



NUCLEAR ENERGY INSTITUTE

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Mr. David B. Matthews
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555

PROJECT NUMBER: 689

Dear Mr. Matthews:

Enclosed for NRC review and comment is draft NEI 96-07, Revision 1C, *Guidelines for 10 CFR 50.59 Evaluations*. The revised guidance in Enclosure 1 reflects consideration of industry and NRC comments received on the September 17 draft of the document. Enclosure 2 is a table that indicates the disposition of the NRC's November 3 comments.

In addition to numerous clarifications and refinements to the September 17 draft, the enclosed Revision 1C includes the following new material:

- Section 4.3.8 has been revised to reflect the discussions during our November 2 public meeting on the meaning of *approved by the NRC for the intended application* as that phrase is used in the rule definition of *departure from a method of evaluation described in the FSAR (as updated)*.
- Sections 3.3 and 4.1.2 have been clarified to reflect that risk impacts of temporary changes used to support maintenance activities are assessed and managed under the Section a(4) of the Maintenance Rule, and as such, 10 CFR 50.59 does not apply to such changes.
- Consistent with new 10 CFR 50.59(c)(3) and associated statements of consideration, Section 1.2.1 has been revised and new Section 4.1.5 has been added to reflect that fire protection-related changes should be evaluated under the fire protection license condition established by licensees based on Generic Letter 86-10. Fire protection changes would not also be subject to 10 CFR 50.59 unless the changes effect non-fire protection design functions of SSCs.



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10 CFR 50.59(c)(3) and this guidance are expected to clarify longstanding confusion concerning overlapping change control criteria in the fire protection area. In public comments on DG-1094, "*Fire Protection for Operating Nuclear Power Plants*" (due to NRC by January 7, 2000), NEI intends to propose guidance for licensee evaluation of fire protection changes that is consistent with GL 86-10 and the clarified scope of 10 CFR 50.59.

We look forward to discussing the revised guidance with you in a public meeting in early January. Following that interaction, we plan to make final adjustments to the guidance as necessary and forward the final draft of NEI 96-07, Revision 1, to you for NRC endorsement.

If you have any questions concerning the enclosed draft guidance, please contact me at 202-739-8081, or Russ Bell at 202-739-8087.

Sincerely

A handwritten signature in cursive script that reads "Anthony R. Pietrangelo".

