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

Methodology RAI 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: In-service 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.

Response:

In response to the staff's comment for the need to improve clarity and avoid interpretation issues, changes will be made to specific sections of the document to address this concern. Specifically, more detailed guidance will be provided for the treatment of the cumulative change in Core Damage Frequency (CDF) and Large Early Release Frequency (LERF) for internal events, external events, and shutdown events. In addition, the treatment of the cumulative change in CDF/LERF resulting from all STI changes from a baseline starting point will be addressed. Other changes were made in response to the staff's specific comments given below. Where approved guidance and methods are given elsewhere, references will be made to these approved documents. The document is not intended to be a handbook or cookbook. In addition, the requirements given in the methodology are not overly prescriptive.

Methodology RAI 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).

Response:

Separate paths for the treatment of HSSC and LSSC will be eliminated. Specifically, Steps 5 through 11 (except Step 7) in Figure 1 will be deleted. A new step (Step 15) will be added for System Engineering Assessment to determine appropriate monitoring requirements (existing Maintenance Rule (MR) monitoring or any other additional monitoring) based on the SSC risk significance. This should eliminate any confusion related to the treatment of HSSCs and LSSCs. See revised Figure 1 for more details.

b. On page 8 it is stated: *"The categorization may be conducted on 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.

Response:

Step 6 has been deleted from the process. Categorization of SSCs is no longer included in the process.

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 STls related to interacting SSCs (i.e., SSC failures appearing in same minimum cut sets) are extended. Since the proposed process for extending STls 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.

Response:

Categorization of SSCs is no longer included in the process. The treatment of SSC (both HSSC and LSSC) has been combined into one assessment path. See revised Figure 1.

Methodology RAI 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 STls? 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.

Response:

Step 12 has been revised to reflect the treatment of the total and cumulative effect on CDF and LERF (see new Figure 2). Two types of CDF/LERF changes are considered:

1) Step 12-A2 in Figure 2 covers the calculation of the total change on CDF/LERF for internal events, external events, and shutdown events.

2) Step 12-A4 in Figure 2 covers the integrated impact of any previously approved changes that must be factored into the cumulative change. That is, the cumulative change is calculated by including all previously revised unavailability values due to all STI extensions (not just the sum of the individual assessments). It should be noted that, Step 19 for periodic re-assessments now allows for a re-baselining of the cumulative impacts of STI

changes once it can be demonstrated that the revised surveillance frequencies are included in the base PRA model (all modes). As part of this step, cumulative impact of certain STI changes do not need to be carried out in future after the rebaselining, if the associated cumulative increase in CDF and LERF is below 1.0E-6 and 1.0E-7 per year, respectively, due to all PRAs. (see Step 19 description for more details).

3) Common cause failure probabilities will be adjusted as part of the sensitivity studies conducted in Step 14 in the revised Figure 1. The impact of interactions among STIs will be considered in calculating cumulative risk changes in Step 12 in the revised Figure 1.

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.

Response:

Refer to the revised methodology discussion for Step 8 that includes the guidance indicated in this RAI question as well as guidance on how to practically apply this guidance.

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 those 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.

Response:

It is the intent of the process that all revised STI changes will eventually be rolled into the base PRA model results. Step 19 for periodic re-assessments now allows for a re-baselining of the cumulative impacts once it can be demonstrated that the revised surveillance frequencies are included in the base PRA model (all modes). This implies that updates could be performed to refine the values utilized for the initial individual STI assessments. If this is not done, then the original assumptions regarding the impact of the revised STI will need to be factored directly into the updated base model. Either of these approaches is acceptable to allow for re-baselining of the cumulative impacts that are accumulated in Step 12-A4.

d. Guidance for integrating the impact of external events and events occurring during shutdown operation is needed.

