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October 28, 2005

Mr. T. R. Tjader, Senior Reactor Engineer
Technical Specifications Section
Reactor Operations Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Tjader:

Enclosed are the following draft materials relative to risk-informed technical specification initiative 5B, which proposes to relocate Surveillance Test Intervals to licensee control using an NRC approved risk-informed methodology. Limerick units 1 and 2 are the pilot plants for this initiative.

1. Draft response to NRC request for additional information on Limerick pilot submittal
2. Draft response to NRC request for additional information on initiative 5B methodology document (NEI-04-10)
3. Draft revision to NEI-04-10 Section 4.0 "Surveillance Frequency Control Program Change Process"
4. Sample charter for integrated decision panel

These materials are provided in draft so that we may obtain NRC feedback prior to proceeding with the formal responses. We request a teleconference with NRC to obtain feedback on these materials following your initial review.

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Please contact me at (202) 739-8081, or Biff Bradley (202) 739-8083 if you have any questions.

Sincerely,

Anthony R. Pietrangelo

Enclosures

c: Mr. Glenn Stewart, Exelon
Mr. Fred Emerson, GE
Mr. Travis Tate, NRC

ATTACHMENT

Limerick Generating Station, Units 1 and 2
Docket Nos. 50-352 and 50-353

Proposed Technical Specifications Change to Relocate Surveillance Test Intervals to a Licensee-Controlled Program (Risk-Informed Initiative 5b)

Response to Request for Additional Information

In Reference 1, Exelon Generation Company, LLC (Exelon), requested a change to the Technical Specifications (TS), Appendix A, of Facility Operating License Nos. NPF-39 and NPF-85 for Limerick Generating Station (LGS), Units 1 and 2, respectively. The proposed change relocates the surveillance test intervals (STIs) of various TS surveillance requirements from the TS to a new licensee program, the Surveillance Frequency Control Program, which is being added to the Administrative Controls section of TS. This license amendment request (LAR) was submitted as a pilot in support of the Boiling Water Reactor Owners' Group (BWROG) Risk-Informed Initiative 5b, "Relocate Surveillance Test Intervals to Licensee Control."

In Reference 2, the NRC requested additional information concerning the LGS LAR (Enclosure 1 to the Reference letter). Each NRC question is restated below followed by our response.

Question 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.

Response

It is our understanding that, in response to the RAIs, the methodology is being modified to not differentiate between high safety significance components (HSSCs) and low safety significance components (LSSCs) any more. The revised methodology thus addresses the NRC concern stated in the RAI. Limerick would follow this revised process when issued.

Question 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.

Response

The full statement from page 1 of Attachment 1 referred to above clearly states that future changes to the STIs, i.e., ***Surveillance Test Intervals,*** will be evaluated in accordance with the licensee-controlled program, and the STIs may be revised without prior NRC approval. There is no wording in this sentence, or in Attachment 1, to suggest that licensees can make changes to the NRC-approved methodology without prior NRC approval. In fact, previously, on page 1 of Attachment 1, we make the statement that revisions to the STIs will be made in accordance with the Surveillance Frequency Control Program which is being added to the Administrative Section of TS and is predicated on use of the NRC-approved methodology. Specifically, as indicated on the TS markup pages 6-18a provided in Attachments 2 and 3 of Reference 1, the Surveillance Frequency Control Program being added to the Administrative Section of TS requires: "Changes to the Frequencies listed in the Surveillance Frequency Control Program shall be made in accordance with NEI 04-10, "Risk Informed Method for Control of Surveillance Frequencies." As a result, there is no need to provide revised wording for page 1 of Attachment 1 of Reference 1.

Question 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.

Response

Section 4.1, Steps 1 through 4 of the Initiative 5b methodology document, NEI 04-10, provide the steps for identifying commitments and evaluating the effect of changing commitments on overall plant safety. In particular, Step 3, "Change the Commitment," states:

> "In Step 3, change the commitment using NRC-approved process such that the Frequency can be revised using the SFCP process. Changing the NRC commitment is a separate activity. Return to the SFCP process after the commitment has been changed. If the NRC does not permit the commitment change, go to Step 4, ..."

Step 3 directs the use of a separate NRC-approved process for evaluating the commitment changes. In Regulatory Issue Summary 2000-17, "Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff," the NRC endorsed the industry guideline NEI 99-04, "Guideline for Managing NRC Commitment Changes," as an acceptable method for managing and changing regulatory commitments. Rather than spell out specific detailed steps for reviewing and evaluating commitment changes within the methodology document, Step 3 will continue to direct the use of an NRC accepted process for making changes to commitments.

However, this step will be revised to make specific reference to the industry guidelines for making commitment changes.

In addition, since Step 2 is the step where the determination of whether or not making the commitment change is acceptable to the NRC is performed, Step 2 will be revised to reference NEI 99-04 as well. Both Steps 2 and 3 will be revised as indicated below.

Step 2: Can Commitments be Changed?

In Step 2, a check is made to determine if the NRC commitments can be changed. Evaluating changes to NRC commitments is a separate activity based on a method acceptable to the NRC for managing and changing regulatory commitments, e.g., NEI 99-04. If the commitments can be changed without prior NRC approval, go to Step 3. If the commitments cannot be changed without prior NRC approval, go to Step 4.

Step 3: Change the Commitment

In Step 3, change the commitments using a method acceptable to the NRC, e.g., NEI 99-04, such that the STI can be revised using the SFCP process. Return to the SFCP process after the commitment has been changed, and continue the SFCP process with Steps 5 and 6.

Question 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."

Response

The statement *" 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."* is consistent with Step 19 of the draft version of NEI 04-10. All quantitative results of the sample STI changes were summed up appropriately and compared to the limits of R.G. 1.174. Where there were no quantitative results, for example seismic risk, the qualitative evaluation indicated minimal to no impact on risk. Thus they would not impact the cumulative result.

It is our understanding that NEI 04-10 is being revised to clarify the comparison of the realistic PRA results and the bounding risk analysis results to their respective acceptance criteria as well as to clarify the consideration of the qualitative results by the IDP. Limerick will follow the revised guidance when issued.

Question 5.

It is stated (page 2 of Attachment 4): *"For those cases where the STI cannot be modeled in the PRA 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.

Response

It is our understanding that NEI 04-10 is being revised to clarify the comparison of the realistic PRA results and the bounding risk analysis results to their respective acceptance criteria, as well as to clarify the consideration of the qualitative results by the IDP. In the updated NEI 04-10 methodology, the results of the quantitative bounding analysis would not be combined with "best-estimate" analysis, but would be checked against an acceptance criteria of < 1E-6 CDF and < 1E-7 LERF. Similarly, results of the qualitative analyses would not need to be directly combined with "best-estimate" analysis. Results of the qualitative analysis would be reviewed and sent to the IDP for its consideration. Limerick will follow the revised guidance when issued.

Question 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.

Response

Step 18 was exercised by example STIs 3 through 6, which analyzed for internal events CDF and LERF and tracked the cumulative total. Step 16 was exercised in the control rod notch STI example (STI #1). The individual control rods are not modeled in the Limerick PRA and could not easily or practically be modeled. The bounding analysis performed used a global basic event representing mechanical failure of the control rods to insert into the reactor core. This is the failure being "looked for" in the surveillance requirement. Since this event represented failure to insert sufficient rods to bring the core subcritical, modifying this event bounded the surveillance requirement being evaluated.

The cumulative effect on CDF and LERF and sensitivity study evaluations were performed for STIs 3 through 6 which were analyzed quantitatively. Results of the sensitivity studies were presented to the IDP for consideration of the STI assessment.

An additional candidate STI change will be developed that more fully exercises the determination of the cumulative effects on CDF and LERF and considers the impact on the results from additional sensitivity studies. See the response to RAI Question 10 below.

Question 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.

Response

No phased implementation was deemed necessary because the performance history showed that the equipment was unlikely to have issues at the new frequency. Given that there is no change in the normal operation, maintenance or environmental conditions for the SSCs and the interval extension (one week to one month) is not large, it was considered unlikely that a new common cause failure mechanism would occur.

Given that the Maintenance Rule performance criteria specifically monitors the attribute that would indicate that the increased surveillance interval was allowing additional failures, the IDP determined that the Maintenance Rule performance criteria was sufficient since it directly addressed the identification of a change in failures for the components impacted by the STI change. If an increase in the number of unplanned inoperable rods did occur after the implementation of the revised STI that warranted an (a)(1) characterization of the system under the Maintenance Rule, the most likely corrective action would be to revert to the original STI. This could be handled under the Maintenance Rule, but would also require re-evaluation as part of the periodic reassessments performed by the IDP (Refer to the discussion in Step 20 of the revised NEI 04-10 methodology).

