

February 22, 1999

SECY&-99-054

FOR: The Commissioners

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

SUBJECT: PLANS FOR FINAL RULE - REVISIONS TO 10 CFR PARTS 50, 52,
AND 72: REQUIREMENTS CONCERNING CHANGES, TESTS, AND
EXPERIMENTS

PURPOSE:

This paper (1) provides an overview of the comments received on the proposed rulemaking on 10 CFR 50.59, (2) forwards the staff's proposals to resolve several issues related to implementation of § 50.59 and (3) recommends final rule language for a revision of § 50.59 and related provisions in Parts 50, 52, and 72. These changes affect the regulatory requirements controlling licensee changes, tests, and experiments for production and utilization facilities and for facilities for independent storage of spent nuclear fuel and high-level radioactive waste.

SUMMARY:

The staff is revising § 50.59 (and related sections) to clarify the criteria that determine when changes require evaluation by the licensee and when changes require NRC approval before they are implemented. A few key issues from the proposed rule and from the public comments on the proposed rule require Commission direction before the staff can finalize the rulemaking package. This paper discusses (1) the background of the proposed rulemaking, (2) the public comments on the proposed rulemaking, and (3) staff recommendations for the final rule based upon review of these comments. In addition, this paper contains staff's recommendation concerning the question of the scope of § 50.59 as requested by a Staff Requirements Memorandum (SRM) dated March 24, 1998.

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BACKGROUND:

Section 50.59 defines the conditions under which reactor licensees may make changes to their facilities or procedures, or to conduct tests or experiments without prior NRC approval. In general, such changes, tests, or experiments may be carried out unless they would involve a change to the technical specifications, or an unreviewed safety question (as defined in § 50.59(a)(2)). Similar language exists in § 72.48 for independent spent fuel storage installations (ISFSI) or monitored retrievable storage installations (MRS) for storage of spent nuclear fuel or high-level waste.

The Commission approved a staff recommendation to initiate rulemaking in its SRM on SECY-97-205, dated March 24, 1998. The Commission directed that the proposed rule allow “minimal” increases in probability or consequences (where minimal is greater than negligible). In this SRM, the Commission also directed staff to consider conforming changes for other parts of the regulations.

The Commission also asked staff to provide (1) a recommendation concerning the scope of 10 CFR 50.59, in February 1999; (2) a status report on the effectiveness of the short-term actions (from SECY-97-205); and (3) recommendations on whether to pursue more resource-intensive and high-impact long-term actions. The staff recommendation concerning the scope of § 50.59 is discussed in this paper below. Commission papers that provide information on the short-term actions include SECY-99-001, dated January 5, 1999 (updating guidance for final safety analysis reports (FSARs)) and SECY-98-224, dated September 28, 1998 (on commitment management). Staff is also preparing a separate memorandum that provides the current status of interactions with the Nuclear Energy Institute (NEI) concerning guidance to determine what constitutes design basis information. The staff recommendations on long-term actions to make Part 50 more risk-informed were provided in SECY-98-300, dated December 23, 1998 (which was also responsive to an April 25, 1997 SRM requesting an integrated approach to the requirements in Part 50 that includes clear, consistent definitions and risk considerations).

In SECY-98-171, dated July 10, 1998, staff forwarded a proposed rulemaking package to the Commission with a recommendation to issue the proposed rule for public comment. In this rulemaking, staff proposed a number of changes to § 50.59, including the addition of definitions and reformatting, deletion of the term “unreviewed safety question,” revisions to criteria to allow changes involving minimal increases in probability or consequences or creation of malfunctions of a different type (but not with a different result from what was previously evaluated), to be made without prior NRC approval. Staff also proposed an approach for “margin of safety reduction” that would focus upon the safety analyses that established the technical specifications. In the proposed rulemaking, similar changes were proposed for those sections in Part 72 relating to change control and also to extend the change control authority to Certificate of Compliance holders (for spent fuel storage cask designs). Other conforming changes necessitated by the changes in §§ 50.59 and 72.48 were also proposed.

In its SRM of September 25, 1998, the Commission approved staff’s proposal to issue a proposed rule for public comment. The Commission did not adopt staff’s proposed recommendation on margin of safety and also offered other questions and issues for consideration. The Commission specified a number of topics for which public comment should be sought in the *Federal Register* (FR) notice, most particularly, for a broad range of options on

margin of safety. Further, individual Commissioner vote sheets were included in the FR notice so that interested parties would understand preliminary views of the Commission on these issues. The proposed rule was published in the *Federal Register* (63 FR 56098; October 21, 1998) for a 60-day comment period ending December 21, 1998.

The Commission's SRM of September 25, 1998, requested staff to complete the rule on an expedited schedule (by February 19, 1999). Because of the range of views on a few important issues, such as margin of safety, staff concluded that Commission direction was needed on an approach for these issues before staff finalized its rule package, as discussed in a memorandum to the Commission dated December 21, 1998.

DISCUSSION:

Fifty-nine letters commenting on the proposed rule were received. A list of the commenters is provided in Attachment 1. Further, Attachment 1 discusses and analyzes the comments, which are organized by topics as presented in the proposed rule. A summary of the major issues and staff recommendations for resolving these issues are presented herein. Commission approval of these recommendations, or selection of an alternative approach is requested so the final rule package can be prepared. In addition, the staff notes the degree of consistency of the proposed approach with the existing industry implementation guidance, NEI 96-07.

The proposed rule reorganized the rule requirements, including separation of the evaluation criteria into seven separate statements. The following discussion refers to this numbering. Attachment 2 presents the revised rule language, which has been modified in accordance with the recommendations presented herein. Additional refinements to the rule language may arise as staff completes the comment review and concurrence process.

1.0 MAJOR TOPICS

1.1 Probability of occurrence of an accident or malfunction of equipment important to safety previously evaluated in the FSAR (as updated) is more than minimally increased (§§ 50.59(c)(2)(i) and (c)(2)(ii))

The proposed rule included language that states that a license amendment was required if there was more than a minimal increase in the probability of an accident or malfunction of equipment important to safety previously evaluated in the final safety analysis report (as updated).

Several comments were offered on the guidance concerning how a minimal increase would be determined. Many commenters stated that evaluations of probability would be qualitative, and they wanted the supplementary information to indicate more explicitly that quantitative analyses are not expected. Commenters also thought that it was not clear how to determine qualitatively that there was no more than a minimal increase in probability if some discernable increase could be noted. NEI has indicated that it does not intend to modify the current guidance in NEI 96-07 that establishes a qualitative "negligible" threshold.

A few commenters wanted some quantitative guidance, particularly to allow use of probabilistic risk analyses. Some commenters suggested reliance on the process established in Regulatory

Guide (RG) 1.174 for changes involving quantitative evaluations. Staff's view is that if greater use is to be made of PRA information, more fundamental changes to the rule would be necessary to provide a coherent set of requirements and that the regulatory processes established in RG 1.174 would have to be reexamined for applicability to changes being made by a licensee without NRC review (for example, criteria for preservation of sufficient defense-in-depth might be needed). Further, applicability to facilities such as nonpower reactors, reactors undergoing decommissioning, and Part 72 facilities would also need to be considered.

While the rule language in Attachment 2 retains the term "minimal", the staff notes that in practice, distinctions between "negligible" and "minimal" cannot be achieved for qualitative evaluations. The staff attempted to provide more quantitative guidance, but was unable to develop a meaningful value that could be used generically (for all accidents and malfunctions), or a means of judging when the increase would be too large, when applied to the deterministic analyses in the FSAR. The staff presently plans to make certain clarifying changes to the guidance offered in the proposed rule supplementary information for qualitative assessments to implement the rule language of "minimal" increases in probability in a manner more akin to a "negligible" standard. Existing guidance in NEI 96-07 concerning "negligible" increases will satisfy the rule requirements. The "minimal" language would allow effects to be more than negligible and yet still satisfy the "minimal" criterion in the rule.

The staff also recommends that the term "probability" be changed to "frequency" for occurrence of accidents, and to "likelihood" for occurrence of malfunctions. The staff concludes that these terms provide a better representation of the attribute of concern, and also how the evaluation would be conducted. Also, as discussed under topic 1.3, the staff proposes to use the term "structures, systems and components" rather than "equipment."

Resolution:

As noted, the staff recommends minor changes to the rule language, as presented in Attachment 2.

1.2 Margin of safety as defined in the basis for any technical specification is reduced (§50.59(c)(2)(vii))

The FR notice solicited comment upon a wide range of options related to the regulatory treatment of margin. Staff included a number of possibilities and also noted that other proposals were welcomed. The range of options presented included deletion of the criterion, as well as options focusing upon specified parameters. For instance, some of the options concerned fission product barrier response with another suboption proposing inclusion of mitigation system capability. Staff considered a range of approaches from "no change" to these parameters, up to meeting specified limits, including a concept of "minimal" reductions. In addition, staff proposed an option that would control evaluation methods used to demonstrate that the selected parameters are satisfied.

Although a large number of comments were submitted, they can be grouped into a few major themes: those supporting the discussion in NEI 96-07 (acceptance limits), those supporting deletion of margin as a criterion, and those supporting a new proposal from NEI.

NEI proposed to replace the existing margin of safety criterion with one that states that a change requires approval if it would result in a design basis limit directly related to integrity of fuel cladding, the reactor coolant system pressure boundary, or the containment boundary being exceeded or altered. NEI noted that this recommendation is not based on the concept of minimal changes because the fission product barrier design parameters of interest are not suited to this approach. Conservative margins were built in when the design basis limits were established, and plants routinely operate at or near these limits, so a “minimal” change concept has little meaning. In its proposal, NEI also proposed controls on evaluation methods associated with demonstrating that the design basis limits have not been exceeded for parameters directly related to fission product barrier integrity. As discussed in their comment letter of December 21, 1998, NEI would define evaluation methods as including such elements as methods for reducing data, correlations, physical constants, and modeling techniques.

Staff examined the NEI proposal to determine whether important design parameters would be protected through application of this criterion in conjunction with the other criteria and regulations. Staff was concerned that the language of “directly related to fission product barrier integrity” might be too narrow. Staff was supportive of the concept of using the design basis as the determinant of when NRC approval was needed and for control of evaluation methods. Thus, the staff’s current proposal would be a modification of that suggested by NEI that focuses upon the effectiveness of systems to protect the barriers, that is, changes would be allowed without prior NRC approval that would close the gap between current calculated values and “controlling” values, provided the barriers are not challenged. This would be demonstrated by showing that the systems are still capable of performing their design functions.

In developing its approach, the staff was seeking to allow flexibility to licensees, yet also to provide confidence that the effects of such changes remain within acceptable boundaries. The staff criteria is intended to broaden the NEI proposal to encompass overall plant performance, including fission product barrier response, mitigation system capability and those support systems that must function for these systems to perform their functions. The focus upon functions (including support systems) and lowest functional capabilities also provides consistency with the philosophy for establishing TS. For certain systems and structures, these capabilities are already included within the TS; this approach thus brings a degree of uniformity to all plants.

The staff has developed the following as recommended rule language for when prior NRC approval is required for a proposed change, test, or experiment. A change would require NRC approval if the change would:

(vii) Result in the design basis capability for any structure, system or component directly related to maintaining the integrity of the physical barriers intended to contain radioactivity (including mitigation systems), or any system necessary to support the functions of these SSC, being exceeded or altered.

(viii) Result in more than a minimal change in a method of analysis described in the final safety analysis report (as updated) that is used to establish design basis values.

IMPLEMENTATION

These criteria would then be implemented through guidance that has the following provisions:

The extent of SSCs that would need to be considered under this criterion are those whose functions are to maintain integrity of the physical barriers intended to contain radioactivity (that is, for reactors, fuel clad, the RCS, the primary containment, and any others), or those used to mitigate accidents or the release of radioactivity, and those support systems that must function in order to assure the functioning of accident prevention and mitigation systems, for the range of accidents and events that the plant is required to withstand.

The design basis capability (for an SSC) is the lowest functional capability that accomplishes the required functions for all required conditions, including the range of accidents and events that the facility is required to withstand. This philosophy is consistent with the 50.2 definition of design bases, and would reflect a condition that if the design basis is not met, some other system or characteristic would be materially impacted, as for instance the fission product barriers being challenged. For purposes of this evaluation, assessment of design basis capability for components is intended to be limited to those components necessary for ensuring the capability of the reactor coolant pressure boundary and containment barriers. Thus, the components would include such items as the reactor vessel, reactor coolant pumps, reactor coolant pressure boundary piping, and containment isolation valves, which have a distinct function in preserving integrity of the barriers. Changes to other components, e.g., other system piping, pumps, supports, etc., may be evaluated in terms of their effect on system functional capability under design basis conditions.

Changes to design basis capabilities would require NRC approval. Where a design basis capability has been established in the FSAR, a change in which the design basis capability continues to be met, as demonstrated by the same analysis methodology as previously used (in the FSAR), does not require NRC approval.

For analytical methods, the staff has proposed a minimal change standard, to allow licensees to use different methods, yet prevent loss of all margin. A change in a method as a single change should be benchmarked by assuring that parameters that are acceptable in the changed method would not cause systems and structures to exceed their design basis capabilities under the method that previously had been approved by the NRC. This determination would be made by comparison to previously acceptable method(s) of evaluation. The staff intends to discuss this criterion with NEI in the near future.

In implementing these criteria for NRC review, staff notes that the licensee remains responsible for demonstrating that TS and other regulatory requirements continue to be met for this revised system capability as part of its safety assessment of the proposed change.

As noted in previous guidance, changes are to be evaluated separately. Thus, if a licensee wishes to make changes to the facility in conjunction with changes to methodology, the above standards would apply to the individual changes.

