April 04, 2001

Mr. Anthony R. Pietrangelo, Director
Risk and Performance-Based Regulation
Nuclear Energy Institute
Suite 400
1776 I Street, NW
Washington, DC 20006-3708

SUBJECT: OBSERVATIONS ON NEI RIP 50 OPTION 2 IMPLEMENTATION GUIDANCE: NEI 00-04, "OPTION 2 IMPLEMENTATION GUIDELINE," AND NEI 00-02, "PROBABILISTIC RISK ASSESSMENT PEER REVIEW PROCESS GUIDELINE" (TAC NOS. MA8584 and MA8899)

Dear Mr. Pietrangelo:

This letter provides our observations regarding revision A2 of your draft guideline; NEI 00-04, "Option 2 Implementation Guideline," submitted to the staff for review by letter dated January 19, 2001. In addition, we are providing feedback on the peer review response information relating to NEI 00-02, "Probabilistic Risk Assessment Peer Review Process Guideline," provided by letter dated January 18, 2001. It is our understanding that you propose to exercise the draft guidelines as part of a pilot program to gain insights applicable to the risk-informed Part 50 Option 2 rulemaking effort. It is our view that the decisions discussed below, in conjunction with the comments provided in the enclosures, will enable licensees to make informed decisions and to go forward regarding participation in the Option 2 pilot plant effort.

Enclosure 1 to this letter describes the classification of our observations. Enclosure 2 discusses the comments grouped into topic areas as further noted below. Enclosure 3 provides comments on NEI 00-02.

Significant Observations and Supporting Staff Criteria

In order to make a determination regarding the nature of the comments to be provided on NEI 00-04, we made several key decisions which are summarized below and also discussed in Enclosure 2 within the context of the NEI 00-04 comments. These decisions reflect our current understanding of the issues and our current vision of the RIP50 Option 2 regulatory framework. The decisions give consideration to the preliminary views discussed in SECY-00-194,"Risk-Informing Special Treatment Requirements", dated September 7, 2000, stakeholder feedback provided in response to SECY-00-194 and during the February 2001 workshop on Option 2, and the lessons learned from the ongoing review of the South Texas exemption request.

Categorization

The RIP50 Option 2 regulatory approach relies upon robust categorization. Accordingly, most of our comments focus on this area. The quality of the probabilistic risk assessment (PRA) required for Option 2 applications is an important component of this approach. We intend to

develop a flexible regulatory framework for implementing Option 2. Examples of approaches licensees could use to categorize SSCs include (1) satisfying Appendix T, or (2) a limited staff review option using NEI 00-02 and NEI 00-04.

Long-Term Containment Integrity

An issue that developed during our review of the South Texas Project exemption request, as discussed at the February 2001 workshop, is the issue of long-term containment integrity, and whether it should be considered within the context of defense in depth. Core damage frequency (CDF) and large early release frequency (LERF) will remain the focus of the Option 2 framework; however, the integrated decision-making panel (IDP) should, as part of its effort to categorize structures, systems, and components (SSCs) based on safety significance, give explicit consideration to long term containment integrity within the context of defense in depth. Accordingly, NEI 00-04 should be revised to contain this guidance. Comment number 16 in Enclosure 2 discusses this issue in more detail.

Treatment of Risk-informed Safety Class 3 (RISC-3) SSCs

In SECY-99-256, the staff states that RISC-3 SSCs will need to receive sufficient regulatory treatment such that these SSCs are still expected to meet functional requirements, albeit at a reduced level of assurance. More recently, in SECY-00-194 the staff discussed its vision for Option 2 stating: “licensees will be required to maintain the functional capability of SSCs using existing or new programs. When functionality is not maintained, licensees will be required to take corrective actions to restore functionality. For RISC-2 SSCs, licensees would be required to control the reliability, availability, and capability of the SSCs consistent with the assumptions in the categorization process. For RISC-3 SSCs, licensees would be required to maintain the design functions of the SSCs at the conditions under which the intended functions are required to be performed as described in the updated FSAR. It is expected that minimal requirements would be established in the rule for this purpose. For both RISC-2 and RISC-3 SSCs, licensees would be required to describe in the updated FSAR how they will meet these requirements through measures and activities such as procurement control, monitoring, and corrective action.”

We believe that the Option 2 regulatory framework should contain high-level elements for treatment processes that, if effectively implemented, will maintain the design functions of RISC-3 SSCs (but with less assurance than obtained for RISC-1 SSCs). We do not plan to review the detailed procedures for implementing these high-level elements based on the low risk significance of the RISC-3 SSCs. In fact, we do not currently believe that the details for implementing these high level elements need to be part of the regulatory framework. This approach relies on a robust categorization process to determine the safety significance of each SSC with its placement in the appropriate RISC category. The staff is continuing its efforts to define the high-level treatment elements for RISC-3 SSCs that need to be specified as part of the regulatory framework. We plan to work with the industry and other interested stakeholders to gain insights on the industry’s approaches for maintaining RISC-3 functionality. We expect, for example, that the pilot effort will help to achieve a mutual understanding of what is needed to effectively implement the high-level treatment elements.

NEI 00-04 Terminology

We have concluded that the correct terminology to use in NEI 00-04 is "design function", the terminology utilized in the new 10 CFR 50.59. By design function, we mean specifically (as discussed in SECY-00-194) "design functions of the SSCs at the conditions under which the intended functions are required to be performed as described in the updated FSAR." Our approach couples the proposed 10 CFR 50.69 to the new 10 CFR 50.59, where facility changes are measured for their impact on design function. When design function is maintained, a proposed change does not affect design basis functional requirements. If a change is made that does not maintain design function, then 10 CFR 50.59 is the appropriate regulatory vehicle to determine whether the change can be made without prior NRC review. NEI should revise the NEI 00-04 language accordingly.

