

April 12, 2005

Mr. Biff Bradley  
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1776 I Street, NW  
Washington, DC 20006-3708

Mr. Michael P. Gallagher  
Director, Licensing & Regulatory Affairs  
Exelon Nuclear  
200 Exelon Way  
Kennett Square, PA 19348

Dear Mr. Bradley and Mr. Gallagher:

The Nuclear Regulatory Commission (NRC) staff is conducting its review of Risk Management Technical Specifications (RMTS) Initiative 5b, Surveillance Frequency Control Program, which includes the Limerick license amendment request (LAR) of June 11, 2004, and the Nuclear Energy Institute (NEI) proposed process methodology document NEI 04-10. Enclosed are staff comments and requests for additional information (RAIs) on the Limerick LAR (Enclosure 1), and on the methodology document NEI 04-10 (Enclosure 2). Additional comments will follow in May 2005. These initial comments are provided in the interest of an efficient and timely resolution of issues.

We are prepared to meet with you to further discuss these comments and RAIs. Please contact me at (301) 415-1187 or e-mail [trt@nrc.gov](mailto:trt@nrc.gov) if you have any questions or need further information on these proposed changes.

Sincerely,

*/RA/*

T. R. Tjader, Senior Reactor Engineer  
Technical Specifications Section  
Reactor Operations Branch  
Division of Inspection Program Management  
Office of Nuclear Reactor Regulation

Enclosures: As stated

cc: See attached page

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Mr. Bradley and Mr. Gallagher

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REQUEST FOR ADDITIONAL INFORMATION ON  
LIMERICK'S LICENSE AMENDMENT REQUEST  
TO RELOCATE SURVEILLANCE TESTING INTERVALS  
TO A LICENSEE-CONTROLLED PROGRAM  
ACCORDING TO RISK-INFORMED INITIATIVE 5B  
(TAC #MC3567 and #MC3568)

1. An important element of the proposed risk-informed Surveillance Test Interval (STI) revision process is the categorization of structures, systems and components (SSCs) into high safety significance (HSS) and low safety significance (LSS). It is not clear whether Limerick proposes to use its Maintenance Rule SSC categorization or the categorization guidance developed for 10 CFR 50.69 (NEI-00-04) or a combination of both. For example, on page 4 of Attachment 4 it is stated: *"Since the LGS Maintenance Rule Expert Panel has already classified this system as risk significant, compliance with NEI 00-04 is achieved. The MRule HSS classification is retained as permitted by the Initiative 5b methodology."* From the review of the Initiative 5b methodology, the staff understands that the Maintenance Rule classification will be retained only for SSCs classified as HSS. Please clarify.
2. It is stated (page 1 of Attachment 1): *"...changes will be evaluated in accordance with the licensee-controlled program, and the STIs may be revised, as appropriate, based on the evaluation results without prior NRC approval."* This statement may be interpreted to imply that the NRC approved methodology for changing surveillance testing intervals may be changed by the licensees, which is not the intent of Initiative 5b. Therefore, this statement needs to be reworded to clarify that STI changes will be evaluated in accordance with the NRC approved process and methodology.
3. It is stated (page 1 of Attachment 1): *"various TS surveillance requirements, including in some cases their associated STIs, were established based on commitments to Regulatory Guides, or based on implementation of NRC-approved Licensing Topical Reports. Within the licensee-controlled program, the surveillance requirements themselves will not be changed.....; however, associated STIs may be modified in accordance with the licensee-controlled program."* The staff agrees that licensees should consider the intent of commitments and evaluate the impact of any changes in commitments on overall plant safety in accordance with the NRC approved process. However, no guidance is included into the current version of the proposed "Methodology for Implementing a Surveillance Frequency Control Program" to ensure that the impact of changing commitments will be fully captured. Such guidance is needed because licensee commitments are made to address a variety of deterministic and probabilistic issues, such as defense-in-depth, safety margins, uncertainties in PRA assumptions and lack of detailed modeling or analysis. Please discuss.
4. It is stated (page 2 of Attachment 4): *"...the cumulative impact of all risk-informed STI revisions on all PRAs (i.e., internal events, external events and shutdown) is compared to the risk acceptance criteria in Regulatory Guide 1.174."* According to this statement CDF and LERF increases will be assessed (from both internal and external events at power