Based on the relatively high threshold which would be established under these proposed criteria, it is likely that many changes requiring a license amendment under these criteria may

also involve a significant hazards consideration. Thus, many license amendments which are necessitated by these two criteria likely will have to be noticed in the *Federal Register* and an opportunity for a hearing provided prior to issuance of the license amendment; any hearing granted on these cases must be completed prior to the issuance of the amendment.

Significant revision to NEI 96-07 is anticipated to explain in detail the criteria and how they would be implemented. The staff believes that the use of examples will help facilitate understanding of these criteria and interpretation of minimal changes with respect to methods.

Resolution:

The staff supports the goals of the NEI approach, but recommends a modification of the approach offered by NEI that focuses on effectiveness of structures, systems and components to protect fission product barriers, rather than just on the barrier parameters themselves. Staff believes that an approach such as that described above would provide a criterion that would control system capability such that barriers are not challenged, yet allow licensees flexibility to make changes that do not prevent the systems from performing their minimum functional requirements.

1.3 Part 72 Changes and related issues

Several commenters stated that the requirements in Part 72 should be made even more consistent with those of §§ 50.59 and 50.71(e). These commenters also believe that certain of the requirements of Part 72 (i.e., release limits, § 72.48 evaluation criteria on occupational exposure and environmental impact, and update frequency and content requirements) are more stringent than the similar provisions in Part 50. These commenters further state that these requirements are not commensurate with the relative potential risks of the two types of facilities. Staff notes that many of these differences are in existing rule requirements and do not arise from the proposed rule changes. The staff has revised Part 72 in response to these comments to provide greater consistency with Part 50. A few of the recommended changes may require renoticing because they were not within the scope of the proposed rule (e.g., removal of the occupational exposure and environmental impact tests from § 72.48), and therefore, the staff proposes to prepare a supplemental proposed rulemaking for any such issues.

Although the bulk of the changes the staff has included in Attachment 2 would conform Part 72 to Part 50's language, staff would propose the reverse in one instance. Staff would propose the use of the term "structures, systems, and components (SSCs) important to safety" in both Parts rather than the term "equipment important to safety" as presently in § 50.59. Staff believes that the term "SSCs important to safety" is already common terminology and is currently reflected in Part 50's general design criteria. Also staff would not propose revising release and accident

limits in the supplemental rulemaking, because such changes would be significantly beyond the scope of the original rulemaking on “changes, tests and experiments.”

Additionally, several commenters stated that the change control process allowed under Part 72 should be expanded to include transportation packages (i.e., casks) certified under 10 CFR Part 71, especially for dual-purpose casks (i.e., casks certified for both the storage and transportation of spent fuel under both Part 71 and 72). Staff notes that current International Atomic Energy Agency (IAEA) safety standards for transportation of radioactive material (i.e., ST-1) do not provide for a § 72.48 type change control process allowing for changes to the design of a transportation package without prior approval. However, staff believes that the comment to provide for a § 72.48 type change control process in Part 71 has merit — if limited to transportation packages used in the domestic shipment of spent fuel. Staff would propose to expand the scope of the suggested change to both dual-purpose casks approved under both Part 71 and 72 and to transport-only casks approved under Part 71. Consequently, this change would apply to casks used to domestically ship spent fuel, including dual purpose casks.

Staff believes that such a regulation in Part 71, while departing from IAEA standard ST-1, would be acceptable for spent fuel transportation packages used in domestic commerce only. Staff also believes that Part 72 licensees that ship spent fuel, Part 72 certificate holders, and Part 71 spent-fuel certificate holders have the necessary experience to implement these potential Part 71 regulations without adversely affecting the safe transport of spent fuel. NRC staff has discussed this concept with staff from the Research and Special Programs Administration of the U.S. Department of Transportation (DOT), and DOT staff did not object to this concept. Staff will coordinate this proposed change to Part 71 with the DOT in the supplemental rulemaking described above. Staff will address the question of allowing a § 72.48 type change control process for all other types of Part 71 transportation packages as part of a different rulemaking (NMSS-C3MP-26, “Compatibility with IAEA Transportation Standards, Part 71”).

Resolution:

Staff recommends acceptance of the comments and proposed resolution as described above. In order to provide a final rule as soon as possible, the staff recommends that a final rule be issued for both §§ 50.59 and 72.48. Staff also recommends that simultaneous with this final rule, a supplemental notice of proposed rulemaking be issued to provide for “§ 71.48” change authority and to address any staff responses to comments which would require renoticing for public comment. Staff recommends that a supplemental final rule on the revisions to Parts 71, and any necessary Part 72 sections, follow within 18 months of issuance of the final rule for Parts 50, 52 and 72 (see Section 2.0 for a discussion of staff proposals for the implementation schedule). Guidance on the changes to Parts 71 and 72 would be developed in concert with the guidance on Part 50 and would be issued in accordance with the implementation schedule discussed below. As noted, other Part 71 changes would be handled as part of a different rulemaking.

1.4 Other issues

In the *Federal Register* notice for the proposed rule, the Commission also specifically sought comment on other topics. For instance, comment was specifically requested as to whether the scope of § 50.59 should be revised to include information other than that “as described in the

safety analysis report.” After careful consideration, staff is not proposing any change to the scope in this rulemaking. As noted, staff has provided definitions of terms such as “facility as described...”, to more clearly define those changes that require evaluation and thus allow others to be screened out without a detailed evaluation. Only a few commenters indicated interest in a redefinition of the scope, and these commenters also suggested it occur as part of a longer-term revision that might be more risk-informed with respect to evaluation criteria as well. As discussed in SECY-98-300, staff is proposing to define a risk-informed scope for use in a number of Part 50 regulations. In this effort, applicability for § 50.59 is being examined. Therefore, the staff concludes that a separate effort to revise the scope of § 50.59 itself is not warranted.

In addition to the topics discussed within this paper, there are some other topics that affect the rule language changes or are otherwise considered to be of Commission interest which are discussed in Attachment 3. These topics include definition of change, need for definition of accident, the evaluation criterion on increase in consequences, and reporting requirements. Other comments received are for the most part editorial or minor comments. Some will be resolved through clarifications of rule language or in implementation or inspection guidance; others will not be adopted. Comment resolution will continue while this paper is before the Commission for deliberation to expedite completion of the final rule package. Attachment 1 contains this information and the final resolutions of the comments will be included with the final rule package when it is submitted.

2.0 ENFORCEMENT AND IMPLEMENTATION STRATEGY AND SCHEDULE

Staff is also interested in obtaining Commission direction concerning timing of implementation of §§ 50.59 and 72.48 and on enforcement strategy. As noted in the comment letter from NEI, time will also be needed to revise existing industry guidance (and NRC endorsement through a Regulatory Guide). Further, guidance for Part 72 licensees (and potentially for Part 71) will need development. Staff will work with NEI and industry to develop specific guidance for Part 72 during this period as well as on the revisions to guidance for reactor licensees. Once the guidance is complete, there will be a need for revisions to procedures, conduct of training, and other activities to facilitate implementation of the revisions to the rule.

These factors would suggest a relatively long period before the rule changes become effective. On the other hand, many reactor licensees may wish to use the enhanced flexibility provided by the revised criteria as soon as possible. Accordingly, the staff recommends that the Commission follow a strategy by which the existing §§ 50.59 and 72.48 rules would remain in effect for an 18 month period and the revised rules would be issued and made effective during this 18 month period. The revised rules, will by their terms, replace the existing rules at the end of the 18 month period. If a licensee (or certificate holder) wishes to implement the revised rule(s) sooner than the 18 month deadline, this could be done upon written notification to NRC of the effective date by which that licensee would implement the revised rule in place of the existing rule. Future development of the inspection and enforcement strategy will also be coordinated with the changes occurring to NRC oversight and assessment processes.

During the period until the revised rules are implemented, staff also recommends that it continue to exercise some enforcement discretion, using the following approach for violations of §§ 50.59 and 72.48:

- 1) The staff intends to exercise discretion to refrain from enforcement action for non-willful violations of existing §§ 50.59 or 72.48 requirements that would not be violations had the evaluations been performed using the revised rule. The staff does not plan to document such matters in inspection reports.
- 2) Failure to perform written evaluations or maintain required documentation would be considered Severity Level IV violations and generally treated as non-cited violations. The failure during the implementation period to submit an amendment as required, where the NRC finds the underlying licensee action acceptable without the need for substantial review, would also be categorized at a Severity level IV (consistent with current practice for enforcement discretion in this area).
- 3) A failure to submit an amendment as required would be considered a Severity Level III violation if either a) a substantial review is needed by the NRC before it could conclude that the licensee's actions were acceptable or b) NRC would not have found the licensee's actions acceptable.
- 4) However, if the licensee's failure to meet the new rule appeared to be in good faith based on either a misunderstanding of the new requirements as a result of lack of guidance or insufficient time to implement changes from the old rule, discretion would be exercised under section VII B.6 of the Enforcement Policy.
- 5) After the effective date for §§ 50.59 and 72.48, a failure to submit a required amendment would be considered a Severity Level III violation. If NRC would not have found the changes made by the licensee or certificate holder (without NRC approval) to be acceptable, the severity level could be increased to a Severity Level II.

The staff would maintain an enforcement panel made up of NRR (and NMSS as applicable), OE, and OGC representatives for some months after publication to maintain consistency. In addition, as part of the final rulemaking package, changes will need to be made to the Enforcement Policy.

CONCLUSION:

Staff is seeking Commission direction concerning the recommendations contained herein, and on the (draft) final rule language presented in Attachment 2. Upon receipt of this direction, staff will then forward a final rule package (including any supplemental proposed rule for Parts 71 and 72) consistent with this guidance as expeditiously as possible.

RECOMMENDATIONS:

1. That the Commission approve staff's recommendations discussed above;
2. That the Commission allow early release of this paper to facilitate industry's interaction with the staff on these proposals and to initiate preparation of guidance.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

The staff will meet with the Advisory Committee on Reactor Safeguards during its March 1999 meeting to discuss the recommendations in this paper.

William D. Travers
Executive Director for Operations

Attachments:

1. Discussion of public comments on the proposed revision to 10 CFR Parts 50, 52 and 72 (63CFR 56098)
2. Recommended final rule language for 10 CFR 50.59 and related provisions
3. Other rule language changes and issues

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DOCUMENT NAME:A:\CPAPER *See previous concurrence

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NAME	WKane*		Bsheron*		SCollins*		JLieberman*	
DATE	2/16 /99		2/17/99		2/18/99		2 /16 /99	
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DISCUSSION OF COMMENTS

This attachment provides the initial staff analysis of the comments received in response to the FR notice published on October 21, 1998 (63 FR 56098), for a proposed revision to 10 CFR 50.59 and related provisions in Parts 50, 52 and 72.

Fifty-nine responses were tabulated. As noted, one filing was a duplicate, so there are fifty-eight documents included in the analysis. A list of the submittals is included in this attachment.

For purposes of analysis, each letter was reviewed to identify comment areas and topics. For the most part, comments were specifically tied to one of the numbered subsections from the notice, so this numbering system was used in the tables that follow. Those comments that could not be tied to one of these sections were placed at the end. A number was assigned to each section or paragraph of each letter that was considered as being a separate comment. The tables group the comments by using a system where the first digit refers to the number assigned to the comment letter (see list), and the second set of numbers link to either the numbering scheme used by the commenter or these staff-assigned numbers, so that all comments could be accounted for, and also grouped with comments on the same topic.

The Nuclear Energy Institute (letter 22) submitted a set of comments that had been circulated among its members in order to provide consolidated views. This is reflected in the 35 letters from power reactor licensees that generally endorsed these comments, sometimes with modification or additional comments. Further, submittals from three law firms, on behalf of a number of licensees, were made. For these reasons, a precise accounting of the number of commenters making a particular comment, or agreeing with a comment, is difficult.

COMMENT LETTERS ON 63 FR 56098

<u>Number</u>	<u>Date</u>	<u>Author name</u>	<u>Affiliation</u>
(1)	11/3/98	Paul Sicard	none
(2)	11/3/98	Brendan Ryan	Kansas State University
(3)	11/18/98	Kurt Schaefer	A&K Nuclear Licensing
4	12/11/98	S. Gambhir	Omaha Public Power District
5	12/18/98	Ian Rickard	ABB-CE
6.	12/17/98	Steven Toelle	USEC
7.	12/17/98	Michael Croson	INEEL
8.	12/18/98	J.Beasley	Southern Company
9.	12/17/98	K. Singh	Holtec International
10.	12/18/98	James Mallay	Siemens Power Corporation
11.	12/21/98	Steven Franz	Morgan, Lewis and Bockius
12.	12/18/98	Richard Phares	Illinois Power
13.	12/17/98	James O'Hanlon	Virginia Power
14.	12/18/98	Sherry Bernhoft	Florida Power
15.	12/18/98	Kenneth Peveler	Alliant Utilities
16.	12/21/98	Daniel Stenger	Winston and Strawn
17.	12/17/98	Michael Kansler	Entergy
18.	12/18/98	Larry Grime	L.A.Grime And Associates
19.	12/18/98	Lester Slaback	NIST
20.	12/18/98	Donna Alexander	CP&L
21.	12/18/98	Ted Fiegenbaum	North Atlantic Energy
22.	12/21/98	Anthony Pietrangelo	NEI
23.	12/21/98	Malcolm Philips	NUGEQ
24.	12/21/98	R. Krich	ComEd
25.	12/21/98	Joseph Quirk	General Electric
26.	12/21/98	Norman Peterson	Detroit Edison
27.	12/21/98	Paul Gaukler	Shaw Pittman Potts ...
28.	12/21/98	(SAME AS 23)	
29.	12/21/98	E.D.Fuller	BNFL Fuel Solutions
30.	12/21/98	G. Zinke	Maine Yankee Atomic
31.	12/21/98	David Powell	PSE&G

32.	12/17/98	John Oddo	YAEC
33.	12/17/98	Lew Myers	First Energy
34.	12/xx/98	Bill Ellis	none
35.	12/18/98	Robert McCredy	Rochester Gas & Electric
36.	12/20/98	Lynne Goodman	none
37.	12/21/98	John Fornicola	GPU
38.	12/21/98	Charles Cruse	Baltimore Gas & Electric
39.	12/21/98	Bradford Houston	Nebraska PPD
40.	12/21/98	Al Passwater	Ameren UE
41.	12/21/98	Matthew Petitclair	none
42.	12/17/98	Rajiv Kundalkar	Florida Power and Light
43.	12/18/98	James Levine	Arizona Public Service
44.	12/18/98	Mike Tuckman	Duke Energy
45.	12/21/98	H.A. Sepp	Westinghouse Electric
46.	12/21/98	Martin Bowling	Northeast Nuclear
47.	12/21/98	James Baumstark	Consolidated Edison
48.	12/21/98	Garrett Edwards	PECO
49.	12/21/98	J. Knubel	NYP&A
50.	12/21/98	Edward Scherer	Southern California Edison
51.	12/21/98	Gary Taylor	SCE&G
52.	12/21/98	Michael Wadley	Northern States Power
53.	12/21/98	Lance Terry	Texas Utilities
54.	12/21/98	M.A. McBurnett	South Texas Project
55.	12/21/98	Richard Muench	Wolf Creek
56.	12/29/98	Richard Olson	none
57.	12/21/98	Mark Burzynski	TVA
58.	12/22/98	Nathan Haskell	Consumers Power
59.	12/22/98	Carl Terry	Niagara Mohawk

A.1 50.59(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.