Question 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.

Response

The important insights or lessons learned from the pilot application at Limerick are provided below. The items involving a revision to the methodology document are also annotated.

1. A step was added in the methodology to review each proposed STI for impact against existing station commitments and pursue changes where appropriate, including evaluation of NRC related commitments per NEI 99-04. Limerick identified the need for this step during evaluation of the control rod exercise test (STI #1) that referenced a vendor recommendation. This insight has been incorporated into the methodology document.

2. The methodology is risk-informed rather than risk-based. The PRA (quantitative) input is only part of the process. In fact, the insights gained during site Integrated Decision-making Panel (IDP) meetings associated with the pilot clearly yielded that qualitative aspects were far more significant for each STI. Qualitative factors included equipment performance history, surveillance test story, vendor recommendations, 10CFR50.65 Maintenance Rule program reliability and unavailability data and performance indicator trends, plant-specific and industry operating experience, and the existence of alternate testing. The cumulative quantitative risk impact of all six pilot STIs was minimal (CDF increase of 2E-9 and LERF increase of 1E-11). This insight is characterized as an observation. Therefore, a revision to the methodology document was not necessary.

3. Risk categorization of each STI using the NEI 00-04 process is only one aspect of the RITS Initiative 5b pilot but would entail a significant resource effort by itself. The risk categorization process is far more rigorous and resource intensive than the approved site Maintenance Rule process. Limerick and industry personnel noted that few U.S. nuclear plants have incorporated the 10CFR50.69 risk categorization process. Therefore, Limerick retained all site Maintenance Rule risk categorizations and evaluated the lone STI characterized as containing low safety significance components by using PRA quantitative analysis which was reserved for HSSC systems per the methodology guideline. In effect, all systems in the pilot were treated and analyzed using the HSSC protocol. Based on Limerick and industry feedback, and as noted in the response to Question No. 1 above, the methodology guideline will be revised to eliminate the risk categorization aspect.

4. Limerick used screening criteria for the selection of the six test case STIs to evaluate in the pilot process. Each STI considered for optimization required a tangible benefit or savings. The benefits considered included nuclear safety aspects such as minimization of reactivity management events and plant transients. The benefits considered also included radiation dose savings, burden reduction (i.e., resources), outage duration savings, simplification of work management coordination for on-line work, reduction of production risk affecting both load drops and plant trips, and improvement of component reliability by reducing number of demands. This insight is being incorporated into the methodology document. A sample STI evaluation form containing a line entry for benefits will be added to the methodology.

5. Limerick confirmed that, just as with the Maintenance Rule Expert Panel, the IDP complemented the PRA results associated with each STI. PRA does not model all plant SSCs that are included in surveillance requirements. Also, as the Maintenance Rule process shows, PRA is not the only input considered. The IDP composition and expertise ensured that equipment performance issues, maintenance practices, operational experience and impacts, surveillance test history and insights, and component–specific insights were factored into the STI review process. The IDP proved to be a very valuable component of the STI pilot process. This was not unexpected based on the similar panel utilized in the

station Maintenance Rule program. This insight is characterized as an observation. Therefore, a revision to the methodology document was not necessary.

6. Compliance to Regulatory Guide (RG) 1.200 is a component of the STI evaluation process and is becoming a pre-condition for any future risk-informed license submittal relying on PRA. Limerick is one of five licensees piloting RG 1.200. The Regulatory Guide requires comparison of the PRA to ASME PRA Standard RA-S-2002 (and addenda). This addition requires significant PRA resources. Limerick was well positioned for RG 1.200 usage since Limerick personnel had already performed a gap analysis against the ASME PRA Standard. A subsequent NRC RG 1.200 assessment team visited Limerick primarily to assess the Regulatory Guide effectiveness but also assessed Limerick's conformance to the Regulatory Guide. This insight is characterized as an observation. Therefore, a revision to the methodology document was not necessary.

7. PRA models will require a revision to facilitate STI evaluation if a standby failure rate term does not already exist in the PRA. Prior to this pilot, the Limerick PRA did not contain any standby failure rate terms. The Limerick PRA was revised to include standby failure rate terms for each of the six test case STIs. Many other licensees will have a similar situation with their station PRA. This task also requires risk management resources for the PRA model revision. Limerick plans to revise the PRA as needed as each STI is evaluated. This insight is characterized as an observation. Therefore, a revision to the methodology document was not necessary.

8. The Limerick IDP identified one STI test case in which equipment reliability history did not support a proposed STI change at this time. This was Limerick STI test case #4, the LOCA-LOOP surveillance test. The PRA analysis supported the proposed STI change from two years to four years. However, the surveillance test actuates certain relays that are only cycled in this surveillance test. These specific relays have a potential contact resistance issue due to build up of an oxidation layer that is mitigated by cycling the contacts every two years. This issue is addressed in the station preventive maintenance program. Thus, extending the interval beyond two years will challenge the reliability of the relays and success rate of the surveillance test. The IDP evaluated this issue and disapproved the STI change pending further reliability analysis or alternate testing. This insight confirms our observations from Item Nos. 2 and 5 above that conclude the STI methodology relies primarily on qualitative aspects and IDP review, and that the PRA input, although necessary to risk-inform the process, is only one contributing component to the process. This insight is characterized as an observation. Therefore, a revision to the methodology document was not necessary.

9. Limerick recognized that, although no single STI nor the cumulative impact of all six test case STIs challenged the RG 1.174 limits specified in the methodology document, the potential exists that one single high risk impact STI could consume a majority of the margin allowed in RG 1.1.74. Limerick did not pre-screen STIs for this effect. However, the benefit of consuming a significant portion of this regulatory margin would have to be balanced against the forfeiture of multiple other proposed STI optimizations. From our experience, the likelihood of a licensee implementing an STI change that consumes the bulk of the RG 1.174 margin is very low. More benefit is achieved by having the capability to optimize multiple STIs. This insight is characterized as an observation. Therefore, a revision to the methodology document was not necessary.

10. Limerick pilot personnel, including IDP members, noted that alternate testing of SSCs affected by an STI adjustment is an important element in the STI evaluation process. If

SSCs affected are tested as often or more frequently than in the current STI through other methods or tests, then supporting the proposed interval change from a qualitative and reliability perspective is more easily justified. However, when the only test that exercises the affected SSCs evaluated for extension is the STI itself, then the evaluation process requires more rigor and technical bases to justify the STI adjustment. This insight is characterized as an observation and is already included in the current methodology document. Therefore, a revision to the methodology document was not necessary.

11. Limerick pilot personnel contributed to various other revisions of the methodology document during its evolution up to and including NEI 04-10, Revised Draft 1, issued in December 2004. These changes included a wholesale redesign of the SFCP process flow chart, the placement of key steps in the process and supporting text for each step. These changes simplified the process and clarified the purpose and requirements for each step. Limerick continues to work with industry personnel on the pending revision of the methodology document as cited in this response as well as the parallel response by NEI for RAIs associated with the NEI 04-10 methodology. The methodology document has been revised to incorporate Limerick feedback associated with these insights.

Question 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.

Response

Limerick followed the draft NEI 04-10 guidance relating to the impact of external events and shutdown events in its decision making process. It was possible to address only the internal events quantitatively. The impact of external and shutdown events was addressed qualitatively. If the external or shutdown event risks can be quantified, those values would be incorporated into the decision-making process in accordance with the guidance document.

Any PRA used quantitatively for the purpose of changing surveillance frequencies would have to meet appropriate available quality requirements just as was done for the internal events PRA in Attachment 5 of our submittal.

As demonstrated in the response to question 8 above, Limerick has actively participated in the improvement of the NEI 04-10 methodology. Limerick will follow the final issued guidance relating to the integration the impact of external events and shutdown events in the decision-making process.

Question 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.

Response

The evaluation against RG 1.200 and the ASME PRA standard looked at the entirety of the level 1 and level 2 internal events PRA against the capability category 2 supporting requirements. Where the PRA model did not fully meet the intent of category 2 for a SR, a gap was identified. These gaps where evaluated for this application in two fashions. First, identifying whether any of the gaps were applicable to all surveillance frequency changes. This would include items such as broad use of generic rather than plant-specific component failure rates. These were evaluated for impact on the results, focusing on sensitivity evaluations such as varying the failure rates upward and downward and reviewing the impact on the numeric results. Second, identifying any of the gaps that were applicable to specific surveillance requirements, such as lack of modeling of the diesel generator initiation logic affecting the surveillance requirement to verify that the diesel generator starts in response to the LOCA or LOOP initiation signal. These were generally addressed by modifying the logic of the model for that surveillance interval change. Any change like this was carried forward in analysis of additional surveillance interval changes.