4-Box Diagram Construction and Usage

The staff's concern regarding the 4-box diagram (i.e., the diagram used to describe the various RISC categories and how SSCs can be categorized into "boxes") is whether "important to safety" SSCs can have some attribute that, if all treatment is removed, would be lost, which in turn causes a design function to not be maintained. The staff described a revised 4-box approach in SECY-00-194 to address this concern. After additional stakeholder input, the staff agrees that the original 4-box approach (with the division between safety-related and nonsafety-related) can be utilized for RIP50 Option 2. This conclusion is based on the concept that Option 2 is not changing the technical requirements for any SSCs including the "important to safety" equipment, and that these requirements would continue to apply even if the SSC is categorized as RISC-4. An Option 2 licensee who wished to change these technical requirements would be free to do so consistent with the criteria and requirements of 10 CFR 50.59

Selective Implementation

The staff's concern with selective implementation, by system, for RIP 50 Option 2 has been the perception that RIP50 Option 2 may not be implemented in a balanced manner. However, as the staff has further developed the conceptual approach for 10 CFR 50.69, we have recognized that a licensee that adopts 10 CFR 50.69 will be required to validate and maintain all the categorization process assumptions, including PRA assumptions. This requirement will exist even if the licensee implements 10 CFR 50.69 for only one component or system. Accordingly, Enclosure 2 contains a question to help the staff better understand how NEI envisions selective implementation will occur, given the need to meet the categorization validation and maintenance requirements anticipated for 10 CFR 50.69.

Prior Review and Approval

The staff intends to retain the "no prior review" alternative, and, therefore, plans to include Appendix T as part of this rulemaking. However, we also plan to modify the regulatory framework to allow Option 2 licensees to propose alternatives that would be subject to prior staff review and approval. One notable alternative could be NEI 00-04, which could be endorsed with a regulatory guide.

Change Control and Licensing Commitments

It is our objective to utilize the current change control mechanisms (10 CFR 50.59 and NEI 99-04) for RIP50 Option 2. Specifically, this means that we expect 10 CFR 50.59 will control changes to the 10 CFR 50.69 categorization and treatment processes, assuming that 10 CFR 50.59 will not allow changes that undermine those processes. Changes are expected to continue to comply with 10 CFR 50.69. We have provided a comment regarding how NEI plans to incorporate guidance into NEI 00-04 on the application of 10 CFR 50.59 to Option 2. We are considering whether the methodology criterion of 10 CFR 50.59 is applicable to this application, and if so, how to apply the criterion.

We have also concluded that NEI 00-04 should indicate that the current endorsed version of NEI 99-04 should be used for commitment management. Based on our current understanding, we do not believe a revision to NEI 99-04 to allow a wholesale replacement of existing RISC-3 SSC commitments with a single commitment, as proposed in the current version of NEI 00-04, would be acceptable. The staff's concerns include the potential to discard commitments that relate to technical requirements for RISC-3 SSCs and the potential to discard RISC-3 commitments affecting RISC-1 SSCs. The staff believes that some level of assessment of individual commitments is needed to ensure that these, or other adverse effects, are avoided when commitment changes are proposed. The staff remains open to ideas that could streamline commitment management, while addressing the aforementioned concerns.

Final Safety Analysis Report (FSAR) Description

Consistent with the precedent being established by our review of the South Texas Project exemption, and our preliminary position in SECY-00-194, we have concluded that NEI should provide guidance in NEI 00-04 on a FSAR description to support RIP50 Option 2. The FSAR description would provide a basis to apply 10 CFR 50.59 as a licensee evaluates potential changes to the RIP 50 Option 2 categorization and treatment processes.

Scope of Rules within Option 2

The staff seeks clarification from NEI on what industry believes should be the scope of special treatment rules for which 10 CFR 50.69 will offer an alternative. Specifically, we are requesting clarification on the following items:

1. Why 10 CFR 50.62 and 10 CFR 50.63 are included within the scope of regulations listed in NEI 00-04 when they do not appear to contain special treatment requirements. It is our view that any changes to implementing special treatment programs (i.e., those that are specified in regulatory guides and other guidance documents, but not explicitly specified in the regulations themselves) should be subject to commitment management, not rulemaking.

2. What are the special treatment requirements specified in 10 CFR 50.48 and 10 CFR Appendix R?

3. What is NEI's position on reporting requirements (e.g., whether 10 CFR 50.73 should be within the scope of RIP 50 Option 2)?

4. What is NEI's position on 10 CFR 50.55a (e.g., identify which portions are proposed to be part of Option 2, specifically ISI, IST, repair and replacement)?

Additionally, we have concluded that 10 CFR 50, Appendix A, General Design Criteria 2, 3, and 4 do not contain any special treatment requirements, and can now be removed from the scope of Option 2 rules.

NEI Comment Response

You did not provide explicit responses to the comments provided in the staff's September 26, 2000 letter, and instead elected to revise NEI 00-04 to reflect the our comments. Some of our issues were not addressed and it is difficult to identify how other topics have been addressed. Licensees contemplating participation in the pilot program could be left in an uncertain position, aware that NRC has concerns in certain areas, but unsure about how those issues are being addressed in the proposed industry guidance. Accordingly, we request an explicit response (or some other approach such as identifying within NEI 00-04 where a given comment is addressed) to each topic both for the September 26, 2000 comments, and for the comments contained herein to permit the staff and other stakeholders to more readily ascertain the status of each comment.

Future Activities

We expect to discuss the comments provided in this letter at the April 17, 2001 meeting, at which time we can discuss your schedule for responding to these observations. Your timely response to this letter will be of great value to our Option 2 rulemaking effort. Questions concerning this letter should be directed to either Tim Reed (301-415-1462) or Eileen McKenna (301-415-2189).

Sincerely

/RA/Signed by D. Matthews
David B. Matthews, Director
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

Enclosures: As stated

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David B. Matthews, Director
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Enclosure 1

CLASSIFICATION OF NRC OBSERVATIONS

Observations are classified in one of three categories. A “comment” is an issue which must be resolved in order for the NRC staff to endorse the guideline. If the issue is not resolved, it is expected the comment will be the basis for a regulatory position taking exception to the guideline. You should feel free to propose alternative solutions to our comments if you feel they adequately resolve the issue.

“Suggestions” are changes we believe can improve or clarify the guideline. Incorporation of these suggestions is not necessary for endorsement of the guideline. However, in some cases, we may conclude that our regulatory guidance address these items if we believe clarification is necessary. These clarifications will not be considered as “exceptions” to the guidance. Again, you should feel free to propose alternatives to address our suggestions.

“Editorial changes” are changes proposed to improve the readability of the guidance, and can be adopted or not as you see fit. We expect to propose additional editorial changes when the guidelines are closer to their final form.