Comment	Commenter & Item Number
Consolidating the existing 10 CFR 50.59 applicability statements into one paragraph that is labeled in a new Section (b) "Applicability"	22-2, 32-2, 39-8
<p><u>Summary:</u> The commenters agreed with the staff's proposal.</p>	
<p><u>Resolution:</u> Retain in final rule</p>	

A.2 Form of Approval (Changes to (a) and (c); Moving Requirement to 50.90 for TS)	
Comment	Commenter & Item Number
Relocate the existing requirement in 10 CFR 50.59(a) and (c) on control of TS to 10 CFR 50.90.	13-1, 17-9, 22-4, 39-9 39-10
<u>Summary:</u> The commenters agreed with the staff's proposal.	
<u>Resolution:</u> Retain in final rule	

A.3 Deletion of USQ Term & Criteria Itemization	
Comment	Commenter & Item Number
1. USQ Term	
bh. Support deletion of the term "USQ"	1-6, 13-1, 17-6, 20-1, 22-3, 32-3, 39-11
2. Breakout of Criteria	
1. Support listing of seven separate criteria	17-8, 22-3, 32-3
b Offers other screening criteria, e.g. impact safety of operation, change to TS, change to facility from its description in the FSAR, etc..	3-14
3. The staff needs to address how to treat previous guidance and accepted practices that have used the term of "USQ."(e.g. GL91-18, Rev 1)	13-1, 22-5
4. Establish a simple process to change the existing TS that contain the term "USQ" or safety evaluation without licensees having to submit license amendments.	17-7, 22-6
<p><u>Summary:</u> The commenters generally agreed with the staff's proposal. However, some commenters expressed concerns that with the proposed rule language change it may inadvertently impact previous guidance and accepted practices that have used the term "USQ." It may also have impact on many licensees' TS which contain "USQ."</p>	
<p><u>Resolution:</u> Retain in final rule. Include text in supplementary information concerning existing guidance. Staff plans to issue inspection guidance following approval of final rule. With respect to TS changes, the staff is considering options - one approach may be to allow pen-and-ink changes to TS substituting the term "requires license amendment" for "unreviewed safety question". Suitable rule text may need to be added to speak to conflicting requirements, noting that the rule supersedes TS text. This approach was used for a final rule on section 50.4, see 51 FR 40303, dated November 6, 1986.</p>	

B.1 Change: Change means a modification, addition, or removal.	
Comment	Commenter & Item Number
<p>Propose alternative definition for change, "<i>Change means a modification or addition to, or removal from, the facility or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.</i>"</p> <p>Believe this change needs to be made because: it will be clear that insignificant changes are screened out of the 50.59 process, which will result in more effective resource allocation by licensees and the NRC. Specifically, evaluation against the seven criteria of the proposed Section (c)(2) should not be required for changes to design details that do not impact design functions or methods of performing or controlling design functions.</p>	<p>20.2(p1), supports focus on design function 21.2(p2) 22.9 (II.A.1, pp3-4) 24.2(p1) 27.12(p9) 35.1(p1) 38.3(II.B.3,p6) 39.1&2(pA1&2) 43.1(p1) 46.1(p1) 52.1&3(p2) 53.1(pA1)</p>
<p>(Similar to above) Unclear what changes constitute "<u>addition.</u>" Could imply that trivial additions (tags) or any new procedure. Need to limit to significant additions. Believe Commission did not intend all additions, but language not precise.</p> <p>Recommend that NRC clarify that "addition" means an addition to <i>the facility</i> that either (1) introduces a new hazard that potentially could affect a safety function described in the FSAR, (2) changes the operation or response of the facility as described in the FSAR, or (3) is otherwise inconsistent with the FSAR or outside the controlling parameters of the design basis as described in the FSAR.</p>	<p>11.7(2.3,p5) 38.3(II.B.2&3,p5&6), specific changes suggested.</p>
<p>"<u>Additions</u>" should be treated the same as tests and experiments. That is, a 50.59 would only be required for procedures that are inconsistent with the FSAR or outside the design basis of the FSAR.</p>	<p>11.8(2.3,p5), 38.4(II.B.3,p6)</p>
<p>Equipment removed from service, or to support <u>maintenance</u>, should not be considered a <i>change</i>, and should instead be controlled by tech specs or the maintenance rule (suggested adding clarification to suppl info in final rule)</p>	<p>1.9(II.B.3,p4) 17.16(II.B.8,p4) 22.10 (II.A.2, p4), 38.7(II.B.8,p8) 52.3(p2)</p>

<p>50.59 evaluations do not have to be performed unless the proposed change meets the definition of <i>change</i> and either the definition of <i>facility</i> or <i>procedure</i> as described in the FSAR (suggested discussion should be added to Suppl info by some commenters)</p>	<p>21.2(p2) 22.11(II.A.3,4,pp4) 24.2(p1) 27.12(p9) 38.3(II.B.2,p6) 39.1&2(pA1&2)</p>
<p>A change to an '<u>analysis method or parameter</u>' is only a <u>change to the facility</u> only if the method or parameter is described explicitly or implicitly in the FSAR.</p>	<p>1.7 (II.B.1,p3) 17.11(II.B.2) 39.2(maybe,pA2) 55.1(p1, notes that method term is too broad)</p>
<p>Provide specific examples for integrated (or <u>interdependent</u>) changes. Clarify, too narrow (comment 11.11 suggested within same accident analysis)</p>	<p>1.8 (II.B.2, p3) 11.11(2.6,p7&8) 27.16(p10-11) adds language (see below)</p>
<p><u>Interdependent</u>, adopt position: "Multiple changes to the facility or its procedures may be evaluated collectively (<u>i.e.</u>, may be considered elements of a single change for purposes of review under section 50.59) if they are interrelated. Changes are considered interrelated if (1) they are interdependent, as in the case where a modification to a system or component necessitates additional changes to other systems and components (or procedures) in order for the modified system to perform its function or comply with its design or licensing basis; (2) they are proposed collectively to address a design or operational issue; or (3) they are otherwise planned as elements of a single project undertaken to restore, maintain or improve plant performance or safety."</p>	<p>27,16 (p10-11), see above as well</p>
<p><u>Interdependent</u>: Proposed position on what constitutes a single change is consistent with the guidance in NEI 96-07. However, there is no need to develop a definition in the rule.</p>	<p>17.15(II.B.7,p4) 39.3(pA2)</p>
<p>Remove discussion of <u>interdependent</u> changes, encourage licensees to group changes provided that net effect reduces risk or is a minimal increase in risk.</p>	<p>7.5(5,p4)</p>
<p><u>Nominal Values</u>, NRC should provide guidance on treatment of nominal values (when do they become a change?).</p>	<p>1.10(II.B.4,p4), 17.12(II.B.4,p3)</p>
<p>If change is made in response to issues in <u>generic communications</u>, does this constitute a 'change' or is it already previously approved by the NRC, and thus a 50.59 or amendment not required?</p>	<p>1.13(II.B.7,p4) 17.14(II.B.6,p4)</p>

<p><u>Replacement</u> of components with equivalent components should only be considered a <i>change</i> if the replacement component has characteristics that are different from those described in the FSAR.</p>	<p>11.22(3.1,p10) 53.1(pA1)</p>
<p><u>50.49 EQ</u>, similar to preceding, equipment replacements that are qualified per 50.49 should not be treated as changes under 50.59; e.g., do not alter underlying design bases.</p>	<p>23.1, 23.4 (p2,3,4)</p>
<p><u>Installation and testing of Mods prior to License Amendment</u> should be allowed provided that the mod is not implemented (and its installation and testing would not require an amend). This is equivalent to drafting a procedure before its approved for use.</p>	<p>11.23(3.2, p11) 12.3(p2-3) 22,7 44.10(p4)</p>
<p>Agree with NEI that GL91-18 approach should remain unchanged. Therefore, to ensure that Appendix B, Criterion 16 and 50.59 do not interfere, suggest 50.59(c)(2) be modified to read, “A licensee shall obtain an amendment to the license pursuant to Section 50.90, prior to implementing a change, test, or experiment unless the activity is in accordance with Section 50, Appendix B, if it would ...”</p>	<p>13.2(p2)</p>
<p>To avoid a legal conflict (that exists today) between 50.59 and GL91-18, a clarification needs to be made such that licensees following GL91-18 will not be in violation of 50.59.</p>	<p>38.5(II.B.6,p8)</p>
<p>Consistent with Commissioner Diaz’s comments, adding definitions is not necessary and only adds confusion. As industry commented on NUREG-1606, changes to the SAR, whether to procedures or the facility, require a 50.59 (unless it is an inconsequential change).</p>	<p>17.10(II.B.1,p3)</p>
<p>If the level of discussion within the <u>FSAR</u> is <u>unaffected</u> by the proposed change, and there is no change to the results of any underlying design analysis, then there is no requirement to perform a 50.59 evaluation.</p>	<p>17.11(II.B.3,p3), 38.3(II.B.3,p6) 39.1&2(pA1&2)</p>
<p>Rule should clearly indicate that “changes” include “additions”. Also should be clear that changes under 50.59 (72.48) are not limited to physical changes, but include standards, procedures or calc methods (which can potentially affect the design bases)</p>	<p>32.4(II.B,p2)</p>
<p>Terms in rule need to be defined, but concerned that by making them part of the rule any subsequent interpretation would require rulemaking.</p>	<p>35.1(p1)</p>

Proposed definition of change fails to recognize that there are two separate changes that need to be defined. The first is the actual change to the plant, which must be evaluated to determine if 50.59 is applicable. The second is the text or drawing change to the FSAR description of the facility, which requires a 50.59 safety evaluation. Safety evaluations should only be applicable to the FSAR described facility and any text-drawing changes. All other changes should screen out.	38.4(II.B.3,p8)
Definition should recognize that changes are only proposed changes. This will avoid the problem with 'de facto design changes'.	38.6(II.B.7,p8)
In §B of the FRN, use of word 'parameter' is too broad, clarify to read, "...changes to parameters that affect regulatory limits", or "effects of the parameter change."	45.1(p1)
Rule should specifically address and exclude from the 50.59 process administrative changes to organizational, reporting relationships, and job titles.	48.2(pA1)
Since the term <u>design bases</u> does not have a consensus, its use can be misleading.	55.1(p1)
The term 'removal' should be clarified to include: removal from service, physical removal, retirement in place, discontinued availability, removal from the FSAR text or tables, and removal from FSAR figures.	56.1(pA1)
If change is <u>limited</u> to those that affect content of UFSAR, then effective scope of 50.59 will be reduced, as practiced by some licensees, who interpret 50.59 to mean that a change to anything that <u>appears</u> in the UFSAR must be evaluated.	56.3(p1)
<p><u>Summary:</u></p> <p>Commenters offered several proposed clarifications and concerns about the definitions. Most were directed at allowing screening of changes that did not affect functions, or of other activities that should not require 50.59 evaluations.</p> <p>A few commenters wanted the rule language to explicitly codify the philosophy in GL 91-18 concerning the "de facto" changes and corrective action.</p>	
<p><u>Resolution:</u> The staff recommends a revision to the rule language on change that would accommodate screening. No rule changes are recommended concerning the "de facto" changes - staff believes existing guidance is adequate. Other comments can be handled through appropriate implementation guidance.</p>	

