NRC review).

In constructing the requirements for controlling margin through consideration of results of analyses, there are three aspects to take into account: (a) Which results/parameters are to be controlled through the § 50.59 process, (b) the degree of change to be allowed without review, and (c) how the changes should be evaluated in demonstrating that the criterion is satisfied.

In the sections below, these three aspects are separately discussed in order to amplify upon the issues under consideration. However, any rule language option would need to include some provision for each of the three aspects.

(a) Which parameters should be controlled?

The margins of safety that would be controlled by the 10 CFR 50.59 process can be characterized in different ways.

OPTION 3(A)(1)—Safety and Regulatory Limits

The margin between regulatory limits and the failure of physical barriers is protected in the regulations (and also in the portion of the Technical Specifications (TSs) called ''safety limits''). The margin, as reflected in approved safety and accident analyses, between the protection afforded by the TSs (e.g., the limiting safety system settings and limiting conditions of operations) and the associated regulatory limits is a possible interpretation as to ''the margin of safety as defined in the basis for any TS'', which would be subject to the 10 CFR 50.59 evaluation process. Thus, one proposal under consideration would be to define ''margin of safety'' as follows:

> The ''margin of safety as defined in any technical specification'' (margin of safety) is the amount (quantitative or qualitative) of margin between the operation of the facility as described in the technical specifications and the exceedance of safety limits listed in the technical specifications or other regulatory limits. In relation to accident analysis, the margin of safety is typically the difference between calculated parameters (e.g., peak fuel clad temperature, maximum RCS pressure, etc.) and the associated regulatory or safety limit. The margin of safety is a product of specific values and limits contained in the technical specifications (which cannot be changed without NRC approval) and other values, such as assumed accident or transient initial conditions or assumed safety system response times, which are not specifically contained in the technical specifications. Any change to the values not specifically contained in the technical specifications must be evaluated for impact on the margin between the calculated result of an accident or transient and the safety or regulatory limit.

With this option, before changing operational characteristics described in the UFSAR (not directly controlled by TS), a safety evaluation must be performed to determine, among other things, if the change results in a reduction in the level of protection afforded by the TS (margin of safety as defined in any TS). Such a reduction would typically occur only if the operational characteristic had been used as a bounding condition in the analysis upon which the selection of TS was based, or in analysis where the acceptability of selected TS values was demonstrated. Licensees could make desired changes to operational characteristics without prior NRC approval, provided that the change does not result in accident analysis results that are nearer the regulatory, or safety, limits than the corresponding results that the NRC used in evaluating the acceptability of the TS during licensing of the facility.

OPTION 3(A)(2)—Fission product barriers—definition

The NRC notes that § 50.36 (requirements for Technical Specifications) has criteria for when TS are to be provided that specifically are tied to design basis accident or transient analysis that either assumes the failure of or presents a challenge to the integrity of a fission product barrier. Thus, the margin as defined in the basis for any TS can be reasonably viewed as that margin associated with preserving integrity of these barriers. Therefore, the NRC is also considering a more explicit linkage to the response of the three fission product barriers generally relied upon to provide protection from uncontrolled release of radioactive materials from a reactor facility. Under such a proposal, the text of the rule would explicitly state that it is the response of fission product barriers (fuel, reactor coolant system, and containment) to accidents, transients, and malfunctions that is being controlled.

The following could be given as a definition of margin of safety and of fission product barrier response. Regulatory guidance would explicitly list the parameters (for PWRs and BWRs) that are to be controlled.

> The margin of safety for any fission product barrier response is the difference between the calculated value and its associated acceptance criteria. Fission product barrier response means those parameters that must be satisfied in the event of postulated design basis events to demonstrate integrity of the fuel, reactor coolant system and containment system barriers.

The following parameters would be included: Fuel and cladding performance (peak cladding temperature, or energy deposition, DNBR or MCPR, oxidation), RCS performance (pressure, flows, stress), and containment performance (peak pressure, containment leakage).

OPTION 3(A)(3)—Specified Parameters

A variant on the previous option would be to actually list the parameters of interest directly in the criterion for prior review, as for instance, the criterion could read:

> (vii) Result in a change to the FSAR (as updated) calculated value of RCS peak pressure, containment peak pressure, or fuel performance (DNBR/MCPR, others), etc.

This variant has the advantage of being more precise, but the rule language would need to be crafted to account for various reactor types.

OPTION 3(A)(4)—Include Mitigation Capability

The Commission is interested in preserving the integrity of both prevention and mitigation capabilities available in the plant, and is therefore considering an option that would include both features within the ''margin'' criterion if the margin criterion is maintained. If this approach were adopted, the definition or the list of parameters would be supplemented with the performance parameters for the

accident mitigation capability of the plant, as for instance, ECCS performance (pressures, flows, actuation values), engineered safety feature performance (flows, pressures, spray effectiveness, system efficiencies).