Enclosure 2

COMMENTS ON NEI RIP50 OPTION 2 IMPLEMENTATION GUIDANCE

Categorization

The RIP50 Option 2 regulatory approach relies upon robust categorization. Accordingly, the majority of the staff's comments focus on this area.

1. In several places (e.g., first paragraph on page 6, first bullet on page 10, and the second to last paragraph on page 14) there is reference to the use of information that is of out-of-date, information from activities that have already been completed as part of a previous risk-informed categorization process, or from IPEs. In some cases, use of out-of-date information may adversely affect categorization results. When such information sources are used, potential limitations have to be considered and accounted for (e.g., by justifying that it does not affect the results).

2. In the second paragraph of page 17, reference is made to PRA cross-comparison studies. What is the role of cross-comparison studies in Option 2 applications?

3. In the first sentence of the third paragraph on page 17 it is not clear what is meant by "where applicable." There are other examples of this throughout the document, for example in the first paragraph on page 71 it is stated "where appropriate, RISC-3 SSC performance would be monitored against functional criteria set to provide assurance that the functions .... will be satisfied." Such wording should be clarified throughout the document.

4. On pages 17 (second paragraph) and 18 (last paragraph), it is stated that NEI 00-02 is one acceptable way to ensure PRA quality. What guides the acceptability of other methods? In neither Sections 2.4.1.2 nor 2.4.1.3 (pages 16-18) is reference made to the anticipated ASME PRA Standard, and how it could be applied. While the ASME PRA Standard has not yet been issued, NEI is aware of its status and familiar with the general character of the ASME Standard, and provisions for its potential use should be acknowledged.

5. In the second paragraph (following the bullets) on page 19, it seems appropriate to ask the PRA analysts to review the fire, seismic and shutdown PRA analyses to take into account the peer review (i.e., internal events) findings as well as to ensure that current information and data are incorporated. It is not clear what process the analyst will go through to carry out these items.

6. In the characterization of PRA quality (Section 2.4.1.3), the documentation of the peer review should also include the reviewers' assessment of which of the modeling approaches or assumptions have been significant in shaping the results, and why they are acceptable for the Option 2 categorization process. This includes addressing some of the grade 3 and 4 findings from the peer review. This issue is related to the performance of sensitivity analyses, the use of compensatory measures to meet certain requirements in NEI 00-02, and to the flexibility allowed in the subtier criteria of NEI 00-02.

7. If the title of Figure 2.4-1 is to remain as “Overall Safety Significance Process,” the endpoints of all paths should lead to the IDP for consideration of defense-in-depth, safety margins, etc. Otherwise, the figure would be more appropriately titled “Use of Risk Analyses for SSC Categorization” or similar. Also, from this figure, there are six different reasons why an SSC can be deferred to the IDP for deliberation. Is there a mechanism to relay to the IDP the reason(s) why they are deliberating on an SSC, i.e., how does the IDP know specifically what it has to focus on?

8. The IDP will be relied upon when a PRA or a screening analysis does not include the SSC (e.g., in the third and sixth paragraphs of page 24, and the third paragraph of page 25). What guidelines will the IDP use in these cases?

9. In the third from the last paragraph on page 25 and in Figure 2.4-2, the evaluation of components within the system is based on whether the component is “required” to support a safety function evaluated in the PRA. The term “required” could be misinterpreted such that a component would not be considered to be “required” if there were a redundant component that could perform the same function. The document should use the term “credited” instead of “required” to avoid this problem.

10. In several places in the document (e.g., the first paragraph on page 26, the second full paragraph on page 27, and Figure 2.4-3), reference is made to “candidate safety significant SSCs” for which safety significant attributes are to be identified. This implies that the SSCs themselves are not safety significant but that certain functions that they perform are safety significant. It is not clear how this relates back to the failure modes modeled in the PRA. For example, in the table on page 27 titled “Example Importance Summary”, none of the failure modes would exceed the F-V guideline by itself, so how would the safety significant attribute of this component be identified? Also, how are passive functions, e.g., preserving pressure boundary, taken into account?

11. In Footnote 4 on page 26, the conclusion that common cause failure (CCF) contributions not be included in the risk achievement worth (RAW) calculation is not supported by the argument in the footnote. The focus appears to be on the conditional probabilities, but the total CCF contribution is also a function of the independent failure probability. The sentence in the text following the footnote call-out could also apply to any single random failure parameter. RAW by its nature is unrealistic. However, CCF should be accounted for in the calculation of SSC importance. It’s not clear what calculational scheme is considered here.

12. In the first full paragraph on page 27, it is stated that the calculation of importance measures for the internal flooding initiator be performed both individually as well as cumulatively with the other internal event initiators. Does this thought also apply to the internal fires and the other external event initiators? Also, how are these two sets of importance results taken into account by the IDP?

13. In Table 2.4-1 there is an apparent mismatch between the requirements in NEI 00-04 and those in NEI 00-02. The tables suggest setting parameters to their 5^{th} and 95^{th} percentile values, yet there is no requirement in NEI-00-02, nor in the subtier criteria to develop such information.

14. In the sensitivity studies proposed in Table 2.4-1 (page 27), the staff believes that it is useful to determine the effects of making global changes to CCF probabilities and human error probabilities (HEPs). However, the purpose of the sensitivity studies to "increase (decrease) all random failure events to their 95th (5th) percentile values" is not as clear. The intent here should be clarified, and perhaps a more restrictive and meaningful set of sensitivity studies identified (e.g., sensitivity studies tied into the findings of the PRA peer review), recognizing that the important issue is that potentially safety-significant SSCs are not misclassified as low safety-significant.

15. On pages 27 - 28, it is not clear what the IDP would do with the results of sensitivity analyses that show that the SSC may be safety significant. Is this SSC automatically considered safety significant? This comment also applies to the last bullet on page 49.

16. In the discussion of defense-in-depth (pages 28 to 30), the concept of preserving the containment barrier should be introduced. This should include two aspects: preventing early releases and maintaining containment integrity in the long term. The last paragraph of page 29 addresses the first of these. Additional discussion is needed to address maintaining the integrity of the containment barrier in the long term, and how the categorization process will account for this. For example, additional criteria addressing "maintaining the containment barrier" should also be added to the list of challenges/criteria on page 30. Also, the focus on only "early" hydrogen burns should be modified to also include late containment failure from late hydrogen burn.