Anthony R. Pietrangelo

Enclosures

c: Eileen McKenna

Resolution Status of NRC Nov. 3 Comments on Draft NEI 96-07, Rev. 1

<u>NRC Comment</u>	<u>Resolution</u>
<p>1. The second bullet in Figure 1 on page 4 should be modified to read, "Is the Activity Controlled by Another Regulation or that contains a Change Process?" The rule only allows exclusion when another regulation contains a change process. The ensuing reference to 10 CFR 50.65 also needs to be removed because it does not contain a change process. Conforming changes need to be made in section 4.1.2. Contemplating adding new loads on a safety bus without performing a 50.59 evaluation by considering it maintenance on a bus is not acceptable. Similarly, contemplating new reactor fuel without performing a 50.59 evaluation by considering it maintenance on the core is also not acceptable.</p>	<p>Changed top box of Fig. 1 to say "Proposed Activity" to encompass changes, tests, experiments and maintenance activities. No changes to 2nd decision block or reference to 10 CFR 50.65.</p> <p>Section 4.1.2 modified to clarify the limitations on what can be considered maintenance. Adding new loads on a safety bus or adopting a new fuel design would not be considered maintenance.</p>
<p>2. It would be helpful to clarify the definition of "design function" to explain how redundancy, diversity and defense-in-depth are captured (pg 11).</p>	<p>In Section 3.3, added "single failure" to the conditions under which design functions may be required to be performed.</p> <p>Added screening consideration to Section 4.2:1:</p> <ul style="list-style-type: none"> • Does the activity reduce the existing SSC redundancy, diversity or defense-in-depth?
<p>3. Item (c)(2) in section 4.3.2 is not clear. What is meant by increasing challenges such that performance is degraded below some point? It would be helpful for this to be clarified.</p>	<p>Section 4.3.2 (c)(2) truncated to read, "Increasing challenges to safety systems assumed to function in the safety analyses."</p>
<p>4. It would be helpful to clarify the definition of "essentially the same." The last sentence provides examples that may confuse users because it states "examples of departures that would be considered 'essentially the same.'" It is important to stress the essentially the same standard is applied to the results of a method not to the departure from a method itself. Although we would expect the results of these examples to be essentially the same the guidance may be interpreted to imply that for these types of changes the "essentially the same" standard does not need to be demonstrated on the results. It may be helpful to provide examples that apply the definition "within the margin of error for the type of analysis being performed....." For example a method is applied using a different computational platform (mainframe vs workstation) however when cases were run on the two systems the difference in the results was always less than 1%. This is less than the margin of error for this type of calculation and the results are essentially the same (pg. 13). Conforming changes also need to be made in section 4.3.8.2.</p>	<p>Last sentence of the Section 3.4 discussion of "essentially the same" modified to read, "Variation in results due to routine analysis sensitivities or calculational differences (e.g., rounding errors and use of different computational platforms) <u>would typically be within the analysis margin of error and thus considered "essentially the same."</u> The suggested example will be added to Section 4.3.8.2 as follows: For example, when a method is applied using a different computational platform (mainframe vs workstation), results of cases run on the two platforms differed by less than 1%, which is the margin of error for this type of calculation. Thus the results are essentially the same, and do not constitute a departure from a method that requires prior NRC approval.</p>

<p>5. The definition for “approved by NRC for the intended application” and the related guidance in section 4.3.8 need to be supported by additional guidance that indicates that a licensee should have established a program that conforms with the guidelines in GL 83-11, as well as further information to assist licensees with how they would determine that a particular application of a different method is technically appropriate for the intended application, and within the bounds of what has been found acceptable by NRC.</p>	<p>Section 4.3.8 modified to address the NRC comment. See in particular 4.3.8.2.</p>
<p>6. On the bottom of page 32 of the guidance, the sentence, “This is not to say that if plant-specific accident frequency calculation or PRA can be used to evaluate a proposed activity in a quantitative sense, it should not be used.” is unclear and is unnecessarily negative. Suggest deletion in favor of the clearer statement in the first complete paragraph on page 33.</p>	<p>Sentence modified to read, “However, a plant-specific accident frequency calculation or PRA may be used to evaluate a proposed activity in a quantitative sense. It should be emphasized....”</p>
<p>7. With regard to the increases in the likelihood of SSC malfunctions, a factor of 2 was proposed as the criterion. Although this criterion is reasonable (on a component level), the guidance needs to be clear at what level this criterion should be applied. For example, a change is being contemplated to a breaker associated with a diesel, should the factor of 2 increase be applied to the breaker, the diesel, the safety train, the onsite electrical power system, or the electrical power system? The guidance states that the evaluation be performed at the same level as the failure modes and effects analysis, however, this is not always clear. Please provide a clear discussion of the level at which the factor of 2 should be applied and provide a rationale for its use.</p>	<p>The following guidance was added to Section 4.3.2.b:</p> <p>The factor of two guideline should be applied based on the nature of the change, e.g., at the component level if the change affects a component or at the system train level if the change affects redundant trains of a system.</p>
<p>8. In the discussion of direct vs. indirect effects, it would be helpful to describe the extent to which indirect effects need to be considered. For example, a change being contemplated to a cooling water system. Should the effect of the change be evaluated on the cooling water system alone or should it extend to the systems the cooling water systems support? Please clarify the extent to which indirect effects need to be considered and provide the rationale.</p>	<p>NEI 96-07, R1, Section 4.2.1.1 says, “Another important consideration is that a change to non safety-related equipment not described in the UFSAR can indirectly affect the capability of SSCs described in the UFSAR to perform their intended design function(s). For example, increasing the heat load on a non safety-related heat exchanger such that the cooling system’s ability to cool safety-related equipment is compromised.</p> <p>Section 4.3.2 says, “Indirect effects also include the effects of proposed activities on the design functions of SSCs credited in the safety analyses. The safety analysis assumes certain design functions of SSCs in demonstrating the adequacy of design. Thus, certain design functions, while not specifically identified in the safety analysis, are credited in an indirect sense.”</p> <p>The guidance is considered adequate.</p>