Response:

Guidance for integrating the impacts of external events and events occurring during shutdown operation is now included in the revised methodology discussion for Step 12 (specifically Steps 12-B1, 12-B2, and 12-B3). Bounding analysis can only be used to screen items at <1.0E-7 CDF and <1.0E-8 LERF. If these screening criteria are not met, refinement to the calculated metrics is desirable since the impact will need to be included in the total impact assessment in Step 12-A2.

Methodology RAI 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 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.

Response:

Refer to the revised methodology discussion for Step 12 and Figure 2 (Evaluate the Total and Cumulative Effect on CDF and LERF). Unless screened by qualitative or bounding analysis, 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 the RG 1.174 limits for CDF and LERF.

b. The industry has often interpreted an increase in CDF of up to 1.0 E-5/yr and in LERF of up to 1.0 E-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 1 E-4/yr. Please confirm.

Response:

Refer to the revised methodology discussion for Step 12 and Figure 2 (Evaluate the Total and Cumulative Effect on CDF and LERF). Specifically, refer to the methodology discussion for Step 12-A4 that includes the appropriate RG 1.174 guidance.

Methodology RAI 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 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.

Response:

The step "RG 1.200 PRA Technical Adequacy" will be revised to show a solid line connection to Step 8 (Associated STI SSC Modeled in PRA?) in the revised Figure 1. With the corrections made to the figure, now it is clear that RG 1.200 is applicable to any PRA, internal, event, external events and shutdown, used in the evaluation. PRA standards for all external events and shutdown PRA are not yet endorsed by the RG 1.200, but when they are, the methodology would require conformance to the revised RG.

Methodology RAI 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 lDP (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.

Response:

Refer to the revised methodology discussion for Step 10 that includes guidance on how to perform bounding and qualitative analysis for initial screening of non-modeled PRA systems or components.

As indicated in Step 12-B2 for modeled PRA systems or components, unless screened by bounding analysis at <1.0E-7 CDF and <1.0E-8 LERF, 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 the RG 1.174 limits for CDF and LERF. The guidance for performing bounding analysis in Step 10 is also applicable for the external events and shutdown risk impacts.

Methodology RAI 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.

Response:

Enhanced guidance on the performance of sensitivity studies is now included in the revised methodology discussion for Step 14. The revised guidance includes the need to ensure that there is no overdue reliance on key modeling assumptions or areas of uncertainty on the results of the risk assessment, and is therefore consistent with the ASME Standard for PRA for Nuclear Power Plant Applications.

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 is 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.

Response:

Refer to the revised methodology discussion for Step 12 and Figure 2 (Evaluate the Total and Cumulative Effect on CDF and LERF). Specifically, Step 12-A1 provides guidance indicating that CCF terms must also be included and adjusted for all components that are uniquely impacted by the STI change. Additionally, Step 14 (Perform Sensitivity Studies) clearly indicates that the CCF terms must also be changed for the initial sensitivity on the standby failure rates used in the base case STI assessment.

Steps 18, 19, and 20 for monitoring and feedback, periodic reassessment, and STI adjustments have also been developed to ensure that undue CCF mechanisms do not occur as a result of the STI change. It should be noted that much of this feedback can occur as part of the existing Maintenance Rule program at the sites.

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?

Response:

The revised methodology does not include a distinction between LSSCs and HSSCs anymore. The total and cumulative impacts will be evaluated for all SSCs that proceed to Step 12. Additionally, sensitivity studies will need to be performed on any STI evaluations that proceed to Step 14 in the revised methodology.

d. It is stated: *"If the sensitivity evaluation shows that the changes in CDF and LERF result of changes in SSCs being evaluated are not within the acceptance guidelines of Regulatory Guide 174, then revised Frequencies may be needed (got 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.

Response:

Refer to the revised methodology discussion for Step 14 (Perform Sensitivity Studies). Specific examples of qualitative considerations that could be utilized to support the STI change even though it may not be supported by the sensitivity studies are provided.

Methodology RAI 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 (i.e., 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 Expect 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.

