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RULES AND DIRECTIVES
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February 21, 2017

Ms. Cindy K. Bladey
Chief, Rules, Announcements, and Directives Branch (RADB)
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: NEI Comments on draft regulatory guide (DG), DG-1334, *Guidance for Implementation of 10 CFR 50.59, "Changes, Tests, and Experiments," 81 Fed. Reg. 94275; Docket ID NRC-2016-0270*

Project Number: 689

Dear Ms. Bladey:

On behalf of the nuclear energy industry, the Nuclear Energy Institute (NEI)¹ appreciates the opportunity to provide comments on the subject DG-1334 proposed revision 1 of Regulatory Guide (RG) 1.187, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, and Experiments'" as requested in the subject Federal Register Notice.

NRC indicates that the purpose of DG-1334 is to clarify "potentially misleading statements in Section 4.3.8 of Nuclear Energy Institute (NEI) 96-07, Revision 1, "Guidelines for 10 CFR 50.59 Implementation", which was endorsed in RG 1.187, Rev 0" and to add "clarification to statements in Section 4.3.5 of NEI 96-07, Revision 1." We believe that the proposed draft clarifications are intended to be consistent with our understanding of NEI 96-07, Revision 1. As written, however, the proposed draft introduces new unclear statements into the guidance in this area. As noted in the attached comments, we recommend several changes to improve the clarity of the guidance.

The NRC's March 6, 2015 Review of Lessons Learned from the San Onofre Steam Generator Tube Degradation Event (ML15015A419) identified the intent to clarify certain potentially ambiguous statements in NEI 96-07, Revision 1. As the SONGS lessons learned report noted, this ambiguity "was not one of the

¹ The Nuclear Energy Institute (NEI) is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations and entities involved in the nuclear energy industry.

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Ms. Cindy Bladey
February 21, 2017
Page 2

causes of the identified shortcomings with the San Onofre evaluation." We also reiterate that the NRC's proposed clarifications are consistent with our understanding of NEI 96-07, Revision 1. In addition to referencing the lessons learned report, our comments reference the "Questions and Answers on 10 CFR 50.59 and NEI 96-07, Revision 1" document dated April, 2001 and included here as Attachment 2 for convenience.

We believe that incorporation of the comments provided in the attachment to this letter will improve the DG and will effectively achieve the NRC's stated objectives.

We appreciate the NRC staff's consideration of these comments. If you have any questions concerning this letter or the attached comments, please contact me.

Sincerely,



Katherine R. Austgen

Attachments

c: Mr. Brian K. Harris, NRC/NRR/DPR/PGCB
Mr. Mark P. Orr, NRC/RES/DE/RGGIB
Mr. David Beaulieu, NRC/NRR/DIRS/IRIB
NRC Document Control Desk

NEI Comments on DG-1334

Affected Section	Comment/Basis	Recommendation
1. A. Introduction, Purpose and Applicable Regulations (first bullet), Page 1, Paragraphs 1 & 3	Both of these paragraphs omit the "tests or experiments not described in the FSAR (as updated)" portion of the regulation.	<p>Revise the Purpose statement as follows:</p> <p>"...may make changes to their facilities and procedures as described in the <u>final safety analysis report (FSAR) (as updated), and conduct tests or experiments not described in the FSAR (as updated)</u>, without prior NRC approval, under certain conditions."</p> <p>Revise the first bullet under Applicable Regulations as follows:</p> <p>"...may make changes to their facilities and procedures as described in the <u>final safety analysis report (FSAR) (as updated)</u>¹, <u>and conduct tests or experiments not described in the FSAR (as updated)</u>, without prior NRC approval."</p>
2. B. Discussion, Background, Page 3	The first sentence should be revised to clearly reflect the language of 10 CFR 50.59(c)(1).	<p>Revise as follows:</p> <p>"Under 10 CFR 50.59, licenses are allowed to make changes in the facility; <u>and</u> procedures <u>as described in the FSAR (as updated), or and</u> conduct tests <u>or experiments</u> not described in the FSAR (as updated), without prior NRC approval <u>provided specific criteria are met</u>."</p>
3. B. Discussion, Background, Departure from a Method of Evaluation, Page 3, 3 rd paragraph	The final sentence quoting of Criterion (viii) is incomplete.	<p>Revise as follows:</p> <p>"Criterion (viii) states, "<i>Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.</i>"</p>

Affected Section	Comment/Basis	Recommendation
4. B. Discussion, Background, Departure from a Method of Evaluation, Pages 3 and 4	There are typos in the quote of the definition in 10 CFR 50.59(a)(2) on page 3 and in the paragraph following the Section 4.3.8 excerpt in the middle of page 4: "(as update)" should be "(as updated)."	Correct "(as update)" to "(as update d)" throughout.
5. B. Discussion, Background, Departure from a Method of Evaluation, Page 4, 1 st paragraph	<p>This paragraph is intended to instruct the 50.59 performer to compare the results of the analysis using the current method against the results of same method with the changed elements; however, this is not what it says. Instead, the paragraphs states, "... consists of comparison between: (1) the results of the analysis using the method of evaluation described in the FSAR (as updated), and (2) the results of the analysis using the current method described in the FSAR (as updated) that has been revised by the proposed change to any of the elements of the method."</p> <p>At first read, (1) and (2) appear to be the same statement phrased slightly different. The confusion may be caused by the term "that has been revised."</p>	<p>To provide a clearer distinction between the current UFSAR described methodology and the methodology that is proposed with the changed elements, revise (2) as follows:</p> <p>"(2) the results of the analysis using the current same method described in the FSAR (as updated) that has-been is being revised by the proposed change to any of the elements of the method."</p>
6. B. Discussion, Background, Departure from a Method of Evaluation, Page 4, 2 nd to last paragraph	<p>The paragraph beginning, "The above excerpt...", appears to mix the potential misinterpretation with the intended clarification and seems to confuse the issue further.</p> <p>Specifically, is the second to last sentence, "Licensees may document a methodology revision as a change from a method described in the FSAR (as update) to another method and would not require a license amendment if the licensee can demonstrate and document that the revised method has been previously accepted by NRC through issuance of an SER for the intended application," intended as 1) continued explanation of potential misinterpretation by licensees, 2) an allowance for 50.59 implementation, or</p>	<p>Consider separating the discussion of the potential misinterpretation and the intended clarification. Clarify this discussion by replacing "Licensees may..." with language from the lessons learned report. Specifically, the report states with respect to NEI 96-07:</p> <ul style="list-style-type: none"> • It [NEI 96-07] could be read to infer that "methodology revision" results could be compared to "the previous revision of the same methodology" instead of being compared to the revision currently specified in the FSAR which may be an earlier

Affected Section	Comment/Basis	Recommendation
	<p>3) a requirement for implementation of 50.59?</p> <p>Although this language in DG-1334 is confusing, NRC's March 6, 2015 Review of Lessons Learned from the San Onofre Steam Generator Tube Degradation Event (ML15015A419) provided a discussion that is clear. DG-1334 should use the clear discussion from the lessons learned report on this issue.</p>	<p>revision than the "previous revision"; and</p> <ul style="list-style-type: none"> It [NEI 96-07] could be read to infer that "methodology revision" results could be compared to "another methodology previously accepted by NRC through issuance of an SER" instead of being compared to the methodology currently specified in the FSAR.
<p>7. B. Discussion, Background, Accident of a Different Type, Page 5, 4th paragraph from the bottom and C. Staff Regulatory Guidance, 1. NEI 96-07, a. Section 4.3.5, Page 6, last paragraph</p>	<p>There is a typo in the modified paragraph and "of" should be added to the third sentence.</p>	<p>Revise the third sentence as follows:</p> <p><i>"The UFSAR evaluates a broad spectrum of transients and accidents, or initiating events. Initiating events are categorized according to expected frequency of occurrence and by type. The type of accident is defined by its effect on the plant. Categorization of initiating events by type provides a basis for comparison between events, which makes it possible to identify and evaluate in detail the limiting cases (i.e., the cases that can challenge the analysis acceptance criteria) and eliminate non-limiting cases from further consideration. Accidents that are non-limiting cases are not discussed in the UFSAR. For example, a postulated pipe break in a small line may not be specifically evaluated in the UFSAR because it has been determined to be less limiting than a pipe break in a larger line in the same area. Therefore, if a proposed design change would introduce a small high energy line break into this area, postulated breaks in the smaller line need not be considered in an accident of a different type."</i></p>
<p>8. B. Discussion, Background,</p>	<p>The draft guidance states "(i.e., a different accident analysis would be needed for this different type of</p>	<p>Further clarify the NRC's proposed modification of the last sentence in Section 4.3.5 as follows:</p>

Affected Section	Comment/Basis	Recommendation
<p>Accident of a Different Type, Page 5, 3rd paragraph from the bottom</p>	<p><i>accident).</i>"</p> <p>The meaning of "different accident analysis" is the major point of this clarification. It is intended to mean that an entirely new event has been "created" and thus an entirely new analysis must be developed.</p> <p>This possibility is remote and was not directly included in NEI 96-07, but it was considered during the development of the statement of consideration. From 64 FRN 53593:</p> <p style="padding-left: 40px;">Allowing changes that result in an accident of a different type (even if the result has previously been analyzed) appears inconsistent with the criterion in § 50.92.</p> <p>The context of the statement above is that the 1999 revision to 10 CFR 50.59 does not allow a licensee to avoid the license amendment process for changes that result in an accident of a different type. For purposes of the guidance, the NRC should clarify that:</p> <ul style="list-style-type: none"> • An accident of a different type does not have to have non-bounded results. <ul style="list-style-type: none"> ○ Since it is a "new event," being bounded by something that doesn't exist is not possible. <p>NEI 96-07, section 4.3.5 attempted to describe what an "accident of a different type" was not.</p> <p>This clarification more completely describes what characteristics such an accident sequence must have to be a "different type".</p>	<p><i>"Accidents of a different type are credible accidents that the proposed activity could create that have an effect on the plant that is different than any previously evaluated in the UFSAR (i.e., a different accident analysis, <u>not simply a revision of an existing analysis</u>, would be needed for this different type of accident)."</i></p> <p>An additional clarifying paragraph should be added as follows:</p> <p><i>"Accidents of a different type would generate a revised event categorization, which then would require a completely new accident analysis. If a tube rupture could be experienced in multiple steam generators, then it would be categorized as a separate event as described above. The existing accident analysis would not be adequate. This would be in contrast to higher flowrates from a single tube failure within a single steam generator. These would only involve revisions to the existing analyses governed by the other 10 CFR 50.59 criteria."</i></p>