Finally, in conjunction with any of these approaches, the Commission is also considering whether there are other parameters important to preservation of barriers that should be explicitly defined. For instance, for fuel stored in spent fuel pools, or for the reactor during periods of shutdown or refueling, there may be other analysis results (water level, pool temperature) in lieu of reactor coolant system pressure. Therefore, the Commission seeks input as to whether there are other parameters of interest beyond those previously offered that should be included within the ''margin of safety'' criterion if that criterion is maintained, and how should the rule language be revised to specify what those parameters might be.

(b) Determination of reduction in margin requiring review

Once the parameters of interest are determined, it is also necessary to define when a reduction in margin warranting NRC review and approval has occurred. The Commission is evaluating options ranging from any ''nonconservative change in calculated values,'' to a ''minimal change'' standard, and ultimately an option that would allow increases up to ''specified limits (acceptance criteria)'' for those parameters that may be established in the regulations or NRC guidance (such approaches to the limits might be controlled in a graduated fashion as was discussed in the section of this notice relating to ''minimal increases''). An option for the degree of reduction would be paired with an option (such as one of those listed in (a) above) to provide the text of the rule.

OPTION 3(B)(1)—No Reduction

One approach would be require that the safety analysis, considering the effect of the change, must show that the accident analysis results are not nearer to any safety or regulatory limit, thus, a ''no reduction in margin'' standard. Possible rule text:

> Changes, or the net effect of multiple changes, which result in a reduction in the margin of safety require prior NRC approval. Changes, or the net effect of multiple changes, which do not cause a reduction in the margin of safety do not require prior NRC approval.

OPTION 3(B)(2)—Minimal Amount—Definition of Margin Reduction

As discussed in other sections of this notice, the Commission concludes that the revised rule should allow licensees some flexibility in making changes, through development of a ''minimal increase'' standard. In considering margins, the Commission is thus weighing how such a concept could be applied. One option would be that NRC approval would be required for a change, test, or experiment if the output values (calculated in the SAR) are altered by more than a minimal amount. The ''margin'' criterion would be modified to state that a change in calculated result of ''more than a minimal amount'' would require prior review and approval. Either in the rule itself, or in guidance, the Commission would define ''minimal amount'', modeled upon the options offered for minimal increases in consequences (see section II.G. of this notice). For example, there could be a fixed amount (percent change) in margin, as long as regulatory limits are still met. If guidance itemizes the parameters, such guidance could also customize how ''minimal'' should be judged for each particular parameter (allowing greater amounts for certain parameters depending on precision of calculations, sensitivity of results and other considerations).

For instance, the definition of ''margin of safety reduction * * *'' might be stated as follows:

> *Reduction in margin of safety* means that as a result of a change, the [MARGIN] is altered in a nonconservative manner by more than a minimal amount.

OPTION 3(B)(3)—Minimal Determined With Respect to Acceptance Criteria (Available Margin)

It is also possible to achieve this result by removing the language referring to margin of safety (and to TS), and defining ''minimal'' in the rule itself in terms of the results or analyses for barrier response, with respect to meeting the acceptance criteria for those barriers. For example, rule language could read as follows:

License amendment needed if as a result of a change, test or experiment:

> (vii) there is more than a 10% reduction in the difference between the calculated value and the acceptance criteria for fission product barrier response to accidents evaluated in the SAR.

If such an approach is followed, the Commission would propose to include a definition of acceptance criteria, such as follows:

> Acceptance criteria are those values, established by NRC regulation or review guidance, to which the licensee is committed through its FSAR (as updated), as the basis for acceptability of response to the postulated accident, transient or malfunction.

(c) Evaluation of effect of the change upon analysis results.

The Commission also notes that the results of safety analyses are subject to variance depending upon the assumptions, analysis methods or analytical techniques used. In many instances, these factors were reviewed by the NRC during its licensing deliberations, and their use may have formed part of the basis for the conclusion that acceptable safety margins were demonstrated. Therefore, the Commission wishes to ensure that proposed changes by a licensee would not invalidate these conclusions by requiring a demonstration that the evaluation techniques and analyses are suitable.

To accomplish this, the Commission is considering having as part of whichever definition of ''margin of safety reduction'' is selected the following statement [Option 3(c)]:

> All analyses and evaluations for assessing the impacts of proposed changes must be performed using methodology and analytical techniques which are either reviewed and approved by the NRC or which are shown to meet applicable review guidance and standards for such analyses.

The alternative to this proposed language would be to rely upon a licensee's design control processes under their quality assurance requirements and program, to provide the assurance that any evaluative work has been conducted with methods and techniques commensurate with the safety significance of the analyses being performed.

Impacts for Part 72 Changes

Certain of the options discussed above may need to be modified for application to independent spent fuel storage facilities or spent fuel storage cask designs in Part 72. While the overall philosophy would be the same, the particular outputs or barriers that would be specified for reductions in margin would have to be defined in terms of the barriers against release of radioactivity afforded by fuel storage facilities. For instance, these might include calculated fuel temperature or cladding oxidation, and stresses (or pressures) on the cask structure. Comment is also requested on the appropriate parameters for facilities licensed under Part 72.

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 effects [1] 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.