Response:

Separate paths for LSSCs and HSSCs have been deleted. Steps 9 and Step 13 have been revised and are now Step 7 and Step 10a, respectively. The new Step 7 deals primarily with the more global qualitative considerations related to the proposed STI changes. The new Step 10a deals specifically with guidance on how to evaluate SSCs when it is determined that the STI change cannot be modeled in the PRA. The outputs from both Steps 7 and 10a are summarized and documented in Step 15 and forwarded to the IDP in Step 16 for their consideration.

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.

Response:

The examples have been added to the list of considerations. This specific list of considerations will be included in the IDP guidance. In addition, the System Engineering Team and IDP will be expected to add their own expertise, knowledge of the specific SSC under consideration, and past experience in identifying qualitative considerations specific to the STI change being considered.

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.

Response:

Separate paths for LSSCs and HSSCs have been deleted. The process has been updated to show more clearly the integration of the different qualitative inputs to the IDP.

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.

Response:

Figure 1 has been changed to reflect System Engineering input (Step 15) to the IDP (Step 16).

Methodology RAI 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. , 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.

Response:

A list of documentation inputs has been added to the new Step 15. The evaluation form used in the Limerick pilot evaluation has been added as an Appendix.

Methodology RAI 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.

Response:

The phrases “reviewing the results quantitatively” and “reviewing the results of the quantitative analyses” have been revised to reflect both quantitative and qualitative tasks. In addition, an example IDP charter based on the Limerick pilot study will be added as an Appendix.

Methodology RAI 11

Monitoring and Feedback is discussed in Step 24 for HSSCs and Step 25 for LSSCs. The 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.

Response:

In the new Step 20, the IDP reviews and adjusts STIs as needed using the guidance given in RG 1.174 and based on the results from the performance monitoring. In addition to the three performance monitoring process attributes listed in RG 1.174, the IDP will consider other considerations listed in the IDP charter given in the appendix. Where it is determined that an adjustment to the STI is required, the process will be directed to Step 13 (Revise STI Values). If no adjustment is required by the IDP review, the process goes to Step 18 (Monitor and Provide Feedback). One of the possible IDP inputs to Step 18 is a change in monitoring or trending requirements in order to provide meaningful data on the condition of a SSC.

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).

Response:

Reference to RG 1.174 has been changed to RG 1.175 and the third attribute in RG 1.175 has been added.

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.

Response:

A new decision Step 20 has been added to the revised Figure 1 to provide either an adjustment required or no adjustment as determined by the IDP review. If an adjustment is required, the process goes back to PRA evaluation.

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.

Response:

Step 27 has been replaced with the decision Step 20. Any changes identified by the IDP are routed to Step 13 (Revise STI Values), or if no adjustments are required are routed back to monitoring the results (Step 18).

Methodology RAI 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.

Response:

Guidance for integrating the impact of external events and events occurring during plant shutdown are included in the revised methodology discussion for Step 12 and Figure 2 (Evaluate the Total and Cumulative Effect on CDF and LERF).

Additionally, RG 1.200 PRA Technical Adequacy is included as a direct input to Step 8 (Associated STI SSC Modeled in PRA?). As such, any PRA used quantitatively for the purpose of changing surveillance frequencies would have to meet appropriate available quality requirements as defined in RG 1.200 and associated standards endorsed in its appendices.

Methodology RAI 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 STls according to the methodology outlined in NEI-04-10. Please discuss.

Response:

RG 1.200 PRA Technical Adequacy is included as a direct input to Step 8 (Associated STI SSC Modeled in PRA?). Utilization of the RG 1.200 guidelines as part of licensees that are planning to implement TSTF-425 are described in Step 5 of the revised NEI 04-10 methodology discussion.

As such, any PRA used quantitatively for the purpose of changing surveillance frequencies would have to meet appropriate available quality requirements as defined in RG 1.200 and associated standards endorsed in its appendices. Therefore, any licensees submitting a License Amendment Request to implement the Initiative 5b methodology would need to include information explaining how the quality of their PRA model meets the RG 1.200 guidelines.