Affected Section	Comment/Basis	Recommendation
9. B. Discussion, Background, Accident of a Different Type, Page 5, 2 nd paragraph from the bottom	<p>The major characteristic of classifying a newly created sequence as an "accident of a different type" is not the analyzed results.</p> <ul style="list-style-type: none"> An "accident of a different type" does not have to have non-bounded results. Simple logic demands that if an accident is of a "different type," then being bounded by a prior analysis is impossible. 	<p>Revise as follows:</p> <p>"This NRC clarification ensures the last sentence would not be inappropriately interpreted to mean that the accident types described in the current UFSAR accident analyses <u>properly could be used to evaluate the different effect on the plant of the newly created, but distinct and dissimilar, accident sequence but that the results of the analysis are not bounding.</u>"</p>
10. C. Staff Regulatory Guidance, 1. NEI 96-07, a. Section 4.3.5, Page 7	<p>Revise the italicized text following "The last sentence...should be read as:" to reflect the corresponding statement in the preceding section, B. Discussion, Background, Accident of a Different Type</p>	<p>Further clarify the NRC's proposed modification of the last sentence in Section 4.3.5 and align with the same earlier statement as follows:</p> <p><i>"Accidents of a different type are credible accidents that the proposed activity could create that have an effect on the plant that <u>current is different than any previously evaluated in the UFSAR accident analysis do not evaluate</u> (i.e., a different accident analysis, not simply a revision of an existing analysis, would be needed for this different type of accident)."</i></p>

Affected Section	Comment/Basis	Recommendation
<p>11. C. Staff Regulatory Guidance, 1. NEI 96-07, b. Section 4.3.8, a., Page 7</p>	<p>It appears this NRC staff clarification is intended to be consistent with the historic industry understanding of this portion of NEI 96-07, Revision 1, Section 4.3.8 guidance as discussed in the "Questions and Answers on 10 CFR 50.59 and NEI 96-07, Revision 1" document dated April, 2001 (enclosed); Q&A E.5.</p> <p>However, the same confusion noted in the corresponding statement in the preceding section B. Discussion, Background, Departure from a Method of Evaluation, exists. NRC's March 6, 2015 Review of Lessons Learned from the San Onofre Steam Generator Tube Degradation Event (ML15015A419) provided a discussion that is clear. DG-1334 should use the clear discussion from the lessons learned report on this issue.</p>	<p>Consider separating the discussion of the potential misinterpretation and the intended clarification. Clarify this discussion by replacing "Licensees may..." with language from the lessons learned report. Specifically, the report states with respect to NEI 96-07:</p> <ul style="list-style-type: none"> • It [NEI 96-07] could be read to infer that "methodology revision" results could be compared to "the previous revision of the same methodology" instead of being compared to the revision currently specified in the FSAR which may be an earlier revision than the "previous revision"; and • It [NEI 96-07] could be read to infer that "methodology revision" results could be compared to "another methodology previously accepted by NRC through issuance of an SER" instead of being compared to the methodology currently specified in the FSAR. <p>Alternately, remove discussion of the potential misinterpretation and focus on the clarification only in C.1.b.a.</p>

Affected Section	Comment/Basis	Recommendation
12. C. Staff Regulatory Guidance, 1. NEI 96-07, b. Section 4.3.8, b., Page 7	This NRC staff clarification contains conditional language, i.e., "could be...", and should be more direct. A direct statement that the "previous revision" must be the licensee's previously described method is consistent with the historic industry understanding of this portion of NEI 96-07, Revision 1, Section 4.3.8 guidance as discussed in the "Questions and Answers on 10 CFR 50.59 and NEI 96-07, Revision 1" document dated April, 2001 (enclosed); Q&A E.22.	For clarity, replace C.1.b.b as follows: "10 CFR 50.59(a)(2)(i) controls when a licensee implements a change to a "previous revision" of a methodology that was "described in the FSAR (as updated)" and no NRC SER exists for the revised methodology."
13. C. Staff Regulatory Guidance, 1. NEI 96-07, b. Section 4.3.8, c., Page 7	<p>This NRC staff clarification should be more direct to reflect the two possibilities for a "departure." As written, it appears inconsistent with the historic NRC/ industry understanding of 1) demonstration of the new method's applicability and 2) determination that the "new method" is specific to the "intended function*" as approved through an NRC SER.</p> <p>It is our understanding that Attachment 4 to NRC's Summary of November 2, 1999 Meeting with NEI on Revision to NEI 96-07 on Implementation of 10 CFR 50.59 – Methods of Evaluation (ML993260078) provides the NRC Staff historic view of the steps necessary to take in determining the new method's applicability and the determination of meeting the "intended application" criteria.</p> <p>The historic industry understanding of this portion of NEI 96-07, Revision 1, Section 4.3.8 guidance is provided in the "Questions and Answers on 10 CFR 50.59 and NEI 96-07, Revision 1" document dated April, 2001 (enclosed); Q&A E.16.</p> <p>*DG-1334 C.1.b.c states "intended function" and we believe this was meant to be "intended application."</p>	For clarity, replace C.1.b.c as follows: "10 CFR 50.59(a)(2)(ii) controls when a licensee replaces the methodology as currently specified in the FSAR (as updated) with another methodology not used at the licensee's plant. The basis for determining that there is no departure under 10 CFR 50.59 shall ensure that the demonstration of applicability of the new methodology becomes part of the licensing basis for the licensee's facility and is specific to the intended application as approved through an NRC SER."

ATTACHMENT 1

Affected Section	Comment/Basis	Recommendation
14. C. Staff Regulatory Guidance, 5. Applicability to 10 CFR 72.48 Evaluations, Page 8	NEI 96-07, Appendix B is the current NRC approved implementation guidance for 10 CFR 72.48. This approval is documented in RG 3.72. Efforts are underway to supersede NEI 96-07, Appendix B with NEI 12-04 and we expect to see a corresponding revision to RG 3.72.	Specific 10 CFR 72.48 implementation guidance endorsement through NRC Regulatory Guide 3.72 should be referred to in this section in addition to the general applicability of NEI 96-07, Revision 1.

**Questions and Answers on 10 CFR 50.59 and NEI 96-07, Revision 1
Update 4—April 2001**

These Q&A supplement the guidance provided in NEI 96-07, R1. They have been informally reviewed and found appropriate by cognizant NRC staff. The Q&A will be maintained on *Infospace*, the NEI member website, and may be revised or supplemented as a result of implementation experience. Revision bars indicate changes and additions to the previous set of Q&A (posted in January 2000).

The following questions and answers are organized by topic as follows:

Questions	Topic Area	Pages
A.1-16	10 CFR 50.59 Applicability	1-6
M.1-11	Maintenance Rule vs. 10 CFR 50.59	6-8
S.1-15	Screening	9-14
E.1-23	Evaluation	15-21
T.1-5	Transition Issues	22-23
G.1-13	General/Miscellaneous	24-30

- A.1. For the purpose of defining the scope of 10 CFR 50.59, my plant considers the UFSAR to include the COLR, Fire hazards report, calculation manuals (e.g., the ODCM), TRM, Technical Specifications Bases, and other licensing basis documents. Going forward, can we adopt a view of the UFSAR scope that is consistent with 10 CFR 50.59 and NEI 96-07, R1?

A. Yes. Technical specifications, technical specifications bases, NRC safety evaluations, and other licensing documents do not fall within the definition of UFSAR for purposes of 10 CFR 50.59, unless explicitly incorporated by reference in the UFSAR. A narrower UFSAR scope consistent with the revised rule and guidance should result in fewer 10 CFR 50.59 screenings and evaluations than if a broader view of the UFSAR is maintained. If you decide to redefine the UFSAR scope (and thus the plant-specific scope of 10 CFR 50.59) going forward, you must, of course, continue to meet technical specification administrative requirements and be mindful of commitments made to NRC.

Improved Technical Specifications licensees are required to control Technical Specifications Bases per 10 CFR 50.59, while others have commitments to NRC to do so. Licensees may maintain such commitments in addition to the required scope of 10 CFR 50.59.

- A.2. Does 10 CFR 50.59 apply to revision of a fuel vendor topical report that is "incorporated by reference" in the UFSAR? Or is 10 CFR 50.59 applied only when a licensee performs an updated analysis using the revised topical?

A. 10 CFR 50.59 would need to be applied to a revision of a fuel vendor topical

report only when a licensee uses an updated analysis based on the revised topical.

- A.3. Are 10 CFR 50.59 reviews required when removing excess detail or obsolete information from the UFSAR?

A. No. Removal of excess detail and redundant or obsolete information per the guidance of NEI 98-03, Appendix A, are considered modifications to the UFSAR, not changes to the facility or procedures. Therefore, per Section 4.1.3 of NEI 96-07, R1, 10 CFR 50.59 need not be applied to such UFSAR modifications.

- A.4. When must 10 CFR 50.59 be applied to a proposed change in a licensee commitment to the NRC? During screening, how would the 10 CFR 50.59 definition of "change" be applied to changes to NRC commitments, which are typically of a programmatic nature (e.g., chemistry, rad con, erosion/corrosion, etc.) and thus not be expected to affect design functions, etc.?

A. Per NEI 99-04, *Guideline for Managing NRC Commitment Changes*, 10 CFR 50.59 should be applied to changes in commitments that are embodied in UFSAR descriptions of the facility or procedures. Screening of commitment changes should be performed in accordance with Section 4.2 of NEI 96-07, R1. If the commitment change screens out from evaluation under 10 CFR 50.59, the commitment change should continue to be processed in accordance with Steps 3, 4, and 5 of the NEI 99-04 commitment change process. If the commitment change screens in, the change is controlled in accordance with 10 CFR 50.59, and prior NRC approval is required if any of the eight 10 CFR 50.59 evaluation criteria are met.