and during shutdown operation) for all STI changes (i.e., STI changes associated with both HSS and LSS SSCs). Please verify. The staff believes this statement must be included in the proposed "Methodology for Implementing a Surveillance Frequency Control Program."

5. It is stated (page 2 of Attachment 4): *"For those cases where the STI cannot be modeled in the PRA, a bounding analysis is performed to provide some indication of the impact on the PRA results. Bounding analyses are either quantitative carried out with available PRA models or qualitative using deterministic considerations."* Please explain how the results of bounding analyses indicating a significant impact on the PRA results will be incorporated in the decision-making process. Will the results of bounding analyses be combined with the results of "best estimate" analyses? Also, please explain how qualitative analyses using deterministic considerations will be considered in the decision-making process.
6. The criteria used for selecting examples of candidate STI extensions are listed on page 3 of Attachment 4. It is stated: *"The selection of STI candidates in these categories was intended to provide the opportunity to exercise all possible legs of the risk-informed methodology."* The staff agrees with the stated goal of exercising the risk-informed methodology. However, a review of the selected examples indicates that such a goal was not achieved. None of these examples go through the important steps of quantifying the risk impact associated with the proposed STI extension, such as Step 18 (Evaluate Cumulative Effect on CDF and LERF), Step 16 (Perform Bounding Risk Analysis) and Step 21 (Perform Sensitivity Studies). Please provide one or more examples that exercise these important steps. Carefully selected examples could provide helpful insights that would help improve the proposed "Methodology for Implementing a Surveillance Frequency Control Program." Since these steps focus on the quantitative aspects of the methodology, IDP participation may not be necessary. Please discuss.
7. Example STI#1 (Control Rod Drive Exercise Test) is categorized as HSS but no additional performance monitoring is proposed above what is required by the Maintenance Rule (i.e., to monitor the number of unplanned inoperable rods occurring in 24-month periods). Also, it is concluded that no phased implementation is necessary. Please explain how the basis for such a conclusion supports the assumption made in the risk analysis that no new common cause failure mechanisms, in addition to the failure of the mechanical portion of the reactor protection system, are likely due to the STI extension.
8. A major objective of the pilot application of Initiative 5b at Limerick is to provide feedback input to the methodology document (NEI-04-10). Please list important insights or lessons learned from this pilot application that have or should have been included in the methodology document.
9. The staff expects the final methodology document (NEI-04-10) to include guidance on acceptable ways of integrating the impact of external events (e.g., internal fires, internal floods and seismic) and events occurring during plant shutdown, in the decision-making process. The staff also expects the final methodology document to include minimum quality expectations of risk assessments for external events and shutdown operation. Attributes for available information, approaches and tools (e.g., screening analyses, approximate event trees and risk insights) should be identified and discussed. Please

discuss Limerick's capability to integrate safely the impact of external events and shutdown operation in the decision-making process. Since this issue has not been finalized yet in the methodology document, Limerick can provide useful input to this document. The staff expects Limerick to demonstrate its capability to integrate safely the impact of external events and shutdown operation in the decision-making process in accordance with the guidance that will be included in an NRC approved final methodology document.