<p>9. The discussion on screening changes to methods of evaluation in section 4.2.1.3 needs to be modified. The position that a method referenced, but not described, in the FSAR does not require a 50.59 evaluation is not acceptable. Similarly, if a change to an element of a method is being considered, and the method is described in the FSAR, a 50.59 evaluation needs to be performed, regardless of whether the element (of the method) is described in the FSAR. The position that a departure can be screened out without a 50.59 "provided the changes do not affect the UFSAR description" of the method is not acceptable, because the FSAR descriptions of the methods are generally not comprehensive descriptions of the methods. Additionally, the guidance should be clear that any changes to methods that are referenced by another method subject to 50.59 need to be changed in accordance with 50.59. For example, a topical for a non-LOCA transient analysis is referenced in the FSAR. The topical describes the use of a system transient code as the basis for the topical. Changes to the system code that affect the non-LOCA transient analysis need to be evaluated under 50.59. Conforming changes also need to be made in section 4.3.8.1.</p>	<p>2nd paragraph and 2nd bullet of Section 4.2.1.3 modified to read as follows:</p> <p>If the method used for performing specific analyses is identified or described in the UFSAR, that method is considered to be described in the UFSAR for purposes of 10 CFR 50.59. Methods of evaluation that may be discussed in references listed at the end of UFSAR sections or chapters are not considered to be described in the UFSAR unless the UFSAR states they were used for specific analyses within the scope of 10 CFR 50.59(c)(2)(viii). Changes to methods of evaluation described in the UFSAR do not require evaluation under 10 CFR 50.59 if the changes are within the constraints and limitations associated with use of the method, e.g., identified in a topical report and/or SER. The following examples illustrate the screening of changes to methods of evaluation:</p> <ul style="list-style-type: none"> • The UFSAR references the name of the computer code used for performing some particular type of analyses, with no further discussion of the methods employed within the code for performing those analyses. Changes to the computer code may be screened out provided that the changes are within the constraints and limitations identified in the associated topical report and SER. A change that goes beyond restrictions on the use of the method should be evaluated under 10 CFR 50.59(c)(2)(viii) to determine if prior NRC approval is required.
<p>10. The manner that redundancy, diversity, and separation are discussed in sections 4.3.2 and 4.3.6 for the different criteria in the rule should be clarified. It appears, through the examples that a reduction in the level of independence would not be permitted by one criterion but may be permitted by another. It may be helpful to provide an example how a reduction in the level of redundancy, diversity or independence would be treated by the guidance as a whole.</p>	<p>Section 4.3.2 has been modified to conform to Section 4.3.6.</p>
<p>11. The guidance on identifying the design basis limits in section 4.3.7 is not consistent with the rule SOC in SECY-99-130. The test of whether the "parameter is crucial to the barrier integrity," or if exceeding the limit "alone would be sufficient for the barriers integrity to be questioned" is too narrow and somewhat subjective. The SOC for the rule defines "design basis limit for a fission product barrier" as "any parameter used to measure the integrity of a barrier." This is a simpler definition that is much less subjective and should be used in the guidance. Additionally, the list of</p>	<p>The SOC for the rule defines "design basis limit for a fission product barrier" as "any parameter used to <u>determine</u> (not measure) the integrity of a barrier." Not all parameters associated with fission product barriers are design bases parameters for purposes of Section 4.3.7. For clarity the sentence containing "alone would be sufficient for the barriers integrity to be questioned," has been deleted. The guidance is consistent with the SOC.</p> <p>For example, exceeding limits for fuel burn-up (not a design bases parameter) would affect fuel internal gas pressure, which <u>is</u> a design bases</p>

example parameters should be expanded to include fuel rod linear heat rate, fuel burn-up limits, RCSection heat-up and cool-down limits, RCSection usage factors, and containment temperature to have a more complete set of parameters.