17. It is not clear what the decision guidelines are for the determination of defense in depth for large early releases. For example, in item 2 on page 11, the document states that review of the classification process would assess the level of D-I-D without credit for SSCs defined as LSS. The discussion on pages 29-30 should describe how this concept would be integrated into the D-I-D assessment for containment-related SSCs. Also, when answers to the questions in the bulleted lists on page 30 are "yes", is the SSC considered safety significant?

18. In Figure 2.4-3, (in the logic branch where importance measures do not include initiating event contribution), it is implied that SSCs that are safety significant because of their severe accident mitigative function can be classified as low safety significant. To be safety significant, these SSCs also have to directly cause a complicated initiating event. Is this a correct interpretation of the figure? It is not clear why the term "complicated" initiating event is introduced, or if it is necessary.

19. In the second paragraph of page 33, it is stated that "components are evaluated using standard importance measures for their mitigation capability and separately for the potential to initiate a fire." Are fire suppression systems considered in this mitigation capability? How is the role of an SSC as a fire barrier treated? Finally, why isn't the above statement also apply to the internal flooding initiator?

20. Please describe the role defense-in-depth plays when FIVE or when seismic margins or NUMARC 91-06 is used for SSC categorization? Are the criteria on page 30 for LERF D-I-D applicable also to fire, seismic, other external events, and shutdown?

21. In the third paragraph on page 37, it is stated that if the seismic CDF is less than 1% of the total, SSCs considered in the seismic PRA can be considered low safety significant from a seismic perspective. Should LERF and other containment integrity issues also be considered (since the seismic event could concurrently affect containment systems or containment bypass systems)?

22. The first bullet on page 46 states “It has a reasonable pedigree”. What does this mean?

23. In the first paragraph of page 49, Figure 2.4-12 was suggested as an example of information that could be communicated to the IDP. It was also stated that this was not a requirement. What is the minimum set of information that is required to be given to the IDP?

24. The first bullet on page 49 could be interpreted to imply that SSCs categorized as safety significant by the PRA can be down-graded by the IDP. If this is correct, what criteria will the IDP use to down-grade an SSC?

25. In the last paragraph of page 52, it is stated that the IDP could review the preliminary categorization either by individual SSC or by groups of SSCs. How would SSCs be grouped for this purpose?

26. In the discussion of defense-in-depth implications on page 54, is the figure on page 29 intended to provide guidelines for the second bullet? Does the discussion on page 30 provide guidelines for the first bullet? Are there guidelines for the third and fourth bullets? In addition, this discussion should also address the integrity of the containment barrier since it is important to consider not only early challenges as reflected by LERF, but longer-term integrity as reflected by late containment challenges.

27. It is not clear how the last three bullets on page 54 are to be applied. If the only intent is to tie the defense-in-depth deliberations back to the results of the PRA, then what is the purpose of the D-I-D deliberations?

28. The first rectangle in Figure 2.4-13 (i.e., review SSC functions) should also include LERF and containment heat removal considerations. It’s also not clear why candidate RISC-4 SSCs do not get the assessment for D-I-D and Safety Margins. In addition, the decision steps to review the critical attributes for RISC 1 and RISC 2 SSCs should also include the identification of these attributes, and the identification of appropriate treatment for these attributes. This topic is discussed in the text on the pages that follow, but should also be reflected in the table.

29. The discussion in the fourth paragraph on page 57 implies that sensitivity studies (bounding analyses) will be performed for all RISC-3 SSCs by increasing the reliability by a factor of 2 to 5. However, on Page 15 of the document, it is indicated that sensitivity studies will be performed for changes where some degradation in performance may be possible. Is it the intent that sensitivity studies be performed for all SSCs categorized as low safety significant (RISC-3) or just those that a licensee determines may experience a degradation in performance?

30. The discussion on the use of sensitivity studies (fourth paragraph on page 57) to evaluate the impact on CDF and LERF should be expanded to indicate that sensitivities to address long term integrity of the containment barrier might also be performed to show the importance of RISC-3 SSCs on the containment barrier, and to justify the categorization of SSCs impacting late containment failure.

31. In the third paragraph under Section 3.1 (page 60) it is stated that the beyond design bases functions are documented, as appropriate, in the design bases documents and the design record files. It's not clear what is meant by "as appropriate." Any credit assumed in the categorization process, especially when such credit is significant, should be documented as part of the categorization process itself.

32. In the third paragraph of page 28, a definition of the basis for a determination of low safety significance for an SSC should be required, not just "expected." [suggestion]

33. The thought captured in the last full paragraph on page 57 is good. It should appear earlier in the document where the RAW and FV criteria are introduced, to recognize that the criteria should be chosen to comport with the base case CDF/LERF (see Regulatory Guide 1.174, Appendix A). [suggestion]

Validation and Maintenance of Categorization Assumptions

34. In the third paragraph under Section 3.1 it is stated that if there is not reasonable assurance that the newly identified function could be satisfied, a licensee has two choices: determine the impact of not crediting the newly identified function, or take action to provide reasonable assurance that the newly identified safety function will be satisfied. How would a licensee go about determining the impact of not crediting the newly identified function or the impact of newly identified conditions ? What criteria are used to determine if removing the function is an acceptable approach? How would a licensee go about providing assurance that the newly identified function will be satisfied consistent with the categorization assumptions? How are these two approaches fed back into the categorization process and how are the effects, in terms of the relative ranking of the other components, addressed? {also applicable to second paragraph under Section 3.2}

35. In the fifth paragraph under Section 3.1 it is stated that a licensee's monitoring and corrective action program provides the necessary tools for assuring resolution of deficiencies and continuing assurance that safety-significant functions will be satisfied. It is not clear what kind of monitoring or corrective actions is proposed. The remainder of the paragraph suggests that the update to the PRA will provide additional insights into the effectiveness of a licensee's categorization and corrective action programs. Wouldn't this be true only for degradations that are detectable during normal operations? {also applicable to third paragraph on page 65 and the middle of page 71}

36. The first full paragraph on page 61 states that an evaluation or analysis of the change is performed to assess how it impacts the original design or operational bases. It is not clear what are "original design or operational bases". Are design bases the same as the 50.2 design bases? What are operational bases? Shouldn't these evaluations be

concerned with the effect of the change on any assumptions in the categorization process? If these assumptions are degraded as a result of the change, then an update to the categorization must be performed and any resulting changes in categorization must be implemented at the time of the change.