Finally, the Commission is proposing a change to the record retention requirements in existing § 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,

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

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[5] 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

[5] The similarity in the language between §§ 72.24 and 50.34(a) and between §§ 72.70 and 50.34(b)(2) is noteworthy.

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.

10 CFR 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 section 223 of the Atomic Energy Act (AEA). New § 72.248 has not been included in paragraph (b) to reflect that certificate holders who fail to comply with this new section would be subject to the criminal penalty provisions of section 223 of the AEA.

10 CFR 72.212(b)(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. Commission Voting Record on SECY–98–171

The staff forwarded to the Commission a proposed rulemaking package on § 50.59 and related regulations in SECY–98–171, dated July 10, 1998. This document was placed in the Public Document Room on July 29, 1998. Subsequently, the Commission voted to approve issuance of a proposed rule for public comments with several additions and changes that are reflected in this notice. The Commission also directed that the record of their decision on SECY–98–171 be included as part of this notice to clearly inform stakeholders on preliminary positions taken by the Commission. The text of the resultant staff requirements memorandum and of the individual Commissioner vote sheets, is presented below.

Commission SRM on SECY–98–171, Dated September 25, 1998

The Commission has approved publication, for a 60 day public comment period, the 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. The Voting Record, which includes the Commissioner votes and this Staff Requirements Memorandum, should be published in the **Federal Register** notice to clearly inform stakeholders on preliminary positions taken by the Commission (Enclosed).

The Commission also approves the staff's recommendations for handling violations of 10 CFR 50.59 and 72.48, including staff plans for exercise of enforcement discretion, while rulemaking is underway.

The Commission requested that the staff specifically solicit public comment in the **Federal Register** notice on:

1. A wide array of options for the margin of safety criterion (50.59(c)(2)(vii) in the proposed rule) and its definition including: (a) Deleting the criterion and definition, (b) a new definition as described in Chairman Jackson's vote, and (c) an option which would decouple the last criterion from technical specifications and focus instead on a new criterion relating to performance of fission product barriers (e.g., reactor coolant system pressure, containment pressure, etc), with minimal changes being allowed up to specified limits, perhaps utilizing a graduated approach similar to the approaches proposed for other criteria.

2. Options for defining ''minimal'' as it pertains to ''probability of occurrence of an accident'' or ''probability of equipment malfunction.''

3. The definitions of ''facility,'' ''procedures,'' and ''tests or experiments,'' including elimination of the definitions.

4. A clear definition of ''accident.''

(This action scheduled for completion October 9, 1998).

The Commission requests the staff to complete the revised 50.59 rule on an expedited schedule.

(This action scheduled for completion February 19, 1999).

All Commissioners approved in part and disapproved in part the 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, and provided additional comments. In their vote sheets, all Commissioners approved the staff's recommendations to approve publication of the proposed rule for public comment, and use of the enforcement discretion guidance in its assessment of severity levels for violations while the rulemaking is underway, and provided some additional comments. In particular, all Commissioners disapproved the staff's proposed margin of safety criterion (§ 50.59(c)(2)(vii) in the proposed rule) and its definition and each Commissioner provided an option for evaluation during the comment period. The Commissioners also specifically requested comments on a number of other issues. Because of the need to finalize this rule as expeditiously as possible and because SECY–98–171 has already been publicly available since July 29, 1998, the Commission agreed to a 60 day comment period, and that the staff complete the revised § 50.59 rule by February 19, 1999. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on September 25, 1998.

Chairman Jackson's Comments on SECY–98–171

I approve, in part, and disapprove, in part, the staffs proposal for rulemaking. I approve the staff's proceeding with issuance of the proposed rule language for public comment in order to support the expedited finalization of a revision to these processes. I disapprove of the specific language proposed by the staff for § 50.59(c)(2)(vii), ''reductions in the margin of safety.''

I agree with the recent letter from ACRS on this rulemaking, in that: (1) 10 CFR 50.59 can accommodate risk-informed decisionmaking. (2) the positions, as presented, on margin of safety may add regulatory burden without a commensurate safety benefit.

I disagree with ACRS in that I believe:

(1) The rulemaking should go out for public comment to foster comment on this high priority issue, and

(2) The regulatory guidance can be worked in parallel with the rulemaking.

I note that a further reason for issuing this package for public comment at this time is that the paper calls for the proper use of enforcement discretion as this rulemaking progresses, thereby providing further stability in the implementation of this rule in the industry.

Further, I propose that the SRM on this SECY, and the voting record, be placed in the FR notice to clearly inform stakeholders on preliminary positions taken by the Commission.

Giving Definition to Minimal

Attached to the recent ACRS letter was ''A Proposal for the Development of a Risk-Informed Framework for 10 CFR 50.59 and Related Matters.'' The proposal forwarded by the ACRS parallels an existing risk-informed approach described in Regulatory Guide 1.174. Regulatory Guide 1.174 describes a method for determining the level of review, based on severe accident implications, for proposed licensing actions. The proposal forwarded by the ACRS describes methodology for creating frequency-consequence curves for Class 1–8 accidents. The proposal states that existing processes could be extended to provide appropriate context for whether the results of a change are ''minimal.'' The proposal also notes that aspects of this type of approach are in use in the international regulatory community. The approach utilized in the proposal forwarded by the ACRS is consistent with the Commission guidance in the Staff Requirements Memorandum of March 24, 1998 on SECY–97–205.