Key areas of uncertainty were also identified and evaluated for impact on either a specific interval change or globally on the complete process in attachment 5 of our submittal. It is intended that this process continue in future interval evaluations.

Limerick will select and evaluate one additional STI example for interval adjustment on a high risk system that should challenge the limits of RG 1.174. Preliminarily, we have selected the High Pressure Coolant Injection (HPCI) system due to the overall high risk importance of this system based on its Risk Achievement Worth (RAW) in the Limerick PRA. The specific STI to be evaluated is the HPCI Pump Valve and Flow test that implements a quarterly surveillance requirement. This evaluation is a hypothetical example since it would require relief from the American Society of Mechanical Engineers (ASME) Section XI requirements for quarterly pump and valve testing. Nonetheless, this STI will be evaluated but the assessment will be limited to a PRA quantitative perspective only. No qualitative aspects such as those cited in RAI response 8 insight number 2 (above) will be assessed. Also, no IDP review will be performed per our discussions with NRC during a public meeting addressing these RAIs on June 3, 2005, as this example is limited to quantitative assessment only. The analysis will include the information requested in this RAI including PRA gap analysis findings relative to ASME Capability Category II and also key sources of uncertainty. The results of this quantitative assessment will follow the revised methodology to consider total and cumulative impacts from all risk contributors for the HPCI STI adjustment and will be summarized in a supplement to this response when completed.

Though not relevant to this submittal which fully addressed PRA quality, the status of items identified in this RAI are as follows. An update of the PRA model has been completed since the submittal of this license amendment request (Ref. 1). The update included adoption of plant-specific failure rates for significant components, update of common cause failure to the most current data set, update of HRA events to current methodologies, re-evaluation of use of repair terms in the model and further expansion of initiating events in the scope of the model. Due to the broad scope of changes to the model, Exelon had a peer review performed on the revised model during the week of October 10-14, 2005. Although no findings are expected to require an immediate update to the model, the final report is pending. The results of the review (i.e., 'B' findings and instances where Capability Category II of the ASME Standard are not met) will be used as input to the SFCP process during the performance of sensitivity studies as delineated in the revised NEI 04-10 methodology.

References:

1. Letter from M. P. Gallagher, Exelon Generation Company, LLC, to U. S. Nuclear Regulatory Commission, dated June 11, 2004

2. Letter from T. R. Tjader, U. S. Nuclear Regulatory Commission, to B. Bradley, Nuclear Energy Institute, and M. P. Gallagher, Exelon Generation Company, LLC, dated April 12, 2005.

DRAFT

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 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.

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 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.

Response:

Step 12 has been revised to reflect the treatment of the total and accumulative 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 once it can be demonstrated that the revised surveillance frequencies are included in the base PRA model (all modes).

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-6 CDF and <1.0E-7 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 E-5/yr and in LERF of up to 1 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 dotted line 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.

~~Don will send GE what was prepared for Limerick RAI 10, and GE will extract the relevant information to respond to this RAI. Don believes that NRC is looking for some kind of a commitment that as RG 1.200 starts including Seismic and SD PRA, they will be factored in the process. Action: Don to send info, Bill to write~~

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 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.

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-6 CDF and <1.0E-7 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 (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 with instructions used in the Limerick pilot evaluation has been added as an Appendix. *Limerick has an action to provide this form.*

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 (Ref. 4) has been changed to RG 1.175 (Ref. 6) 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. , 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 STIs 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.

4.0 Surveillance Frequency Control Program Change Process

The Surveillance Frequency Control Process (SFCP) change process is shown in flow diagrams in the Figures 1 and 2. The process steps are described below:

Step 1: Check for Prohibitive Commitments

In Step 1, all the commitments made to the NRC are collected and reviewed. Some of the commitments to maintain a certain surveillance test interval may have been made in relation to certain other plant issues. As part of this step, such commitments are identified and then, in Step 2, the commitment is examined to determine if it can be changed. If there are no such commitments, then the STI change process continues in Steps 5 and 6.

Step 2: Can Commitments be Changed?

In Step 2, a check is made to determine if the NRC commitments can be changed. Evaluating changes to the NRC commitments is a separate activity based on a method acceptable to the NRC for managing and changing regulatory commitments, e.g., NEI 99-04. If the commitments can be changed without prior NRC approval, go to Step 3 for changing the commitment. If the commitment cannot be changed, without prior NRC approval, go to Step 4.

Step 3: Change the Commitment

In Step 3, change the commitment using a method acceptable to the NRC, e.g., NEI 99-04, such that the STI can be revised using the SFCP process. Return to the SFCP process after the commitment has been changed and continue the SFCP process with Steps 5 and 6.

Step 4: Document that STI Changes Cannot be Changed

This step is entered if, in Step 2, it is determined that the commitment related to a certain STI cannot be changed. Document that STI cannot be changed and the process concludes here.

Alternatively, Step 4 is entered if PRA or qualitative analyses result in the STI change being unacceptable. In that case, the reasons that the STI change is not acceptable should also be documented and the process concludes here for the specific STI being investigated.

Step 5: RG 1.200 PRA Technical Adequacy

NRC has developed a regulatory guidance for trial use to address PRA technical capability. This is RG 1.200 (Reference 7), which addresses the use of the ASME PRA standard, and the NEI peer review process (NEI 00-02) for evaluating PRA technical capability.

RG 1.200 also provides (or will provide) attributes of importance for risk determinations relative to external events, seismic, internal fires, and shutdown.

It is envisioned that plants implementing TSTF-425 would evaluate their PRA in accordance with this regulatory guide. The RG specifically addresses the need to evaluate important assumptions that relate to key modeling uncertainties (such as reactor coolant pump seal models, common cause failure methods, success path determinations, human reliability assumptions, etc). Further, the RG addresses the need to evaluate parameter uncertainties and demonstrate that calculated risk metrics (e.g., CDF and LERF) represent mean values.

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 STI change.

Step 6: Select Desired Revised STI Values

Technical Specifications STIs are identified for improvement. This identification is done based on the difficulty of the test, cost of the test, potential for error during the test and its consequence, and the role of the test on the reliability of the associated function. The licensee should also identify the desired revised STI values.

Following this step, the SFCP process diverges into two paths, both of which need to be followed. One path, starting at Step 7 performs a qualitative evaluation and the other path, starting at Step 8 leads to a quantitative evaluation. Both paths converge later at Step 15.

Step 7: Identify Qualitative Considerations to be Addressed

Qualitative considerations are developed as an input to the IDP. Such considerations include, but are not limited to:

- Surveillance test and performance history of the components and system associated with the STI extension
- Uncertainty associated with the quantitative process
- The impact of systems not quantified using the internal event PRA
- The impact of systems for which LERF results are not available
- The impact of systems for which external events and shutdown PRA are not available
- Past industry and plant-specific experience with the functions affected by the proposed changes
- Impact on defense-in-depth protection.
- Vendor-specified maintenance frequency

- ASME and other code-specified test intervals
- Consideration of the impact of a SSC in an adverse or harsh environment.
- Consideration of the benefits of detection at an early stage of potential mechanisms and degradations that can lead to common cause failures.

The above list of qualitative considerations is not intended to be a complete list. The System Engineering Team will add other qualitative consideration based on their expertise, knowledge of the specific SSC under consideration, and past experience. The IDP in their review of the STI change follows through these same qualitative considerations.

The qualitative considerations are summarized in Step 15 and presented to the IDP (Step 16) along with the quantitative considerations from Step 14 and qualitative or bounding analyses from Steps 10a, 10b, and 10c.

Step 8: Associated STI SSC Modeled in PRA?

(Note: Parts of the discussion in Step 10 relating to initial assessments of various types of PRAs is applicable here also. It was included in Step 10 for ease of presentation)

Check if the surveillance or the associated systems or components are modeled in the PRA. At this point, the focus is on the full power internal events PRA, although the question is applicable for external events PRA and shutdown PRA as well.

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, Section 2.3.3). 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 may not be 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.

In practice, to assess if the STI change can be adequately characterized by the PRA. This means that the following actions should occur:

- Determine all components that are uniquely impacted by the proposed STI change. That is, develop a list of components that are only exercised by the test such that their test-limited risk contribution would be directly affected by the STI change. Establish that the PRA modeled components sufficiently represent the components uniquely impacted by the proposed STI change.