37. The second paragraph on page 64 states that for a majority of licensees, the only changes associated with the programs for RISC-2 SSCs are linked to a licensee's configuration control and NRC reporting programs. Its not clear what is intended by this statement. This statement is unnecessary and we suggest it be deleted. The document should instead identify the key attributes of what is required and allow each licensee to determine what changes are necessary.

38. The second full paragraph on page 64 states that for RISC-2 SSCs, a performance monitoring program plus existing controls and specifications are sufficient. What are the existing controls? What is necessary?

39. The second full paragraph on page 64 states that the maintenance rule monitoring is sufficient if the performance criteria were based on functional failures, not just on maintenance preventable functional failures. This should be strengthened to say that the functions assumed in the categorization are being monitored.

40. The third full paragraph on page 64 states that a licensee should review and, where appropriate, establish new performance thresholds for RISC-2 SSCs. How does a licensee determine when it is appropriate to do so?

41. The third full paragraph on page 64 and the 8 items that follow should be strengthened to say that licensees must perform the review and must consider all 8 items provided. The performance criteria for monitoring must be justified by this review and approved by the IDP. As currently written a licensee may or may not do this.

42. In many places the document suggests review of PRA assumptions. This should refer to categorization assumptions (which include the PRA, Seismic Margins if no Seismic PRA is available, FIVE if no fire PRA is available, Shutdown Configuration Management if no shutdown PRA is available, Defense in Depth, Safety Margins, ...) and not be limited to PRA assumptions.

43. The discussion related to reporting on page 66 should also apply to the safety significant "beyond design bases" functions of RISC-1 SSCs.

44. On page 4, 2nd paragraph, the guidance states that existing regulatory requirements will be maintained for nonsafety-related SSCs "absent compelling justification to change them." What sort of justification is envisioned? Does such justification include a 50.59 test and/or something similar? Related item, page 6, 3rd paragraph, how will attributes of RISC-2 SSCs within the scope of the regulations be preserved?

45. Page 64, 4th paragraph provides attributes of a review which should be conducted if a licensee's maintenance rule program addresses only maintenance-preventable functional failures. Why isn't this set of attributes applicable to all licensees? It is

conceivable that a licensee's 50.65 program could be doing something more than monitoring MPFFs, but may not be as comprehensive as this list.

46. Page 66, 1st full paragraph discusses RISC-2 SSCs with beyond design basis functions. Is it possible for an SSC to be RISC-2 without a beyond design basis function? Shouldn't changes affecting safety-significant beyond design basis capability be assessed to the same standard for both RISC-1 and RISC-2 SSCs? (Refer also to page 61 first paragraph)

Maintenance of RISC-3 Functionality

47. NEI 00-04 suggests that commercial programs can provide reasonable assurance of the functional capability of RISC-3 SSCs. Appendix A of NEI 00-04 provides examples of typical commercial program elements applicable to these SSCs, as well as RISC-2 and RISC-4 SSCs. Appendix A states that these typical program elements "are provided for information, not guidance." We believe that the Option 2 regulatory framework should contain high-level elements for treatment processes that, if effectively implemented, will maintain the design functions of RISC-3 SSCs (but with less assurance than obtained for RISC-1 SSCs). We do not plan to review the detailed procedures for implementing these high-level elements based on the low risk significance of the RISC-3 SSCs. In fact, we do not currently believe that the details for implementing these high level elements need to be part of the regulatory framework. The staff presently believes these elements are Design Control, Procurement, Installation, Maintenance, Inspection, Test and Surveillance, Corrective Action Program, Management and Oversight, and Configuration Control. NEI 00-04 should define these elements as being required for implementation of Option 2. This approach relies on a robust categorization process to determine the safety significance of each SSC with its placement in the appropriate RISC category. The staff is continuing its efforts to define the high-level treatment elements for RISC-3 SSCs that need to be specified as part of the regulatory framework. We plan to work with the industry and other interested stakeholders to gain insights on the industry's approaches for maintaining RISC-3 functionality. We expect, for example, that the pilot effort will help to achieve a mutual understanding of what is needed to effectively implement the high-level treatment elements.

    The staff does not believe that the detailed description of the implementation of the high-level treatment elements should be part of the regulatory framework. However, the staff expects to remain informed of the industry's approaches for maintaining RISC-3 functionality, and to work with the industry to gain insights as part of the pilot effort, providing feedback as appropriate.

48. The discussion on pages 72 and 73 is inconsistent and misleading. It is the staff's understanding that RISC-3 SSCs will still be subject to two ASME risk-informed code cases and therefore to 10 CFR 50.55a with regard to repair and replacement.

NEI 00-04 Terminology

49. The staff has concluded that the correct terminology to use in NEI 00-04 is "design function", the terminology utilized in the new 10 CFR50.59. By design function, the staff

means specifically (as discussed in SECY-00-194) “design functions of the SSCs at the conditions under which the intended functions are required to be performed as described in the updated FSAR.” The staff’s approach couples the proposed 10 CFR 50.69 to the new 10 CFR 50.59, where facility changes are measured for their impact on design function. When design function is maintained, a proposed change does not affect design basis functional requirements. If a change is made that does not maintain design function, then 10 CFR 50.59 is the appropriate regulatory vehicle to determine whether the change can be made without prior NRC review. NEI should revise the NEI 00-04 language accordingly.

4-Box Construction and Usage

50. The staff’s concern regarding the 4-box diagram (i.e., the diagram used to describe the various RISC categories and how SSCs can be categorized into “boxes”) is whether “important to safety” SSCs can have some attribute that, if all treatment is removed, would be lost, with the result that a design function may not be maintained. The staff described a revised 4-box approach in SECY-00-194 to address this concern. After additional stakeholder input, the staff agrees that the original 4-box approach can be utilized for RIP 50 Option 2. This conclusion is based on the concept that Option 2 is not changing the technical requirements for any SSCs including the “important to safety” equipment, and that these requirements would continue to apply even if the SSC is categorized as RISC-4. An Option 2 licensee who wished to change these technical requirements would be free to do so consistent with the criteria and requirements of 10 CFR 50.59

51. On page 53, under review of safety significant SSCs (RISC-1 & -2) it is stated that for RISC-2 components, “the IDP review will focus on attributes which were identified as important to the core damage prevention and mitigation functions of the SSC since these SSCs have no safety design basis.” Shouldn’t the IDP review the aspects of these SSCs that make them important to safety (ITS) also ? Also, on page 55 related to IDP categorization of RISC-4 there is no mention of ITS functions.