limit for the integrity of the fuel cladding. For similar reasoning, linear heat rate and RCS usage factor are likewise not design bases parameters. Because some licensees may consider limits on RCS heat-up and cool-down as design bases limits, these will be added to the table in Section 4.3.7 (with an asterisk indicating that these parameters are typically controlled by technical specifications limits). For clarification, the first bullet under "Identification of affected design basis limits for fission product barriers" has been revised as follows:

- **The parameter is fundamental to the barrier's integrity.** Design basis limits for fission product barriers establish the boundaries, or limits of the design bases as defined in 10 CFR 50.2. They are the limiting values for parameters that directly determine the performance of a fission product barrier. That is, design bases limits are fundamental to barrier integrity and may be thought of as the point at which confidence in the barrier begins to decrease.

For purposes of this evaluation, design bases parameters should be distinguished from other parameters that—while they may affect fission product barrier performance—are of secondary importance. For example, a change to fuel burn-up limits would be evaluated for its effect on clad strain to determine if it caused the limiting value for fuel internal gas pressure to be exceeded. Thus fuel internal gas pressure is a fundamental design bases limit for fuel cladding integrity, and fuel burn-up is a secondary/subordinate parameter/limit. Similarly, linear heat rate and RCS usage factor limits affect the fuel cladding and RCS boundary but are subordinate, respectively, to the design bases limits for fuel temperature and RCS stresses.

In the context of containment barrier integrity, containment temperature is not a design bases parameter. It is a function of containment pressure which is the parameter of principal interest with respect to retaining fission product materials. Containment temperature is significant to environmental qualification, which is considered elsewhere in the 10 CFR 50.59 evaluation.

12. The second bullet describing conditions not considered departures is not clear (pg 53) because terms like "fundamental assumptions" are not well understood, in all cases. Additionally, the description does not appear to be consistent with the rule definition of departure, because it implies that certain changes can be considered not departures, even if they are not NRC approved and not essentially the same (or conservative).

The bullet in question has been deleted.

<p>13. Section 4.3.3 on p. 38 describes in detail current dose guidance in Parts 50 and 100 and SRPs in terms of whole body and thyroid doses. A new final rule amending Part 50 for the voluntary use of alternative source terms (in terms of TEDE dose) is expected to be approved soon. It may be helpful to reference this rule and its provisions once it is issued.</p>	<p>Appropriate changes to the guidance will be considered based on the forthcoming changes to Part 50 concerning alternative source terms.</p>
<p>14. NEI 96-07 does not provide any specific guidance regarding application of 10 CFR 50.59 for the review of digital retrofits. A large effort was undertaken by the staff, EPRI, NEI, and the utilities to establish guidance (Generic Letter 95-02) for determining which digital retrofits could or could not be implemented without NRC review under the existing rule requirements. NEI 96-07 should provide detailed guidance that is both clear and unambiguous regarding digital retrofits (which ones can and cannot be retrofitted without NRC review). Examples would be helpful in this regard.</p>	<p>The following changes have been made to Section 4.3.6:</p> <p>Thus, for instance, if failures were previously postulated on a train level because the trains were independent, a proposed activity that introduces a <u>cross-tie or credible common mode failure (eg, as a result of an analog-to-digital upgrade) should</u> be evaluated further to see whether new outcomes have been introduced.</p> <p>The following example was also added:</p> <p>For example, if a feedwater control system is being upgraded from an analog to a digital system, new components may be added which could obviously fail for reasons other than the components in the original design. If, however, the end <u>result</u> of the component or subsystem failure is the same as, or is bounded by, the results of malfunctions currently described in the UFSAR (i.e. failure to maximum demand, failure to minimum demand, failure as-is, etc.) then this activity or change would not be creating a "malfunction with a different result".</p>
<p>15. The discussion provided in Section 4.2, "SCREENING", seems to indicate that all safety related digital retrofits and non-safety related digital retrofits that impact SSC's are controlled by the 10 CFR 50.59 process. This would include new technology such as digital/software that is not an existing part of a plant's design basis. This would mean that an analysis per 10 CFR 50.59 process is required. Is this the intent of the NEI guidance? If not, there should be more detailed guidance regarding the systems and their subsequent inclusion into the 50.59 screening process. Factors that would lead to this somewhat all-inclusive screening process would be the introduction of a need for the determination of software quality, the increased susceptibility to EMI/RFI, the change in systems response times and the change in system calibration procedures including possible set point and allowable value changes due to increased accuracies. Examples in this area would be helpful for the licensee to aid in its decision making process.</p>	<p>The intent of the guidance is that all safety related and non-safety related tests, experiments or changes (including digital retrofits) that affect SSC's are subject to 10 CFR 50.59 screening and, if necessary, evaluation.</p>