<p>B.2 Facility As Described: 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.</p>	
Comment	Commenter & Item Number
Delete <i>“required to be included or”</i> from §§ii & iii. Requirements for FSAR are in §50.34(b) and 50.71(e)	10.2(p1) 11.10(2.5,p6) 22.12 (II.B.1,pp5) 27.13(p9) 39.4(pA3) 52.2(p2)
Replace <i>“required to be included or”</i> with a reference to the definition of safety-related SSCs contained in 50.2	31.1(p1)
Delete <i>“methods of operation”</i> from §§ii because the information is captured by the definition proposed for “procedures as described”	22.13 (II.B.2,pp5)
Endorse treatment of information <u>“incorporated by reference”</u> as in NEI 98-03. Commenter 38 suggests the definition of incorporated by reference be added to the rule.	1.11(II.B.5,p4), 17.13(II.B.5,p4) 38.12(II.E.2,p11)
Limit criteria (iii) to ‘plant-specific input variables and results’ from the evaluations included in the FSAR.	3.6(3(a),p6&A-1)
Delete third criterion (50.59(a)(2)(iii), on evaluations and methods because its inclusion discourages licensees from adopting new (improved) methods.	7.10(10,p6)
Modify definition to include only “those aspects of systems, structures and components as are described in the final safety analysis report.” As proposed by staff, any change to a SSC would require 50.59. Need to screen out some changes.	27.12(p9) 39.4(p2&3)
Discussion in NOPR is inconsistent in use of FSAR, sometimes uses SAR, where FSAR would be appropriate.	38.2(II.B.1,p5)

Support Chairmans position that definition of procedures (and by extension of facility), needs clarification. Specifically, suggest: 'Facility as described in the final safety analysis report (as updated) means (1)[sic] The FSAR description of the design, function or method of performing the function of any system, structure or component (SSC).	38.8(II.B.9,p8&9)
Limit applicability of 50.59 to design bases to FSAR-described design bases.	38.19(p11)
Clarify in the rule or NRC endorsed guidance that there is no need for 50.59 evaluations for 'second tier' programs such as procurement specs, evaluation methods and other sub-tier design info docs that are controlled by App B.	44.1(p1)
'As described in the final safety analysis report (as updated)' may narrow the scope of the regulation, in practice, because some licensees have interpreted current language to include licensing documents not specifically reference in the FSAR text.	56.2
<p><u>Summary:</u></p> <p>Commenters offered ideas on other ways to phrase the requirements, especially with respect to the language of "required to be included".</p>	
<p><u>Resolution:</u> The staff has accepted some of the comments concerning wording of the definition of facility. See also comments on "change" - other comments will be addressed in the statement of considerations for the final rule.</p>	

<p>B.3 FSAR (As Updated): 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).</p>	
Comment	Commenter & Item Number
<p>Replace “<i>as modified as a result of changes made pursuant to Section 50.59 and Section 50.90, and, as applicable, Section 50.71(e) and (f),</i>” with, “<i>as updated per the requirements of 10 CFR 50.71(e).</i>” This is consistent with NEI 98-03</p>	<p>18.2(p2) didn’t propose wording, just simplify 22.14(II.C.1,pp5) 39.5(pA3),proposed similar language</p>
<p>To simplify section (c)(2), expand definition of FSAR by including the phrase in criteria (c)(2)(i)-(vi), by adding the following, “<i>For purposes of implementing this section, the FSAR (as updated) is considered to include evaluations performed pursuant to this section and analyses performed pursuant to Section 50.90 after the last update of the final safety analysis report pursuant to Section 50.71 of this part.</i>”</p>	<p>18.2(p2)didn’t propose wording, just to simplify 22.15(II.C2-3,pp5-6)</p>
<p>Agree with NEI 22,15 comment, except delete phrase, “<i>evaluations pursuant to this section and</i>”</p>	<p>39.5(pA3&4)</p>
<p>Delete from §(c)(2)(i-iv), “<i>...or evaluations performed pursuant to this section and analyses performed pursuant to Section 50.90 after the last final safety analysis report was updated pursuant to Section 50.71 of this part.</i>”</p>	<p>39.5(pA3)</p>
<p><u>Summary:</u></p> <p>Commenters offered rephrasing of the definition to reduce complexity in the rule text.</p>	
<p><u>Resolution:</u> The staff recommendation is to revise the final rule along the lines proposed by NEI to simplify the criteria statements by including the language about other evaluations as part of the definition of FSAR (as updated).</p>	

<p>C.1 Procedures: 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.</p>	
Comment	Commenter & Item Number
<p>Delete “<i>conduct of operations.</i>”</p> <p>Basis: while required to be in FSAR, admin procedures are under Appendix B (&50.54), criteria in §(c)(2) don’t work, changes don’t meet proposed change (see comments 22.11-12) definition.</p>	<p>11.9 (2.4,p5-6), except asked for clarification 22.16(II.D,pp6-7) 27.14(p10) 52.4(pA2)</p>
<p>The proposed definition or procedures is welcome and will reduce utility burden by not requiring 50.59 reviews of support procedures.</p>	<p>1.14(II.C.1,p4)</p>
<p>Add criteria of, “The analytical methods of the evaluations required to be included in the FSAR (as updated) for such SSC and which demonstrate that their intended function(s) will be accomplished”.</p>	<p>3.6(3(b),p6&A-2)</p>
<p>Proposed new definition of ‘procedures as described’ is more definitive than the current rule and appropriately emphasizes operator actions and response times, which can affect critical factors in the safety analysis.</p>	<p>32.5(II.C,p3)</p>
<p>Share Chairman’s concern that definition of procedures is flawed (p56115). Suggest following definition: “Procedures as described in the final safety analysis report (as updated) means the FSAR description of the operation and control (including assumed operator actions and response times), of any system, structure, or component (SSC) and information on conduct of operations.</p>	<p>38.9(II.C.1,p9)</p>
<p>Discuss and clarify that ‘information on conduct of operations’ excludes procedures of an administrative nature.</p>	<p>48.3(pA1)</p>
<p>Terminology of “assumed operator actions” is too vague, should only include explicitly described (in the FSAR) operator actions as changes under 50.59</p>	<p>55.1(p1)</p>
<p><u>Summary:</u> Several commenters offered clarifications of the definitions. The major objection was to the phrase “conduct of operations”, which many thought was too broad and would encompass administrative procedures not suitable for 50.59 review.</p>	
<p><u>Resolution:</u> The staff recommends clarifications to the definition, including deletion of the words “conduct of operations”</p>	

C.2 Applicability Re. Procedures: The provisions in this section do not apply to changes in procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

Comment	Commenter & Item Number
Support the change	17-17, 22-8, 32-5, 39-46, 57-4
Expand the scope to include modifications to the plant as well as to procedures.	22-8
Clarify how 10 CFR 50.59 applies to TRM COLR, ODCM, PTLR, FPR and Safeguards Contingency Plan	57-4 1-44
<p><u>Summary:</u> There are 5 comments commenting on this item; they all agreed with the staff's proposed change. However, some commenters suggested the staff go further: (1) to expand the scope to include modifications to the plants, not only "procedures" and (2) to clarify how 10 CFR 50.59 applies to some special documents, such as Technical Requirements Manual, Core Operating Limits Report, Offsite Dose Calculation Manual, Pressure and Temperature Limits Report, Fire Protection Report and Safeguards Contingency Plan. As noted under topic N, the change process for topical reports was also raised by commenters.</p>	
<p><u>Resolution:</u> The staff plans to accept the wording revision proposed by NEI. Other comments will be addressed in the SOC or guidance as applicable.</p>	

D. Test and Experiments: 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).

Comment	Commenter & Item Number
Definition acceptable	1-15,32-6
Definition should be in guidance or use NEI 96-07 definition	17-18
Recommends the use of the term “activity” rather than “condition” to be consistent with the proposed rule language and to avoid confusion with discovered “conditions” covered by GL 91-18.	22-18
50.59 should define tests and experiments and address how their control as procedures should be controlled	38-10
Term “reactor or any of its SSCs” could be misleading. May want to reference 50.2 definition of design bases	39-7

Summary:

Of the 58 responses received, there were 15 responses that did not address this item, 35 responses that indicated agreement with the comment from NEI and 5 independent comments. The majority of the comments supported the proposed wording with minor clarifications. The suggestion to revise the section to address procedures that control tests and experiments should not be necessary as the proposed wording appears to be well understood.

The comment from NEI had no objection to the proposed wording except to recommend the use of the term “condition” rather than “activity” in the final rule so as to avoid confusion with discovered “conditions” which are by the guidance in Generic Letter 91-18, Revision 1. Two responses agreed with the proposed wording as written. One response recommended placing the definition in the guidance or using the definition from NEI 96-07. One response felt that because “tests and experiments” are controlled by procedures, Section II.D should be revised to address how the control of these activities as procedures is controlled.

See also comments under topic P about use of the term “design basis”.

Resolution: The staff proposes to retain the definition with some clarifications, such as referring to “activity” rather than “condition.”

E.1 Final Safety Analysis Report - Definition: 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).
(See B.3)

Comment	Commenter & Item Number
Should be made clear that TS and their Bases are part of the FSAR. In some cases, the TS, have detail not in the FSAR, such as applicable modes, that may be relevant to 50.59.	38.11(II.E.1,p9&10)
Define the FSAR such that it recognizes it is updated so that each time FSAR is stated, it is not necessary to add the term (as updated). Adds no value.	38.12(II.E.3,p11)
Propose following definition for FSAR in 50.59: <i>“The set of licensing basis documents used to support issuance of a plant operating license. These documents include, but are not limited to, the Facility Operating License, the NRC Safety Evaluation Report, the UFSAR, Selected Licensee Commitments, the Technical Specifications, and other licensing documents.”</i>	44.2(p1&2)
<u>Summary:</u> Only a few comments were received on this subitem, generally seeking clarification.	
<u>Resolution:</u> No changes to rule text planned. While staff agrees with last comment with respect to implementation, the definition is considered too broad to be included in the rule.	

E.2 Safety Analysis Report and Pending Changes: ...as previously evaluated in the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to section 50.90 after the last final safety analysis report was updated pursuant to section 50.71 of this part.

Comment	Commenter & Item Number
<p>A change could be made (50.59 or 50.90) that would significantly lower probability or consequences from that described in the FSAR. Normally, the FSAR would not be updated to reflect this. Literal compliance with proposed wording would make the new evaluation become the acceptance criteria for all future 50.59 evaluations. Could also require that all previous 50.59/50.90 evaluations be reviewed to ensure most conservative result is reflected in the FSAR.</p>	<p>1.21(II.G.2,p11) 4.1(1,p1)</p>
<p>It is appropriate for proposed rule to require evaluation to include changes already made for which the UFSAR update has not been submitted, to ensure the evaluation is based on most up to date information.</p>	<p>32.7(II.E, p3)</p>
<p>The phrase “and safety analyses pursuant to Secs 72.56 or 72.244” [corresponding part wording is “and safety analyses performed pursuant to Sec 50.90]” used in six of the license amendment criteria makes it appear that a licensee could prepare a license amendment pursuant to 70.56 or 72.244 [50.90] and use the associated safety analysis for subsequent changes permitted by 72.48 [50.59] before the amendment is approved.]</p>	<p>7.6 (would also apply to Part 50)</p>
<p><u>Summary:</u> Commenters had concerns on two aspects - whether the rule would require systematic review of all evaluations since the last update, and whether the rule language suggests that licensees update the FSAR or use as the baseline for evaluation amendment requests that are still pending.</p>	

Resolution: See also topic B.3. The staff still concludes that it is appropriate for licensees to consider changes made subsequent to the last update to ensure that evaluations reflect current configuration of the facility. The process that a licensee would follow to confirm this is not being prescribed. If the changes were such that the FSAR information (description, analysis) is still accurate, subsequent changes could be evaluated with respect to the FSAR(as updated) description - otherwise, there should be a planned FSAR update awaiting submittal that should be used as the basis for review.

With respect to the last issue, this can be addressed in guidance or the supplementary information. Staff believes that this is not generally misunderstood and notes that existing language in 50.71(e) that refers to evaluations in support of requested amendments could be similarly misinterpreted. However, staff also notes that other rule changes in 50.59, such as in (c)(1) make more explicit the need to obtain approval before implementation. Staff also plans to revise “requested” amendments to instead say “approved amendments” in 50.71(e)

F. Probability or Consequences No More Than Minimally Increased:
Result in more than a minimal increase in ... previously evaluated in either the final safety analysis report ...