52. On page 4, last paragraph, and Figure 2.4-2 the text indicates that the default pathway for SSCs that are “important to safety”, “augmented quality”, or whose failure could affect the function of safety related SSCs, is into RISC-2 rather than RISC-4. However, this mapping is not reflected in Figure 2.4-2 (and corresponding figures for other risk contributors), or in the related discussions of these figures. (The figures show these SSCs as being mapped into RISC-4, without questioning whether the SSCs are “important to safety” and whether there are reasons why the SSCs are not safety-significant.)

53. The last paragraph on page 2 indicates that “regulatory requirements are applied for all categories except RISC-4.” We suggest that the guidance should say that regulatory treatment requirements are not applicable to RISC-4.

Selective Implementation

54. The staff's concern with selective implementation by system for RIP50 Option 2 has been the perception that RIP50 Option 2 may not be implemented in a balanced manner. However, as the staff has further developed the conceptual approach for 10 CFR 50.69, we have recognized that a licensee that adopts 10 CFR 50.69 will be required to validate and maintain all the categorization process assumptions, including PRA assumptions. This requirement will exist even if the licensee implements 10 CFR 50.69 for only one component or system. Accordingly, please describe how you propose to selectively implement Option 2 on a system basis, given the need to meet the categorization validation and maintenance requirements of 10 CFR 50.69.

Prior Review and Approval

55. The staff intends to retain the "no prior review" alternative, and, therefore, plans to include Appendix T as part of this rulemaking. However, we also plan to modify the regulatory framework to allow Option 2 licensees to propose alternatives that would be subject to prior staff review and approval. One notable alternative could be NEI 00-04, which could be endorsed with a regulatory guide. The NEI guidance should be revised to reflect this type of regulatory framework.

56. The guideline should address the regulatory mechanism NEI believes should be used as the means for NRC approval.

Change Control and Licensing Commitments

57. It is the staff's objective to utilize the current change control mechanisms (10 CFR 50.59 and NEI 99-04) for RIP50 Option 2. Specifically, this means that the staff expects 10 CFR 50.59 will control changes to the 10 CFR 50.69 categorization and treatment processes, assuming that 10 CFR 50.59 will not allow changes that undermine those processes. Changes are expected to continue to comply with 10 CFR 50.69. The staff is considering whether the methodology criterion of 10 CFR 50.59 is applicable to this application, and if so, how to apply the criterion. In this regard, does NEI plan to incorporate guidance into NEI 00-04 on the application of 10 CFR 50.59 to 50.69 (to control changes to the categorization and treatment processes) ?

58. We have also concluded that NEI 00-04 should indicate that the current endorsed version of NEI 99-04 should be used for commitment management. Based on our current understanding, we do not believe a revision to NEI 99-04 to allow a wholesale replacement of existing RISC-3 SSC commitments with a single commitment, as proposed in the current version of NEI 00-04, would be acceptable. The staff's concerns include the potential to discard commitments that relate to technical requirements for RISC-3 SSCs and the potential to discard RISC-3 commitments affecting RISC-1 SSCs. The staff believes that some level of assessment of individual commitments is needed to ensure that these, or other adverse effects, are avoided when commitment changes are proposed. The staff remains open to ideas that could streamline commitment management, while addressing the aforementioned concerns. NEI 00-04 should be revised to reflect this comment.

59. On page 61, 2nd full paragraph, the guidance states that "if the determination or licensee management concludes there is insufficient assurance that the 'beyond design basis' safety function would be satisfied following the implementation of a change, a licensee assesses the change against the minimal increase in risk standard defined in §50.59." Why isn't a change assessed against that standard regardless? Does 50.59 provide meaningful control to assure beyond design basis performance is not excessively degraded?

FSAR Description

60. Consistent with the precedent being established by our review of the South Texas Project exemption, and our preliminary position in SECY-00-194, we have concluded that NEI should provide guidance in NEI 00-04 on a FSAR description to support RIP50 Option 2. The FSAR description would provide a basis to apply 10 CFR 50.59 as a licensee evaluates potential changes to the RIP 50 Option 2 categorization and treatment processes.

Scope of Rules Within Option 2

61. The staff seeks clarification from NEI on what industry believes should be the scope of special treatment rules for which 10 CFR 50.69 will offer an alternative. Specifically, we are requesting clarification on the following items:

    1. Why 10 CFR 50.62 and 10 CFR 50.63 are included within the scope of regulations listed in NEI 00-04 when they do not appear to contain special treatment requirements. It is our view that any changes to implementing special treatment programs (i.e., those that are specified in regulatory guides and other guidance documents, but not explicitly specified in the regulations themselves) should be subject to commitment management, not rulemaking.

    2. What are the special treatment requirements specified in 10 CFR 50.48 and 10 CFR Appendix R?

    3. What is NEI's position on reporting requirements (e.g., whether 10 CFR 50.73 should be within the scope of RIP 50 Option 2)?

    4. What is NEI's position on 10 CFR 50.55a (e.g., identify which portions are proposed as part of Option 2, specifically ISI, IST, repair and replacement)

Additionally, we have concluded that 10 CFR 50, Appendix A, General Design Criteria 2, 3, and 4 do not contain any special treatment requirements, and can now be removed from the scope of Option 2 rules.

Editorial Comments

62. On page 15, last paragraph, the document states that "one of the guiding principles is that changes in treatment should not degrade performance for RISC3 SSCs, and RISC2

SSCs would be expected to maintain or improve in performance...". The latter part of the statement is not included as a guiding principle and should be added.

63. On page 1, Section 1., first paragraph, it is stated that there was no consideration of the probability of occurrence of the design basis accidents. A basic principle that was originally applied to plant design was that the most frequent occurrences yield little or no adverse consequences, and that the most improbable extreme situations, having the potential for the greatest adverse consequences to the public should have a low probability of occurrence. The acceptance criteria used in the analysis of the various categories of events were set accordingly.