- A.5. Are detailed design calculations (not contained in the UFSAR), sensitivity studies and preliminary analyses of alternative methods of evaluation for a change subject to the "methods of evaluation" criterion of 10 CFR 50.59?

A. No. Analyses that are not part of the UFSAR and analyses of a preliminary nature are not considered "methods of evaluation" within the scope of 10 CFR 50.59(c)(2)(viii).

- A.6. Must editorial changes to UFSAR-described procedures (otherwise subject to 50.59) be subject to 50.59 (screening/evaluation)?

A. No. Per Section 4.1.3 of NEI 96-07, R1, editorial changes to the UFSAR (including referenced procedures, topical reports, etc.) may be made without applying 10 CFR 50.59.

- A.7. What constitutes a minor correction to a drawing?

A. Examples of minor corrections to a drawing include a correction to resolve an inconsistency with other UFSAR information (text, table or other drawing) or a

correction to information on the drawing that is incidental—not material—to the UFSAR description related to the drawing.

- A.8. What if I correct information in the UFSAR to resolve an inconsistency with other UFSAR information and determine that I provided the incorrect information to the NRC in support of a past licensing action or in response to a request for information?

A. You should identify the mistake and the correct information to your NRC project manager as quickly as possible and take appropriate corrective action.

- A.9. What is the status of a 10 CFR 50.59 evaluation for a proposed change that is determined to require prior NRC approval via license amendment?

A. For changes implemented via license amendment (or other more specific regulatory process), 10 CFR 50.59 requirements for evaluation, record keeping and reporting do not apply. Typically, the information contained in 10 CFR 50.59 evaluations for changes that require prior NRC approval is used as input to a license amendment request. The 10 CFR 50.59 evaluation itself (if any) may be retained by the licensee or discarded, because the LAR and SER essentially supersede the 10 CFR 50.59 evaluation as the documented basis for the change. Changes implemented via license amendment should not be included in periodic 10 CFR 50.59 summary reports to the NRC under 10 CFR 50.59(d).

- A.10. Moved to E.20

- A.11. (Restored) NEI 96-07, Revision 1, Section 4.1.4, identifies types of procedures that do not affect control or performance of design functions and would not be subject to control under 10 CFR 50.59. What criteria are to be used to evaluate and implement changes to such procedures if 10 CFR 50.59 (and Appendix B) do not apply?

A. Administrative and managerial procedures such as those identified in Section 4.1.4 should be controlled in accordance with licensee procedures, e.g., Quality Assurance Program. 10 CFR 50.59 should be applied to changes to plant procedures that affect performance or control of design functions. (See also Section 4.1.4).

- A.12. If a change to the emergency preparedness or safeguards program implemented under 10 CFR 50.54 results in the need to update the UFSAR, is a 10 CFR 50.59 review of the change required because the UFSAR is affected?

A. No. While safeguards or EP program changes may indeed affect summary description of these programs in the UFSAR, no 10 CFR 50.59 review is required provided the changes do not impact other aspects of the facility or procedures. Of course, the UFSAR must be updated to reflect such changes in accordance

with 10 CFR 50.71(e). If impacts are identified other than those related to security or EP, the change should also be reviewed under 10 CFR 50.59. For example, if erection of a new security barrier would affect the ability of operators to take required action, the new barrier should be reviewed under 10 CFR 50.59 as well as 10 CFR 50.54(p).

- A.13. How would a change to a BWR operating limit for MCPR (minimum critical power ratio) be treated under the new 10 CFR 50.59 rule? Is the OLMCPR a design basis limit for the fuel cladding?

A. The MCPR operating limit is typically identified in the Core Operating Limits Report (COLR) which is controlled in accordance with the administrative technical specification. Because a more specific change control process applies, 10 CFR 50.59 c(4) provides that 10 CFR 50.59 need not be applied in addition to administrative technical specification requirements.

As identified in NEI 96-07, R1, Section 4.3.7, MCPR is the associated design basis limit for BWR fuel cladding, not the OLMCPR. The OLMCPR is established such that the MCPR Safety Limit is not exceeded.

- A.14. The revised 10 CFR 50.59 allows, indeed requires, use of more specific change control requirements when they exist and apply to a proposed activity. Specifically, paragraph 10 CFR 50.59(c)(4) states, "The provisions in this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes." Sections 1 and 4.1 of NEI 96-07, Revision 1, provide additional information about this allowance.

How should activities be handled that fall within the scope of a program for which a separate change process exists, but do not rise to the level of changing the program described in the UFSAR? For example, a proposed change relates to equipment or procedures used to meet Emergency Plan requirements as established by 10 CFR 50.47 and Appendix E, but the change does not require update of the E-Plan incorporated by reference in the UFSAR. Is such a change considered subject to the more specific criteria of 10 CFR 50.54(q), even though the change does not require the E-Plan (UFSAR) to be updated? Or, must 10 CFR 50.59 be applied because 10 CFR 50.54(q) is not applicable?

A. 10 CFR 50.54(q) would govern. 10 CFR 50.59 would be applied only if the change involves E-Plan procedures or equipment that also perform, support or impact design functions as defined in NEI 96-07, Revision 1. The new c(4) provision in 10 CFR 50.59 recognizes that other regulatory requirements provide a framework of processes for evaluating certain changes, either by establishing specific change control criteria or by defining the requirements that a specific scope of SSCs/procedures must meet. NEI 96-07, Revision 1, states, "Together with 10 CFR 50.59, these processes form a framework of complementary

regulatory controls over the licensing basis. To optimize the effectiveness of these controls and minimize duplication and undue burden, it is important to understand the scope of each process within the regulatory framework.”

When an activity can be classified solely within an area where there exists specific change control criteria, the change should be evaluated to determine if it affects the information in the relevant plan or program document incorporated in the UFSAR. If so, the appropriate criteria should be applied to determine if prior NRC approval is required, and the E-Plan/UFSAR should be updated accordingly. If not, the activity may be implemented in accordance with the licensee Appendix B processes provided underlying regulatory requirements (e.g., 10 CFR 50.47 and Appendix E for EP) continue to be met. In addition to EP, other discrete areas where there exist more specific change control criteria include security [10 CFR 50.54(p)], quality assurance [10 CFR 50.54(a)] and fire protection [FP license condition]. EP, Security and FP changes that do not require update of associated program documents and the UFSAR do not, by default, fall within the scope of 10 CFR 50.59. Licensees may, of course, apply the 10 CFR 50.59 process in addition to the more specific change control requirements.

In addition, as identified in Section 4.1.1 of NEI 96-07, Revision 1, 10 CFR Part 20 meets the intent of 10 CFR 50.59(c)(4) in the sense that Part 20 establishes the specific regulatory requirements that govern activities affecting normal operating doses and effluents. Thus Part 20 establishes the “more specific criteria” that the “as-changed” program must meet. Provided no aspects of the proposed Part 20 activity fall within the scope of 10 CFR 50.59 (i.e., affect design functions), then 10 CFR 50.59 is not applicable.

Note: Via a process linked to the framework of change processes, it is important to ensure that the UFSAR is updated as appropriate in accordance with 10 CFR 50.71(e) to reflect changes made via any of the change processes.

- A.15 If a method of evaluation is not described in the UFSAR as being used in the safety analysis, but is used to calculate new operating limits included in the Core Operating Limits Report to ensure the safety analysis remains valid for an operating cycle, does this method have to be treated as if it were used in the safety analysis?

A. Section 3.10 of NEI 96-07, Rev. 1, defines three categories of UFSAR methods within the 10 CFR 50.59 meaning of “facility.” One of those is methods “used in analyses that demonstrate that design bases limits for fission product barriers are met.” Therefore, in general, methods described in the UFSAR that are used to determine design bases limits for a fission product barrier (e.g., “Criterion 7” parameters), would be subject to 10 CFR 50.59. However, for the case identified in the question, the change is controlled by more specific NRC requirements (the COLR technical specification). Therefore, per 10 CFR 50.59(c)(4), 10 CFR 50.59

doesn't apply to the review.

- A.16 Do changes to methodologies used to perform LOCA analyses, the results of which may be reported in the COLR, have to be considered in the new 50.59 process, or are these treated as only part of the 50.46 process, in which case 50.59 would not even be applicable?

A. 10 CFR 50.46 would apply. See answer to previous question.

Maintenance Rule vs. 10 CFR 50.59

- M.1. Consider a planned maintenance activity that involves placing the plant in a configuration other than that described in the UFSAR. The altered plant condition is expected to be in effect for less than 90 days at power, but a situation develops that will require the altered configuration to be in place longer than 90 days. Should 10 CFR 50.59 be applied to the altered plant configuration?

A. Temporary alterations to the facility or procedures to support maintenance that exist for more than 90 days at power should be treated as changes, and 10 CFR 50.59 applied accordingly. Upon determining that an unforeseen delay will cause the temporary alteration to be in place longer than 90 days at power, timely 10 CFR 50.59 screening, and if required, evaluation should be performed. If the temporary alteration meets one or more of the 10 CFR 50.59 evaluation criteria, the licensee should promptly communicate the situation to cognizant NRC staff and submit a license amendment request, on an expedited basis if necessary, for NRC approval to leave the temporary alteration in effect past 90 days. Pending approval of the LAR, the licensee need not remove the temporary alteration.

When a maintenance configuration is to remain in effect longer than planned, the risk assessment performed in accordance with paragraph a(4) of the Maintenance Rule should be revisited to confirm it is still valid.

- M.2. Deleted. Control of maintenance procedures addressed in guidance (Section 4.1.2).

- M.3. When does the 90-day clock start for maintenance-related temporary alterations?

A. The 90-day clock pertains to temporary alterations that are put in effect during power operations to support a maintenance activity. The clock starts when the temporary alteration is implemented, e.g., when a barrier is removed. This may occur prior to the actual start of the maintenance activity. The clock stops when the temporary alteration is removed and the affected portion of the facility and/or procedures is restored to its as-designed condition.

M.4. When the same altered plant configuration is necessary to support separate maintenance work orders, how do you calculate the 90-day at power limit for triggering review under 10 CFR 50.59?