Comment	Commenter & Item Number
Comments are discussed in sections G.1 and G.2	

G.1 Guidance on “More Than Minimal” - Probability	
Comment	Commenter & Item Number
<p>Unclear whether the guidance on a change in accident classification is intended as the definition of a more than minimal increase in probability of an accident or as an example of such an increase.</p> <p>NRC should provide guidance on whether a change in probability class for an event analyzed in the SAR constitutes merely an increase in probability or the change in probability class results in a new accident.</p> <p>NRC should recognize that changes within the frequency classification do not constitute an increase in probability. An increase in probability would be realized only if the event moved into a more frequent classification.</p>	22-20, 1-19, 17-19, 18-3, 38-16
<p>Does not agree with the proposed wording concerning the concept of minimal increase. “Minimal” is itself an arbitrary expression. The NRC uses an oversimplified depiction of safety analysis in trying to define “minimal increase”. However, safety limits involve many parameters.</p>	2-2 29-3
<p>Modify the discussion on probability of equipment malfunction in Section II.G of the NOPR to “<i>The probability of malfunction of equipment important to safety previously evaluated in the FSAR (as updated) is no more than minimally increased not increased</i> if design requirements are met.”</p>	22-21 39-13 43-2
<p>Agrees with the statement “the probability of malfunction... is no more than minimally increased if ‘design basis’ assumptions and requirements are still satisfied [i.e.],” but recommends deletion of the reference to “procurement requirements as a design basis assumption or equipment” because procurement requirements normally are in excess of the design bases requirements and procurement requirements do not establish the design basis; the design basis helps to determine the procurement requirements.</p>	18-5
<p>The evaluation of a change against the probability of malfunction criterion should be performed consistently. Modify it to “The Commission believes that the probability of malfunction is more than minimally increases if a new failure mode as likely as existing modes is introduced. The determination of whether the probability of malfunction is introduced is more than minimally increased should be made either at a the component level, or consistent with the failure modes and effects analyses in the FSAR, taking into account single failure assumptions, and the level of change being made.”</p>	22-21 20-3 22-22 18-4 31-3 11-5 38-17

<p>The guidance in the final rule should expressly reflect Commissioner McGaffigan’s comments, and expressly state that, although the current NEI guidance certainly satisfies the rule, the rule affords greater flexibility than that provided for by the current NEI guidance.</p> <p>Recommends that the NRC develop quantitative standards for “minimal increase” and define “minimal” in the context of probability.</p>	<p>27-3,27-4</p>
<p>Quantitative methods (e.g., PRA) could be used to better define when a change involves more than a “negligible” --- but less than a “minimal” --- increase in probability and thus may be implemented without obtaining a license amendment.</p> <p>NRC needs to provide additional guidance on using risk insights, if there is an increase in probability of undesired outcome.</p>	<p>22-23 32-9 1-18 38-15 27-4 39-13</p>
<p>Agrees with the proposed guidance which states that several provisions in NEI 96-07 satisfy the proposed standard on minimal. However, the NRC should clarify that NEI 96-07 does not represent the outer bounds of what is acceptable under the proposed rule because NEI 96-07 was developed to implement the current rule, which is more restrictive than the proposed rule.</p>	<p>11-4, 32-8</p>
<p>The above positions would not require the term “minimal increases in probability” to be defined. If the above approaches are not acceptable, the NRC should endorse the existing industry positions presented in NEI 96-07.</p>	<p>17-19</p>
<p>Agrees with NRC’s conclusion and the proposed language that “minimal increase” should not require prior NRC approval.</p> <p>NRC should provide clarifications to the proposed rule to clarify and better define what is meant by minimal.</p>	<p>27-2 36-2</p>
<p>In defining minimal increase in probability or consequences, the SOC should explicitly acknowledge that in the case of non-power reactors, these risks are already minimal so that the primary thrust of a 50.59 analysis in this instance is more in terms of consistency with SAR than quantitative assessment. This adds burden to both NRC and licensees.</p>	<p>19-2</p>
<p>The NRC concludes that licensee can treat changes in external hazard design requirements as potentially affecting equipment probability rather than as accident probability. - This should be reflected in guidance.</p>	<p>39-14</p>
<p>Agrees with the proposed rule change to allow a minimal increase in probability, and corresponds to NSAC-125 and NEI 96-07</p>	<p>1-17</p>

Summary:

Most comments agree with NEI comments and/or NEI 96-07. Specifically, these comments address:

- ▶ need a description/definition of “minimal increase”
- ▶ evaluations of changes against the probability of malfunction criterion should be performed at a level consistent with existing analyses in the FSAR
- ▶ clarify position if the resulting probability (even though increased) still satisfies the event frequency classification provided in FSAR, whether the change is considered to be more than a minimal increase

Resolution: The staff was not able to provide a definitive standard for “minimal” that is more than “negligible” as judged in a qualitative evaluation. Quantitative criteria that might use PRA would be best developed in a different context, such as RG 1.174, rather than for the existing criteria of changes in probability of FSAR accidents and malfunctions. The proposed guidance offered in the FR notice will be modified to respond to the comments, and will either be part of a RG or included in industry guidance.

G.2 Guidance on “More Than Minimal” - Consequences	
Comment	Commenter & Item Number
Clearly state that the term “consequences” refers to radiological dose.	22-24,20-4, 38-14, 39-15, 43-3, 44-4, 59-2
<p>Prefers the third option in NOPR because it is easier to implement and it is self limiting. With following comments:</p> <p>Acceptance guidelines - NOPR approach is too restrictive, illogical, and lacks regulatory standing. Recommends changes allowed by the lesser of the following:</p> <ul style="list-style-type: none"> • 10% of the margin to 10 CFR limits, or • the applicable acceptance guidelines (if any). 	22-24, 20-5, 33-1, 11-6, 13-3, 38-21, 43-3, 51-1, 52-6, 38-22, 1-22, 59-3, 39-17, 39-18
<p>NRC should endorse the existing guidance of NEI 96-07 which sets the limit as the value accepted by the NRC in the SER, which are generally tied to the acceptance limits in the NRC SRP.</p> <ul style="list-style-type: none"> • provide examples on why it is more preferable to determine increases in consequences based upon the SRP and/or SER acceptance limits instead of the values documented in the SAR • Tying “increase in consequences” to the values reported in the SAR rather than to the acceptance limits quoted in the SER will penalize those plants which maintain a greater level of detail in the SAR. 	1-20
To maintain the original NRC acceptance bases, plants should be categorized as Pre-SRP and Post-SRP plants. For Post-SRP plants, the SRP acceptance dose criteria per accident type, used as the basis for their original NRC acceptance, should be used as threshold values for determining a minimal increase in consequences. For Pre-SRP plants, the graduated percentage table in FR 56105 should be acceptable as long as the limits are based on full Part 100 guideline values.	3-3
Acceptance limits should be based on SER rather than those reported in SAR..	17-20 27-7
Agrees with the second Option which addresses the concern of cumulative affect.	17-22

NRC should address the case of plants that have lowered dose due to one changes and subsequently increased dose due to a later change. The concern is that the minimal increase definition might require review for the second change while it might not had the first change not been made.	1-21, 4-1,17-23
For the example given in the second paragraph under “Consequences of an accident or malfunction” in Section II.G (a bounding analysis that is still satisfied), the example has no increase in consequences because the new analysis result remains bounded by the previous analysis result.	17-24
Supports percentage guidance of 20% versus 10% as proposed by the draft guidance.	18-6, 27-6 39-19, 44-5
Does not agree with the NRC’s position on “controlling” inputs, assumptions, and methodologies associated with dose calculations, not described in the FSAR, as rigidly as those described in the FSAR. This goes beyond the scope and intent of 50.59 rule.	38-19
Commenters believe that changes to methodology related to consequence calculations that have been generically accepted by NRC (such as ICRP dose conversion factors or SRP assumptions concerning fission product scrubbing) can be used by licensees without approval.	1-36 (p.16),17-31
Consequences of “malfunctions” and consequences of “accidents” should be combined into one, (not discussed separately as existed in the proposed rule). Consequences are based on analyzed DBAs.	18-9, 38-20
The graduated approach seems to capture the spectrum of potential licensee scenarios while not impacting the basis for acceptability. This option provides the maximum flexibility by referencing to the limit.	32-9
Agrees with option 3, which allows for minimal changes up to a certain percentage of remaining margin. Guidance should expand upon the application to GDC 19 considerations, and whether it should be included in the scope.	39-16
Recommends that the new rule be applied appropriately to the radiological consequences of accident and not to the radiological consequences associated with normal operations or anticipated operational occurrences.	59-2

Summary:

Most comments agree with NEI's comments in that, a clear statement should be included that states the term "consequences" refers to radiological dose. In addition, most comments received endorse NEI's comments on Option 3 with the acceptance limits to which minimal is applied being regulatory values (Part 100, GDC 19) or not to exceed any applicable SRP guidelines. Also, comments supported proposal of 10% of the margin to Part 100 limits (with a few comments proposing 20%). Some commenters would prefer use of the limit alone, without a "minimal increase" standard.

Resolution: The staff proposal on consequences is presented in the Commission Supplementary information and guidance will address other issues raised by the comments

<p>H.1 Accident - Definition: 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.</p>	
Comment	Commenter & Item Number
No need to change the definition of "accident" that exists in guidance such as NEI 96-07	11-13
Accidents should be limited to the bounding "design basis accidents"	17-25
Definition of the term "accident" should be in the guidance for implementation of 50.59 and not in the final rule. The definition used by industry since 1989 is part of NSAC-125 and currently in NEI 96-07.	22-19,33-3
Commenter concurs with NEI and espouses the definition of accident used in Reg Guide 1.70.	25-1 25.4
Suggests definition of an accident to include DBAs, AOOs, and special events that are analyzed to demonstrate safety	39-21 39-22
Proposed wording vague, suggests using the definition in 50.49 and NEI 96-07	33-3
Definition of DBE reasonable, can be more specific by referring to accidents analyzed in the SAR, including AOOs and external events which result in accidents analyzed (also could treat external events as malfunctions).	1-24
Definition of accidents tied to SAR Chap. 15 events is very different from CDF used in PRA	1-25, 17-26
Delete "required to be analyzed or accounted for by the Commission" from the definition	44-8
Definition of event should be "a combination of postulated challenges and failure events against which plants are designed to ensure adequate and safe plant response"	44-8
The proposed wording is too convoluted to be applied consistently. Propose using "new failure mode with a different result to safety items, new limiting AOO, or sequence of events resulting in a rad release above current operating limit in App-I or section 20"	3-3

Adding phrase “design basis accident” to the three criteria referring to accidents is adequate. Adding a definition unnecessary	32-10
Add “credible” to definition of accident	44-7
<p><u>Summary:</u></p> <p>Of the 58 responses received, 11 responses did not address this item, 35 responses indicated agreement with the comment from NEI, and 11 responses gave independent comments.</p> <p>The response from NEI recommended that the term “accident” should not be defined in the rule but should be in the guidance for implementation of 50.59. NEI also stated that the definition of “accident “ used by industry since 1989 is part of NSAC-125 and is currently in NEI 96-07.</p> <p>Only two responses agreed with the definition as written. Almost all responses felt that the NRC definition tended to expand the scope of an “accident of a different type.” Several comments recommended criteria such as, “creates the possibility of a new limiting AOO (transient), or creates a new sequence of events that can result in a radiological release (via a normal pathway) above a current operating, Section 50 App. I or Section 20 limit.”</p>	
<p><u>Resolution:</u> Staff recommendation is to provide guidance, either in RG or industry guidance document on understanding of accident - no rule language changes (beyond “is created”) are recommended.</p>	

H.2 Design Basis Accident of a Different Type (in Criteria): 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 section 50.90 with respect to design basis accidents after the last final safety analysis report was updated pursuant to section 50.71 of this part.	
Comment	Commenter & Item Number
For an event to be classified as a design bases “accident” it must have radiological dose consequences and require plant design change as corrective action	3-1, 3-4
Endorses proposed use of DBA in the criteria for accident of a different type	11-14
Commenters concur with NEI in general but the phrase “accident of a different type” should be defined in the rule. Commenter emphasizes that the change needs to result in a new failure mode, new release path, or has a new sequence of events that results in significant cladding failure	3-4, 25-1 25-4
Agrees with the proposed wording and emphasizes that the accidents should be “credible”	27-11
Adding phrase “design basis accident” to the criteria referring to accidents is adequate. Adding a definition unnecessary	32-10
There should be a list of types and examples of accidents of a different type	38-24
For an accident to be of a different type it must result in a new or greater fission release path than originally considered or result in a new fission product barrier failure mode. Suggest using “would this be included if the FSAR was being written today.”	3-1
10. Concerned that a slightly different initiator that leads to the same DBA would be considered a new accident	36-4
Commenter believes revised language of “with a different result” should also be used here	38-25
Do not use “Design Basis Accident” as this is a severely limited definition for some older plants	39-20 39-23 44-6

Summary:

Of the 57 responses received, 12 responses did not address this item, 34 responses indicated agreement with the comment from NEI, 9 responses gave independent comments.

Only a few responses indicated that use of the term “design basis accident” was acceptable as written. The remaining independent responses indicated that the term “design basis accident” would not be understood consistently by licensees and that the term should be defined in the guidance. Most of these comments favored making it clear that the term “accident of a different type” referred to design basis types of accidents and gave criteria to be used to define this term. As an example, GE emphasized that “an accident of a different type means an accident that results in a new fission product release path, results in a new fission product barrier failure mode, or creates a new sequence of events that results in significant fuel cladding failures.”

Resolution: The staff recommendation is to include discussion in guidance but not to include the term “design basis” in the criterion on accident of a different type.