64. It is not clear what is meant by the first two sentences in Item 2 under the second bullet on page 11. Perhaps the guidance should be revised to indicate that the current design basis is not changed and defense in depth is being maintained.

65. In the middle of page 57 it is stated that sensitivity studies should be realistic. Later it is stated that they are bounding. These statements are conflicting. Consideration should be given to deleting them.

66. The second sentence under 3.1 which indicates that there is no change to the regulatory treatment for these safety-related, safety significant SSCs is not necessary and may be misleading. In fact there may be some changes in treatment (e.g., validation of assumptions in categorization).

67. In the fourth paragraph under Section 3.1 it is stated that these newly credited functions provide additional safety assurance beyond the current acceptable levels of safety. This should say that maintaining these functions provides additional assurance that the current level of safety is maintained. It would also be appropriate to say that these functions go beyond those required by the deterministic licensing basis of the plant. New plant and regulatory focus on these significant functions will serve to enhance personnel awareness/knowledge of the functions that significantly affect safety and will therefore result in a better focus on safety. This also applies to the second paragraph under Section 3.2.

68. The last sentence in the first paragraph on page 61, related to a risk-informed 10 CFR 50.59, should be deleted. We currently have no proposal to make changes to section 50.59. {also applicable to first full paragraph on page 66}

69. On page 18, 1st paragraph of section 2.4.1.3, the paragraph does not appear to add value to the document. We suggest that it be deleted.

70. The discussions of system classifications, such as those for RISC-2 starting on page 66 can be misleading. A system may have components that map into any RISC category. It can be confusing to imply that all of the instrument air system is RISC-2, for example. Similarly, a high pressure safety injection system can have individual pieces in all the categories.

71. In the next to last paragraph on page 54, the statement "If any of the above conditions are true" should be changed to "If any of the above conditions are not met."

Comments on NEI 00-02, "Probabilistic Risk Assessment Peer Review Process Guideline"

Summary

NEI 00-02 provides guidance for a formalized PRA review process and, as such, it provides some level of consistency and objectivity to the review. The staff believes that the peer review process can be of value in helping licensees understand the strengths and weaknesses of their PRAs and that the grading of elements provides a characterization of a PRA that can be easily communicated to the licensee and other stakeholders. The staff believes that the use of NEI 00-02 together with the ASME PRA Standards (as endorsed by the staff) as criteria, and with Appendix T to guide the use of PRA results in the categorization process could lead to an Option 2 application requiring no prior staff review and approval. However, if NEI 00-02 is used with the sub-tier criteria as transmitted to the NRC in NEI's letter of January 18th, 2001, some prior staff review of the PRA will be required for Option 2 submittals. The focus of the NRC review will be in areas where the staff believes that there are insufficient or unclear acceptance criteria for PRA subelements that could impact Option 2 categorization. Finally, to fully take advantage of the PRA peer review process, the staff believes that guidance in NEI 00-04 has to better address and account for review findings from the NEI 00-02 process.

Discussion

The Option 2 categorization process can be compatible with a range of PRAs that vary in degree of conservatism and plant-specificity. In general, a less rigorous PRA would justify fewer SSCs being put in the low safety significance category (RISC-3 or RISC-4). The desired result is that there is confidence that SSCs that are categorized as RISC-3 or RISC-4 are of low safety significance. In principle it does not matter whether the elements of the PRA are judged to be grade 2, 3, or 4 (in the NEI 00-02 grading scheme) as long as it is clear what the implications are during the categorization of SSCs.

The process to demonstrate the low safety significance of SSCs is provided in Appendix T and also in NEI-00-04, and the objective of the NRC review of NEI-00-02 is to understand how it can help provide confidence in the Appendix T or NEI-00-04 process. In terms of the PRA used for Option 2, the Staff has to be convinced of the following:

- the PRA is capable of supporting a categorization of SSCs according to risk significance, i.e., it has the appropriate level of detail in the model to represent the impact of the target SSCs on risk. This does not mean that the SSCs have to be explicit in the model, though the system safety function they support must be included explicitly, or there must be a clear recognition of the function being inherently reliable (and the basis for this reliability).

- the PRA model logic is coherent (i.e., interfaces between tasks are correctly handled) and represents the design and operational practices of the plant.

- the underlying assumptions and models used are appropriate (realistic or conservative with respect to the application)

The first issue, establishing the cause-effect relationships, is discussed to a large extent in documents such as SRP Chapter 19 or the EPRI PSA Applications Guide (EPRI TR-105396). Since NEI 00-02 does not specifically address this issue, guidance provided in Appendix T and NEI 00-04 has to deal with this subject.

The second issue, assuring a coherent PRA logic model, is one which the PRA Standards documents and NEI 00-02 are designed to address. One of the goals of the peer review is to provide an assessment of how well the process for performing a PRA has been carried out. When a licensee uses the NEI-00-02 process, the end result should be a peer review that judges whether certain PRA elements meet an implied standard and identifies those elements that do not. Such a peer review will help focus the licensee's IDP deliberations and NRC review.

The third issue, whether assumptions and models used are acceptable for the application, is an essential part for Option 2 decision-making process. It is not the purpose of NEI 00-02 to provide guidance on what assumptions and models are acceptable for a specific application, therefore, Appendix T and NEI 00-04 will have to address this issue. However, the staff believes that the peer review should identify and document those aspects of the PRA, (e.g., assumptions, models, degree of approximation) that have a significant impact on the PRA results.

Comments on NEI 00-02 and the Associated Subtier Criteria

With the above discussion in mind (i.e., staff expectations of the NEI 00-02 PRA peer review process, and how the process will be used in conjunction with NEI 00-04), general comments on NEI 00-02 are provided below. These comments are based on the review of the PRA peer review guidelines found in NEI 00-02 (submitted to the NRC in April 24, 2000), and responses to the staff's RAIs and the revised "subtier criteria" submitted to the NRC in January 18, 2001.