<p>16. 10 CFR 50.59 Criterion 2 addresses a minimal increase in the likelihood of occurrence of a malfunction. The NEI guidance document indicates that changes in design requirements affect the likelihood of a malfunction (design requirements could include software quality, EMI/RFI, and operability characteristics). Since a digital retrofit invalidates some of the analog design requirements/characteristics, this would appear to result (according to Section 4.3.2) in more than a minimal increase in the likelihood of malfunction. System reliability when reviewed along with the UFSAR FMEA for digital retrofits leads to questions as to what the quantifiable change in reliability would be since digital system reliability is extremely difficult to quantify or even estimate. A detailed writeup using several digital retrofit examples would be beneficial.</p>	<p>Design requirements for digital retrofits would be consistent with and would replace – not invalidate – those of the old analog I&C. We do not agree that such a change would automatically result in more than a minimal increase in the likelihood of malfunction. This would need to be evaluated. Like other types of changes, this evaluation may be largely qualitative in nature such that the difficulty in quantifying any change in reliability is not considered an obstacle to completing the 10 CFR 50.59 evaluation. No change in the guidance is considered necessary.</p>
<p>17. In sections 3.11 and 4.1.4 on procedures, it may be helpful to add a short discussion that explains why procedures for work control or for conduct of operations are not included (in contrast to procedures that concern individual system operation) to assist in the screening process.</p>	<p>Clarifications were made to Sections 3.11 and 4.1.4 to address the NRC comment as well as industry comments</p>
<p>18. Page 37: In this section, the guidance gives examples of when there is less than a minimal increase in the likelihood of occurrence of a malfunction of a SSC important to safety (i.e., when NRC review is not required). The guidance states, "(when) the change would not cause applicable design stresses to exceed their code allowables." This example could be misleading to the reader. In many cases, a component's functionality is established by vendors at a lower stress or deformation limit than those required by a code. For example, the ASME Boiler and Pressure Vessel Code establishes stress limits for piping, pumps, valves, etc. to ensure the pressure integrity of the component - not necessarily the functionality of the component. It is not unusual for a pump vendor to specify stress limits for its casing (that are much lower than ASME Code allowable stress limits) to ensure that the pump will not bind. Similarly, NSSSection vendors often specify lower stress limits or deformation limits for certain reactor internals that are below the Code allowables to ensure the functionality of the reactor internals (e.g., rod insertion) under design basis loading conditions.</p> <p>As stated, the document gives the impression that there is less than a minimal increase in the likelihood of occurrence of a malfunction of a SSC as long as design stresses remain within code allowables. The NEI document should acknowledge that requirements to ensure the functional capability of SSCs might be more restrictive than code allowables.</p>	<p>Ex. 2 in this section modified as follows:</p> <p>The change would not cause applicable design stresses to exceed their ASME Code allowables or other applicable design limit (if any) for stress, deformation, etc. For example, to ensure pump functionality, vendor-specified stress limits for a pump casing may be well below the ASME Code allowable.</p>