A. If the same temporary alteration is necessary to support successive maintenance work orders, the 90 day clock begins when the plant alteration is put in effect (see previous question) and runs continuously until the plant is restored to its as-designed condition. If a temporary alteration to facilitate one or more MWOs is expected to be in effect longer than 90 days, the altered plant configuration should be treated as a change, and 10 CFR 50.59 should be applied accordingly. If the first MWO completes in 60 days and the temporary alteration is not restored before starting work on a second MWO, the 90-day clock does not reset. 10 CFR 50.59 should be applied if the temporary alteration is to be continuously in effect for more than 90 days at power, without regard for the number of MWOs involved.

M.5. If a maintenance activity is to last for more than 90 days at power but does not involve a temporary facility or procedure alteration, is 10 CFR 50.59 review required?

No. 10 CFR 50.59 is to be applied to facility or procedure alterations lasting more than 90 days at power that are implemented in support of a specific maintenance activity. If there are no such alterations, then no 10 CFR 50.59 review is required in connection with the maintenance activity, regardless of how long it takes.

M.6. Since, by definition, a design change is not maintenance, must 10 CFR 50.59 be applied to temporary changes to support implementation of a design change?

A. No. As discussed in Section 4.1.2, the design change itself must be reviewed under 10 CFR 50.59, but the actual implementation of the change, including any required temporary alterations, is effectively a maintenance activity that is assessed and managed under Section a(4) of the maintenance rule. As with a temporary alteration to support maintenance, 10 CFR 50.59 should be applied to a temporary alteration that supports a design change if it is to be in effect more than 90 days.

M.7. Why was "90 days at power" selected as the threshold for when a plant alteration in support of maintenance should be reviewed under 10 CFR 50.59 (in addition to the MR a(4) assessment)?

A. Ninety days was chosen because the vast majority of maintenance activities are completed in less time, thus requiring 10 CFR 50.59 reviews to be performed for a small percentage of cases. Ninety days was also viewed as the point at which a plant alteration to support maintenance begins to seem more like a change in terms of its effect on the facility design and ability to respond to events.

The focus on time “at power” (typically defined as Modes 1 & 2) reflects the NRC concern that long-term temporary alterations to support maintenance activities can raise questions about the validity of the safety analyses, which largely address at-power events.

M.8. What if I plan to attach a strip recorder to troubleshoot a recurring transient for as long as it takes to collect the information need to correct the problem? Do I need to track the time that the recorder is connected to determine when a 10 CFR 50.59 review is required?

A. If a testing or monitoring device is to be connected to plant systems for an indeterminate amount of time (i.e., there is no schedule established for removing the maintenance-related temporary alteration), the licensee should apply 50.59. 10 CFR 50.59 need not be applied to temporary alterations expected to be in effect 90 days or less at power. If, in the situation cited, the offending transient has occurred irregularly over a period of weeks/months, it is reasonable to expect that the recorder would need to be connected to the plant for more than 90 days, and 10 CFR 50.59 should be applied.

M.9. Is a surveillance test required by technical specifications considered a maintenance activity that is assessed and managed under 10 CFR 50.65(a)(4) and not 10 CFR 50.59?

A. Yes. However, it must be emphasized that compliance with technical specifications must be maintained regardless of whether an activity is reviewed under 10 CFR 50.59 or 10 CFR 50.65(a)(4).

M.10. While not a requirement of MRa(4), can I apply a “MRa(4)-like” risk assessment process to control changes to my maintenance/surveillance procedures?

Yes. And this practice may expedite / simplify the a(4) assessment required for each application of the maintenance procedure.

M.11. Are refueling activities, and changes to related procedures, considered maintenance activities subject to 10 CFR 50.65(a)(4), or are they “procedures described in the UFSAR” subject to 10 CFR 50.59?

A. Fuel handling “refueling” activities (i.e., fuel assembly shuffles performed in both the vessel and the spent fuel pool, fuel movement to/from the vessel to the spent fuel pool), and changes to the procedures for controlling those activities, are part of plant operations that are described in the UFSAR. Moreover, fuel handling accident scenarios are addressed in the safety analyses. As such, 10 CFR 50.59 applies to changes to these activities and procedures. In contrast to actual fuel handling, activities performed in preparation for moving fuel (reactor disassembly activities such as CEA/ICI removals, etc.) are maintenance

activities covered by 10 CFR 50.65(a)(4). 10 CFR 50.59 does not apply to such maintenance activities

10 CFR 50.59 Screening

S.1. In the definition of change, what does “affect” mean? Does “affect” mean effect on SSC design functions, or does it mean effect on the UFSAR description of design functions?

A. “Affect” refers to the direct or indirect effects of an activity on SSC design functions. The actual UFSAR description of the design function may or may not require updating as a result of the activity. See also Q&A S.2.

S.2. If a proposed activity would not cause the description in the UFSAR to become inaccurate, can the activity be screened out?

A. Screening is a review of technical information supporting a proposed activity to determine whether UFSAR-described design functions would be adversely affected. A determination that an activity does not adversely affect design functions should be based on a thorough understanding of affected SSCs and the effects of the proposed activity on them. Determination that an activity would not cause the UFSAR description of SSC design functions to be inaccurate is an indicator, but is not the determining factor for screening the activity out. The documented basis for screening an activity out should be expressed in terms of the lack of adverse effect (direct or indirect) that the proposed activity would have on design functions, not on whether or not the description in the UFSAR is affected.

For example, if a proposed change would reduce the reliability of a design function, the change may not cause the UFSAR description to become inaccurate (unless the UFSAR discusses the reliability of the design function). However, this change should be screened in because there is an adverse effect on a design function. Upon 10 CFR 50.59 evaluation of such a change, the licensee may determine that the reduced reliability results in a negligible or minimal increase in the likelihood of malfunction. Assuming none of the other seven evaluation criteria are met, the change may be made without prior NRC approval.

Focusing screening determinations primarily on whether the change renders the UFSAR inaccurate may result in unnecessary 10 CFR 50.59 evaluations being performed for activities that do not meet the definition of “change.” This is because changes that do not adversely affect design functions may nonetheless require the UFSAR to be updated to reflect the change, but would not require a 10 CFR 50.59 evaluation. The key point in determining that a 10 CFR 50.59 evaluation is not required is that no design function, method of performing or controlling a function, or evaluation that demonstrates intended functions will

be accomplished, is adversely affected. Whether the words in the UFSAR need to be changed is a secondary matter. 10 CFR 50.59 is not a UFSAR change control process; its purpose is to identify changes to the facility or procedures that require prior NRC review and approval.

- S.3. Deleted. Benign/beneficial effects addressed in guidance (Section 4.2.1).
- S.4. How, if at all, has the concept of “indirect” effects changed in the revised NEI 96-07 guidance?

A. The concept of indirect effects has not changed. There are two common historical usages for the term “indirect effects,” and both are relevant under the revised guidance. First, the term may be used to reflect that in addition to a primary or direct effect on a particular design function (and associated UFSAR information), a change may have subtler or indirect effects on other design functions that must be considered. For example, in addition to considering the effect on diesel loading and sequencing of a new or larger load, there may be environmental effects on SSCs in the room as a result of the additional heat generation.

“Indirect effects” will also continue to be used to describe changes affecting SSCs that are not explicitly described in the UFSAR, but nonetheless affect the UFSAR-described design function of a larger or connected SSC.

- S.5. A licensee proposes to move a load from the nonsafety-related power supply to a safety-related dc bus. This change therefore affects the calculations/analyses that demonstrate that the plant can withstand and respond to a station blackout. Does this change screen in because it affects “an evaluation that demonstrates intended functions will be accomplished?”

A. No. This is a change to the facility that would be screened to determine whether UFSAR-described design functions are adversely affected. For example, the licensee would consider whether the new load or new load sequence would cause station batteries to be unable to power other required loads for the entire SBO coping duration.

The third part of the “change” definition covering changes that affect “an evaluation that demonstrates intended functions will be accomplished” pertains only to changes in methods of evaluation used to establish the design bases or in the safety analyses—not to physical or procedure changes that may affect evaluations.

- S.6. The three-part definition of change uses the terms “design function,” “function,” and “intended function.” Do these terms mean the same thing?

A. Yes. All three parts of the “change” definition refer to “design functions”

as that term is discussed in Section 3.3 of NEI 96-07, R1.

- S.7. NEI 96-07, Revision 0, considers equivalent replacements to be a maintenance activity that is not subject to 10 CFR 50.59 screening or evaluation. In Revision 1, equivalent replacements are considered changes that must be screened. Why the difference?

A. Equivalent replacements were moved into screening because the engineering (equivalence) assessment performed to determine that a full 50.59 evaluation is not required is analogous to the 10 CFR 50.59 screening review. Equivalence assessments of the physical and performance characteristics of non-identical replacement items are qualitatively different than assessments to determine whether 10 CFR 50.59 must be applied (as discussed in Section 4.1 of the guidance). If an equivalence assessment determines that a replacement item is equivalent to the item it is replacing, this is tantamount to the screening determination that the change does not adversely affect design functions. Thus, equivalence assessments can serve as the basis for determining that a change may be screened out.

Provided the licensee's equivalence assessment (and corresponding 50.59 screening) confirms that there is no adverse effect on design functions, the end result is the same as with the Revision 0 guidance: there is no need for a full 50.59 evaluation of equivalent replacements. (Of course, the UFSAR should be updated per 10 CFR 50.71(e), as appropriate.)

Some licensees have expressed interest in revising their 10 CFR 50.59 procedure to allow use of their equivalence determination process as a second screening method/form for use in reviewing replacements with non-identical components. This would be an alternative to the typical 10 CFR 50.59 screening process/form (like the one developed by USA) that would be used for all other types of changes. Under this approach, 10 CFR 50.59 processes/procedures would recognize, consistent with NEI 96-07, Revision 1, that equivalent replacements are a category of changes that are subject to 10 CFR 50.59 (screening). This approach is entirely consistent with NEI 96-07, Revision 1, and would obviate the need for licensees to complete a separate step/form to do a 10 CFR 50.59 screen for equivalent replacements.

It should be recognized that licensees who take this approach should ensure that personnel performing equivalence determinations receive training equivalent to that of 10 CFR 50.59 screeners. To dovetail with 50.59, the licensee equivalence process should include a focus on determining that the equivalent replacement (i.e., change) "does not adversely affect design functions."