In general, the staff believes that NEI 00-02 provides a process for the peer review of PRAs and that this review will be useful in the Option 2 categorization process. NEI 00-02 and its subtier criteria have many elements of the draft ASME PRA standards, and the peer review process can be of value in helping licensees understand the strengths and weaknesses of their PRAs. However, we believe that there are some subtier criteria that are not sufficiently clear or sufficiently specific to provide a third party with confidence that the criteria are met. We are also unsure on how certain information from the peer review process (e.g., PRA conservatisms and compensatory actions that could affect the conclusions) will be communicated to the Option 2 categorization process. These issues are discussed more in detail below.

Criteria not sufficiently clear to allow uniform implementation

Although NEI states that the results from the PRA review process have been shown to be consistent and reproducible by the peer review teams, it is nonetheless important to the NRC and other stakeholders that the process itself is clear and understandable. That is dependent on subtier criteria which are defined in a manner that provides an unambiguous understanding of what the assigned subelement grades mean.

We believe that there should be minimum subtier criteria for all subelements and all grades that clearly differentiate between acceptable and unacceptable subelements and among the different grades. In our review of the NEI subtier criteria, we found that there are several subelements in which no subtier criteria are specified for a Grade 2 and, in three cases, for a Grade 3. The staff understands that, in many of these instances, requirements for a subelement are beyond the scope of that grade, however, in other cases there should be minimum requirements even for Grade 2. (For example, the subtier criterial for subelement AS-13 implies no time phased evaluation requirements for Grade 2. The staff believes that, even for Grade 2, there should a recognition of the impact of such things as battery life and room cooling time on the development of accident sequences. If this aspect of time phasing is not taken into account, there could be a non-conservative bias in the results.)

Although the use of the word "may" in the subtier criteria has been reduced in the revised NEI submittal, there are still several places where its use allows for a broad interpretation by the peer reviewers, and the basis for this interpretation may not be made apparent to decision-makers during the application of the PRA results. Again using subelement AS-13 as example, the requirement for Grade 3 is that the list of time phased events "may be included in a realistic assessment ..." Understanding how these events impact the development of important accident sequences and their subsequent quantification is important for Option 2 applications. After examining the issues included in the list and determining that they have no significant impact on results, one could then choose to not explicitly incorporate them into the PRA. This would provide flexibility in modeling while at the same time ensuring that results from the analysis are sufficiently realistic to support their intended use. Proper documentation by the peer reviewers as to why these events are unimportant would be of great benefit to decision-makers in Option 2 applications.

It also appears that in many cases, the difference between Grade 3 and Grade 4 requirements is the use of "should" vs. "shall". The use of the word "should" in the criteria can lead to situations where peer reviewers apply different subjective interpretations of the requirements. The grading of subelements for different PRAs could be inconsistent because of this approach. This conclusion is further supported in that different peer reviewers are used to review different PRAs.

The use of terms that are not clearly defined can also lead to non-uniform implementation of the subtier criteria. Examples include the use of the word "influence" with regard to CDF or LERF, the word "critical" when identifying systems that need to be modeled, and the terms "involve" and "reasonable." The interpretation of these terms is left up to the individual peer reviewer. Without specific criteria, it would be difficult for the NRC or another third party to judge the adequacy of subelements that use such terms.

Finally, it is not clear to the staff that certain subtier criteria are adequate for Option 2 applications. Some examples include:

> i) IE-14, where criteria for interfacing systems LOCA should include an identification of all significant potential pathways. This would be useful input to the IDP even if the ISLOCA frequencies were argued to be low.

ii) IE-6, where the treatment of initiators that affect multiple units should include consideration of reliance on cross-ties; the need for shared systems to be parsed among the units; and the impact of support state initiators that trip both units.

iii) HR-9, where the process for identifying human errors must include the examination of a plant's procedures. (Note: HR-9 suggests using other PRAs to identify important post-initiator human errors for Grade 3, whereas HR-10 suggests use plant procedures and plant-specific operating experience to identify and quantify HEPs.)

iv) Treatment of Uncertainty: One of the requirements of Reg Guide 1.174 is that the sources of uncertainty be identified and their impact on the results understood. There is no requirement, even for Grade 4, to assess the uncertainty except by comparison with a PRA for which a full uncertainty analysis has been performed. There should be an identification of sources of uncertainty and an assessment of their impact on results, although this assessment may not necessarily be quantitative.

Documentation of relevant findings to be communicated to IDP

An important aspect of a peer review process is the documentation of its findings. Documentation should include findings of how the PRA subelements compare to an implied standard or benchmark, and where there are differences with the standard or benchmark, a description of these differences. However, it does not appear that the NEI 00-02 process requires documentation of the basis for assigning a grade 3 to a PRA subelement (a Grade 3 has been designated as the most appropriate grade for Option 2 applications). This could limit the usefulness of the peer review in cases where the subtier criteria are not clear (as discussed previously), or in cases where compensatory measures or conservatisms can be used to show compliance with the subtier criteria.

The NEI PRA Peer Review process allows for the use of compensating measures when a PRA subelement does not meet the criteria for a particular grade. The grading of a PRA element should be based on minimum criteria to achieve a certain grade. If compensating measures are identified, these measures should be evaluated for each application and not just for the base PRA. Furthermore, the criteria for accepting the compensating measures should also be a function of the application. The peer review team can identify existing compensating measures, but the acceptability of the compensating measures should be evaluated for each application. For Option 2 applications, the IDP should address whether the SSC categorization would likely change due to the compensating measure. Therefore, documentation of such measures is important.

Another area where documentation of peer review findings is useful is when conservative modeling or assumptions are allowed by the subtier criteria. For example, if a PRA does not credit systems such as CRD, main feedwater, or the PCS as mitigation systems, the results in terms of CDF or LERF would be conservative, however, this could also result in incorrect ranking of SSCs.

NRC Review of Option 2 Submittals Which Utilize the NEI 00-02 PRA Peer Review Process

When Option 2 applications are submitted to the NRC, and if the NEI 00-02 process is used to show that the PRA is of sufficient quality for the application, some prior staff review of the PRA will be required. The focus of the NRC review will be in areas where the staff believes that there are insufficient or unclear acceptance criteria for PRA subelements that could impact Option 2 categorization. Guidance for the NRC review will be dependent on the Option 2 implementation guidance provided in NEI 00-04, and will take advantage of lessons-learned from pilot plant implementation of the NEI 00-02 and NEI 00-04 processes.