Without commenting on the specifics of the proposal forwarded by the ACRS, I am convinced that changes to nuclear plants can be evaluated in a risk-informed context. Any such approach would benefit from paralleling existing methodology. Careful consideration would be required to ensure that the ''consequence'' and ''frequency'' standards are appropriate for a § 50.59 type application. For instance, ''consequences'' could be evaluated at one of the following levels: Fractional releases, off-site or on-site doses, or

challenges to fission product release barriers. ''Frequency'' could be evaluated for Class 1–8 accidents or for design basis accidents using existing guidelines for risk-informed regulation. The level at which consequences and frequency of events were tracked would also impact the type of parallel, deterministic (e.g., protection of redundancy, defense in depth, etc.), considerations against which changes would have to be evaluated. For instance, evaluating consequences at the level of the loss of a single barrier, or occurrences of accident sequence initiators, might allow elimination of parallel, deterministic, considerations such as ''margin.''

It is of some concern to me that the whole staff has pursued risk-informed approaches to issues like the review of TSs, the use of Graded Quality Assurance, and programs like Inservice Inspection and Inservice Testing, the staff appears to be more reluctant to allow risk-informed approaches if the result is the relinquishment of review and approval authority. Because prior NRC review and approval impacts the cost and schedule of licensed activities, we must ensure that we require such prior review and approval only when justified or required by mandate. We should not limit the application of risk-informed regulation as a means to ensure continued NRC reviews and approvals of licensed activities. This message is complimentary to my oft repeated message to industry that the use of risk information is ''double-edged,'' that is that relief and additional regulatory scrutiny may both result from its use.

Margin of safety

The staff proposes to provide a specific definition of ''Reduction in margin of safety associated with any technical specification,'' and to revise the current provisions of 10 CFR 50.59(a)(2)(iii) to explicitly refer to this definition. While I commend the staff on its efforts to provide clear, definitive, requirements in this proposed rulemaking, I am concerned that the proposed rule is not consistent with policy direction established by the Commission in the SRM dated March 24, 1998. I concur that it is important that the staff has the independence to (and, I believe, has the responsibility to) inform the Commission when there are concerns with Commission guidance (as it did in COMSECY 98–013). However, I believe that when the staff proposes to take action that is inconsistent with Commission direction, it is obliged to provide a clear and complete rationale for the proposed departure. I do not feel that the staff has met that obligation for the ''margin of safety'' aspect of this proposed rule. However, this said, I do not disagree with the staff's conclusion that we should be careful to understand, and maintain, a consistent regulatory basis on ''margin of safety.'' We must proceed in a manner that does not call into question the existing deterministic basis for ''reasonable assurance'' of public safety embodied in plants Technical Specifications (TSs).

My previous discussions with the staff have indicated that it is extremely difficult (and probably not legally defensible) to allow decreases in the ''margin of safety'' when the upper and lower limits between which ''margin'' may exist are not defined in relation to the regulatory requirements for safe operation. Based upon these discussions, I can only assume that the staff is hesitant to allow direct reductions in margin within the ''basis'' for TSs because some such changes could create a de-facto change in the TSs themselves. The staff may also be concerned by the lack of consistency in the ''margin of safety in the basis for TSs'' associated with the different generations of existing licenses (e.g., older customized TSs compared to improved standardized TSs), and associated with the different methods utilized in the technical review and approval of the TS (e.g., some TSs might be based on maintaining margin between accident analysis results and acceptance limits, while other TSs might be based on margin which was built into analytical techniques and methodologies used in the accident and safety analysis, with no ''margin'' between the results and the acceptance limits, etc.).

The staff's proposed method of requiring prior agency approval to changes of input assumptions, analytical methods, etc., for those parameters which affected the selection of TSs, results in the newly controlled parameters being treated essentially the same way as values in the TSs. It also appears that implementation of the staffs proposed control over a broad range of parameters used in the safety analysis would effectively prevent any change to the facility that would result in a ''minimal change in consequence,'' a condition allowed elsewhere in the proposed rule. In other words, it is not clear what type of changes would successfully pass the 10 CFR 50.59 test for allowed ''minimal increases in consequences,'' without failing the test for ''no reductions in the margin of safety.'' I do not believe that the potential safety significance of *all* the parameters to be covered under the proposed definition of a reduction in the margin of safety *always* justify the requirement of prior NRC approval.

The staff should continue to work to establish a technically sound method for allowing licensees to make plant changes where there is only ''minimal'' impact on safety. If fundamental conflicts exist with allowing reductions in some ''margins of safety,'' especially those on which the validity of TSs are based, then staff should provide a clear explanation of this, and should address how other changes to the structure of the regulation, which do not create fundamental conflicts, can be made in a manner which achieves the Commission's objective of removing unnecessary burdens from licensees.