- S.8. Must the determination of whether a change is adverse (and therefore requires evaluation under 10 CFR 50.59) be based solely on the UFSAR description of the

design function, or can additional design information be considered?

A. Screening determinations are based on the technical/engineering information supporting the proposed change, which typically includes UFSAR information as well as more detailed design calculations, analyses, etc., from outside the UFSAR. For example, a licensee proposes to compensate for noise affecting a transmitter's output with a change to the transmitter's electronics. The UFSAR states that this transmitter provides indication in the control room and an auto-close signal to control room ventilation system dampers upon detection of radiation above the setpoint. The electronics change will cause a two-second delay in the generation of the auto-close signal.

From detailed analyses of the control room HVAC system (maintained outside the UFSAR), it is determined that the damper moves from full open to full closed in 15 seconds and that the dose consequence analysis for the control room does not take credit for closure of the dampers until one minute following the high radiation signal. Based on this information, the change to the transmitter electronics, including the two-second delay in generation of the high radiation signal, is determined to have no adverse effect on UFSAR-described design functions.

- S.9. NEI 96-07, Rev. 0, specifies that a "reduction in margin of safety" exists when the difference between the "acceptance limit" and the design failure point of an SSC is reduced. This may occur by increasing acceptance limit or decreasing the design failure point (or both). In criterion (c)(2)(vii) of the revised rule and the associated NEI 96-07, Revision 1, guidance, the focus is on exceeding/altering design bases limits (which equate to the "acceptance limits" in Revision 0), and there is no specific reliance on the design failure point. Under the revised rule and guidance, if a proposed activity reduces the design failure point of an SSC but maintains the design bases limit, is this an adverse affect on a design function (i.e., would the activity screen in?), and if so, would prior NRC approval be required for this activity?

A. No, the proposed activity would not adversely affect a design function. Reducing the failure point of an SSC does not affect the design bases limit, therefore the change would screen out. No 10 CFR 50.59 evaluation would be required.

Note: It must be ensured that the reduction in failure point does not violate a licensing bases commitment to maintain a minimum margin between the design failure point and the acceptance/design bases limit, e.g., that the failure point must exceed the acceptance/design bases limit by at least a factor of three.

- S.10. Section 4.2.1.3 of NEI 96-07, Revision 1, provides that changes to an element of a method of evaluation can be screened out as long as they do not exceed the limitations or constraints which are described in the Licensing Topical Report

(LTR), Safety Evaluation Report (SER), and correspondence between the NRC and the methodology owner, regardless of whether the changes are conservative or non-conservative. Is it the intent, in other words, that only those changes which exceed the limitations or constraints of the methodology require a full 50.59 evaluation, even if they result in a gain in margin?

A. Yes

S.11. How should licensees distinguish between constraints and limitations contained in LTRs, SERs, etc., and other statements that merely describe how a method of evaluation was evaluated or used in a particular application? For example, if the LTR for a lattice physics methodology describes its application to a particular fuel design (e.g., Westinghouse 15x15), but does not specifically identify fuel designs as a limitation or constraint on the application of the methodology, can it be applied to a different fuel design (e.g., Westinghouse 16x16 or CE 16x16) without it being considered a change to the methodology, e.g., in a mixed core that contains fuel from both vendors?

A. As discussed in NEI 96-07, R1, Section 4.2.1.3, changes to methods of evaluation that are within the constraints and limitations contained in LTRs, SERs, etc., may be screened out. Technical description in LTRs, SERs, etc., concerning the application of the methodology may effectively constitute, and should be viewed as, additional constraints and limitations on the use of the method. In the above example, the reference to the Westinghouse 15x15 fuel design should be viewed as a constraint or limitation of the methodology unless the LTR, SER, etc., states that the methodology may be used for other fuel designs.

For purposes of 10 CFR 50.59 screening, if a methodology change is consistent with established limitations and constraints, as well as any technical description of its approved application, the change may be screened out. For example, if the LTR in the above example stated that the methodology was primarily intended for use on the Westinghouse 15x15 fuel design, but may be applied to other fuel designs, then applying the method to other fuel designs may be screened out provided all other limitations and constraints of the methodology continue to be met.

S.12. If the Licensing Topical Report for a transient methodology states that the lower plenum region of the reactor vessel is treated as one node in the thermal-hydraulic portion of the model, is it considered a change to the methodology if this region is split into multiple nodes?

A. Yes.

S.13. Consider the example of a change to a 3D core simulator model to add the nuclear effects of control blade history (CBH) on fuel bundles that are controlled

for long periods of time. This may be precipitated by new operating strategies which were not being used at the time the simulator model was approved; therefore, the LTR, SER, etc., may not address whether a CBH model was part of the methodology. In this case, would it be acceptable to screen out the change to add a CBH model if it did not result in any of the constraints or limitations on methodology discussed in the LTR, SER, etc. being exceeded?

A. No. Addition of new calculational features to analysis models may not be screened out because the modified methodology would not be consistent with the terms of the LTR, SER, etc. The effect of such new features on the analysis results should be evaluated under 10 CFR 50.59(c)(2)(viii) to determine if the results are conservative or essentially the same.

S.14. If a feature of a method of evaluation is briefly described, but not discussed in detail, in the LTR and is not explicitly addressed in the SER, is this an element of the methodology? If not, then it is our understanding that changes to that feature can be screened out because they would not constitute changes to the methodology. Using the example in the previous question, suppose an LTR for a 3D core simulator code states that the methodology includes the effects of control blade history, but provides no further information. Can changes to that model, or elements of that model be screened out? If so, would that include going so far as to turn off the CBH feature all together? If these changes cannot be screened out, does that mean that no changes to the CBH portion of the methodology can be made without performing a full 50.59 evaluation?

A. If the LTR and/or SER identifies that a particular feature is modeled in the methodology, but does not say how the feature is modeled, licensee changes to the modeling of the feature may be screened out on the basis that the change is consistent with the terms of the approved methodology. However, because the LTR and/or SER says that the feature is modeled, a change to turn the feature off would not be consistent with the terms of the LTR/SER and would screen in.

S.15. In some cases the NRC has approved a mechanism for making certain changes to methodologies. May changes made in accordance with these mechanisms be considered within the constraints and limitations of the methodology, and therefore screened out? For example, GE's Amendment 22 process for licensing new fuel designs explicitly includes a way of determining new coefficients for their GEXL/GEXL-Plus critical power correlation based on new data. Therefore, new GEXL/GEXL-Plus coefficients should not be considered changes to physical coefficients as defined in Section 3.10 of NEI 96-07, Rev. 1, because they are developed using a previously approved mechanism.

A. Changes made in accordance with a mechanism that is built in to the approved methodology need not be considered changes for purposes of 10 CFR 50.59, i.e., they may be screened out. Of course, the UFSAR should be updated to reflect the change, as appropriate.

10 CFR 50.59 Evaluation

E.1. For purposes of Criteria 3 & 4 on consequences, is the 10% maximum increase a one time total that licensees must track, or do licensees re-baseline after every change and have a new 10% for each successive change?

A. The dose consequence results are re-baselined after each change and a new 10% increase is permitted for each successive change up to the applicable SRP guideline.

E.2. My UFSAR references a vendor topical on fuel design, and the vendor plans to revise certain analyses, including elements of methodology, as part of my next reload. Do those methodology changes require prior NRC approval?

A. Even though the methodology "belongs to the vendor," the licensee must evaluate the proposed change against criterion c(2)(viii) prior to implementation. In this case, dialog between the licensee and the vendor needs to establish what methodology elements were changed and whether the results are conservative or essentially the same.

E.3. A revision to the existing method for calculating post-LOCA containment pressure that maximizes containment pressure after LOCA is obviously worse for containment performance but results in improved ECCS performance. Is this a conservative or non-conservative change? Does increased containment pressure constitute a reduction in margin that would require prior NRC approval based on the evaluation of consequences under (c)(2)(iii)?

A. In the context of criterion 8, a revised LOCA analysis method that results in higher peak containment pressure is considered conservative with respect to the old method. Containment performance, considered under criterion 7, would not be affected so long as the design basis limit for containment integrity (e.g., 50 psig) is not exceeded. The concept of reduction in margin has been eliminated in favor of objective evaluation against design basis limits for fission product barriers. Because the containment barrier is assumed to be intact up to its design basis limit, the higher calculated containment pressure would have no effect on dose or the consequence evaluation required by criterion 3.

If a change to a method would result in a lower peak containment pressure, the change would be non-conservative with respect to the Criterion 8 evaluation.

If the purpose of the revised containment pressure analysis was to demonstrate increased backpressure in support of ECCS performance, the higher calculated peak containment pressure would be a non-conservative result, and the methodology revision would require prior NRC approval.

E.4. If a number of non-linked changes collectively do not trigger any of the 10 CFR 50.59 criteria, must they be evaluated separately?

A. Yes.

E.5. When using a new NRC-approved methodology (e.g., new or upgraded computer code) to provide more precise results, if the end result is an increase in margin to the acceptance criteria (i.e., non-conservative and not essentially the same), would this be considered a departure requiring prior NRC approval?

A. No. Per the rule definition of *departure*, the “conservative or essentially the same” criterion is inoperative when using a new method approved by the NRC for the intended application.

E.6. Suppose a new, NRC approved methodology is evaluated and found appropriate for the intended application under Criterion 8. The new method specifies a new design basis limit for a fission product barrier. May the proposed methodology change be implemented without prior NRC approval based on Criterion 8, or is prior NRC approval required based on Criterion 7?

A. The proposed methodology change may be implemented without prior NRC approval based on Criterion 8. The Criterion 8 review combines the NRC approval of the new methodology, including the specified fission product barrier design basis limit, and the licensee evaluation that ensures the new methodology is appropriate for the intended application. This integrated review provides basis for implementing the change without prior NRC approval. This is consistent with the intent that the “conservative or essentially the same” criterion be inoperative when evaluating use of a new, NRC-approved methodology. Similarly, the 10% minimal increase limit in Section 4.3.3 does not apply if a higher dose is calculated using a new, NRC approved methodology that was found appropriate for the intended application under Criterion 8.

