U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

16.1 RISK-INFORMED DECISION MAKING: TECHNICAL SPECIFICATIONS

The NRC policy statement on probabilistic risk analysis (PRA) (Reference 1) encourages greater use of this analytic technique to improve safety decision making and improve regulatory efficiency. The NRC staff's PRA Implementation Plan (Reference 2) describes activities planned or under way to expand this use. One activity under way in response to the policy statement is PRA use in support of decisions to modify an individual plant's technical specifications (TSs).

Licensee-initiated TS changes consistent with currently approved staff positions (*e.g.*, regulatory guides (RGs), standard review plans (SRPs), branch technical positions, or the Standard Technical Specifications (STSs) (References 3-7)) normally are evaluated by the staff using traditional engineering analyses. Licensees are not expected to submit risk information in support of proposed changes. Licensee-initiated TS change requests that go beyond current staff positions may be evaluated by the staff using traditional engineering analyses as well as the risk-informed approach of RG 1.177, "An Approach for Plant-Specific Risk-Informed Decision Making: Technical Specifications" (Reference 8). A licensee may be asked to submit supplemental risk information not in the original submission. If risk information on the proposed TS change is not provided, the staff reviews the licensee's information for whether the application can be approved using traditional methods to approve or reject the application.

Rev. 1 - [Month] 2007

Section 182a of the *Atomic Energy Act* requires applicants for nuclear power plant operating licenses to state:

> [S]uch technical specifications, including information of the amount, kind, and source of special nuclear material required, the place of the use, the specific characteristics of the facility, and such other information as the Commission may, by rule or regulation, deem necessary in order to enable it to find that the utilization ... of special nuclear material will be in accord with the common defense and security and will provide adequate protection to the health and safety of the public. Such technical specifications shall be a part of any license issued.

In Section 50.36, "Technical Specifications," of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," (Reference 9), the Commission established its regulatory requirements for TS content with emphasis on the prevention of accidents and the mitigation of accident consequences. The Commission expected applicants to incorporate into their TSs items directly related to maintenance of the integrity of physical barriers designed to contain radioactivity. Pursuant to 10 CFR 50.36, TSs are required to have the following five specific categories: (1) safety limits, limiting safety system settings, and limiting control settings, (2) limiting conditions for operation, (3) surveillance requirements, (4) design features, and (5) administrative control.

Since the mid-1980s, the NRC has been reviewed and granted TS improvements based, at least in part, on PRA insights. Some of these improvements have been proposed by the Nuclear Steam Supply System owners groups to apply to entire classes of plants. Many others have been proposed by individual licensees. Typically, the proposed improvements relax one or more TS allowed outage times (AOTs) or surveillance test intervals (STIs).[1]

In its July 22, 1993, final policy statement on TS improvements (58 FR 39132) (Reference 10), the Commission stated that it:

> ...expects that licensees, in preparing their Technical Specification related submittals, will utilize any plant-specific PSA or risk survey and any available literature on risk insights and PSAs ... Similarly, the NRC staff will also employ risk insights and PSAs in evaluating Technical Specifications related submittals. Further, as a part of the Commission's ongoing program of improving Technical Specifications, it will continue to consider methods to make better use of risk and reliability information for defining future generic Technical Specification requirements.

The Commission reiterated this point in July 1995 when it issued the revision to 10 CFR 50.36 (Reference 11).

In August 1995, the NRC adopted the policy statement, including the following, for the expanded use of PRA (Reference 1).

---

[1] The improved STSs (NUREGs 1430-1434) (References 3-7) use the terminology "Completion Times" and "Surveillance Frequency" in place of 'Allowed Outage Time" and Surveillance Test Interval."

1. The use of PRA technology should be increased in all regulatory matters to the extent supported by the state of the art in PRA methods and data to complement the NRC deterministic approach and support the NRC traditional defense-in-depth philosophy.

2. PRA and associated analyses (*e.g.*, sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state of the art, to reduce unnecessary conservatism in current regulatory requirements, RGs, license commitments, and staff practices. Where appropriate, PRA should support the proposal of additional regulatory requirements in accordance with 10 CFR 50.109 (Backfit Rule) (Reference 12). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. Of course, the intent of this policy is to comply with existing rules and regulations unless they are revised.

3. PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review.

4. In its safety goals for nuclear power plants and subsidiary numerical objectives the Commission must consider uncertainties in making regulatory judgments on the need to propose and back-fit new generic requirements for nuclear power plant licensees.

In approving the policy statement, the Commission expected its implementation to improve the regulatory process in three areas: foremost, through safety decision-making enhanced by PRA insights; through more efficient use of agency resources; and through a reduction of unnecessary burdens on licensees.

RG 1.177 (Reference 8) describes an acceptable method for assessing the nature and impact of proposed TS changes by considering engineering issues and applying risk insights. Licensees submitting risk information (whether on their own initiative or at the request of the staff) should address each of the principles of risk-informed regulation addressed in RG 1.177. Licensees should explain how chosen approaches and methods (whether quantitative or qualitative, traditional or probabilistic), data, and criteria for risk consideration are appropriate for the decisions to be made.

REVIEW RESPONSIBILITIES

Primary - Organization responsible for the review of technical specifications

Secondary - None

I. AREAS OF REVIEW

NRC SRP Section 19.1 (Reference 13) provides general guidance for evaluating risk-informed regulatory changes. The specific areas of review for risk-informed TS changes are the following four elements:

1. Element 1: Define the Proposed Change. The reviewer should confirm that the licensee has explicitly identified the particular TSs affected by the proposed change and

has cited related available engineering studies (*e.g.*, topical reports), methods, codes, and PRA studies. The licensee also should determine how affected systems, components, or parameters are modeled in the PRA and identify all PRA elements affected by the change. This information collectively should describe the TS change and outline the method of analysis. The licensee should describe the proposed change and how it meets the Commission's PRA Policy Statement objectives of enhanced decision-making, more efficient use of resources, and reduction of unnecessary burden.

2. Element 2: Perform Engineering Analysis. The reviewer should confirm whether the licensee has examined the proposed TS change to verify that it meets applicable rules and regulations. In addition, the licensee should determine the change's impact on defense-in-depth aspects of the plant's design and operation and the adequacy of safety margins following the proposed change. The licensee should consider how plant and industry operating experience and whether potential compensatory measures could be taken to offset any negative impact of the proposed change.

   The licensee also should evaluate the proposed change for impact on plant risk. The evaluation explicitly should consider the specific plant equipment affected by the proposed TS changes and the effects on the functionality, reliability, and availability of the equipment. The necessary scope and level of detail of the analysis depend on the particular systems and functions affected, and there are cases for which a qualitative, rather than quantitative, risk analysis is acceptable.

   The licensee should state the rationale supporting the acceptability of proposed changes by integrating probabilistic insights with traditional considerations for a final risk determination. That determination should consider continued compliance with applicable rules and regulations, the adequacy of the traditional engineering evaluation of the proposed change, and the change in plant risk as to acceptance guidelines. All these areas should be addressed adequately before the change is acceptable.

3. Element 3: Define Implementation and Monitoring Program. The reviewer should confirm whether the licensee has considered implementation and performance monitoring strategies so (A) no safety degradation occurs because of the TS changes and (B) the engineering evaluation of the impact of the proposed changes reflects the actual reliability and availability of TS structures, systems, and components (SSCs) evaluated. This confirmation ensures that the conclusions drawn from the evaluation remain valid.

4. Element 4: Submit Proposed Change. The final element is documentation of the analyses and submission of the license amendment request.

Review Interfaces

Other SRP sections interface with this section as follows:

SRP Section 16.0 provides general review guidance for TS. This SRP section is used as referenced from SRP Section 16.0 for review of risk-informed applications.

SRP Section 19.1 provides general review guidance for determining the technical adequacy of PRA results for risk-informed activities.

The specific acceptance criteria and review procedures are contained in the referenced SRP sections.

II. ACCEPTANCE CRITERIA

Requirements/SRP Acceptance Criteria

Specific SRP acceptance criteria acceptable to meet the relevant requirements of the NRC's regulations identified in SRP Section 16.0 are as follows for review described in Subsection I of this SRP section. The SRP is not a substitute for the NRC's regulations, and compliance with it is not required. However, an applicant is required to identify differences between the design features, analytical techniques, and procedural measures proposed for its facility and the SRP acceptance criteria and evaluate how the proposed alternatives to the SRP acceptance criteria provide acceptable methods of compliance with the NRC regulations.