<p>19. Page 46: In NEI's table, NEI provides typical design basis limits. For the RCS boundary, NEI notes that "Stresses" (as well as clad temperature and clad oxidation) are "commonly controlled by 10 CFR 50.46 and/or a specific Technical Specification and therefore would not be subject to evaluation under this criterion." RCS boundary stresses are controlled under 10 CFR 50.55a, not 50.46 or Tech Specs.</p>	<p>The table note will be modified to say, "These parameters are commonly controlled by 10 CFR 50.55a, 10 CFR 50.46 and/or</p>
<p>20. As discussed in Section B.2 of the SOC for 10 CFR 50.59 (64 FR 53587), supplemental guidance or examples are needed for implementation specific to 10 CFR Part 54, the license renewal rule. As required by 10 CFR 54.21(d), summary descriptions of programs for managing the effects of aging and the evaluation of time-limited aging analyses (TLAAs) must be incorporated into the FSAR. As discussed in the SOC for license renewal, [60 FR 22482], by incorporating the descriptions into the FSAR, subsequent changes are controlled by §50.59. Guidance and examples should be added (either to 1.2, 3.6, 3.11, or 4.2.1), to discuss applicability of the 50.59 process to the summary descriptions of license renewal programs and TLAAs contained in the FSAR (as updated).</p>	<p>We have modified Sections 3.6 and 3.11 so that the first sentence under "Discussion" of the definitions of "facility/procedures as described in the UFSAR" reads as follows:</p> <p>The scope of information that is the focus of 10 CFR 50.59 is the information presented in the original FSAR to satisfy the requirements of 10 CFR 50.34(b), as updated per the requirements of 10 CFR 50.71(e), <u>and as supplemented pursuant to 10 CFR 54.21(d).</u></p> <p>This change underscores that changes affecting information contained in supplements to the UFSAR to support license renewal—like all other UFSAR information—is subject to 10 CFR 50.59, including screening and, if necessary, evaluation, to determine in prior NRC approval of the change is required. Additional guidance and examples on screening and evaluation of activities subject to 10 CFR 50.59 beyond that already presented in draft NEI 96-07, R1, is not considered necessary.</p>
<p>21. In section 4.1.3, the applicability guidance provides an example of FSAR changes that would not be subject to the 50.59 process, i.e., minor changes to drawings such as correcting mislabeled valves. It may be helpful to provide an example of what might be viewed as "a minor change to a drawing", but which would require further evaluation (either screening or 50.59 evaluation). For instance, consider a change to a standby lineup to reposition a valve in a safety system from the position noted on an FSAR drawing.</p>	<p>The draft guidance allows minor <i>corrections</i> to drawings. Changes would need to be screened and, if necessary, evaluated under 10 CFR 50.59. Corrections include resolution of inconsistencies within the UFSAR and correction of drawing information that is incidental—not material—to the UFSAR description related to the drawing.</p> <p>Example 5 in Section 4.2.1.2 addresses the change of a valve position indicated in the UFSAR.</p>

<p>22. In section 3.3, p.11, The definition of temporary change should be revised to include bypasses installed to support maintenance activities that are no longer "in progress". (This comment relates to the broader issue of when "indefinite out-for-maintenance" becomes a change).</p>	<p>Sections 3.3 and 4.1.2 have been revised. The revisions make clear that temporary changes are considered to be part of a maintenance activity provided they are removed at the conclusion of the activity</p>
<p>23. In section 3.7, p. 15, second paragraph, fourth sentence, revise to read "Therefore pending UFSAR revisions that have received final approval for incorporation..."</p>	<p>Sentence revised as suggested</p>
<p>24. It may be helpful to include a cross-reference in section 4.2.1 to the guidance on compensatory actions in section 4.4 (one can get there through the definition of change, in section 3.3, but a simpler reference is suggested).</p>	<p>The following will be added to Sections 4.2 and 4.3: Specific guidance for applying 10 CFR 50.59 screening (evaluation) to temporary changes proposed as compensatory measures for degraded non-conforming conditions is provided in Section 4.4.</p>