10. A precondition for implementing Initiative 5b by a licensee is to demonstrate the technical adequacy of the base PRA model that will be used to assess risk changes associated with STI extensions. Limerick states (page 3 of Attachment 5) that the technical adequacy of their base PRA model is, in general, based on Capability Category II of the ASME PRA Standard (endorsed by RG 1.200) for all ASME Supporting Requirements (SRs). On page 3 of Attachment 5 it is also stated that in cases where SRs are identified as less than Capability Category II, the PRA technical adequacy for the application is shown to have little or no impact on the calculated results and the decision making. It is stated that the impact assessment is addressed by one or more of the following techniques: (1) model change, (2) sensitivity calculations, or (3) bounding risk-informed arguments. The staff agrees that this process is consistent with RG 1.200. However, this process was implemented only for the six example STI assessments, performed so far, which do not go through the important steps of quantifying the risk impact associated with the proposed STI extension. Thus, the objective of demonstrating PRA technical adequacy for Initiative 5b in cases where SRs are identified as less than Capability Category II was not completely achieved. Please discuss actions that would provide additional confidence in Limerick's PRA technical adequacy to support Initiative 5b. Actions that the staff believe would provide such confidence are listed below.
  - Perform additional risk assessments for carefully selected STI extension examples (as discussed also in RAI #6) to provide helpful insights regarding SRs that are identified as less than Capability Category II. In these examples, a broader scope of PRA gap analysis findings and key sources of uncertainty than those associated with the examples performed so far should be addressed.
  - Implement planned PRA upgrades related to documentation, identification of key model uncertainties, data and human reliability analysis, treatment of repair and completeness of initiating events.
  - Perform an independent review of the PRA upgrades upon completion.



REQUEST FOR ADDITIONAL INFORMATION ON DRAFT NEI-04-10  
(METHODOLOGY DOCUMENT FOR RISK-INFORMED INITIATIVE 5B)

1. General Comment: The staff review finds that the proposed approach includes most of the basic features that are required to provide confidence that any STI changes made by licensees will not result in significant risk increases. This approach incorporates guidance and methods primarily from Regulatory Guide 1.175 (An Approach for Plant-Specific, Risk-Informed Decision-Making: Inservice Testing), NEI-00-04 (10 CFR 50.69 SSC Categorization), NUMARC 93-01 (Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants), Regulatory Guide 1.174 (An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis), Regulatory Guide 1.160 (Monitoring the Effectiveness of Maintenance at Nuclear Power Plants) and NUREG/CR-6141 (Handbook of Methods for Risk-Based Analyses of Technical Specifications). However, the staff believes that the current draft document, entitled "Methodology for Implementing a Surveillance Frequency Control Program," needs to incorporate more effectively guidance and methods found elsewhere and create, to the extent possible and necessary, a stand-alone document. Such a document is needed to improve clarity and avoid issues of different interpretation that may arise when Initiative 5b is implemented since the source documents are either more generic in nature or tailored to similar but different applications. Please discuss.
2. The categorization of SSCs is a crucial step of the proposed approach because of the significantly lower requirements for low safety significance components (LSSC). The staff review of the proposed methodology and approach identified the following areas which need clarification:
  - a. Step 8 (NEI 00-04 Categorization) of Figure 1 is confusing. Step 8 should be a decision block, like Step 6, with outputs to both Step 9 (for those SSCs which the Maintenance Rule process has categorized as LSSC and the NEI 00-04 process did not change the categorization and for those SSCs which the Maintenance Rule process has categorized as HSSC but the licensee used, successfully, the NEI 00-04 process to re-categorize to LSSC) and to Step 12 (for those SSCs which the Maintenance Rule process has categorized as LSSC but the NEI 00-04 process changed the categorization to HSSC and for those SSCs which the Maintenance Rule process has categorized as HSSC but the licensee used, unsuccessfully, the NEI 00-04 process to re-categorize to LSSC).
  - b. On page 8 it is stated: *"The categorization may be conducted on a functional level or on an SSC level, as discussed in NEI 00-04. This is discussed in detail in Step 8."* The staff could not find such a discussion in Step 8. Please explain. In your explanation also please include a discussion of whether and how the categorization criteria (e.g., Fussell-Vesely greater than 0.005) are impacted when the categorization is conducted at the functional level.