1. Traditional Engineering Guidelines

   A. Defense in Depth. The licensee's engineering evaluation should state whether the impact of the proposed TS change is consistent with the defense-in-depth philosophy. The intent is to maintain the philosophy of defense in depth, not to prevent changes in achieving defense in depth. The defense-in-depth philosophy traditionally has been applied in reactor design and operation for multiple means of performing safety functions and preventing the release of radioactive material. It continues to be effective in accounting for uncertainties in equipment and human performance. When a comprehensive risk analysis can be done, it can help determine the appropriate extent of defense in depth (*e.g.*, balance among core damage prevention, containment failure, and consequence mitigation) to protect public health and safety. When a comprehensive risk analysis is not done, traditional defense-in-depth considerations should account for uncertainties. The evaluation should consider intent of the general design criteria (GDCs), national standards, such engineering principles as the single-failure criterion, the impact of the proposed TS change on barriers (both preventive and mitigative) to core damage, containment failure or bypass, and the balance among defense-in-depth attributes. The licensee should select the engineering analysis techniques, whether quantitative or qualitative, traditional or probabilistic, appropriate to the proposed TS change.

   The licensee should assess whether the proposed TS change meets the defense-in-depth principle. Defense in depth consists of numerous elements that can be assessment guidelines. Other equivalent acceptance guidelines also may be used.

   Consistency with the defense-in-depth philosophy is maintained if:

   (i) A reasonable balance among prevention of core damage, prevention of containment failure, and consequence mitigation is preserved (*i.e.*, the proposed TS change does not change the balance among these principles of prevention and mitigation to the extent required by 10 CFR 50.36 (Reference 9)). TS change requests should consider whether anticipated operational changes made by a TS change could introduce or could increase the likelihood of new accidents or transients (as required by 10 CFR 50.92) (Reference 14).

(ii) Over-reliance on programmatic activities to compensate for weaknesses in plant design is avoided (*e.g.*, use of high reliability estimates based primarily on optimistic program assumptions).

(iii) System redundancy, independence, and diversity are maintained commensurate with the expected frequency and consequences of challenges to the system (*e.g.*, there are no risk outliers). The licensee should consider:

(1) Whether appropriate restrictions are in place to preclude simultaneous equipment outages that would erode the principles of redundancy and diversity.

(2) Whether compensatory actions when entering the modified AOT for pre-planned maintenance are identified.

(3) Whether the TS change specifies that voluntary removal of equipment from service should not be scheduled when adverse weather conditions or other situations that likely may subject the plant to abnormal conditions are predicted.

(4) Whether the TS change impact on the safety function should be considered (*e.g.*, impact of an AOT change for the low-pressure safety injection system on the overall availability and reliability of the low-pressure injection function).

(iv) Defenses against potential common cause failures are maintained and the potential for introduction of new common cause failure mechanisms is assessed (*e.g.*, TS change requests should consider whether the anticipated operational changes from an AOT or STI change could introduce any new common cause failure modes not previously considered).

(v) Independence of physical barriers is not degraded. TS change requests should address the independence of barriers as not degraded by the change (*e.g.*, containment system TS change).

(vi) Defenses against human errors are maintained. TS change requests should consider whether the anticipated operation changes from an AOT or STI change could change the expected operator response or introduce any new human errors not previously considered (*e.g.*, change from maintenance during shutdown to maintenance at power when different personnel and different activities may be involved).

(vii) The intent of the GDCs in 10 CFR Part 50, Appendix A (Reference 15), is maintained.

B. Safety Margins. The engineering evaluation should assess whether the impact of the proposed TS change is consistent with the principle of maintaining sufficient safety margins (Principle 3). An acceptable set of guidelines for that assessment are summarized here. Other equivalent guidelines are acceptable. Sufficient safety margins are maintained when:

(i) Codes and standards (*e.g.*, American Society of Mechanical Engineers, Institute of Electrical and Electronic Engineers) or alternatives approved by the NRC are met (*e.g.*, the proposed TS AOT or STI change is not in conflict with approved codes and standards for the subject system).