- Determine an appropriate time-related failure contribution for the all of the components to be analyzed as identified in the previous step. The time-related failure contribution can be based on recognized data sources or plant-specific data. If neither is available, then as indicated above, the total failure probability should be assumed to be time-related.

- Ensure that the model includes appropriate common cause failure terms for the components that are uniquely impacted by the STI change.

If all three of the conditions are appropriately included in the PRA model, then proceed to Step 12 to perform the Total and Cumulative CDF and LERF evaluation for the revised STI values. If the base PRA model does not appropriately address one or more of the three pre-conditions, then proceed to Step 9.

Step 9: Can STI Be Modeled in PRA?

Step 9 is entered if in Step 8 it is determined that the systems or components associated with the STI is not adequately included in the base PRA model. In this step, the analyst has to decide if the STI can be adequately characterized in the PRA model. The determination pertains to all PRAs, including external events and shutdown, but the initial focus is on the internal events PRA.

If it is determined that the STI can be adequately modeled in the PRA with some revisions, proceed to Step 11. Otherwise, proceed to Step 10.

Step 10: Perform Qualitative or Bounding Risk Analysis

(Note: A detailed account of how to approach the various types of PRAs, internal events, external events and shutdown, is given as part of description of this step. Portions of the descriptions are applicable only to Step 8 described earlier. However, they have been included here for a more cohesive presentation.).

Step 10 is entered from Step 9 when it is determined that the STI change cannot be modeled in the plant PRA. In such a case, the PRA analyst will have to perform qualitative or bounding analysis that would provide some indication of the impact of the STI change on the results. A qualitative analysis would involve no use of numerical values in the assessments whereas a bounding analysis would involve some use of numerical values in the assessment. To account for the

potential different approaches and the special considerations associated with the different risk contributors, this step has been subdivided to provide further clarification.

Performance of Initial Assessments

An initial qualitative evaluation can be performed at the system/structure level. If the system/structure is found to have a role in a particular portion of the plant's risk profile, then a component level evaluation can be performed.

The first question in the qualitative evaluation process involves the role the SSC plays in the prevention and mitigation of severe accidents. If the SSC is not involved in severe accident prevention or mitigation, including containment functions, then the qualitative screening process is terminated and the STI evaluation proceeds with no CDF and LERF change reported for the STI change. However, this qualitative assessment must be performed for all risk contributors (internal events, external events, and shutdown), and the STI change must still be assessed for other considerations (see Step 7) and presented to the IDP.

Some guidelines for performing initial assessments for each of the risk contributors are given below. The results of the assessment will lead to one of the following outcomes:

1) The qualitative information is sufficient for presentation to the IDP
2) The assessment confirms conclusion in Step 8 that the STI change can be evaluated in the PRA(s) and the evaluation continues in Step 12.
3) The assessment results in the identification of potential contributors that become candidates for bounding analysis (refer to Step 10b and 10c)
4) Depending on the outcome from the bounding analysis in Steps 10b and 10c, there is also the potential that more detailed modeling could be desirable to perform an appropriate evaluation of the STI change. In that case, the process would refer back to Step 11 to revise the PRA as needed to perform the detailed assessment.

Initial Assessment for Internal Events

If an SSC is involved in the prevention or mitigation of severe accidents, then the first risk contributor evaluated is from the internal events PRA. The question of whether an SSC is evaluated in the internal events PRA (or any of the analyses considered in this guideline) must be answered by considering not only whether it is explicitly modeled in the PRA (i.e., in the form of basic event(s) – see Step 8) but also whether it is implicitly evaluated in the model through operator actions, super components or another aggregated event sometimes used in PRAs. The term "evaluated" means:

- Can its failure contribute to an initiating event?

- Is it credited for prevention of core damage or large early release?

- Is it necessary for another system or structure evaluated in the PRA to prevent an event or mitigate an event?

Some SSCs are implicitly modeled in the PRA. It is important that PRA personnel that are knowledgeable in the scope, level of detail, and assumptions of the plant-specific PRA make these determinations. By examining the attributes listed above, it is possible to address even implicitly modeled components. If in Step 8 the SSC was determined to be explicitly modeled and evaluated in the internal events PRA, then the internal event evaluation process is used to determine the acceptability of the STI change as depicted in Step 12. However, if the SSC is determined to be only implicitly modeled, then a bounding analysis should be performed as described in Step 10b.

If the SSC is not evaluated in the internal events PRA (either explicitly or implicitly), then the SSC can be qualitatively screened with the information presented to the IDP. This initial screening is from the standpoint of internal events as not having an impact on the CDF and LERF metrics. The evaluation is continued with fire risk.

Initial Assessment from Fire Events

If the plant has a fire PRA, then the next step of the screening process is to determine whether the SSC is evaluated in the fire PRA. In making this determination, specific attention should be given to structures and the role they play as fire barriers in the fire PRA. It is important that PRA personnel that are knowledgeable in the scope, level of detail, and assumptions of the plant-specific fire PRA make the determinations with respect to fire PRAs. If in Step 8 the SSC is determined to be explicitly modeled and evaluated in the fire PRA, then the fire PRA evaluation process is used to determine the fire risk metric inputs associated with the STI change as depicted in Step 12.

If the plant does not have a fire PRA, a fire risk evaluation is required, such as the *EPRI Fire Induced Vulnerability Evaluation (FIVE).* Again, it is important that personnel that are knowledgeable in the scope, level of detail, and assumptions of the fire risk evaluation (FIVE) make these determinations. If in Step 8 the SSC is determined to be explicitly modeled and evaluated in the FIVE analysis, then the FIVE process should be utilized to determine the acceptability of the STI change as depicted in Step 12.

If the SSC is determined to be only implicitly modeled in the fire PRA or FIVE methodology process, then a bounding analysis should be performed as described in Step 10b.

If the SSC is not involved in either a fire PRA or FIVE evaluations, then the SSC can be qualitatively screened with the information presented to the IDP. This

initial screening is from the standpoint of fire risk as not having an impact on the CDF and LERF metrics. The evaluation is continued with seismic risk.

Initial Assessment from Seismic Events

If the plant has a seismic PRA, then the next step of the screening process is to determine whether the SSC is evaluated in the seismic PRA. Often, structures are explicitly modeled in seismic PRAs. Again, it is important that PRA personnel that are knowledgeable in the scope, level of detail, and assumptions of the plant specific seismic PRA make these determinations. If the SSC is determined to be explicitly modeled and evaluated in the seismic PRA, then the seismic PRA evaluation process is used to determine the seismic risk metric inputs of the STI change as depicted in Step 12.

If the plant does not have a seismic PRA, then a seismic risk evaluation, such as a seismic margin analysis (SMA) that was performed in response to the IPEEE should be performed. Steps 8 and 9 are not applicable for this case. Personnel knowledgeable in the scope, level of detail, and assumptions of the SMA should determine the seismic importance. If the SSC structure is included in the SMA, then qualitative information must be developed that supports the acceptability of the STI change with respect to the seismic risk (go to Step 10a).

Additionally, if the SSC is determined to be only implicitly modeled in the seismic PRA, then a bounding analysis should be performed for consideration in Step 10b.

If the SSC is not involved in either a seismic PRA or SMA, then the SSC can be screened qualitatively with the information presented to the IDP. This initial screening is from the standpoint of seismic risk as not having an impact on the CDF and LERF metrics. The evaluation is continued with other external events risk.

Initial Assessment from Other External Events

If the plant has a PRA that evaluates other external hazards, then the next step of the screening process is to determine whether the SSC is evaluated in the external hazards PRA. Often, structures are explicitly modeled in external hazards PRAs. Personnel knowledgeable in the scope, level of detail, and assumptions of the external hazards PRA should make these determinations. If the SSC is determined to be explicitly modeled and evaluated in the external hazards PRA, then the external hazards PRA evaluation process is used to determine the external hazards risk metric inputs of the STI change as depicted in Step 12. If the plant does not have an external hazards PRA, then it is likely to have an external hazards screening evaluation that was performed to support the requirements of the IPEEE. Once again, personnel knowledgeable in the scope, level of detail, and assumptions of the external hazards analysis should make these determinations. If the SSC is evaluated in the external hazards analysis,

then qualitative information must be developed that supports the acceptability of the STI change with respect to the external hazards risk for consideration in Step 10a or a bounding analysis should be performed for evaluation in Step 10b.