Of course, if the new barrier design basis limit differs from a limit specified in the technical specifications, a technical specification amendment request must be submitted under 10 CFR 50.90 to make the change.

E.7. (a) When an analysis yields a result that is an input to a UFSAR safety analysis, is the result/input considered an element of the safety analysis method that is subject to control under criterion 8? (b) Are the methods used in the subsidiary analysis that yielded the result/input subject to control under criterion 8?

A.a Not unless the safety analysis methodology, described or referenced in the UFSAR, requires that a specific input parameter be calculated in a specific manner (e.g., 95/95 limit value, 10-year average, etc.),

A.b Yes.

As an example, auxiliary feedwater flow rate as a function of steam generator pressure is an input to the safety analyses commonly presented in UFSAR Chapter 15. In this context, the flow rate is not part of the methodology. It is also necessary to ensure that the assumed auxiliary feedwater flow rate can be delivered. To the extent that the methodology used to calculate the deliverable flow rate is described in the FSAR, it is subject to evaluation against Criterion viii.

- E.8. "Specified factors to account for uncertainty in measurements or data" is identified in definition 3.10 as one element of methodology controlled under (c)(2)(viii). If the UFSAR reflects that a licensee has assumed a 3-sigma uncertainty on an input parameter, without having to do so because of an NRC requirement, is prior NRC approval required to change this assumption?

A. If the licensee can conclude, based on review of the SER, related correspondence and other sources, that NRC did not credit the use of the 3-sigma uncertainty to offset other input parameters or model limitations, then the 3-sigma uncertainty may be considered as "discretionary conservatism" and changed without prior NRC approval.

- E.9. If a value is taken from a reference document for use in a safety analysis or to establish design bases, is the value an input or part of the method? Does it matter if the reference document is an ANSI standard (not approved by the NRC) versus a topical report that was approved by NRC?

A. The value is an input unless the acceptability of the methodology is dependent on the degree of conservatism inherent in the value. If the NRC accepted a methodology (vs. an analysis) because the initial power was 4.5% higher than necessary, the value (regardless of its source) is a part of the methodology.

- E.10. If a proposed activity would cause a miniscule exceedence (e.g., 0.01%) of a design basis limit for a fission product barrier evaluated under Criterion 7, is prior NRC approval required?

A. Yes. Design Basis Limits for fission product barriers are treated as absolute limits. On a more practical note, only the appropriate significant digits need be considered when making this determination.

- E.11. 10 CFR 100.11(a)(1 & 2) provide whole-body and thyroid dose limits for, respectively, the exclusion area boundary (initial two hours following an accident) and the low population zone (event duration). Should the guidance in Section 4.3.3 be applied to the UFSAR-described EAB or the LPZ dose? For example, if a change would increase the LPZ dose by more than 10% of the margin to the Part 100 limit, but increases the two-hour EAB dose only minimally, is prior NRC approval required?

E.12. Section 4.3.2 of NEI 96-07, R1, says that a change that reduces system/equipment redundancy, diversity, separation or independence requires prior NRC approval. Does this mean reductions from redundancy, diversity, separation or independence described in the UFSAR? Or is prior NRC approval required only if the change reduces redundancy, diversity, separation or independence below the level required by the regulations?

A. A change that reduces redundancy, diversity, separation or independence of UFSAR-described design functions is considered more than a minimal increase in the likelihood of malfunction and requires prior NRC approval. Licensees may, however, without prior NRC approval, reduce excess redundancy, diversity, separation or independence, if any, to the level credited in the UFSAR.

E.13. Deleted. "Mission doses" addressed in guidance (Section 4.3.3).

E.14. Section 4.3.8.2 of NEI 96-07, R1, includes a number of considerations for determining whether or not a new, NRC approved method of evaluation may be considered "approved by the NRC for the intended application." What is the intent of this guidance and to what extent should documentation of criterion 8 evaluations reflect these considerations?

A. Recognizing that criterion 8 is new to licensees, the considerations in Section 4.3.8.2 were provided as examples to assist reviewers in identifying the range of factors that may be applicable when evaluating whether a methodology change may be implemented without prior NRC approval. Not all of the given considerations may be relevant to a given change, and knowledgeable analysts should consider additional factors that may be relevant to determining the acceptability of a change. The considerations should not be viewed as additional 10 CFR 50.59 criteria, but may indicate that a proposed methodology change is or is not "approved by the NRC for the intended application." Documentation of criterion 8 evaluations should address the considerations given in Section 4.3.8.2 and others, as applicable, in accordance with their significance to the evaluation.

E.15. Deleted. Question withdrawn.

E.16. Use of a particular analytical method is reflected in the UFSAR for Licensee A, however, the NRC did not discuss their review or acceptance of the methodology in their SER. Can Licensee B apply the methodology consistent with the application by Licensee A and consider the method "approved by the NRC for the intended application?"

A. The method used by Licensee A is considered implicitly approved by the NRC. Licensee B must first be qualified to perform safety analyses per Generic Letter 83-11, Supplement 1. Then, since the SER is silent on the matter, Licensee B must be able to obtain an adequate understanding of the methodology, its existing application, and limitations on its use from other sources on which to base a further application of the methodology. If these two conditions are met, Licensee B may apply the method and consider it approved by the NRC for the intended application. The basis for determining the methodology is appropriate for the intended application should be documented in the 10 CFR 50.59 evaluation. Other sources of information about the methodology may include the FSAR, topical report, licensee responses to NRC requests for additional information, other licensee correspondence with NRC, and Licensee A personnel familiar with the existing application.

E.17. Section 4.2.1.3 says a change to an existing methodology may be screened out if the change is within the constraints and limitations associated with use of the method. What if no information exists concerning relevant constraints and limitations on use of the methodology?

A. If relevant constraints and limits on use of a methodology are not known, then changes to the method should be screened in for evaluation under Criterion (c)(2)(viii) of 10 CFR 50.59. If results using the modified methodology are conservative or essentially the same, then the change does not require prior NRC approval.

E.18. May I switch from ICRP-2 to ICRP-30 dose conversion factors under Criterion (c)(2)(viii) of 10 CFR 50.59?

A. NRC has approved ICRP-30 dose conversion factors for use in certain applications. If a licensee proposes to use ICRP-30 in an application that is analogous to that for which it was approved by NRC for another licensee, and other conditions for use of ICRP-30 are met, then ICRP-30 may be considered a methodology that is "approved by the NRC for the intended application" and applied without prior NRC approval. Note: NRC has, in some cases, required that analyses based on ICRP-30 reflect use of the alternate source term. Per 10 CFR 50.67(b)(1), use of the AST may itself require prior NRC approval.

E.19. Are methodologies published by NRC in NUREGs or NUREG/CRs considered "approved by the NRC for the intended application?"

A. Not necessarily. In order to be considered "approved by the NRC for the intended application," such methods must be approved in an SER or otherwise accepted by NRC as part of a plant's licensing basis.

E.20. If I answer "Yes" to Criterion 1, does my 10 CFR 50.59 evaluation still have to address the other seven criteria because I know at that point that the proposed change will require prior NRC approval?

A. No. Given a "yes" answer to one of the eight 10 CFR 50.59 evaluation criteria, the licensee must decide whether to cancel or modify the change, or seek prior NRC approval via the license amendment process. If the decision is to request a license amendment, the licensee does not need to complete the 10 CFR 50.59 evaluation (see previous question). However, the licensee must ensure that complete information concerning the impact of the change is developed and provided to the NRC in support of the LAR. For example, in addition involving more than a minimal increase in the frequency of occurrence of the accident, the proposed change may also result in a more than minimal increase in consequences and other impacts. All relevant effects of the change would need to be addressed in the LAR.

E.21. On page 63 of the NEI 96-07, Rev. 1 there is a table that shows fission product barriers and the design basis parameters for each one. Linear heat rate is one of the parameters listed for fuel cladding with a typical design basis limit of peak linear heat rate in units of kW/ft. For BWRs, Average Planar Linear Heat Generation Ratio (APLHGR) limits (nodal kW/ft) listed in the COLR are chosen to ensure the (1% plastic) clad strain design limit (which is listed as a separate design basis limit for fuel cladding) is not exceeded. Is there a new design basis limit that BWRs will now have to consider, or is the linear heat rate covered by the clad strain criteria?

A. If APLHGR limits are specified and meet the intent of design basis limit for FPBs described in Section 4.3.7, then APLHGR limits should be considered barrier DBLs for your plant. The list of barrier DBLs in 4.3.7 is generic, for illustration purposes only, and includes the barrier DBLs that are applicable for most plants.

E.22. Section 4.3.8.1 of NEI 96-07, Rev. 1, states, "Analytical results obtained by changing any element of a method are 'conservative' relative to previous results, if they are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines)." However, it is unclear what is meant by "previous results." In some sectors of the nuclear industry, methods of evaluation have evolved since the original versions were approved by the NRC. This is especially true in the areas related to nuclear fuel (e.g., fuel thermal-mechanical design, bundle neutronic design, thermal-hydraulic evaluations, core design, and safety analyses). Most of these changes are insignificant with respect to the results and were not considered to be a change in the methodology. Therefore they may not have been submitted to the NRC for their approval. Given this long-standing approach to most changes, under the new 50.59 rule what will be the standard for determining if a change to a method of evaluation is non-conservative (i.e., results in a gain in margin) during the evaluation process?

An additional factor bearing on this question is that the passage of time and technology and the unavailability of the original computer codes may make it impossible to use the original version of the methods of evaluation as the standard for comparison.

A. The determination of whether a methodology change produces results that are conservative or essential the same should be based on comparison with the methodology/analysis of record in the UFSAR (i.e., the current licensing basis). The analysis methods reflected in the UFSAR are considered "approved by the NRC for the intended application." It is not necessary or expected that the effects of future methodology changes be compared to methodology/results for which there is explicit NRC approval. It is expected that evolutions over the years in analysis methods approved by the NRC are consistent with the terms of the original NRC approval and that future changes will be reviewed with respect to their impact on the results of the methodology in their evolved (current) state. While most of these methodology changes are probably insignificant as the question states, some may have affected the summary description of the analysis in the UFSAR. As required by 10 CFR 50.71(e), and as a matter of sound configuration management, licensees need to ensure that their analyses of record in the UFSAR reflect the effects of methodology changes made over the years that may or may not have been reviewed under 10 CFR 50.59 or reported to NRC.