Attachment ''A'' to this vote describes one alternate method for addressing the issue of ''margin of safety.'' This alternative would maintain existing margins of safety (associated with TSs), while providing greater flexibility to licensees in implementing changes to their facilities. This alternative is based on methodology similar to that described in NEI 96–07. This methodology requires evaluating the effect of proposed tests and changes on the accident analysis *results* (rather than inputs, as proposed by the staff), in cases where TSs are based on accident analysis considerations. Prior NRC approval of changes, tests, and experiments would be limited to those cases where there was a net effect on the accident analysis results. The alternative also recognizes the significance of the analytical techniques used in the safety or accident analysis, and would require some form of prior approval for analytical methods used to support changes when the change did not have prior NRC approval. This approach could provide staff reasonable assurance that the assumptions made by the license reviews are not invalidated. The staff should evaluate this option, along with other comments in this area, during the comment period.

In considering the technical and regulatory underpinning of this clause of § 50.59, I have become concerned that we are evaluating incremental changes to a provision which is not well suited to such changes. I am concerned that the result may be the addition of yet another layer of regulatory process rather than the elimination of any unnecessary layers. For this reason, the staff should be receptive to internal or public comments on feasible alternatives which eliminate the discussion of ''the margin of safety in the basis of TSs,'' while maintaining the integrity of the plant's licensing basis. I envision that it may be possible to eliminate the rule

language criteria on ''margin of safety'' if evaluations of ''frequency'' and ''consequences'' are performed at a level of significance which bounds allowable ''minimal'' reductions in margin.

Accident of a Different Type

In determining the effect of any proposed change to § 50.59, it will be necessary to more clearly understand what an ''accident of a different type'' is. The staff should provide a more definitive definition of an accident than was included in COMSECY–98–013. The information provided by the staff should address, as a minimum, the following:

(1) What is an ''accident'' under this section, and is it consistent with other existing regulations (e.g., § 50.92, § 50.34, Appendix A of part 50, etc.)?

(2) Is an ''accident of a different type'' better described as an ''initiating event (e.g., loss of feedwater, loss of offsite power, new common mode failure mechanism, etc.) of a different Type?''

(3) What are the bounds which limit those ''accidents'' which are the subject of this Section (e.g., only those initiating events which, when evaluated using approved analytical techniques, result in transients with the potential to challenge fission product barriers, etc.)?

Procedures

I commend staff on inserting a definition for the term ''Procedures as described in the final safety analysis report (as updated).'' However, I am concerned that the definition provided may cloud the distinction between: (1) Those procedures which must be screened, or evaluated, under § 50.59, and (2) the criteria which necessitates a full safety evaluation. I believe that staff seeks to indicate that all procedures which are described as being required in the FSAR are subject to a § 50.59 screening. The screening would identify the need for a full safety evaluation only if a proposed procedure change created a change to the ''information in the FSAR regarding how structures, systems, and components are operated and controlled. . . .'' Staff should solicit comment on this definition and clarify the proposed definition, as required, in the final rule.

Making the Rule Risk Informed

I note with interest that members of the ACRS believe that there are substantial barriers in the existing deterministic framework of 10 CFR part 50 to the concept of allowing ''minimal'' changes in accident probabilities or consequences. In my previous vote on SECY–97–205, ''Integration and Evaluation of Results from Recent Lessons-Learned Reviews,'' I approved the staff's proposal to develop the framework for risk-informed regulatory processes. In particular, I called for the staff to develop a series of milestones by which the Commission could ''chart its course in its move to more risk-informed regulatory processes.'' Additionally, I promoted the idea of promulgating a new regulation in 10 CFR part 50, that would make clear how the Commission uses risk information in its decision-making. In proceeding with the ''short-term'' changes to 10 CFR 50.59 (and related regulations; ''short-term'' actions from SECY–97–205), and in responding to the ACRS, the staff should re-evaluate whether the Agency should initiate action to provide for a risk-informed framework that would allow for the efficiencies to be gained through use of risk-informed, performance-based revisions to our regulatory processes.

Attachment "A" to Chairman Jackson's vote sheet on SECY–98–171

''Straw Man'' on Margin of Safety

Regarding margin:

- The margin between regulatory limits and the failure of physical barriers is protected in the regulations (and also in the portion of the Technical Specifications (TSs) called ''safety limits'').
- The margin, as reflected in approved safety and accident analyses, between the protection afforded by the TSs (e.g., the limiting safety system settings and limiting conditions of operations) and the associated regulatory limits is ''the margin of safety as defined in the basis for any TS.''
- The margin between normal plant or system operation and the ''bounding'' assumptions used in accident analysis is below the threshold of safety significance that requires NRC prior approval for changes.
- The results of safety and accident analyses are subject to significant variance, depending on the analytical techniques and methods used in the analysis. Where a licensee wishes to make a change in their facility without prior NRC approval, the effects of the change must be evaluated using analytical techniques and methods which are NRC approved for the application, or which are reviewed and vetted (but not subject to specific NRC approval) in a NRC approved manner.