If the SSC is not involved in either an external hazards PRA or external hazards screening evaluation, then the SSC can be screened qualitatively with the information presented to the IDP. This initial screening is from the standpoint of external hazards risk as not having an impact on the CDF and LERF metrics. The evaluation is continued with shutdown risk.

Initial Assessment from Shutdown Events

If the plant has a shutdown PRA, then the next step of the screening process is to determine whether the SSC is evaluated in the shutdown PRA. Personnel knowledgeable in the scope, level of detail, and assumptions of the shutdown PRA should make the determination. If the SSC is explicitly modeled and evaluated in the shutdown PRA, then the shutdown PRA evaluation process is used to determine the external hazards risk metric inputs of the STI change as depicted in Step 12.

If the plant does not have a shutdown PRA, then it is likely to have a shutdown safety program developed to support implementation of NUMARC 91-06. Once again, personnel knowledgeable in the scope, level of detail, and assumptions of the NUMARC 91-06 program should make this determination. If the SSC is determined to be credited in the NUMARC 91-06, then qualitative information must be developed that supports the acceptability of the STI change with respect to the shutdown risk for consideration in Step 10a or a bounding analysis should be performed for evaluation in Step 10b.

If the SSC is not involved in a shutdown PRA or NUMARC 91-06, then the SSC can be screened qualitatively with the information presented to the IDP. This initial screening is from the standpoint of shutdown risk as not having an impact on the CDF and LERF metrics.

Step 10a: Qualitative Analysis Sufficient for IDP?

This step is performed to determine if qualitative information is sufficient to provide confidence that the net impact of the STI change would be negligible (or zero) from a CDF and LERF perspective. It is recognized that in certain cases, such as a SMA, qualitative analysis is the only evaluation that can be performed.

For each risk contributor as determined in the initial assessments performed in Step 10 above, if the qualitative information is deemed sufficient, then proceed to Step 15 and provide the basis for the qualitative conclusions to the IDP. Since only qualitative considerations are provided in this case, then the impacts of the STI change are not incorporated into the cumulative impacts described in Step 12.

However, if the qualitative information is not deemed sufficient for each contributor, then proceed to Step 10b to perform a bounding analysis as required.

If the seismic risk was evaluated using the SMA, then a determination needs to be made if the SSC impacted by the STI change is part of the success path or not, and the information conveyed to the IDP in Step 15. Similarly, if the plant had performed other external hazards analysis or a NUMARC 91-06 safety program for shutdown risk, a qualitative evaluation should be made by personnel knowledgeable in the scope, level of detail, and assumptions of the analysis to conclude if the SSC impacted by the STI change has an important contribution in the evaluation, and the information conveyed to the IDP in Step 15.

Step 10b: Bounding Analysis Below 10-6 CDF and 10-7 LERF?

This step is performed to provide bounding impacts from the STI change given that qualitative considerations alone were deemed insufficient to bring to the IDP.

Bounding analysis can be performed for those SSCs that are not explicitly modeled in the PRA model, but rather are implicitly included in the model at the initiating event, mitigating system, or functional level. In that case, a basic event (or basic events) associated with the initiating event, mitigating system, or function can be identified to use as surrogates for the SSC to be investigated. Reasonable variations to the basic event value(s) should then be explored to determine the potential bounding impact of the STI change.

Alternative evaluations for the impact from external events and shutdown events are also deemed acceptable at this point. For example, if the ΔCDF and ΔLERF values have been demonstrated to be very small from an internal events perspective based on detailed analysis of the impact of the SSC being evaluated for the STI change, and if it is known that the CDF or LERF impact from external events is not specifically sensitive to the SSC being evaluated (either by comparison of the base PRA model results or by qualitative reasoning), then the detailed internal events evaluations and associated required sensitivity cases can be used to "bound" the potential impact from external events and shutdown PRA model contributors.

If the bounding analysis clearly indicates that the ΔCDF and ΔLERF evaluation is below the 10^{-6} CDF and 10^{-7} LERF limits, then proceed to Step 15 and provide the results of the bounding analysis to the IDP. However, since the STI is not directly modeled in the PRA but the bounding analysis shows that the impact of the STI change is negligible, then the impacts of the STI change are not incorporated into the cumulative impacts described in Step 12.

If the bounding analysis does not clearly indicate that the STI change is below the 10^{-6} CDF and 10^{-7} LERF limits, consider a revised STI value and proceed to Step 10c.

Step 10c: Revised STI Values Allow Bounding Analysis Below 10^{-6} CDF and 10^{-7} LERF?

It is not anticipated that this step will be answered in the affirmative too often, but is provided for completeness. This step is entered if the bounding analysis indicates that the results will not clearly fall below the 10^{-6} CDF and 10^{-7} LERF limits at the desired STI value, but could be more clearly below the limits if a reduced STI value is attempted. If it is appropriate, at this stage, the PRA model can be refined to help model the STI change more explicitly than in the original model.

If the revised bounding analysis clearly indicates that the STI change is below the 10^{-6} CDF and 10^{-7} LERF limits, then proceed to Step 15 and provide the results of the bounding analysis performed in Steps 10b and 10c to the IDP. However, since the STI is not directly modeled in the PRA but the bounding analysis shows that the impact of the STI change is negligible, then the impacts of the STI change are not incorporated into the cumulative impacts described in Step 12.

If the revised bounding analysis does not clearly indicate that the STI change is below the 10^{-6} CDF and 10^{-7} LERF limits, then proceed to Step 4, document that the STI cannot be changed and stop. Alternatively, one could determine that detailed modeling could be performed to more accurately reflect the CDF and LERF impacts from the STI change. In that case, one would proceed to Step 11 to revise the PRA as needed to perform a more detailed assessment.

Step 11: Revise PRA Model as Needed

Step 11 is entered from Step 9 when it is determined that the STI change can be modeled in the PRA, but some revisions are required or from Step 10 when bounding analysis are not sufficient to support the STI change request. In either case, the following actions should occur:

- Modify the PRA model as required to ensure that it includes adequate representations of the items identified in Step 8.

- If necessary, re-establish base case CDF and LERF values based on the current STI values for the affected components.

Upon completion of this step, one proceeds to Step 12 to perform the Total and Cumulative CDF and LERF evaluation for the revised STI values.

Step 12: Evaluate Total and Cumulative Effect on CDF and LERF (See Figure 2)

In Step 12, two types of effects on CDF and LERF are considered from all PRAs (internal events, external events, and shutdown). The first effect involves the <u>total</u> CDF/LERF from all PRAs for each individual STI analyzed, and the second

effect involves the cumulative CDF/LERF change from all STI changes. These are described below.

a) For each individual STI analyzed, a change in CDF/LERF for internal events, external events, and shutdown events calculated from a realistic PRA, an acceptance criterion of 1E-06/yr for CDF and 1E-07/yr for LERF will apply. These values are carried forward to b) where the cumulative change of all STI changes are considered.

   However, where conservative or bounding estimates of CDF/LERF are used for external events or shutdown events, if it can be reasonably shown that that the ΔCDF or ΔLERF contribution for external events or shutdown events is less than 1E-06/yr for CDF and 1E-07/yr for LERF, the change in CDF/LERF from STI changes for external events or shutdown events need not be considered further.

b) For a cumulative change in CDF/LERF resulting from all STI changes from a baseline starting point, an acceptance criterion of 1E-05/yr for CDF and 1E-06/yr for LERF will apply. The total CDF must be reasonably shown to be less than 1E-04/yr when using the 1E-05/yr CDF criterion. In addition, the total LERF must be reasonably shown to be less than 1E-05/yr when using the LERF 1E-06/yr criterion. These acceptance criteria are consistent with RG 1.174.

Figure 2 illustrates this process. Steps A and B are performed in parallel to examine the impacts from the internal events PRA model as well as the external events and shutdown PRA models as applicable.

Step 12-A1: Calculate the ΔCDF and ΔLERF values from the Internal Events PRA

This step involves exercising the internal events PRA model as addressed in Step 8 or Step 11. The process involves the following:

- Adjust the time-related failure contribution for the all of the components that are uniquely impacted by the STI change. As indicated in Step 8, the time-related failure contribution can be based on recognized data sources or plant-specific data. If neither is available, the total failure probability should be assumed to be time-related.

- Adjust the common cause failure (CCF) terms for the components that are uniquely impacted by the STI change. This adjustment should be proportional to the adjustment made for the independent time-related contributions to the total independent failure probability.