<p>I. Malfunction with a Different Result: Create a possibility for a malfunction of equipment important to safety with a different result than any previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to section 50.90 after the last final safety analysis report was updated pursuant to section 50.71 of this part.</p>	
Comment	Commenter & Item Number
Distinction between accident probability and failure rate of safety equipment is unnecessary and counterproductive	2-3
Malfunctions of equipment should be considered different if the new failure mode results in a different outcome than previously considered	3-2
NEI supports the change to "Create the possibility for"; use of the phrase "important to safety"; and change to "malfunctions with a different result."	22-46
Agrees with proposed wording	32-11,39-24
NRC definition of a malfunction is too broad, NEI-96-07 is narrower, A different malfunction exists only if result as described in FSAR is different regardless of cause e.g. air versus a motor operated valve	38-26
Adding the term "of equipment important to safety" is inappropriate & should not be pursued. Suggests "If a possibility for a malfunction of a different type with a different result, of FSAR-described equipment, than any evaluated previously in the FSAR is created."	38-27
This evaluation is part of the design change evaluation and should not be part of the evaluation for need of an amendment. If a design evaluation determines a change from FSAR is effected, <u>then</u> a 50.59 evaluation is required	38-26 38-27
<p>Summary: Commenters generally agreed with the proposed rule change. Some had concerns about interpretations on the level (that is, subcomponent, component or system) at which malfunctions need to be considered. As noted in comments on Part 72 (topic M), some commenters seek greater commonality in terms, equipment important to safety vs. SSC important to safety.</p>	
<p>Resolution: The staff recommends proceeding with the language as offered in the proposed rule - other issues can be addressed in the guidance. Staff will retain SSC ITS in Part 72 as this term is defined and modify 50.59 to conform. Consideration of changes to definitions of ITS is part of SECY-98-300.</p>	

J. Margin of Safety- Several Options were offered for comment; also, the notice invited commenters to offer other proposals for NRC consideration.	
Comment	Commenter & Item Number
1. Ten commenters specifically stated that they strongly oppose option 1 (control inputs to analyses) as being too restrictive, making inputs equivalent to TS requirements. (Others would seem to agree by virtue of endorsing NEI comments). One agreed that this was best approach if NRC allowed compensating changes such that the validity of TS LCO or SL is maintained.	1-27, 11-1, 17-28,18-7, 22-17, 27-8, 36-7, 38-28, 39-27, 46-2. (3-10)
2. Fifteen commenters favor option 2 (delete margin as criterion). Basis given is that other criteria (including the TS and rules) are sufficient. A few commenters said not acceptable to delete, as this might leave gaps which might lead NRC to redefine probability or consequence criteria, or that there may be non-accident events involving malfunctions of equipment "not important to safety" not covered (e.g., generator load rejection). One thought the NEI proposal would "collapse" to deletion of margin since the TS include all the parameters covered by the NEI proposal for particular plants	1-32, 7-7,9-2, 10-1,11-2,12-1,14-1,17-29,18-7, 31-2, 32-12, 33-4, 38-29, 48-10 (3-11, 25-2) 26*
3. Option 3(A) variations (Results of analyses, specific parameters) - many commenters had issues with the options as outlined in the notice, either that the parameters selected were not appropriate, or that there would be uncertainty about which parameters involve margins. Alternative proposals were offered.	1-28, 3-12, 17-30
One commenter stated there was a need to clarify which safety analyses are covered - e.g., for ventilation or support systems performance vs. ECCS or other systems	1-31
NEI proposed to replace the margin of safety criterion with a criterion that requires NRC review for a change that would: result in a design basis limit directly related to the integrity of fuel cladding, RCS pressure boundary, or containment boundary being exceeded or altered.	22-17,27-9
Commenters noted that some fission product barriers are covered by other requirements, e.g., PCT is covered by 50.46	3-12, 22-17, 25-5
The parameters affected should only be those directly related to Fission product barriers.	1-28, 7-30, 11-2, 22-17

This criterion should only apply where there are clearly defined “design basis limits”	1-30; 3-9, 22-17
One commenter stated that changes involving mitigation systems were covered by the other evaluation criteria and thus did not need to be part of a “margin” criterion	11-1
One commenter wanted clarification in the SoC that changes to equipment qualification (including accident profiles) are not reductions in margin if 50.49 still satisfied.	23-
4. Amount of Reduction allowed without review - notice offered range of options from no net change up to not exceeding limits	
Several comments stated that reductions in margin would only occur from the design basis limits (or other terms) without restriction to minimal reduction in the difference between the calculated value and the limit, as suggested in some of the options.	1-29, 3-13, 18-7,36-2
Some commenters preferred the terminology in 96-07 of reductions being measured from “licensed acceptance limits”, One commenter would clarify that these are the limits approved by NRC and would modify NEI words to read “a prescribed NRC acceptance or design code limit is exceeded or altered”. (These commenters also favored increases up to these limits without a “minimal” concept).	3-13, 25-2, 44-9 (NRC limit)
Minimal reductions in margin from the limits should be allowed - to extent of precision of analysis	11-24
One commenter believes that approval should only be required if the limits would be exceeded, but that a change in the amount of “margin” to the limit might be established as a reporting criterion, as is done in 50.46 for PCT.	1-2
5. Evaluation Methods	
a. Some commenters stated that methods should not be controlled by 50.59 because the limits are conservative. These commenters stated that they should be allowed to use methods approved by NRC through SRP or other process without need for 50.59 or NRC approval. Allow licensees’ design control QA to govern.	1-36, 17-31, 36-8, 38-22,39-37

<p>b. A few commenters stated that different methods should be reviewed/approved by NRC or meet applicable guidelines or standards; OR produce results that are consistent with licensing basis methods; OR changes to methods should be evaluated under 50.59 as a separate change.</p> <p>NEI states that input assumptions can be adjusted, but must be reviewed as separate changes</p>	<p>11-25, 22-17</p>
<p>6. Other Comments</p>	
<p>a. Two commenters proposed that there be alternate criteria for decommissioning reactors (fuel removed) - one states that fission product barriers not the issue, but would add environmental impact. Another suggested limiting the scope to systems related to spent fuel pool cooling or radiological waste.</p>	<p>36-6, 46-3</p>
<p>b. Part 72 parameters for “margin” should be those with potential to increase prob. or amount of offsite releases (containment of fuel: subitems-temperature, pressure)</p>	<p>17-36, 22-31</p>
<p>e. A few commenters said that as part of the final rule, the staff should state that basis for any TS is limited to bases section. In contrast, another commenter would modify the definition of SAR to include the TS and their bases, and then the “bases for any TS” are in the SAR, and the other criteria are enough.</p>	<p>1-43, 27-10</p>
<p>f. The discussion on margin could be used to provide guidance on NSHC “significant” reduction in margin</p>	<p>1-33</p>
<p><u>Summary:</u></p> <p>NEI proposed alternative of meeting design basis limits directly related to fission product barriers. Several commenters favored deletion of the concept instead. Many expressed second preferences, that is, they would support NEI’s approach if deletion was not accepted or the reverse. Some commenters thought that evaluation methods should not be controlled by 50.59, others agreed with NEI proposal that methods must be either reviewed and approved by NRC or otherwise meet applicable standards.</p>	
<p><u>Resolution:</u> The staff proposal is discussed in the Commission paper. Guidance will be developed to ensure consistent implementation.</p>	

K. Safety Evaluation	
Comment	Commenter & Item Number
Support removal of the term "safety evaluation" in favor of simply "evaluation"	1-37, 17-32, 22-5, 39-38
<p><u>Summary:</u> There are 4 commenters commenting on this item; they all agreed with the staff's proposed change.</p>	
<p><u>Resolution:</u> Retain in final rule - see also topic A.3 regarding changes to TS which refer to "safety evaluations"</p>	

L. Reporting and Record Keeping - Update requirements (effects of changes)	
Comment	Commenter & Item Number
There should be no change in the requirements for summarizing individual 50.59 evaluations associated with the rule change	1-38
Proposes no changes to 50.71(e) because changes are captured by the existing requirements of 50.71(e) and that using NEI 96-07 guidance, changes in probability of equipment malfunction or accident probability are not quantifiable, such that 50.59 evaluation criteria is met only if there is no discernible change in probability.	17-3, 20-6 22-26-a 22-26-b 52-9 32-8
Disagree with any change in 50.71(e) - including the net effect of increases in probability and consequences adds burden on licensees	18-8, 21-1, 35-2, 36-5, 39-47, 44-6, 48-1, 51-2, 4-2, 38-23, 38-31, 39-15
Disagree with additional requirements because: 12. The provision for increasing consequences by a minimal amount is self-limiting. 13. Any changes to these parameters (sufficiently important, they should be captured in FSAR) would require corresponding changes to the FSAR, which would be "reported" in required FSAR updates,	43-5 57-3 1-23 33-2
No discussion on how to implement on this additional reporting requirement. The industry should be given an opportunity to work with the NRC to address the implementation concerns.	48-1 51-2
Agrees with the proposed language for 50.59(d)(3) clarifying that records of changes in the facility must be retained throughout any license renewal term.	22-25 17-34
The proposed additional reporting requirements should be the subject of a careful cost benefit analysis by the staff. The staff proposes to require that effects of changes be reflected in the UFSAR including new analysis performed at the Commission's request. This requirement should be explicitly identified in subsequent Commission requests for analysis and factored into future 50.109 determinations.	57-3

Summary:

The majority of comments are against any additional reporting requirements and any change to 50.71(e), and endorse NEI 96-07 guidance. The basic arguments are:

- ▶ the provision for increasing consequences by a minimal amount is self-limiting; and that any changes to the parameters (important enough to be captured in FSAR) would require corresponding changes to the FSAR, which would be “reported” in required FSAR updates.
- ▶ any changes to 50.71(e) and additional reporting requirements could add burden on licensees.

Resolution: The staff accepts the comments about reporting of cumulative effects. Minor wording changes would still be proposed for 50.71(e) for consistent terminology - see also comments on Part 72 (topic M).

M. Part 72	
Comment	Commenter & Item Number
1. Misc. Sections (72.3, .9, .24, .56, .86, .212)	
a. 72.56 is not clear if it applies to site-specific licensees, general licensees, or both	17.II.M.12; 22.3.13
b. The requirements of 72.48 (e.g., records) should also be applied to general licensees performing 72.212 evaluations	22.3.7b
c. The NRC should create provisions for emergency and exigency processing of license amendments as allowed by 50.91(a)(5) and (6) in Part 72	22.3.15
2. 72.48 (Parallel to Items A and K above) - Structure	
a. Limit the scope of 72.48 reviews to important to safety SSCs vs all SSCs described in the SAR	7.2
b. 72.48 can be simplified by changing the definition of SAR and not referring to the "FSAR as updated"	7.8
c. Eliminate occupational exposure and environmental tests from (b)(2) to conform to 50.59. One commenter suggested that an environmental criterion may be appropriate for decommissioning reactors in 50.59, instead of other criteria such margin.	11.2.10c, 17.II.M.6; 22.3.5; 29.3b; 48.2.3, 36.6
d. The risk from casks is much less than from reactors; however, many of the proposed requirements are more restrictive than Part 50	17.II.M.1; 22.3.a

e. The environmental impact test should be retained for site-specific licensees	48.2.4a
f. Certificate holders cannot perform an environmental assessment test because they do not have an EIS to evaluate changes against	48.2.4b
g. General licensees should evaluate any environmental impacts against the reactor facility EIS under 50.59 not 72.48	48.2.4c
3. 72.48 (Parallel to Items B, C, D above) - Scope of Definitions	
a. The term FSAR is confusing given that no PSAR exists	7.1a
b. 72.48 process should evaluate changes made after the ISFSI license is issued but before the FSAR is submitted per 72.70	7.1b
c. switch the order of paras (a)(2) and (a)(3).	7.3
d. Discussions of interdependent changes should be eliminated from 72.48, even if NRC retains it in 50.59	7.5
e. Use “equipment important to safety” instead of SSCs (i.e. proposes to conform terminology with 50.59)	17.II.M.7; 22.3.6
f. The phrase “required to be included” should be deleted from 72.48(a)(3)(ii) and (iii) (see also topic B re 50.59)	29.1
g. Delete “an ISFSI or MRS” from the definition of FSAR for a GL because the FSAR only includes the cask.	48.2.1
h. Clarify the wording in paragraph (a)(2)(iii) on NRC prior approval. Sample language provided. (See also topic E.3)	48.2.2

4. 72.48 (Parallel to Item E above) - Criteria Reference as FSAR Plus Other Evaluations	
a. Eliminate para (a)(3)(iii) "evaluations"	7.10
5. 72.48 (parallel to Items F and G above) - More than Minimal Increase	
a. Require the linkage of changes with minimal increases	7.6
b. "more than minimal" is subjective. Provide regulatory guidance on this issue. (See also topic G.1)	29.2
c. The phrase "more than minimal" should be used instead of "significant" for occupational exposure and environmental impact tests	29.3a
6. 72.48 (parallel to Items H and I above) - Accident of a Different Type	
a. Add "significant" to para (b)(2)(v) and (b)(2)(vi) or "minimal increase in risk"	7.9
7. 72.48 (parallel to Item J above) - Margin of Safety	
a. Delete Margin of Safety	7.7, 11.2.11a; 48.2.5
b. Any parameters used in margin of safety should include only those with the potential to increase the probability or consequences of an offsite release (e.g., fuel and cladding temperature, cask temperature or internal pressure)	22.3.2a
c. Release/accident limits for Part 50 should also be used for Part 72	22.3.2b
8. 72.48 (Parallel to Item L above) - Records and Reports	

a. Reports should be submitted at the same frequency as 50.59 (24 months)	11.2.10b, 17.II.M.11; 22.3.12; 29.4
9. 72.70 SAR Updating Specific Licensees	
a. Clarify the format for SAR updates before the FSAR is issued.	7.1c
b. Requires more info than 50.71(e) does (i.e., proposes to conform to 50.71(e))	11.2.10d, 17.II.M.5, 17.II.M.9e; 22.3.4
c. the change from “ contain all the changes necessary ...” to “ describe the effects of all the changes necessary ...” is excessively burdensome and was not properly accounted for in the backfit and paperwork reduction analyses	17.II.M.2; 22.3.1
d. Use the 24 month update frequency of 50.71	17.II.M.9a; 22.3.9a
e. The requirement to update the SAR every 6 months before fuel is loaded is overly restrictive.	17.II.M.9b; 22.3.9b
f. FSAR submittal 90 days before loading may not allow time for inclusion of 72.48 changes found during pre-op testing.	17.II.M.9c; 22.3.9c
g. Does the preload SAR requirement apply to general licensees	17.II.M.9d; 22.3.9d
h. The 6 month cutoff date in 50.71(e) for updating the FSAR should be included in 72.70	11.2.10e, 17.II.M.10; 22.3.10
i. If no 72.48 changes occur in a year, a letter stating no changes were made to the FSAR is adequate - see 50.71(e)(2)	22.3.11; 32.II.M.1

j. Clarify that this section only applies to site-specific licensees	48.2.6
10. 72.216 SAR Updating - General Licensee	
a. Requires more info than 50.71(e) does (i.e., conform to 50.71(e))	11.2.10d, 17.II.M.5; 22.3.4; 48.2.7
b. The impact of this requirement has not been addressed in the paperwork reduction, backfit or reg analyzes	17.II.M.8a; 22.3.7a
c. An implementation schedule for this section should be provided	17.II.M.8b, 22.3.8
d. Use the 24 month update frequency of 50.71	17.II.M.9a
e. The 6 month cutoff date in 50.71(e) for updating the FSAR should be included	11.2.10e, 17.II.M.10
f. Guidance on timeliness of reviewing 72.48 changes sent by the GL to the certificate holder should be provided.	17.II.M.13a; 22.3.14
g. Site-specific licensees should also be informed of GL or CoC holder 72.48 changes	17.II.M.13b
h. If no 72.48 changes occur in a year, a letter stating no changes were made to the FSAR is adequate - see 50.71(e)(2)	22.3.11; 32.II.M.1
i. The provision on replacement pages should apply to generic FSAR changes only.	48.2.8
j. Instead of sending FSAR changes to the CoC holder send the summary of 72.48 changes. Also require this within 30 days, not the annually	48.2.9

k. Revise the wording on FSAR revision numbers, it is confusing	48.2.10
11. 72.244 through 72.248 - SAR and Amendments for Certificate Holders	
a. Requires more info than 50.71(e) does (i.e., proposes to conform to 50.71(e))	11.2.10d, 17.II.M.5; 22.3.4
b. Clarify that the updated FSAR need not be limited to the most current design	11.2.11b
c. Use the 24 month update frequency of 50.71	17.II.M.9a; 29.5
e. The 6 month cutoff date in 50.71(e) for updating the FSAR should be included	11.2.10e, 17.II.M.10
f. Guidance on timeliness of reviewing 72.48 changes sent by the certificate holder to the GLs should be provided.	17.II.M.13a; 22.3.14
g. Site-specific licensees should also be informed of GL or CoC holder 72.48 changes	17.II.M.13b
h. the change from “ contain all the changes necessary ...” to “ describe the effects of all the changes necessary ...” is excessively burdensome and was not properly accounted for in the backfit and paperwork reduction analyses	22.3.1
i. If no 72.48 changes occur in a year, a letter stating no changes were made to the FSAR is adequate - see 50.71(e)(2)	22.3.11; 32.II.M.1