- c. The process does not include any feedback mechanism to ensure that SSCs categorized as LSSC still remain of low safety significance when the proposed process to extend STI is implemented. Significantly higher Fussell-Vesely values are possible as a result of STI extensions. It should be noted that an SSC specific Fussell-Vesely value can increase not only by extending an associated STI but also when STIs related to interacting SSCs (i.e., SSC failures appearing in same minimum cut sets) are extended. Since the proposed process for extending STIs includes significantly lower requirements for SSCs categorized as LSSC (e.g., no additional monitoring beyond existing Maintenance Rule requirements and no evaluation of the cumulative effect on CDF and LERF), please discuss why such a feedback mechanism is not necessary to control potential risk increases associated with such SSCs.
3. The calculation of the cumulative impact of STI extensions on risk, in terms of CDF and LERF increases (Step 18), is an important step of the proposed approach since such risk increases are used directly in the decision making process. The staff review of the proposed methodology and approach identified the following areas which need clarification or additional guidance:
    - a. A more detailed description of Step 18 "Evaluate Cumulative Effect on CDF & LERF" is needed to make it clear what is meant and how are to be calculated the cumulative CDF and LERF changes associated with all STI extensions. Some questions that one can ask are: Are risk changes associated with STI extensions obtained by addition of all minimum cut set frequencies associated with both internal and external events at power and during shutdown operation? If this approach is approved and at a certain point in time a certain STI extension is considered, would the risk impact (i.e., the sum of the impacted minimum cut sets) include all revised unavailability values due to all STI extensions (i.e., both the one under consideration and all other previously implemented by using this approach)? What is an appropriate modification of common cause failure contributions in the minimum cut sets to reflect the new STIs? Will the impact of interactions among STIs be considered in calculating cumulative risk changes? Will the cumulative risk impact of STI extensions associated with both HSSC and LSSC be assessed and used in the decision making process? The answers to such questions need to be incorporated appropriately as guidance in the industry's methodology document.
    - b. In general, the failure probability values of components used in PRAs consist of a time-related contribution (i.e., the standby time-related failure rate) and a cyclic, demand-related, contribution (i.e., the demand stress failure probability). The risk impact of a proposed STI extension should be calculated as a change of the test-limited risk (see Regulatory Guide 1.177, page 25). Since the test-limited risk is associated with failures occurring between tests, the failure rate that should be used in calculating the risk impact of a proposed STI extension is the time-related failure rate associated with failures occurring while the component is in standby between tests (i.e., risk associated with the longer time to detect standby-stress failures). Therefore, caution should be taken in dividing the failure probability into time-related and cyclic demand-related contributions because the test-limited risk can be underestimated when only part of the failure rate is considered as being time-related while this is not the case. Thus, if a breakdown of the failure probability is considered, it should be

justified through data and/or engineering analyses. When the breakdown between time-related and demand-related contributions is unknown, all failures should be assumed to be time-related to obtain the maximum test-limited risk contribution. Please include guidance to address the standby versus demand failures issue in calculating the risk impact of proposed STI extensions.