Direct changes to technical specifications require prior NRC approval. Before changing other operational characteristics described in the UFSAR, a safety evaluation must be performed to determine, among other things, if the change results in a reduction in the level of protection afforded by the TS (margin of safety as defined in any TS). Such a reduction would typically occur only if the operational characteristic had been used as a bounding condition in the analysis upon which the selection of TS was based, or in analysis where the acceptability of selected TS values was demonstrated. Licensees can make desired changes to operational characteristics without prior NRC approval, provided that the change does not result in accident analysis results that are nearer the regulatory, or safety, limits than the corresponding results that the NRC used in evaluating the acceptability of the TS during licensing of the facility.

This regulatory position could be codified by adding the following footnote to Section 50.59(a)(2)(iii):

The ''margin of safety as defined in any technical specification'' (margin of safety) is the amount (quantitative or qualitative) of margin between the operation of the facility as described in the technical specifications and the exceedance of safety limits listed in the technical specifications or other regulatory limits. In relation to accident analysis, the margin of safety is typically the difference between calculated parameters (e.g., peak fuel clad temperature, maximum RCS pressure, etc.) and the associated regulatory or safety limit. The margin of safety is a product of specific values and limits contained in the technical specifications (which cannot be changed without NRC approval) and other values, such as assumed accident or transient initial conditions or assumed safety system response times, which are not specifically contained in the technical specifications. Any change to the values not specifically contained in technical specifications must be evaluated for impact on the margin between the calculated result of an accident or transient and the safety or regulatory limit. Changes, or the net effect of multiple changes, which result in a reduction in the margin of safety require prior NRC approval. Changes, or the net effect of multiple changes, which do not cause a reduction in margin of safety do not require prior NRC approval. All evaluatory work in assessing the impact of proposed changes must be performed using methodology and analytical techniques which are either reviewed and approved by the NRC or which are reviewed and vetted in a manner approved by the NRC.

Commissioner Diaz's Comments on SECY–98–171

I consider this rulemaking effort to be our short term fix for the 50.59 rule, not the longer term risk-informed rule enhancement discussed in SECY–97–205.

I approve the publication of this rulemaking package for a 90-day public comment period, contingent upon the additions described in the last paragraph of my comments. I propose that the package also include the Commissioners' votes for public consideration. The purpose of issuing the rulemaking package is to expedite rulemaking by opening the process for

public comments during the Commission's continuing deliberation on this matter. It should be made very clear to all stakeholders that publication of the package is an invitation to participate in improving the rulemaking. In fact, I do not agree with several of the proposed positions in this paper, as delineated in my specific comments below.

I agree with the staff's recommendation to remove the reference to ''unreviewed safety question'' from § 50.59 and to make conforming changes in parts 50, 52, and 72. I also agree with staff's proposal to allow a minimal increase in the probability of occurrence or consequence of an accident or malfunction previously evaluated, and to *not allow* the creation of an accident of a different type or malfunction of equipment important to safety with a different result than any previously evaluated.

I agree with the ACRS comments in their June 16, 1998, letter regarding the definition of ''reduction in margin of safety.'' Notwithstanding the staff's suggestion of a possible Commission interpretation, the language ''altered in a nonconservative manner'' can still be interpreted as a de facto ''zero increase'' standard for the 50.59 criterion on margin of safety. I believe the risk-informed § 50.59 approach suggested in the ACRS letter deserves serious consideration as part of longer term improvements and should be considered in the staff's response, due in February 1999, to the SRM for SECY–97–205.

The current language in § 50.59(a)(2)(iii) (''margin of safety as defined in the basis for any technical specification'') is, in fact, defined and bounded by the technical specifications. Therefore, as long as the licensee proposed change, test, or experiment under § 50.59 is not in violation of the technical specification requirements, the requisite margin of safety is maintained, and it is possible to eliminate ''reduction of margin of safety'' from the rule as a condition requiring prior staff approval. This change will eliminate the existing ambiguity in the use of § 50.59 for changes with minimal safety significance. This alternative should also be published for public comment; it is consistent with the safety envelope provided by the technical specifications and is a straightforward improvement that will match with the eventual conversion to a risk-informed rule.

I support the staff's recommended changes in the reporting and record keeping requirements relating to § 50.59. The enforcement policy and its corresponding implementation guidance should be changed in accordance with the revised § 50.59 rule. I recommend that, during the rulemaking period, the enforcement policy be revised to grant discretion (i.e., suspend issuance of Level IV violations) under Section VII.B.6 for those § 50.59 violations of little or no safety significance.

I do not agree with the recommended definitions of ''facility'', ''procedures'', ''reduction in margin of safety'', and ''tests or experiments.'' These definitions appear to increase prescriptiveness at the input of the licensees' change process instead of the output, and therefore, are more broad-based than the definitions to date. I believe that these definitions will create more burden for the NRC and licensees, are not consistent with the original intent of the § 50.59 rule, i.e., to evaluate whether the licensee proposed changes will result in inadequate protection of public health and safety, and therefore, are not necessary.