<p>j. Instead of sending FSAR changes to the GL send the summary of 72.48 changes. Also require this within 30 days, not the annually</p>	<p>48.2.9</p>
<p><u>Summary:</u></p> <p>Comments relate to following areas:</p> <ul style="list-style-type: none"> -clarification of requirements relative to the three types of entities (site-specific licensees, general licensees and certificate holders - consistency of the proposed requirements between 50.59 and 72.48 (and other provisions such as for updating requirements) - consistency of existing requirements in 72.48 with comparable requirements in Part 50, and commenters views that Part 72 is more restrictive even though the risks are less. 	
<p>Resolution: Staff intends to provide any necessary clarifications in the rule language or supplementary information. In the Commission paper, the staff has made a recommendation on how to proceed with existing requirements and consistency issues. Staff notes that some of the requirements in Part 72 are more restrictive in certain respects (e.g. release limits) because other Part 50 requirements were not imposed (offsite emergency planning).</p>	

N. Other Request for Comment Issues	
Comment	Commenter & Item Number
1. Scope	
a. Include vendor topical reports (or develop parallel process).	1-12,17-13
b. NEI proposals on scope could allow reduction of some defense-in-depth requirements. Reliance solely on analytical bases is not robust or resilient approach.	1-16
c. Agree with NEI recommendation for follow-on rulemaking to determine appropriate, risk-informed scope.	5-2, 22-27,50-2
d. USAR is good choice for scope - any decision to increase or decrease scope should heavily weigh the practicality of implementing and enforcing any new screening criteria.	52-10
e. Could limit scope of required evaluations by designating which parts of the SAR are subject to 72.48 (or50.59) - would allow information to remain in SAR and not require evaluations of programmatic material	7-1
f. Commenter suggests that for decommissioning reactors, scope of rule could be limited to changes that affect SSC related to spent fuel pool cooling and radiological waste.	46-3
2. Backfit Issues	
a. NRC underestimates the impact rule change will have on NRC licensing reviews.	1-41
b. NRC underestimates the cost to utilities of additional submittals to NRC.	1-42

c. Even prospective application of the rule may require a more detailed backfitting analysis.	16-2
d. NRC has not adequately addressed backfit burdens for Part 72 licensees	17-30, 22-30
<p><u>Summary and approach to resolution:</u></p> <p>No summary is provided because of the range of topics.</p> <p>Comments will be considered in different ways - for example, scope issues will be examined in contemplated risk-informed changes to Part 50. Backfit issues will be considered during preparation of final regulatory analysis for final rule (staff notes that analysis for Part 72, although not ready at time of SECY-98-171, was included in the published documents for review).</p>	

O. Implementation Comments	
Comment	Commenter & Item Number
1. Guidance	
a. NRC and NEI should work together to provide examples that do and do not meet the evaluation criteria.	1-4, 17-5
b. Provide examples of changes for which it is appropriate or inappropriate to consider as integrated changes.	1-8
c. Provide examples of cases where activities normally viewed as maintenance would require 50.59 evaluation.	1-9
d. Provide detailed guidance on treatment of nominal values contained in SAR.	1-10,17-12
e. Provide clear and specific examples for “margin of safety” issue.	1-34
f. Commenter provides checklist for guidance document.	3-14
g. NRC should endorse industry guidance via RG prior to effective date of amended rule. Hold workshop to run test cases.	5-3, 22-45, 38-1, 52-11
h. Update NUREG-1606 with Section II of supplementary information or endorse NEI 96-07	7-4
i. Provide guidance that clarifies methods for implementation appropriate to non-power reactors.	19-1

j. NRC needs to either update or supersede (listed) guidance documents to the industry to ensure consistent guidance remains.	38-32
k. Revision of the rule not required, just issue RG, one commenter suggests that NRC just endorse NEI 96-07. Another commenter suggests revising rule to match NEI 96-07.	1-1, 2-1,17-1
l. Publish guidance concurrent with rule for format and content of license amendments when 50.59(c)(2) not met e.g., should proposed FSAR change be included, how should updating be conducted while pending)	39-10
2. Timing of implementation of rule	
a. NRC should define implementation period to allow utilities to revise their 50.59 processes (and changes to NEI 96-07)	1-3, 17-4, 57-2
b. Rule changes should expressly be limited to prospective application	16-1
c. Ensure that final rule is within bounds of proposed rule or provide opportunity for public comment on any portions of final rule that have substantially changed from proposed rule.	16-4, 32-1
3. Enforcement	
a. Staff should not issue NOVs for violations of existing rule language that will be changed under proposed rule	22-29, 39-48, 54-1
b. Only take enforcement during interim rulemaking period for deviations from NEI 96-07	17-3

<p>c. "Grandfather" policy should be applied to past evaluations done in good faith using industry guidance unless willful violation</p>	<p>22-47, 39-48</p>
<p><u>Summary:</u> Several comments were submitted that suitable guidance was needed to support the final rule, both as industry implementation guidance (endorsed by NRC), and inspection guidance.</p>	
<p><u>Resolution:</u> The staff agrees that guidance is needed and has provided a recommended implementation and enforcement strategy in the Commission paper.</p>	

P. Other Issues	
Comment	Commenter & Item Number
1. SIMPLER PROCESS: Create a more streamlined process than license amendments for changes that don't meet 50.59 evaluation criteria but which would not otherwise require NRC approval. License amendment process for changes not affecting TS or license is not necessary.	1-5, 22-28, 16-3, 27-1
2. RISK INFORMED REQUIREMENTS	
a. Proposes that a reasonable approach to risk-informed 50.59 would use CDF and LERF as well as risk insights for improving deterministic criteria.	1-40
b. Additional, longer-term rulemaking should address risk-informed changes	17-2, 55-2
c. Differences in acceptance criteria used for Chapter 15 analyses and PRA's should be understood and considered in determining acceptance criteria or defining "accident" in any risk-informed rule	17-26
d. Risk-informed approach to 50.59 should consider (1) some role for determining acceptability of changes based on CDF or LERF, (2) risk insights for improving the deterministic evaluation criteria that would have to remain a part of 50.59 to address non-severe accident impact.	17-31

e. Ensure that risk-informed 50.59 does not become added regulatory layer.	17-31,
f. Eliminate the requirement that licensees independently assess the impact of a change in the facility on the probability and consequences of a malfunction of equipment important to safety in those circumstances where a licensee has incorporated the possibility of equipment malfunction in a probabilistic assessment of the probability and consequences of the accidents that the malfunction would affect.	27-5
3. OTHER DEFINITIONS	
a. NRC should define terms “important to safety” and “design basis” particularly with respect to equipment for which probabilities and consequences of malfunctions have previously been evaluated in the FSAR. One commenter suggested substituting “safety-related” for important to safety.	3-5, 38-18, 52-7, 57-1
b. Define “design bases” in terms that are not subject to varying interpretations.	18-20, 55-1
4. CHANGES TO OTHER RULES	
a. Consider 50.59-like process for Part 71	5-4,22-32, 29-1
b. Modify 72.48 to allow changes in a dual-purpose cask without prior NRC approval under Part 71 and Part 72 (transportation and storage)	11-15, 32-14
c. Revise 76.68 concurrently with 50.59	6-1

d. Clarify acceptance limits of 10 CFR 51.52 re burnup assumptions for transport of spent fuel and clarify if this is subject to 50.59.	1-35
e. Incorporate all substantive provisions (e.g., definitions) in proposed revisions to 50.59 into ABWR design certification rule.	11-16,25-3

Summary and Resolution: No summary is provided because of the variety of comments. Several of the areas raised by these comments are considered as outside the scope of the proposed rule. Comments will be forwarded to staff responsible for the areas mentioned, and will be considered in future staff actions. See also recommendations in Commission paper.

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 or addition to, or removal from, the facility or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

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

(i) The structures, systems, and components (SSC) that are described in

the final safety analysis report (FSAR) (as updated),

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

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

(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 updated per the requirements of § 50.71(e) or § 50.71(f), as applicable.

(4) *Procedures as described in the final safety analysis report (as updated)* means those procedures that contain information described 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).

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

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

or

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

(b) Applicability. This section applies to each holder of a license authorizing operation of a production or utilization facility, including the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent

cessation of operations required under § 50.82(a)(1) or a reactor licensee whose license has been amended to allow possession but not operation of the facility.

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

- (i) A change to the technical specifications incorporated in the license is not required, and
- (ii) The change, test or experiment does not meet any of the criteria in paragraph (c)(2) of this section.

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

- (i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the final safety analysis report (as updated);
- (ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the final safety analysis report (as updated);
- (iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the final safety analysis report (as updated);
- (iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the final safety analysis report (as updated);
- (v) Create a possibility for an accident of a different type than any previously evaluated in the final safety analysis report (as updated);

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

(vii) Result in the design basis capability for any SSC directly related to maintaining the integrity of the physical barriers intended to contain radioactivity (including mitigation systems), or any system necessary to support the functions of these SSC, being exceeded or altered; or

(viii) Result in more than a minimal change in a method of analysis described in the final safety analysis report (as updated) that is used to establish design basis values.

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

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

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

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

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

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

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

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

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

(c) ★ ★ ★

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

with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program and a justification for subsequent operation to the Director, Office of Nuclear Reactor Regulation. Any changes to the facility as described in the final safety analysis report (as updated) which are attributable to the noncompliances and which require a license amendment pursuant to § 50.59(c)(2) and any changes to the technical specifications, shall also be identified.

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

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

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

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

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

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

§50.71 Maintenance of records, making of reports.

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(e) Each person licensed to operate a nuclear power reactor pursuant to the provisions of § 50.21 or § 50.22 of this part shall update periodically, as provided in paragraphs (e)(3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the operating license, to assure that the information included in the report contains the latest information developed. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submission of the original FSAR, or as appropriate the last update to the FSAR under this section. The submittal must include the effects¹ of: all changes made in the facility or procedures as described in the FSAR; all safety analyses and evaluations performed by the licensee either in support of approved license amendments, or in support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2) of this part; and all analyses of new safety issues performed by or on behalf of the licensee at Commission request. The updated information shall be appropriately located within the update to the FSAR.

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

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5. Section 50.90 is revised to read as follows: [same as proposed rule]

§ 50.90 Application for Amendment of license or construction permit.

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

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

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

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

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

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

VIII. Processes for Changes and Departures

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B. Tier 2 information

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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 frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the 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 a SSC important to safety previously evaluated in the plant-specific DCD;

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

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

(7) Result in the design basis capability for any SSC directly related to maintaining the integrity of the physical barriers

intended to contain radioactivity (including mitigation systems), or any system necessary to support the functions of these SSC, being exceeded or altered; or

(8) Result in more than a minimal change in a method of analysis described in the plant-specific DCD that is used to establish design basis values.

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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.

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X. Records and Reporting

A. Records.

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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

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B. Tier 2 information.

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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 frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the 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 a SSC important to safety previously evaluated in the plant-specific DCD;

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

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

(7) Result in the design basis capability for any SSC directly related to maintaining the integrity of the physical barriers intended to contain radioactivity (including mitigation systems), or any system necessary to support the functions of these SSC, being exceeded or altered; or

(8) Result in more than a minimal change in a method of analysis described in the plant-specific DCD that is used to establish design basis values.

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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.

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X. Records and Reporting

A. Records.

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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.

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

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

§ 72.9 Information collection requirements: OMB approval.

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

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

§ 72.24 Contents of application: Technical information.

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

13. Section 72.48 is revised to read as follows:

§ 72.48 Changes, Tests and Experiments.

(a) Definitions for the purposes of this section:

(1) Change means a modification or addition to, or removal from, the facility or spent fuel storage cask design or procedures

that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

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

- (i) The systems, structures, and components (SSC) that are described in the FSAR (as updated),
- (ii) The design and performance requirements for such SSCs described in the FSAR (as updated), and
- (iii) The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs which demonstrate that their intended function(s) will be accomplished.