- c. Regulatory Guide 1.200 requirements for configuration control of a PRA, to be used to support risk-informed regulations, include: (1) a process for monitoring PRA inputs and collecting new information; (2) a process that ensures that the cumulative impact of pending changes is considered when applying the PRA; and (3) a process that evaluates the impact of changes on previously implemented risk-informed decisions that have used the PRA. The proposed methodology should include application-specific guidance regarding the implementation of these requirements. For example, information from the monitoring of changes in component failure rates associated with risk-informed STI extensions can be used to confirm the assumption of constant failure rates used in the risk assessments, to update failure rates and to revise STI extension related risk impacts. Since the assessed STI extension-related risk increase includes not only the impact of the proposed STI change but also the impact of all previous STI changes, monitoring and data trending could be used to revise the cumulative risk impact if it can be established that a previous STI change had no impact on the associated component's unavailability used in the PRA. Please discuss.
  - d. Guidance for integrating the impact of external events and events occurring during shutdown operation is needed.
4. In the description of Step 19 (Comparison of the total CDF & LERF changes to RG 1.174 limits) it is stated: *"...the cumulative impact of all risk-informed Surveillance Frequency changes on all PRAs (internal event, fire, flood, seismic event and shutdown) must also meet the RG 1.174 limits for CDF and LERF changes."* Although the staff agrees with this statement, there has been a difference in the understanding and implementation of this statement between the staff and the industry. The staff review of the proposed methodology and approach identified the following areas which need additional guidance:
- a. It should be made clear in the methodology document that the total cumulative risk increase (i.e., the sum of all risk increases from both internal and external events at power as well as during shutdown) associated with all risk-informed STI extensions will be compared to RG 1.174 limits for CDF and LERF. Please confirm.
  - b. The industry has often interpreted an increase in CDF of up to 1E-5/yr and in LERF of up to 1E-6/yr to be small and, therefore, acceptable. However, the guidance provided in RG 1.174 states that this is acceptable only when the plant's baseline risk from all sources (i.e., both internal and external events at power as well as during shutdown) has been reasonably assessed (i.e., uncertainties were also addressed) and is lower than 1E-4/yr. Please confirm.
5. In the description of Step 7 (RG 1.200 PRA Technical Adequacy) it is stated: *"This step is shown in dotted line since this is actually related to the adequacy of the SFCP process itself, and getting the process ready for the evaluation, rather than the impact of the*

*Frequency change.*" Please clarify this statement and explain why input from RG 1.200 is shown only for LSSC in Figure 1. Also, a discussion is needed on how the *"attributes of importance for risk determinations relative to external events, seismic, internal fires and shutdown,"* provided in RG 1.200, should be used to address PRA technical adequacy. Please discuss.

6. In the description of Step 16 (Perform Bounding Risk Analysis) it is stated: *".... when it is determined that the Frequency change cannot be modeled in the plant PRA .....the PRA analyst will have to perform bounding analyses that would provide some indication of the impact of the Frequency change on the PRA results. Bounding analyses are either quantitative analysis carried out with available PRA models or qualitative evaluation using deterministic considerations). Results of the analyses are sent to the IDP (expert panel) in Step 22."* More detailed guidance of how bounding analyses will be performed and used in the decision making process is needed. How *"qualitative evaluations using deterministic considerations"* associated with an HSSC will be performed and integrated with quantitative risk assessments? One or more examples may help clarify this issue. Also, how will a bounding risk analysis be performed and used in cases where the STI change is partially modeled in the PRA (e.g., internal events only)? Should not the results of a bounding analysis be combined with other PRA results associated with the proposed STI change and then used in the RG 1.174 criteria? Please discuss.
7. The staff believes that a more detailed discussion of Step 21 (Perform Sensitivity Studies), including additional guidance, is needed to clarify the following points:
  - a. It is stated that risk sensitivity studies will be carried out by changing the unavailability terms for PRA basic events that correspond to SSCs being evaluated. This statement indicates that only uncertainties associated with the components for which an STI change is proposed will be addressed in the decision making process. The staff believes that an assessment of the impact of uncertainties associated with key modeling assumptions on the results of the risk assessment should also be addressed (this issue has been listed in the American Society of Mechanical Engineers (ASME) "Standard for PRA for Nuclear Power Plant Applications" which has been endorsed by Regulatory Guide 1.200). Please discuss.
  - b. It is stated that the effect of common cause failures (CCFs) should be addressed either by the use of sensitivity studies or by the use of qualitative assessments that show that the CCF contribution would not become significant under the revised STIs, such as the use of phased implementation, staggered testing and monitoring for common cause effects. The staff believes that guidance is needed on how sensitivity studies and "qualitative assessments" will be identified and used to address the effect of CCFs. Also, please clarify whether the discussion on CCFs in this step concerns all CCFs or only those CCFs that have significant uncertainty associated with them (guidance on the modification of CCF contributions in the minimum cut sets, to reflect the new STIs, should be part of Step 18). Strategies, such as phased implementation, staggered testing and monitoring for common cause effects can be used to address uncertainties in CCF probabilities. However, guidance is needed to characterize the implementation of appropriate strategies and to ensure their effectiveness in eliminating significant uncertainties.