E.23. As discussed in Section 4.3.8 of NEI 96-07, Rev. 1, analytical methods are a fundamental part of demonstrating how the design of a nuclear plant meets regulatory requirements and why the facility's response to design basis accidents and events is acceptable. That section recognizes that "... these analytical methods were described in the UFSAR and received varying levels of NRC review and approval during licensing." What is the significance of these "varying levels of NRC review and approval" with respect to 10 CFR 50.59?

A. Regardless of the level of NRC review/approval for a given analysis methodology, methods described in the UFSAR (i.e., the current licensing basis) are considered approved by the NRC for the intended application. It is assumed that the UFSAR has been updated as appropriate in accordance with 10 CFR 50.71(e) to reflect changes that may have affected the methodology as described in the UFSAR since the original, or most recent, NRC review/approval. These methodologies/analyses of record in the UFSAR should be used as the baseline for determining whether a methodology change produces results that are conservative or essential the same. And, as discussed in Section 4.3.8.2, UFSAR methods may be used by the same licensee or another licensee in analogous applications, provided doing so can be determined technically appropriate based on a thorough understanding of the terms of the existing application and conditions/limitations on its use.

Transition Issues

T.1. Which 10 CFR 50.59 (old or new) applies when evaluation of a change is begun before the effective date of the new rule, but either the evaluation is not complete or the change is not implemented until after the new rule becomes effective?

A. The version of 10 CFR 50.59 (old or new) that should be applied is based on the date on which the 10 CFR 50.59 screening/evaluation is begun. Thus, the old process may be applied for 10 CFR 50.59 reviews begun up to March 13, 2001, the effective date of the revised rule, or plant-specific implementation date, if later (see Q&A T.4). This is acceptable because the old rule is generally conservative with respect to the new. However, for changes to methods of evaluation proposed between the time the new rule takes effect and some later plant-specific implementation date, licensees should ensure that screening/evaluation is consistent with the intent of the new rule and approved guidance.

T.2. What can I do if I submitted a license amendment request for a change that met one of the three evaluation criteria of the existing/old 10 CFR 50.59, but meets the minimum increase standard and could be implemented without prior NRC approval under the revised rule?

A. Licensees may modify or withdraw pending LARs at any time.

T.3. If new or unexpected information is discovered after the revised rule takes effect that necessitates revision of a completed 10 CFR 50.59 evaluation based on the existing/old rule, should the new/revised or the existing/old 10 CFR 50.59 rule be used to revise the evaluation?

A. The evaluation may be revised based on either the new/revised 10 CFR 50.59 or the existing/old rule, at the discretion of the licensee. However, the new/revised rule and guidance should be applied in the following cases:

- If the required revision reflects an increase in the effect of the change such that one or more criteria of the new/revised rule are met. (In this case the licensee should, of course, seek a license amendment for the change).
- If the new information necessitates a change to the previously evaluated activity that is significant to the evaluation

Whichever version of 10 CFR 50.59 is used to revise the evaluation, only the portion affected by the new information (e.g., the consequence evaluation) need be revised. Re-evaluation to the new criteria of the unaffected portions of the 10 CFR 50.59 evaluation is at the licensee's discretion.

T.4. Licensees typically schedule training of personnel so as not to compete with planned outages. Based on the March 13, 2001, effective date of the rule, and the large number of plant staff that require training, 10 CFR 50.59 training would have to take place during outages for many plants. To ease transition to the new 10 CFR 50.59 rule, can a licensee opt to continue to use the (more conservative) existing/old rule for a period of time until procedures and training are completed on the new rule? Would an exemption request be required?

A. As identified by NRC at the April 10-11 Licensing Issues Workshop, licensees can continue to follow the "old" rule for a transitional period of time beyond the March 13, 2001, effective date of the new rule to complete procedure revision and training (if the 90 days proves to be insufficient). No exemption request is needed. It is recommended that licensee keep the appropriate NRC staff informed of their implementation status to avoid misunderstandings.

Similarly, the implementation schedule for 10 CFR 72.48 lags that for 10 CFR 50.59 by at least two months. To avoid having to use both the old and new change processes for this period, can a licensee opt to continue to use the (more conservative) existing/old 10 CFR 50.59 and 10 CFR 72.48 until both revised rules are in effect?

A. Yes. See above.

T.5. The revised maintenance rule, including the new a(4) provision, went into effect before the revised 10 CFR 50.59 rule. During the period between the effective dates of the two rules, are licensees required to perform both a(4) assessments and 10 CFR 50.59 reviews for plant alterations to support maintenance?

A. No. Both the revised maintenance rule a(4) guidance and that contained in NEI 96-07 for 10 CFR 50.59 reflect that maintenance activities, including associated plant alterations lasting 90 days or less, are to be assessed and managed under the a(4) provision (no 10 CFR 50.59 review required). In approving the maintenance rule a(4) guidance (RG 1.182), the Commission noted in their May 1, 2000, SRM on SECY-00-0074 that, "Until the revised 10 CFR 50.59 rule becomes effective, performing a 50.65(a)(4) assessment in lieu of a 10 CFR 50.59 review may result in literal noncompliance with the existing 10 CFR 50.59 rule." They directed that, "Should this occur, the [NRC] staff should continue its policy of exercising enforcement discretion for violations of the existing rule that would not be violations of the revised 10 CFR 50.59 rule." Thus, licensees may at any time begin using a(4) instead of 10 CFR 50.59 to assess plant alterations (lasting <90 days) that support maintenance activities. Similarly, licensees may stop performing 10 CFR 50.59 reviews for maintenance procedure changes, consistent with forthcoming guidance on 10 CFR 50.59 and applicability of Part 50, Appendix B, criteria to control of such changes.

General/Miscellaneous

G.1. Appendix A of NEI 98-03, *Guidelines for Updating FSARs*, provides for removal of excessive detail from UFSARs. Rather than apply 10 CFR 50.59 to a given change affecting such UFSAR information, can licensees remove the information in accordance with NEI 98-03 and proceed with the change?

A. Regardless of whether a proposed change affects information contained in the UFSAR, changes that are not controlled by another regulation must, at a minimum, undergo 10 CFR 50.59 screening. Removing affected information from the UFSAR may be appropriate based on the guidance contained in NEI 98-03, however, doing so does not lessen the applicability of 10 CFR 50.59 to the change. That said, a change that affects only UFSAR details that are considered excessive with respect to providing an understanding of the safety analyses and design bases (NEI 98-03 criteria) would most likely not meet the 10 CFR 50.59 definition of "change," and thus screen out.

G.2. When does a UFSAR change become part of the UFSAR? Is it when the change is implemented? Or when the associated UFSAR update is approved?

A. A UFSAR change becomes part of the UFSAR for purposes of 10 CFR 50.59 when it is approved for incorporation in the next UFSAR update required under 10 CFR 50.71(e). This is typically after the change is implemented.

G.3. What are the implications for no significant hazards determinations under 10 CFR 50.92, which retains a criterion for "no reduction in margin of safety," now that the "margin of safety" criterion has been eliminated from 10 CFR 50.59?

A. None. The 10 CFR 50.59 rulemaking does not effect 10 CFR 50.92, or determinations of no significant hazards. While the term "margin of safety" is as subjective in the context of 10 CFR 50.92 as it was for 10 CFR 50.59, this is not considered a problem going forward. This is because required licensee submittals under 10 CFR 50.90, "no significant hazard" determinations and the ultimate approval of license amendment requests will be based on the licensee's submittal, including complete technical rationale supporting the requested action. This process will continue as it always has.

It should be noted that the existing/old 50.59 says "margin of safety as defined in the basis for any TS." Clearly, the 50.59 rulemaking has clarified the intent of that phrase by focusing on those design bases limits that ensure the integrity of fission product barriers. In contrast, 50.92 says "significant reduction in margin of safety" (without qualifying reference to technical specifications). This implies a different (broader) scope of factors relevant to the "margin of safety" criterion under 50.92 than under 10 CFR 50.59.

G.4. Technical specifications, procedures, NRC commitments, and regulatory guidance often reflect that a "10 CFR 50.59 evaluation" should be performed under certain circumstances, e.g., for compensatory action to address degraded or non-conforming conditions or when making a change to the TRM or technical specifications bases. How should this be interpreted going forward, recognizing that the 10 CFR 50.59 process has two parts: screening and evaluation?

A. References to 10 CFR 50.59 in procedures, commitments and guidance that are based on the existing/old rule should be viewed going forward as references to the complete 10 CFR 50.59 process. All activities subject to 10 CFR 50.59 should be subject to the screening provisions based on the definitions in the revised rule, and if necessary (if the activity screens in), to the evaluation provisions (and associated documentation/reporting requirements).

G.5. Are there any inconsistencies between the Statements of Consideration for the final 10 CFR 50.59 rule and final draft NEI 96-07, R1?

A. While the SOC are not part of the revised 10 CFR 50.59 regulation, NEI 96-07, R1 is largely consistent with them. Based on extensive public discussions and comment resolution between the industry and the NRC staff, two aspects of the SOC have been clarified in final draft NEI 96-07, R1. Following endorsement of NEI 96-07, R1, by the NRC, the industry guidance will take precedence over the SOC in these areas.

First, 10 CFR 54.21(d) requires that the UFSAR be supplemented for license renewal with summary descriptions of time-limited aging analyses and aging management programs. The SOC state that changes to this license renewal information require "evaluation" under 10 CFR 50.59(c)(viii). The intent of the SOC discussion was to include TLAA and (as applicable) aging management programs within the scope of "design bases and safety analyses" for purposes of criterion 8 so that if associated evaluation methods were described in the UFSAR they would fall within the definition of "methods of evaluation" and thus, the scope of 10 CFR 50.59. The industry guideline reflects that all changes subject to 10 CFR 50.59 may first be screened to determine if evaluation against the eight criteria of 10 CFR 50.59 is required. Thus, contrary to the SOC, changes to time-limited aging analyses and aging management programs for license renewal that screen out based on the definitions and guidance in NEI 96-07, R1, do not require evaluation under 10 CFR 50.59.