- Re-evaluate the CDF and LERF values based on the revised independent and CCF failure probabilities identified above. Use the revised CDF and

LERF values to determine the ΔCDF and ΔLERF values for the contribution from the internal events model in Step 12-A2.

Step 12-B1: ΔCDF and ΔLERF Insignificant Based on Qualitative Analysis?

This step involves performing a qualitative assessment of the potential impact on CDF and LERF from external events and shutdown PRAs. The guidance provided in Step 10 for performing qualitative assessments should also be utilized here.

For each contributor (e.g. fire, seismic, shutdown) where it can be qualitatively determined that the net impact of the STI change is negligible, one can proceed to Step 12-A2 without including its contribution to the total CDF and LERF impact. For each contributor where it cannot be qualitatively determined that the net impact of the STI change is negligible, then the analyst must proceed to Step B2 to perform a Bounding Analysis.

Step 12-B2: ΔCDF and ΔLERF < Below 10^{-6} CDF and 10^{-7} LERF from Bounding Analysis?

This Step is entered if in Step 12-B1 when a qualitative determination was not sufficient to establish that the net impact on CDF and LERF is negligible from the STI change. In this case, an initial bounding analysis of the impact from external events and shutdown can be considered. The guidance provided in Step 10b for performing bounding analysis should also be utilized here. Alternatively, the use of conservatively biased external events or shutdown PRA models is also deemed sufficient for this step.

For each contributor (e.g. fire, seismic, shutdown) where conservative or bounding analysis can be utilized to determine that the net impact of the STI change is less than 1E-06/yr for CDF and 1E-07/yr for LERF, then one can proceed to Step A2 without including its contribution to the total CDF and LERF impact. For each contributor where conservative or bounding analysis cannot be utilized to determine that the net impact of the STI change is less than 1E-06/yr for CDF and 1E-07/yr for LERF, then the analyst must proceed to Step B3 to refine the analysis if possible. In any event, any contributors to CDF and LERF from external events or shutdown that do not screen out at Step 12-B1 or 12-B2, will need to be included in the total impact assessment in Step 12-A2.

Step 12-B3: Calculate the ΔCDF and ΔLERF from External Events / Shutdown PRAs

This step is entered from Step 12-B2 if conservative or bounding analysis does not show that the net impact of the STI change is less than 1E-06/yr for CDF and 1E-07/yr for LERF. At this point, refinement to the conservative or bounding analysis needs to be pursued since the impact will be included in the total impact

assessment in Step 12-A2. The degree of margin and the ability to adequately characterize the impact will determine the amount of refinement that is done.

The final ΔCDF and ΔLERF values calculated from this step must be compared against the criterion of 1.0E-6/ year for CDF and 1.0E-7 for LERF. If the criteria are met, then the increase in CDF and LERF values calculated in this step must be added to the corresponding other PRA contributors in Step A2. If the CDF and LERF criteria are not met, then proceed to Step 13 to consider a revised surveillance test interval for re-evaluation in Step 12 or to Step 4 to end the process.

Step 12-A2: Calculate Total Effect on CDF and LERF for Individual STI Change

This step simply involves summing the ΔCDF and ΔLERF values determined in Step 12-A1 and in Step 12-B3 (if applicable). These values are utilized to see if the total CDF and LERF change is within RG 1.174 limits.

Step 12-A3: Total Change Below 10^{-6} CDF and 10^{-7} LERF?

In Step 12-A3, the total CDF and LERF change from the individual STI change being assessed is compared to RG 1.174 limits for CDF and LERF changes. If the RG 1.174 limits are met, then proceed to Step 12-A4 to evaluate the cumulative impacts of all STI changes. If the RG 1.174 limits for CDF and LERF changes are not met, proceed to Step 13 to consider a revised surveillance test interval for re-evaluation in Step 12 or to Step 4 to end the process.

Step 12-A4: Cumulative Change Below 10^{-5} CDF and 10^{-6} LERF?

In Step 12-A4, the cumulative CDF and LERF change from all of the individual STI changes is compared to RG 1.174 limits for CDF and LERF changes. This means that the integrated impact of any previously approved changes using this process must be factored into the cumulative change. That is, the cumulative change should be calculated by including revised failure probabilities due to all STI extensions (not just the sum of the individual assessments). Additionally, the total CDF must be reasonably shown to be less than 1E-04/yr when using the 1E-05/yr CDF criterion and the total LERF must be reasonably shown to be less than 1E-05/yr when using the LERF 1E-06/yr criterion. If the RG 1.174 limits are met (for both internal and external events at power as well as during shutdown), then proceed to Step 14 to perform sensitivity studies. If the RG 1.174 limits for CDF and LERF changes are not met, proceed to Step 13 to consider a revised surveillance test interval or to Step 4 to end the process.

Step 13: Revise STI Values

Step 13 is entered when it is determined that the Surveillance Frequency revisions do not meet the RG 1.174 acceptance criterion in Steps 12-A3 or 12-A4, are not

supported by sensitivity study results (Step 14), or are not accepted by the IDP (Step 16 or Step 20). The surveillance frequencies are adjusted accordingly and re-evaluated in Step 12.

Step 14: Perform Sensitivity Studies

Carry out risk sensitivity studies by changing the unavailability terms for PRA basic events that correspond to SSCs being evaluated. As stated in Section 8 of NEI 00-04, the basic events for both random and common cause failure events should be increased for failure modes impacted by the changes. A factor of three is appropriate as a sensitivity value because it is representative of the change in reliability between a mean value and an upper bound (95^{th} percentile) for typical equipment reliability distributions. For example, for a lognormal distribution the ratio of the 95^{th} percentile to the mean value would be approximately 2.4 for an error factor of 3 and 3.5 for an error factor of 10.

Additional sensitivity cases should also be explored for particular areas of uncertainty associated with any of the key contributors or if there are open Gap Analysis items when compared to the ASME Standard Capability Category II that would impact the results of the assessment.

In practice, this means that the following steps should be performed.

- At a minimum, re-perform all of the ΔCDF and ΔLERF determinations assuming that the standby failure rate is 3 times larger than that used in the base case assessment. Simultaneously adjust the standby failure contribution to the total common cause contribution by the same factor of three. Compare the revised CDF and LERF results to the RG 1.174 limits. Depending on the synergy of the contribution from all of the affected components due to the STI change, the net impact may be more than a factor of three on the calculated ΔCDF and ΔLERF evaluations.

- Determine if there is an impact from the STI change on the frequency of event initiators (those already included in the PRA and those screened out because of low frequency). For applications in this initiative, potentially significant initiators include valve failure that could lead to interfacing system loss-of-coolant accidents (LOCAs) or to other sequences that fail the containment isolation function. Include sensitivity case results that account for these items if it is determined that they are applicable for the STI change. Compare the revised CDF and LERF results to the RG 1.174 limits.

- Examine the key contributors to the delta assessment. From this evaluation, perform the following:

- Ensure that there is not overdue reliance on post-accident recovery of failed components (e.g. repair or ad-hoc manual actions, such as manually forcing stuck valves to open). However, credit may be taken for proceduralized implementation of alternative success strategies. If there is overdue reliance on post-accident recovery of failed components, then re-perform the analysis with no credit taken for these repair or recovery actions. Compare the revised CDF and LERF results to the RG 1.174 limits.

- Ensure that there is not overdue reliance on particular assumptions or areas of uncertainty especially if there are open Gap Analysis items when compared to the ASME Standard Capability Category II that would impact the results of the assessment. If there is overdue reliance on particular assumptions or if there are areas of uncertainty that would not be encompassed in the factor of three sensitivities identified above, then re-perform the analysis with revisions made to the basic event values associated with the key areas of uncertainty. Compare the revised CDF and LERF results to the RG 1.174 limits.

If the sensitivity evaluations support the STI changes (i.e. RG 1.174 limits are still met), then go to Step 15. Alternatively, if the sensitivity evaluations show that the changes in CDF and LERF as a result of changes in SSCs being evaluated are not within the acceptance guidelines of RG 1.174, then revised frequencies should be considered (go to Step 13). However, it could be possible to proceed to Step 15 if the results of the sensitivity studies are only slightly above the limits whereas the base case results are well below the limits. Qualitative considerations would have to be developed to provide to the IDP at that point to provide confidence that proceeding with the STI change is still acceptable even though sensitivity studies indicate that the change could exceed the RG 1.174 limits for the individual STI change.

Some 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 listed below.