- c. The statement *"The evaluation should be performed so that the truncation of LSSCs is considered"* needs clarification. How is this statement related to Step 21 on sensitivity studies and how will the truncation of LSSCs be considered in the decision making process?
  - d. It is stated: *"If the sensitivity evaluation shows that the changes in CDF and LERF as a result of changes in SSCs being evaluated are not within the acceptance guidelines of Regulatory Guide 1.174, then revised Frequencies may be needed (got o Step 20)."* The use of wording, such as "may be needed," does not provide clear guidance of how to use the results of sensitivity studies in the decision making process. Also, no mention is made regarding the potential need to perform sensitivity studies to address the combined effect of uncertainties.
8. Steps 9 and 13 discuss "Qualitative Considerations" for LSSCs and HSSCs, respectively. The staff identified the following areas that need clarification and/or additional guidance:
- a. The descriptions of Step 9 and Step 13 include the same qualitative considerations. Some of these considerations deal with uncertainties associated with the quantitative process or lack of modeling in the PRA (e.g., external events). Therefore, such qualitative considerations cannot be considered independently from the risk assessments. The description of Step 9, which deals with LSSCs, should clarify that qualitative considerations of uncertainties or lack of modeling of external events are associated with the risk-informed categorization process of NEI 00-04 (Step 8). Similarly, the description of Step 13, which deals with HSSCs, should clarify that such qualitative considerations are associated with the risk assessments used in the decision-making process (Steps 14 to 21). It seems that the "quantitative steps of the process" provide input to the qualitative considerations, and vice versa. In this respect, there should be some integration of quantitative and qualitative information at various steps before it reaches the Expert Panel (Step 11 for LSSC and Step 22 for HSSC). The proposed methodology (NEI-04-10) should provide guidance on the integration of quantitative and qualitative information at the various steps before it reaches the Expert Panel. Please discuss.
  - b. There are benefits associated with surveillance tests, which change with the STI, that are not explicitly quantified. An example is the detection at an earlier stage of potential failure mechanisms and degradations that can lead to common cause failures. Such test benefits should be included in the list of "qualitative considerations." Another important "qualitative consideration" should be whether a component is in an adverse or harsh environment. The staff believes that the list of "qualitative considerations" included in the methodology document (NEI-04-10) should be as complete as possible to ensure that no important consideration is overlooked by licensees implementing Initiative 5b. A brief description of each "qualitative consideration" would help clarify the importance of each of these considerations in the decision-making process.
  - c. There is no guidance provided on the integration of qualitative and quantitative information by the Expert Panel in Step 22 for HSSCs. Also, there is no guidance provided on how to take into account the qualitative considerations in changing an LSSC STI (Step 10). Please discuss.