Second, the SOC state that licensees may adopt a new method of evaluation only if it has been specifically approved by the NRC for the intended plant/application or enjoys "generic" NRC approval. In addition to these cases, NEI 96-07, R1, provides that licensees qualified per Generic Letter 83-11, Supplement 1, to perform safety analyses may adopt methodologies approved by the NRC for other plants provided the methodology is technically appropriate for the

intended application.

- G.6. According to NEI 96-07, R1, I may change my 10 CFR 50.2 design bases without prior NRC approval, except those that ensure the integrity of fission product barriers, provided that the change does not meet any of the eight evaluation criteria of 10 CFR 50.59. Is that true?

A. Yes, it is true. Except for criterion 7, 10 CFR 50.59 does not treat changes to 10 CFR 50.2 design bases any differently from other changes to the facility or procedures.

Historically, NRC reporting requirements have reflected a distinction between 10 CFR 50.2 design bases and other design information. Specifically, 10 CFR 50.72 required licenses to report to NRC in 1-hour conditions "outside the design bases." Recognizing that "outside the design bases" conditions rarely imply a safety concern that must be immediately reported to the NRC, the NRC recently revised its reporting requirements to eliminate "outside the design bases" as a reporting criterion.

- G.7. NEI 96-07, R1, says that 10 CFR 50.59 should be applied to temporary changes that are not related to maintenance and maintenance-related plant alterations lasting >90 days. Do these have to be reported to the NRC?

A. If the temporary change required a 10 CFR 50.59 evaluation (i.e., did not screen out), it must be reported to the NRC like any other activity that received a 10 CFR 50.59 evaluation.

- G.8. Why were most of the considerations (from NEI 96-07, Revision 0, and early drafts of Revision 1) for determining whether there is an increase in accident frequency or malfunction likelihood removed from Section 4.3.1 and 4.3.2?

A. The considerations were removed because they would have uncertain status in a guidance document endorsed by the NRC. They may have been interpreted as criteria that, if met, would indicate prior NRC approval was required, or it could have been interpreted that 10 CFR 50.59 evaluations were considered incomplete unless each consideration was addressed. Neither of these, of course, was intended. Rather, the considerations were intended to indicate the breadth of factors that may be appropriate to consider for a given 10 CFR 50.59 evaluation. Not all considerations are relevant to all evaluations. Licensees may wish to identify such considerations in their 10 CFR 50.59 implementation materials to ensure all relevant factors are considered.

- G.9. Does NEI plan to make conformance with NEI 96-07, R1, an industry initiative?

A. No. We believe the NRC endorsement of NEI 96-07, R1, obviates the need for an industry initiative and provides adequate incentive for licensees to follow the

industry guidance.

G.10. Does NEI 96-07, R1, and the associated regulatory guide supercede 10 CFR 50.59-related information and guidance contained in past NRC bulletins, generic letters, etc.?

A. NEI 96-07, R1, and the associated RG reflect the revised 10 CFR 50.59 rule that will apply to licensees going forward. Conforming changes to NRC inspection guidance are in progress. However, past NRC bulletins and generic letters containing guidance related to 10 CFR 50.59 are not being updated and their applicability should be assessed on a case-by-case basis. Where NEI 96-07, R1, includes 10 CFR 50.59 implementation guidance in an area that was addressed by a prior NRC generic communication, the revised guidance and RG take precedence. It should be recognized that 10 CFR 50.59 implementation may have only been one aspect of the information presented in an earlier NRCB or GL, and other information presented might still be valid.

Where the revised guidance cannot be directly applied to a situation addressed previously by the NRC, the licensee should assess the prior information in the context of the revised rule and guidance and proceed accordingly.

The examples below illustrate the applicability of prior NRC guidance concerning 10 CFR 50.59 implementation in light of the new rule and NEI 96-07, R1. These example can be used as a guide for assessing the applicability of other past NRC guidance related to 10 CFR 50.59:

- NRC Bulletin 80-10 addresses actions to be taken when it is discovered that previously uncontaminated systems have become contaminated. The Bulletin requires a licensee to "perform an immediate safety evaluation of the operation of a previously non-contaminated system as a contaminated system." This requirement is no longer appropriate or applicable. Based on current guidance, these "discovered" situations should be treated as a degraded /nonconforming condition in accordance with the licensee's corrective action program. In addition, the licensee should perform an operability assessment in accordance with NRC Generic Letter 91-18. If the "discovered" situation will be accepted "as is," then 10 CFR 50.59 should be applied to this final corrective action.
- NRC IE Circular 80-18 identifies review criteria of radwaste system design changes. These criteria pertain to the technical/engineering evaluation that demonstrates that the change is safe, effective and meets all applicable codes and standards. This is no different than any other change that has to be determined to be technically appropriate prior to applying 50.59. Thus the criteria identified in IEC 80-18 for radwaste design changes would be addressed as part of the up-front technical/engineering evaluation. The 50.59 screening, and, if necessary, evaluation for such changes should be

based on the technical/engineering information supporting the change.

- NRC Generic Letter 93-08 (and associated Information Notice 97-28) deals with the relocation of certain instrument response time limits from the Tech Specs to the UFSAR to allow licensees to control changes to these limits under 10 CFR 50.59 and not require a license amendment request. The requirements and guidance in this GL and related IN remain valid under the new rule.
- That portion of Generic Letter 91-18, Revision 1, dealing with 10 CFR 50.59 review of compensatory measures to address degraded/nonconforming conditions was essentially incorporated into NEI 96-07, R1. Thus the revised guidance has no effect on the prior NRC guidance, and GL-91-18, R1, remains valid.
- NRC Bulletin 95-02 addressed when an analog to digital upgrade may be made under 10 CFR 50.59 (i.e., without prior NRC approval) based on the old 10 CFR 50.59 rule. The need for prior NRC approval for future A/D upgrades should be based on evaluation under the revised 10 CFR 50.59 criteria, including the minimal increase standard. Also, the most relevant criterion for A/D upgrades is now whether the change would cause a malfunction with a different result—not whether there would be a malfunction of a different type.
- NRC Bulletin 96-02 addressed NRC concerns regarding movement of heavy loads over safety-related equipment, and when NRC approval is required prior to such movements. Movement of heavy loads is typically a part of a maintenance activity that, going forward, will be assessed and managed under 10 CFR 50.65(a)(4). Together with 10 CFR 50.59(c)(4), which provides that if more specific requirements apply to control of an activity, 10 CFR 50.59 need not also be applied, these new requirements supercede the conclusion of NRCB-96-02 that such activities constitute “unreviewed safety questions” under 10 CFR 50.59 and therefore a license amendment request must be submitted.

Nonetheless, NRCB-96-02 contains useful information and considerations for licensees contemplating movements of heavy loads and thus the bulletin continues to be valid in that respect.

When implementing the revised 10 CFR 50.59 rule and guidance, licensees should also be mindful of commitments made to NRC in response to generic or plant-specific communications such as NRCB-96-02. It may be necessary/appropriate in accordance with licensee procedures to notify NRC that a prior commitment has been changed in light of revised 10 CFR 50.59 rule and guidance.

G.11 Regarding the 10 CFR 50.59 review of temporary facility/procedure changes to compensate for degraded or nonconforming conditions, Section 4.4 of NEI 96-07, R1, states, "The intent is to determine whether the temporary change (not the degraded condition) impacts other aspects of the facility or procedures described in the UFSAR." What is the intent of this guidance, and how does this differ from 10 CFR 50.59 screening/evaluation of permanent changes?

A. Degraded and non-conforming (D/NC) conditions typically affect design functions such that they are no longer "as-designed" or "as-described in the UFSAR." This situation makes it problematic to apply 10 CFR 50.59 to the temporary change/compensatory action because it is difficult to distinguish between the D/NC condition and the proposed compensatory action. Section 4.4 provides specific guidance for applying 10 CFR 50.59 to a temporary facility/procedure change proposed as a compensatory action for a D/NC condition.

It is not intended that 10 CFR 50.59 be applied to the D/NC condition. (Per Generic Letter 91-18, the affected SSCs must be determined to be operable, and per 10 CFR Part 50, Appendix B, the D/NC condition must be corrected in a timely manner commensurate with safety.) Rather, the intent of the Section 4.4 guidance is that the temporary change/compensatory action should be screened under 10 CFR 50.59 for adverse effects on UFSAR-described design functions, etc., other than those that are degraded/nonconforming. This guidance differs from that for permanent changes in Section 4.2, which prescribes screening for adverse effects on all design functions, etc., including the design function directly affected by the change.

If a temporary change/compensatory action "screens in" (i.e., there would be adverse effects on other SSC design functions), Section 4.3 guidance for the required 10 CFR 50.59 evaluation should be applied. The focus of the evaluation in such cases is on the adverse effects on these other design functions.

G.12 GL 91-18, R1 (Inspection Manual Part 9900 - Operability) provides that in certain cases, a temporary procedure change that substitutes manual action for automatic action may be acceptable, from an operability perspective, to compensate for a D/NC condition. How should 50.59 be applied to such a temporary procedure change?

A. Provided that performance of the proposed manual action would not adversely effect design functions, etc., other than those that are already degraded or nonconforming, the proposed temporary procedure change (manual action) would "screen out." If the procedure change/manual action has adverse effects on design functions, etc., other than those that are degraded/nonconforming, a 50.59 evaluation would be performed to determine if a license

amendment request must be submitted for the temporary change.

G.13 10 CFR 50.59(c)(3) provides that the UFSAR is considered to include pending UFSAR changes resulting from activities implemented under 10 CFR 50.59 since submittal of the last required UFSAR update. Does this include temporary alterations reviewed under 10 CFR 50.59, e.g, maintenance temp alts in effect more than 90 days at power and temp alts to compensate for a degraded or nonconforming condition?

A. Generally not. According to NEI 98-03, only temporary changes that are expected to be in place throughout the next required periodic UFSAR update cycle (i.e., last more than 12-24 months) would be reflected in the UFSAR and subject to 10 CFR 50.59(c)(3). Most maintenance temp alts and compensatory actions are relatively short-term in nature and thus do not trigger a UFSAR update.