On the other hand, the ''accident'' in the proposed revisions to § 50.59 should be defined. The ''accident of a different type than any previously evaluated'' as described in the proposed § 50.59(c)(2)(v) should be of the same safety significance as the ''accident'' in the proposed § 50.59(c)(2)(I) and (c)(2)(iii). The staff should determine if the anticipated operational transients and the postulated design basis accidents described in the FSAR form a sufficient basis for the § 50.59 evaluation.

The staff should continue its interactions with NEI in resolving the differences between the NRC's position on § 50.59 implementation guidance and that contained in NEI 96–07. The regulatory guide for § 50.59 that endorses a revised NEI 96–07, with exceptions and clarifications, as appropriate, should be developed concurrently with the rulemaking process.

In summary, the staff should proceed with publishing the existing rulemaking package, and concurrently solicit public comment on the following alternatives: (1) eliminate ''reduction of margin of safety'' as a condition requiring prior staff approval, (2) eliminate the broadened definitions of ''facility'', ''procedures'', ''reduction in margin of safety'', and ''tests or experiments,'' and (3) clearly define ''accident'' in the proposed revisions to § 50.59. I urge the staff to complete the revised § 50.59 rule and the associated regulatory guide by the end of March, 1999.

Commissioner McGaffigan's Comments on SECY–98–171

I approve publishing this rulemaking package for a ninety-day public comment period. However, like my colleagues, I do not agree with the staff proposal regarding ''reduction in the margin of safety associated with any technical specification.''

As the Chairman points out, the definition of ''reduction in margin of safety * * *'' would extend the requirements for prior agency approval to underlying aspects (e.g., input assumptions) of parameters that affected the selection of technical specifications, and result in the newly controlled parameters being treated essentially the same way as values in the technical specifications. This is the wrong way to go.

It is clear from my colleagues' and my vote that the margin of safety criterion (§ 50.59(c)(2)(vii) in the proposed rule) and the definition will need to be fixed in the final rule. My concern at this point is that the staff discuss a wide enough array of options in the **Federal Register** notice to ensure that the proposed rule will not have to be renoticed before being finalized. Commissioner Diaz has proposed to simply delete the criterion and definition as not needed. The Chairman has proposed essentially a new definition. Another option would decouple the last criterion from technical specifications and focus instead on a new criterion relating to performance of fission product barriers (e.g., RCS pressure, containment pressure. etc), with minimal changes being allowed up to specified limits, perhaps utilizing a graduated approach similar to the approaches proposed for other criteria. Comment should be solicited on this option as well.

I believe that the staff has done a good job in proposing options for defining ''minimal'' for consequences of an accident or malfunction. On probability, however, the staff has essentially only said that NEI 96–07 satisfies the proposed NRC standard for a ''minimal'' increase. That is a good step forward, and will bring regulatory stability. I believe that in choosing the word ''minimal'' the Commission intended to grant greater flexibility than the NEI 96–07 ''so small'' or negligible standard. The staff should continue to try to give better definition to ''minimal'' as it pertains to ''probability of occurrence of an accident'' or ''probability of equipment malfunction'' and solicit comment on this.

Finally, I endorse the use of enforcement discretion under Section

VII of the Enforcement Policy as the rulemaking proceeds for those § 50.59 violations of little or no safety/risk significance. The staff should treat (vice ''consider treating'' as proposed by staff) as minor violations cases where the violation of existing rule requirements would not constitute a violation under the rule were it revised as proposed. I do not object to documenting such minor violations in inspection reports because the rule is still in a proposed revision stage.

V. 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).[6]

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.

[6] 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.

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 seeking comment on a range of options relating to margin of safety, including the option proposed by NEI.

VI. Request for Comment

The Commission requests comments on the proposed rule, as discussed in Section II above. In addition, the Commission is seeking comment on a number of specific issues related to this rulemaking. All commenters are encouraged to provide specific comments on the following issue areas:

1. The Commission is seeking input on a number of options relating to the criterion of margin of safety reduction, and its definition. Some possible alternatives are presented in Section II.J as being representative of the range of approaches under consideration, but the Commission is open to other proposals that commenters may wish to put forth as representing the best means to provide a clear understanding of which margins should fall within the regulatory envelope of requiring approval if they would be reduced as a result of a change, test or experiment, if the margin of safety criterion were to be retained.

2. The Commission is interested in options for defining what constitutes a ''minimal'' increase in the probability of occurrence of an accident previously evaluated in the FSAR or in the probability of equipment malfunction (refer to Section II.G). This might include suggested examples of changes

that commenters believe represent only a ''minimal increase'' in probability.

3. The Commission is interested in comments upon the proposed definitions for such terms as ''facility as described in the FSAR,'' ''procedures as described in the FSAR,'' and ''tests or experiments'' (refer to Sections II.B, C, and D). The Commission is soliciting views on whether (1) definitions are necessary, (2) the proposed definitions are desirable, even if not necessary, and (3) whether the suggested definitions are clear and focused upon the appropriate changes that should be evaluated. In this light, the Commission is also interested in comments on a broader view of the scope of changes that should be evaluated; for instance, should the scope be linked to the SAR, or should the focus of changes to the facility be linked to another set of regulatory information?