- d. In the description of Step 9 it is stated that qualitative considerations are developed as an input to the Expert Panel. However, in Figure 1, it is stated that the Expert Panel identifies the qualitative considerations to be addressed. Please clarify.
9. The descriptions of Step 11 (for LSSCs) and 23 (for HSSCs) mention that the new surveillance frequency must be documented. The staff believes that guidance is needed to ensure that adequate documentation of the basis for the change, not just the change itself, is provided. This documentation should include enough information to be used in subsequent potential STI revisions and NRC audits. Examples of such information include: (1) List of SSCs impacted by the proposed STI extension, their categorization as either HSSC or LSSC, and whether all SSC's failure modes that the surveillance test is expected to detect are modeled in the PRA; (2) The assessed risk impact; (3) How external events and events occurring during plant shutdown were treated in the risk assessments (e.g., PRA modeling, bounding analysis, or demonstration of negligible impact); (4) A list of areas of uncertainty that could impact the results used in the decision making process, including a list of sensitivity studies performed to support decision making; and (5) A list of bounding assessments and qualitative considerations used in the decision making process. In addition, documentation of monitoring, feedback and periodic re-assessment activities will be needed. The inclusion of a documentation outline/example in NEI-04-10 (perhaps as an Appendix) would provide guidance to licensees regarding minimum documentation expectations. Please discuss.
10. Steps 10 and 22 discuss the review and approval of a proposed STI extension by an expert panel, the Integrating Decision-making Panel (IDP), for LSSCs and HSSCs, respectively. It is stated: *"This step involves the use of an IDP (expert panel), which in addition to reviewing the results quantitatively, is charged with the task of reviewing the Frequency extensions qualitatively."* Please clarify what is meant by reviewing the results quantitatively (as opposed to reviewing the results of the quantitative analyses). In addition, the staff believes, the methodology document should state clearly the IDP's expected functions and provide general guidelines on how to perform such functions. Please discuss.
11. Monitoring and Feedback is discussed in Step 24 for HSSCs and Step 25 for LSSCs. A general staff comment is that the material discussed in Step 24 is taken directly from Regulatory Guide 1.175 without much effort to adapt it to the needs of a "methodology" document supporting STI extension. For example, RG 1.175 states that two important aspects of performance monitoring are *"...whether the Surveillance Frequency is sufficient to provide meaningful data..."* and *"whether the testing methods, procedures and analysis are adequately developed to ensure that performance degradation is detected."* The methodology document (NEI-04-10) should discuss the potential impact of a proposed STI extension on these two "important aspects" and provide guidance on how to take into account these aspects when an STI extension is proposed. Considerations related to "performance monitoring" may pose limitations on a proposed STI extension and/or result in monitoring program changes. Please discuss.

In addition, clarification is needed on the following areas:

- a. Please explain why one of the three attributes of a licensee's performance monitoring program listed in RG 1.175, which calls for trending of appropriate parameters to



provide assurance that the component will remain operable over the extended test interval, was not included in the "methodology" document (NEI-04-10).

- b. Please clarify why Step 24, labeled "Monitoring and Feedback," does not include a discussion of any feedback mechanism. It is noted that a short discussion on feedback is provided in Step 26 (Periodic Re-assessment). However, a more detailed discussion of a performance-based feedback mechanism is needed. Such a mechanism should be able to feed back information from the performance monitoring program to the corrective action program and to the PRA. Please discuss.
  - c. In Step 27 (IDP Reviews Experience Results) it is stated that any changes identified by the IDP are routed to Step 24 (Monitoring and Feedback). This loop appears to mask the potential need to revise (downwards) an extended STI to address performance issues established by the monitoring program. Please clarify.
12. The methodology document (NEI-04-10) should provide guidance on acceptable ways of integrating the impact of external events (primarily internal fires, internal floods and seismic) and events occurring during plant shutdown, in the decision-making process. This guidance should also discuss minimum quality expectations for licensee performed risk assessments related to external events and shutdown operation. Attributes for available information, approaches and tools (e.g., screening analyses, approximate event trees and risk insights) should be identified and discussed. Licensees implementing Initiative 5b should provide with their License Amendment Request information demonstrating that they have the capability to integrate safely the impact of external events and shutdown operation in the decision-making process. Please discuss.
13. Licensees implementing Initiative 5b should provide with their License Amendment Request information explaining how the quality of their PRA models meets RG 1.200 guidelines and that their PRA models can safely be used to extend STIs according to the methodology outlined in NEI-04-10. Please discuss.