- There is plant-specific or industry experience available with other components of the same type that indicate that the failure probability will not be impacted by the STI change. In this case, the standby failure probability utilized for the assessment is not representative of real degradation impacts such that the implementation of the standby failure increase in the sensitivity studies is overly conservative.

- The performance of the test causes unavailability time that when factored into the analysis compared to the potential increase in the failure probability offsets the actual risk increase incurred.

- There are other considerations (e.g. there is an increased likelihood of plant trip associated with the performance of the test) that when factored into the analysis compared to the potential increase in the failure probability offsets the actual risk increase incurred.

Step 15: Summarize Qualitative and Quantitative Assessments and Establish Recommended Monitoring to be Addressed by IDP

The results from the following qualitative and quantitative assessments are documented and summarized for consideration by the IDP in Step 18:

- The results from the qualitative considerations from developed in Step 7.
- The results from the evaluation of the total and cumulative effect on CDF and LERF generated in Step 12.
- The results from the sensitivity studies conducted in Step 14.
- The results from the qualitative and bounding analyses conducted in Step 10a, 10b, and 10c for STI SSCs not modeled in the PRA.
- Recommended monitoring for SSCs.

Step 16: IDP Approval or Adjust STI

This step involves the use of an IDP that, in addition to reviewing the results quantitatively, is charged with the task of reviewing the STI extensions qualitatively.

The qualifications for the IDP members are very similar to the one for the Maintenance Rule. Normally the same IDP/expert panel is used as for the Maintenance Rule implementation. A specialist with experience in surveillance tests and system or component reliability should also be added to the IDP. Details on the qualification of the IDP members are given in NEI 00-04.

If the IDP approves the change, the changes are implemented and documented for future audits by NRC. If the IDP does not approve certain STI extensions, then the STI value is not revised (in Step 13).

The IDP has additional responsibilities. These relate to making recommendations on the way the revised surveillance intervals are implemented (for instance, a phased implementation), reviewing the cumulative impact of all changes carried out over a period of time, and monitoring the impact of changes on failure rates.

Step 17: Document New STI and Implement the Changes

The STI changes approved by the IDP are documented appropriately and then implemented by revising plant procedures, affected documents, and training the personnel as needed. The SFCP process stops here, however, long-term monitoring is still required per Step 18.

Step 18: Monitoring & Feedback

The purpose of performance monitoring in the SFCP process is twofold. First, performance monitoring should help confirm that no failure mechanisms that are related to the revised surveillance frequencies become important enough to alter the failure rates assumed in the justification of program changes. Second, performance monitoring should, to the extent practicable, ensure that adequate component capability (i.e., margin) exists relative to design-basis conditions so that component-operating characteristics, over time, do not result in reaching a point of insufficient margin before the next scheduled test. Regulatory Guide 1.175 (Ref. 6) provides guidance on performance monitoring when testing under design basis conditions is impracticable.

Two important aspects of performance monitoring are whether the test 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. Component failure rates should not be allowed to rise to unacceptable levels (e.g., significantly higher than the failure rates used to support the change) before detection and corrective action take place.

For acceptance guidelines, monitoring programs should be proposed that are capable of adequately tracking the performance of equipment that, when degraded, could alter the conclusions that were key to supporting the acceptance of revised surveillance frequencies. Monitoring programs should be structured such that SSCs are monitored commensurate with their safety significance. This allows for a reduced level of monitoring of components categorized as having low safety significance.

The performance monitoring process should have the following attributes:

- Enough tests are included to provide meaningful data, and
- The test is devised such that incipient degradation can reasonably be expected to be detected.
- The licensee trends appropriate parameters as required by the ASME Code Case and as necessary to provide reasonable assurance that the component will remain operable over the test interval.

The output of this step is sent to Step 19.

Step 19: Periodic Re-assessment

The SFCP contains provisions whereby component performance data periodically is fed back into the component test strategy determination (i.e., test interval and methods) process. This would include results of component or train level monitoring and results of Maintenance Rule (or §50.69 monitoring).

Measures should be in place to identify the need for more emergent program updates (e.g., following a major plant modification or following a significant equipment performance problem). The results of these periodic re-assessments are fed back to the IDP in Step 20 for evaluation.

Part of the periodic re-assessment includes updating of the PRA. When the PRA models (all modes) are updated, if the revised surveillance frequencies are included in the base model then the change in CDF/LERF should be removed from the cumulative value that is tracked in Step 12-A4. If the revised frequencies are not incorporated in the updated base model, then the analysis for those frequencies should be reviewed to ensure that the conclusions remain valid.

Step 20: IDP Reviews & Adjusts STI as Needed

Step 20 is entered from Step 19 where the operating experience feedback following STI change implementation is reviewed periodically.

The IDP would be responsible for periodic review of performance monitoring results (from Step 19) and attendant re-assessment of the program. Any changes identified by the IDP are routed to Step 13, or if no adjustments are required are routed back to monitoring the results.