4. As part of the present rulemaking, the Commission is seeking comment on the need for a clear definition of accident as it is used in § 50.59 to reflect the Commission's intent that the ''accidents'' referred to are those dealt with in the safety analysis report (see Section II.H of this notice for discussion of issues related to definition of accident).

5. In addition to the NRC proposals in Sections II and III, the Commission is also interested in receiving comments on the proposals and language suggested by NEI (Section V).

VII. 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, DC 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) 415–5905; e-mail CAG@nrc.gov.

VIII. 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.

IX. 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 3150–0132.

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, DC 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, DC 20503.

Comments to OMB on the collections of information or on the above issues should be submitted by November 20, 1998. 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.

X. 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, DC 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–11–F–1, U.S. Nuclear Regulatory Commission, Washington DC 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.

XI. 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.

XII. 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.

XIII. 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 part 50 : 50.59,: 50.66, and : 50.71; and 10 CFR part 72: 72.48,: 72.70,: 72.212, and : 72.248, under one or more of sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

XIV. 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 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 as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) without obtaining a license amendment pursuant to § 50.90 only if:

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

(ii) The change, test or experiment does not meet any of the criteria in paragraph (c)(2) of this section. 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 § 50.90 after the last final safety analysis report was updated pursuant to § 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 § 50.90 after the last final safety analysis report was updated pursuant to § 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 § 50.90 after the last final safety analysis report was updated pursuant to § 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 § 50.90 after the last final safety analysis report was updated pursuant to § 50.71 of this part;

(v) Create a possibility for a design basis 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 § 50.90 with respect to design basis accidents after the last final safety analysis report was updated pursuant to § 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 § 50.90 after the last final safety analysis report was updated pursuant to § 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, paragraph (b), introductory text, paragraphs (b)(4), (c)(2), and (c)(3)(iii) are revised to read as follows:

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

* * * * *

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

(1) * * *

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

(c) * * *

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

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

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

(3) * * *

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

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

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

* * * * *

4. In § 50.71 paragraph (e) 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 effects [1] 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.

* * * * *

5. Section 50.90 is revised to read as follows:

§ 50.90 Application for Amendment of license or construction permit.

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

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

PART 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 a design basis 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, and Section X.A.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 a design basis 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 amended by revising the definition for *independent spent fuel storage installation or ISFSI* to read as follows:

§ 72.3 Definitions.

* * * * *

Independent spent fuel storage installation or ISFSI means a complex designed and constructed for the

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

* * * * *

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

§ 72.9 Information collection requirements: OMB approval.

* * * * *

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

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*—As used in this section:

(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.

(3) 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.

(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 or controlled and information describing 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 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 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 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 §§ 72.56 or 72.244 after the last Final Safety Analysis Report was updated pursuant to §§ 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 §§ 72.56 or 72.244 after the last final safety analysis report was updated pursuant to §§ 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 §§ 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 § 72.56 or § 72.244 after the last final safety analysis report was updated pursuant to § 72.70, § 72.216 or § 72.248, of this part, as applicable;

(v) Create the possibility for a design basis 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 §§ 72.56 or § 72.244 with respect to design basis accidents after the last final safety analysis report was updated pursuant to § 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 §§ 72.56 or § 72.244 after the last final safety analysis report was updated pursuant to § 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) of this section. 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), (b), introductory text, and (b)(2) are revised to read and a 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 this part 72 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 72.1, 72.2, 72.3, 72.4, 72.5, 72.7, 72.8, 72.9, 72.16, 72.18, 72.20, 72.22, 72.24, 72.26, 72.28, 72.32, 72.34, 72.40, 72.46, 72.56, 72.58, 72.60, 72.62, 72.84, 72.86, 72.90, 72.96, 72.108, 72.120, 72.122, 72.124, 72.126, 72.128, 72.130, 72.182, 72.194, 72.200, 72.202, 72.204, 72.206, 72.210, 72.214, 72.220, 72.230, 72.238, 72.240, 72.244, and 72.246.

17. In § 72.212, paragraph (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 paragraph (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 14th day of October, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 98–28066 Filed 10–20–98; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–269–AD]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model MD–90–30 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain McDonnell Douglas Model MD–90–30 series airplanes. This proposal would require modification of the right and left main landing gear (MLG) hydraulic damper assemblies or replacement of the MLG hydraulic damper assemblies with modified and reidentified hydraulic damper assemblies. This proposal is prompted by reports indicating that, during overhauls, the MLG hydraulic dampers assemblies failed or had damaged spring retainers due to insufficient material thickness of the spring retainers. The actions specified by the proposed AD are intended to prevent failure of the hydraulic damper assemblies of the MLG, which could result in vibration damage and collapse of the MLG.

DATES: Comments must be received by December 7, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–269–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from The Boeing Company, Douglas Products Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Dept. C1–L51 (2–60). This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California.