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

(i) For site-specific licensees, the Safety Analysis Report for a facility submitted in accordance with § 72.24, as amended and supplemented, and as updated in accordance with § 72.70;

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

(iii) For certificate holders, the Safety Analysis Report for a spent fuel storage cask design submitted in accordance with § 72.230, as amended and supplemented, and as updated in accordance with § 72.248.

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

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

- (i) Outside the reference bounds of the design bases as described in the FSAR (as updated) or
- (ii) Inconsistent with the analyses or descriptions in the FSAR (as updated).

(6) *Facility* means either an ISFSI or an MRS.

(b) This section applies to:

(1) each holder of a license issued under this part, and

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

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

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

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

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

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

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

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

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

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

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

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

(vii) Result in the design basis capability for any SSC directly related to maintaining the integrity of the physical barriers intended to contain radioactivity (including mitigation systems), or any system necessary to support the functions of these SSC, being exceeded or altered; or

(viii) Result in more than a minimal change in a method of analysis described in the final safety analysis report (as updated) that is used to establish design basis values.

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

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

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

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

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

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

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

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

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

(6)(i) A general licensee shall provide a copy of the record for any changes to a spent fuel storage cask design to the applicable certificate holder within 30 days of implementing the change.

(ii) A specific licensee using a spent fuel storage cask design, approved pursuant to subpart L of this part, shall provide a copy of the record for any changes to a spent fuel storage cask design to the applicable certificate holder within 30 days of implementing the change.

(iii) A certificate holder shall provide a copy of the record for any changes to a spent fuel storage cask design to any general or specific licensee using the cask design within 30 days of implementing the change.

(iv) A licensee or certificate holder receiving a record of such changes shall review the record within 60 days for applicability to its facility or cask design, respectively.

14. Section 72.56 is revised to read as follows:

§72.56 Application for amendment of license.

Whenever a holder of a specific license desires to amend the license (including a change to the license conditions), an application for an amendment shall be filed with the Commission fully describing the changes desired and the reasons for such changes, and following as far as applicable the form prescribed for original applications.

15. Section 72.70 is revised to read as follows:

§ 72.70 Safety analysis report updating.

(a) Each licensee for an ISFSI or MRS shall update periodically, as provided in paragraphs (b) and (c) of this section, the final safety analysis report (FSAR) to assure that the information included in the report contains the latest information developed.

(1) The licensee shall submit an original FSAR to the Commission, in accordance with § 72.4, within 90 days after issuance of the license.

(2) The original FSAR shall be based on the safety analysis report submitted with the application and reflect any changes and applicant commitments developed during the license approval and/or hearing process.

(b) Each update shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submission of the original FSAR, or as appropriate the last update to the FSAR under this section. The update shall include the effects¹ of:

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

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

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

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

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

- (2) The update shall include a list of effective pages, indicating the current revision for each page;
 - (3) Each replacement page shall include both a change indicator for the area changed, e.g., a bold line vertically drawn in the margin adjacent to the portion actually changed, and a page change identification (date of change or change number or both);
 - (4) The update shall include (i) a certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittal, or that no such changes were made; and (ii) an identification of changes made under the provisions of § 72.48, but not previously submitted to the Commission;
 - (5) The update shall reflect all changes up to a maximum of 6 months prior to the date of filing; and
 - (6) Updates shall be filed every 24 months from the date of issuance of the license.
- (d) The updated FSAR shall be retained by the licensee until the Commission terminates the license.

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

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

§ 72.80 Other records and reports.

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

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

§ 72.86 Criminal penalties.

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

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

§ 72.212 Conditions of general license issued under § 72.210.

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(b) ★ ★ ★

(2)(i) Perform written evaluations, prior to use, that establish that (A) conditions set forth in the Certificate of Compliance have been met; (B) cask storage pads and areas have been designed to adequately support the static load of the stored casks; and (C) the requirements of § 72.104 have been met. A copy of this record shall be retained until spent fuel is no longer stored under the general license issued under § 72.210.

(ii) The licensee shall evaluate any changes to the written evaluations required by this subparagraph using the requirements of § 72.48(c). A copy of this record shall be retained until spent fuel is no longer stored under the general license issued under § 72.210.

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(4) Prior to use of this general license, determine whether activities related to storage of spent fuel under this general license involve a change in the facility Technical Specifications or require a license amendment for the facility pursuant to § 50.59(c)(2) of

this chapter. Results of this determination must be documented in the evaluation made in paragraph (b)(2) of this section.

19. In § 72.216, paragraph (d) is added to read as follows:

(Proposed rule is withdrawn)

20. 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.

21. 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.

22. Section 72.248 is added to read as follows:

§ 72.248 Safety analysis report updating.

(a) Each certificate holder for a spent fuel storage cask design shall update periodically, as provided in paragraph (b) of this section, the final safety analysis report (FSAR) to assure that the information included in the report contains the latest information developed.

(1) The certificate holder shall submit an original FSAR to the Commission, in accordance with § 72.4, within 90 days after the spent fuel storage cask design has been approved pursuant to § 72.238.

(2) The original FSAR shall be based on the safety analysis report submitted with the application and reflect any changes and applicant commitments developed during the cask design review process. The original FSAR shall be updated to reflect any changes to requirements contained in the issued Certificate of Compliance (CoC) and information contained in the NRC staff's safety evaluation report (SER) for the cask design. However, the entire CoC and SER need not be directly inserted into the FSAR.

(b) Each update shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the certificate holder or prepared by the certificate holder pursuant to Commission requirement since the submission of the original FSAR, or as appropriate the last update to the FSAR under this section. The update shall include the effects¹ of:

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

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

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

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

(2) The update shall include a list of effective pages, indicating the current revision for each page;

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

(4) The update shall include (i) a certification by a duly authorized officer of the certificate holder that either the information accurately presents changes made since the previous submittal, or that no such changes were made; and (ii) an identification of changes made under the provisions of § 72.48, but not previously submitted to the Commission;

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

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

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

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

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

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

ATTACHMENT 3: OTHER RULE LANGUAGE CHANGES AND ISSUES

OTHER RULE LANGUAGE CHANGES AND ISSUES

In addition to the topics discussed in the paper, the staff is providing this discussion of other aspects of the rule that have resulted in changes to the rule language, or that were requested by the Commission. In addition, the staff notes that the comment discussion in Attachment 1 to the paper contains more details on suggested rule language changes and other issues brought forth by the comment letters.

Definitions

A number of comments were received on the definitions, and as a result, certain clarifying changes were made as reflected in the attached draft rule language. One of the more significant changes to definitions was that for “change.” This definition is discussed in more detail below.

Change to the facility as described in the final safety analysis report (as updated)

In the proposed rule, NRC recommended that the word “change,” as written in the existing requirements, be understood to mean the modification of an existing provision (e.g., systems, structures, or components (SSCs); procedures; design requirements; analysis methods or parameters); additions (e.g., new SSCs or procedural steps); and removals from the facility (physical removals or retirement in place or non-reliance on a system to meet a requirement). Further, the supplementary information for the proposed rule stated that changes to evaluative methods, acceptance standards, or other information for an SSC described in the FSAR is also a change to the facility as described. Therefore, the proposed rule included definitions of “change” and of “facility as described in the safety analysis report (as updated),” as well as for procedures as described.

Several commenters stated that revisions were needed to the proposed definitions to allow greater use of screening of proposed changes, that is, for licensees to determine that certain proposed changes to the facility do not require evaluation against the regulatory criteria in § 50.59. Otherwise, the commenters were concerned that even such additions as identification tags or light bulbs might require evaluation under the rule. Thus, they proposed that the definition of “change” be modified by the addition of the highlighted phrase: “a change is a modification, addition or removal *that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.*” This approach would allow certain changes to be made without requiring the review and documentation process for a § 50.59 evaluation.

In practice, the industry uses a two-step process in reviewing changes to its facilities. Step one is a review of the proposed change to determine if it meets the “scope” criteria for review (contained in proposed rule § 50.59(c)(1)), otherwise known as a “screening review.” If the change falls within these definitions, an evaluation against the criteria in § 50.59(c)(2) would be performed. The staff recognizes that many of the changes being made at a facility are such that a licensee could readily determine that the change does not affect the facility, and would never involve any of the evaluation criteria, and, thus, could be screened out, provided the rule language accommodates such an approach. The suggested rule language would codify screening of changes in the regulations. Such clarifications to the definitions would significantly reduce the number of evaluations that need to be performed and therefore would reduce licensee burden. There is some potential for changes to be mistakenly screened out as not affecting functions and, thus, as not requiring an evaluation. Since the rule does not explicitly require documentation of screening, opportunities to correct such errors may be limited. In practice, records of screenings are typically prepared and maintained, as discussed in NEI 96-07. Accordingly, the staff views the potential for undetected errors to be small, and the rule change would provide much greater flexibility and reduce the licensee burden for preparing evaluations for changes that do not warrant such review. Staff also believes that staff burden to inspect and review § 50.59 evaluations would be reduced, thereby allowing staff to focus attention on more significant changes. This approach will require some revisions to existing guidance such as NEI 96-07

especially with respect to how to appropriate screen changes that may affect functions.

Staff recommends adopting the NEI proposal in this area to codify the use of a screening process. Staff plans to supplement existing staff guidance and NEI 96-07 guidance to provide greater assurance that screening activities will be appropriately conducted and documented.

Definition of accident, or design basis accident of a different type

The proposed rule included as a criterion for prior approval if a change, test, or experiment would “create the possibility for a design basis accident of a different type than any evaluated previously in the final safety analysis report (as updated) or in evaluations....” The FR notice suggested a definition of “accident” and requested comment as to whether a definition was needed and on the language offered in the notice. Most commenters stated that a definition of “accident” was not needed in the rule but could be discussed in guidance. A few commenters offered alternative definitions for “accident” or more specifically, “accident of a different type.” Several agreed with the premise that only “design basis” accidents were to be considered, distinguishing these from the spectrum of accidents typically considered in a PRA and from incredible accidents that might be created as a result of a change. Minor changes to NEI 96-07 may be useful to clarify understanding of accident of a different type.

Staff does not recommend adding a definition of “accident” or using the terminology of “design basis accident of a different type” in the rule. The staff concludes that a suitable definition for accident previously evaluated in the FSAR, that would be included in guidance, is the following:

Accident previously evaluated in the FSAR (as updated) means an accident described in the final safety analysis report (as

updated) including accidents such as those traditionally found in Chapter 15 of the final safety analysis report, and those accidents described in the final safety analysis report dealing with floods, fires, seismic events, other external hazards, water-solid over pressure, anticipated transient without scram, and station blackout.

**Consequences of an accident or malfunction of equipment important to safety previously evaluated in the FSAR (as updated) are more than minimally increased
(§§50.59 (c)(2)(iii) and (c)(2)(iv))**

In addition, the proposed rule included language that would permit a minimal increase in consequences. To assist in implementation, the supplementary information for the proposed rule included options for guidance to explain how “a minimal increase” should be applied. One of the options offered by staff was that minimal increases would correspond to a fraction (i.e., 10%) of the difference between the FSAR calculated value and the applicable acceptance guidelines (regulatory values or Standard Review Plan values as applicable).

During the comment period, NEI proposed that the staff’s guidance be modified such that there is no more than a minimal increase in (radiological) consequences if the increase is less than or equal to 10 percent of the difference between the FSAR calculated values and the guidelines established in the regulations (e.g., Part 100 or Part 50 General Design Criterion 19), but also if the increase did not exceed any other acceptance guidelines (if applicable). While NEI acknowledged staff’s concerns about changes being made without review that would approach the regulatory guidelines, it also believes that the guidelines in the SRP that establish acceptance criteria of “small fraction of Part 100 limits” for particular events already provide sufficient regulatory control such that licensees should not be restricted from increases up to these values. Some commenters thought 20% was a more reasonable fraction of the difference to specify as minimal. Still other commenters favored allowing increases up to regulatory limits

(without use of a term such as minimal increase), believing that the “consequences previously evaluated” includes the limits that were used as the basis for the licensing determination.

The staff agrees that establishing controls on the margin to the SRP guidelines is not necessary, and, thus, proposes to revise its guidance on interpretation of “minimal” increases to make this clarification. The staff’s proposal will require some revisions to NEI 96-07 to explain the use of differences to regulatory guidelines, and the role of other guidelines such as SRP values.

Thus, the staff would agree that there is no more than a minimal increase in consequences if the increase is less than or equal to 10% of the difference between the calculated value and the regulatory guidelines, or as long as the SRP guidelines are met, with the clarification that the SRP guidelines form a basis of minimal increase for all facilities, not just those that were specifically reviewed against its guidelines. This clarification will be discussed in the implementation guidance.

Reporting and Recordkeeping Requirements (§ 50.71(e))

For reporting, the NRC proposed to revise the reporting requirement in § 50.71(e) to require licensees to provide information to enable the staff to monitor potential cumulative impacts for “minimal” increases. Specifically, the proposed rule would interpret the phrase “effects of” to include, for purposes of the FSAR update report, the effects on probabilities and consequences.

This proposal elicited strong opposition. Many commenters stated that this proposal would significantly increase licensee burden, that it was not necessary since the rule would limit the amount of change to “minimal” increases that were insignificant with respect to the licensing basis, and, therefore, that the proposal should not be implemented. As noted by many of the commenters, assessments of probabilities are generally qualitative and would thus be difficult to report on with respect to cumulative effects.

Where analyses are revised to document the effects of changes (involving consequences, or “margins”), the existing language would require the FSAR to reflect the effects of these changes. Further, the way that “minimal” is defined prevents even multiple changes from exceeding limits. The staff recommends acceptance of these comments and proposes to drop the rule language that would require explicit documentation of cumulative effects as part of the update requirements.