Figure 1
Tech Spec Initiative 5 B Process

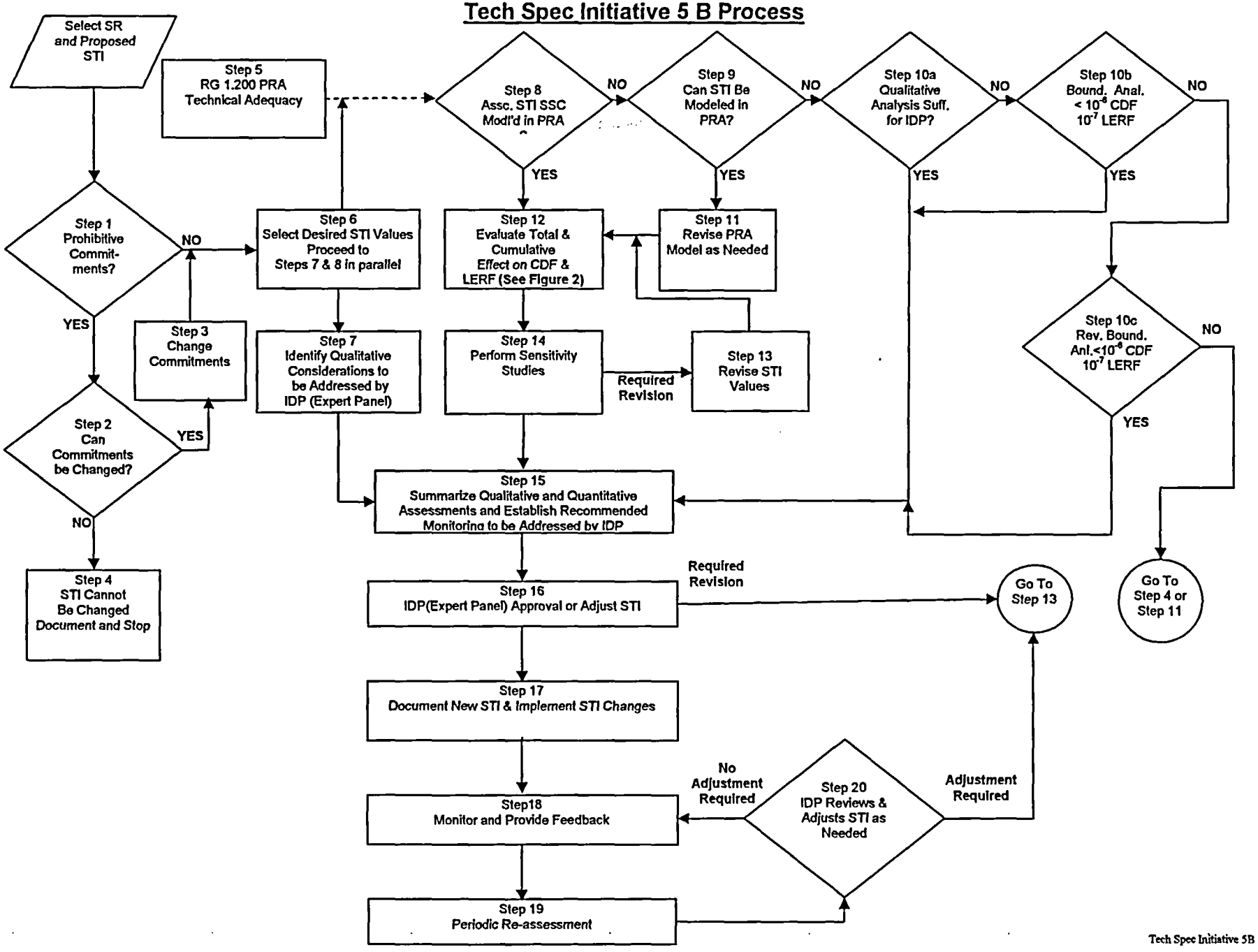
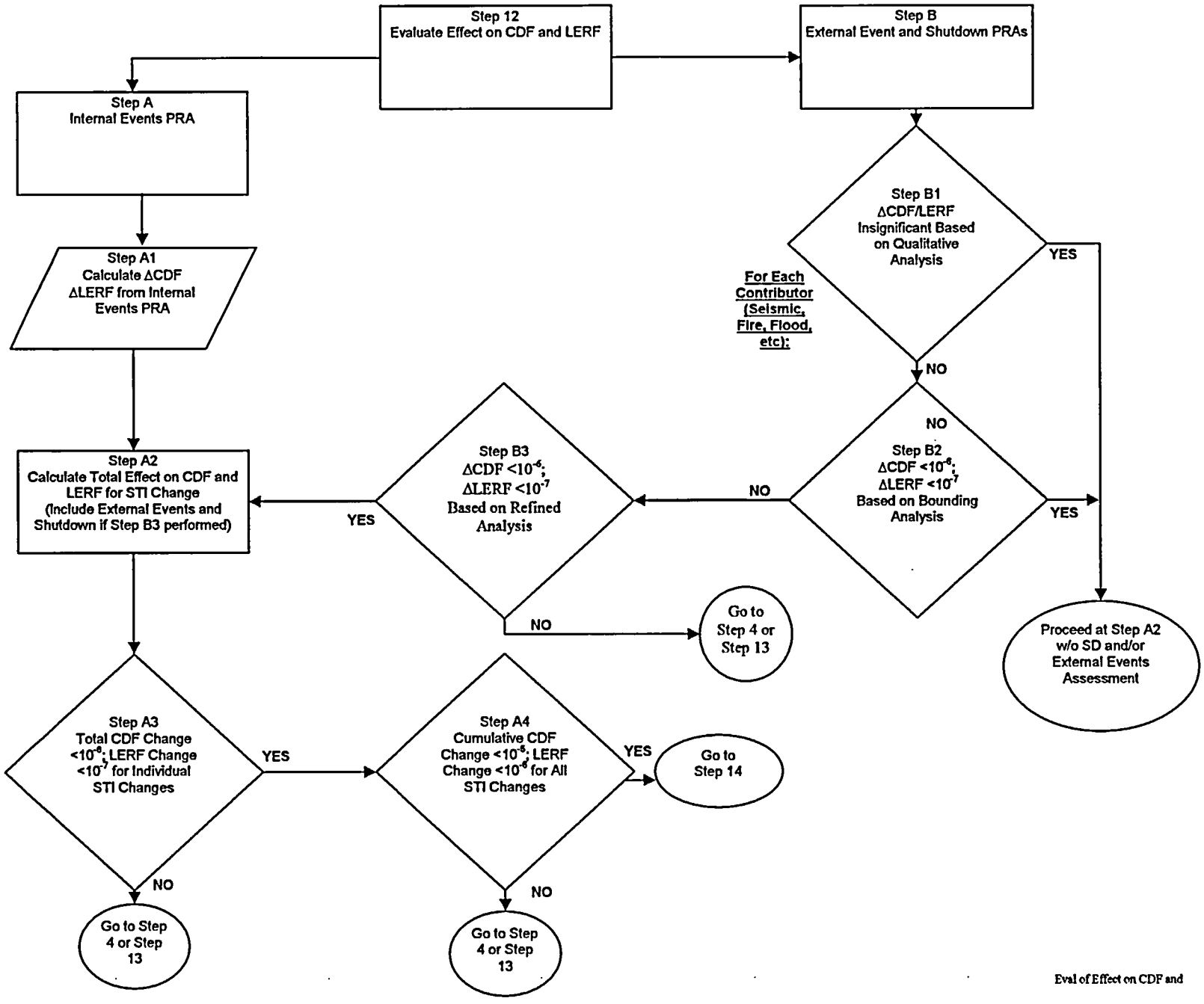


Figure 2
Evaluation of Effect on CDF and LERF



Eval of Effect on CDF and

DRAFT
10/28/05

Sample Plant IDP Charter

Surveillance Frequency Control Program

Overview

The Surveillance Frequency Control Program (SFCP) pursues relocation of STIs from Technical Specifications to a licensee- controlled document such as the Technical Review Manual (TRM). The BWROG and NEI have developed a risk-informed methodology for extending the STI for the relocated tests. The plan is to submit a LAR for relocating the STIs using the methodology developed in NEI 04-10. Plant procedures to support STI implementation will be developed for each individual plant, including a revision to the plant Surveillance Test Program. Procedures are not required to be in effect until the LAR is submitted to the NRC. In the interim, the guideline will govern this process and IDP recommendations will specify the plan for each STI implementation. However, no STI change will be implemented until NRC approval is received.

IDP (Integrated Decisionmaking Panel[1]) Requirement

The STI methodology requires review by an IDP.
This charter provides an overview of IDP composition, roles and responsibilities per the guideline.

IDP Composition

IDP is comprised of the site MRule (Maintenance Rule) Expert Panel, Surveillance Test Coordinator (STC) and Subject Matter Expert (SME) who is a cognizant system manager or component engineer.

IDP Qualifications

- MRule Expert Panel Members: same as MRule Expert Panel qualification
- Surveillance Test Coordinator (STC): a specialist with experience in surveillance tests
- Subject Matter Expert (SME): a specialist with experience in system or component reliability

[1] IDP is a term used in NEI 00-04, 10CFR50.69 SSC Categorization Guideline, Draft Revision D, May 2003, and also US NRC Reg. Guide 1.174, An Approach for Using PRA and Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis, July 1998

IDP Roles & Responsibilities

1. Review the guideline Figure 1 and 2 of the SFCP Process (NEI 04-10) to ensure that the flow chart pathway selected by the presenter(s) is correct for the specific STI.

2. Review the PRA results quantitatively (if applicable).

3. Review the STI extensions qualitatively. Qualitative considerations include:
   a) ST and performance history of the components and system associated with the STI extension
   b) Uncertainty associated with the quantitative process
   c) The impact of systems not quantified using the internal event PRA
   d) The impact of systems for which LERF results are not available
   e) The impact of systems for which external events and shutdown PRA are not available
   f) Past industry and plant-specific experience with the functions affected by the proposed changes
   g) Impact on defense-in-depth protection.
   h) Vendor-specified maintenance frequency
   i) ASME and other code-specified test intervals
   j) Consideration of the impact of a SSC in an adverse or harsh environment
   k) Consideration of the benefits of detection at a early stage of potential mechanisms and degradations that can lead to common cause failures

4. Approval / Disapproval:
   - If the IDP approves the change, the changes will be implemented and documented for future audits by NRC.
   - If the IDP approves the change with comment(s), then the comment(s) will be resolved prior to changes being implemented and documented for future audits by NRC.
   - If the IDP disapproves an STI extension, then the STI value is left unchanged.

5. Implementation and monitoring:
   - Consider phased implementation, by determining if the STI change should be implemented in a single step or in phases. Consider phased implementation for risk significant SSCs .
   - Reviewing the cumulative impact of all STI changes carried out over a period of time. (This is also required by NRC risk-informed Reg. Guides 1.174 and 1.177)
   - Monitoring the impact of changes on failure rates.
     a) The IDP can review a previously approved STI extension at a future date and reduce it if the performance trend shows increase in the failure rate of components or reduced reliability of the systems.
     b) Since it is not easy to detect changes in failure rate in a short time frame, the IDP should recommend surrogate parameters to be monitored in lieu of the failure rates. Typically, these will be performance indicators, for instance, pump discharge and discharge pressure flow in lieu of pump failure rate and valve opening and closing times in lieu of valve failure rate. Similar monitoring is already being done in

response to the Maintenance Rule, it is therefore recommended that this task be added to the same team that carries it out for the Maintenance Rule. Component or train level monitoring would be expected for high risk SSCs . Component failure rates should not be allowed to rise to unacceptable levels (e.g., significantly higher than the failure rates used to support the change) before detection and corrective action take place. The intent of monitoring is to ensure that the component failure rates remain close to those used to support the STI change.

c) Periodic Review of Performance Monitoring Results: If the performance of the system, based on the performance indicator monitoring has a degrading trend, then this should be brought to the attention of the IDP, which would then decide if the STI extension should be revised or revoked.

d) Where there is a very low risk impact from the revised intervals, in general no additional monitoring should be proposed beyond the existing Maintenance Rule performance criteria.