(ii) Safety analysis acceptance criteria in the final safety analysis report (FSAR) are met or proposed revisions provide sufficient margin to account for analysis and data uncertainties (*i.e.*, the proposed TS AOT or STI change does not adversely affect any assumptions or inputs to the safety analysis or justification ensures continued sufficient safety margin). For TS AOT changes, the effect on FSAR acceptance criteria should be assessed, assuming the plant is in the AOT (*i.e.*, the subject equipment is inoperable) and there are no additional failures. The assessment should identify all situations in which entry into the proposed AOT could result in failure to meet an intended safety function.

C. Need for and Adequacy of Change. The licensee has demonstrated that the change is needed for adequate reliability and availability of significant safety systems.

D. Justification. The licensee has provided the justification for the change based on the guidance of subsection III.A of this SRP section.

2. Probabilistic Guidelines. The guidelines stated in RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Current Licensing Basis," Sections 2.2.4 and 2.2.5 (Reference 16), apply to TS change requests. Those sections present risk-acceptance guidelines as functions of the licensee's risk analysis of predicted changes in total core damage frequency (CDF) and large early release frequency (LERF) for the TS change requested. In addition, those sections address cases when the scope of the licensee's PRA does not include a Level 2 (containment performance) analysis, and when, according to the guidelines of RGs 1.174 and 1.177, such an analysis is needed. TS submissions for AOT changes should be evaluated against the risk acceptance guidelines in this section in addition to those in RG 1.174. Application of all risk acceptance guidelines to TS modification proposals will be consistent with the fundamental principle that TS changes result in small increases in the risk to the health and safety of the public (Principle 4, as

described in the "Discussion" section of RG 1.177) (Reference 8). General guidance for evaluating the risk impact from TS and other changes is in SRP Section 19.1.

TS change evaluations may involve some small increase in risk as quantified by PRA models. The usual argument is that such a small increase is offset by the many beneficial effects of the change not modeled by the PRA. The numerical guidelines ensure that the risk increase is small and provide a quantitative basis for the risk increase according to modeled or quantified aspects of the TS change.

The numerical guidelines for an acceptable TS change are taken into account along with other traditional considerations, operating experience, lessons learned from previous changes, and practical considerations for test and maintenance practices. The final acceptability of the proposed change should be based on all of these considerations and not solely on PRA-informed results compared to numerical acceptance guidelines.

The numerical guidelines ensure that any increased risk is within acceptable limits; traditional considerations ensure that the change meets rules and regulations in effect; practical considerations judge the acceptability of the change; and lessons learned from past experience ensure that mistakes are not repeated.

Using the risk measures addressed in RG 1.177, the change in risk should be calculated for the TS changes and compared against the numeric guidelines referenced in this section. In calculating the risk impact of the change, additional changes from the change can be credited *(e.g.*, for an STI change, if the test strategy also is changed, the effect should be incorporated in the risk evaluation).

However, this SRP and RGs 1.177 and 1.174, apply only to permanent (as opposed to temporary or "one-time") changes to TS requirements. TS AOT changes are permanent but, because AOTs are entered infrequently and are temporary by their very nature, the following TS acceptance guidelines for AOT changes evaluate the risk of the revised AOT additionally to the evaluation by the RG 1.174 acceptance guidelines.

A. The licensee has demonstrated that the TS AOT modification has only a small quantitative impact on plant risk. An incremental conditional core damage probability (ICCDP)[2] of less than 5.0E-7[3] is small for a single TS AOT modification. An incremental conditional large early release probability (ICLERP)[4] of 5.0E-8 or less is also small. Also, the ICCDP contribution should

---

[2] ICCDP = [(conditional CDF with the subject equipment out of service) -(baseline CDF with nominal expected equipment unavailabilitics)] x (duration of single AOT under consideration).

[3] The ICCDP acceptance guideline of 5.0E-7 is based upon the hypothetical situation of subject equipment at a representative plant out of service for five hours, causing the CDF of the plant with an assumed baseline CDF of 1.0E-4 per reactor year to increase conditionally to 1.0E-3 per reactor year during the five-hour period. This basis assumes that the majority of repairs can be made in five hours or less and that the NRC has accepted this level of risk for operating plants.

[4] ICLERP = [(conditional LERF with the subject equipment out of service) -(baseline LERF with nominal expected equipment unavailabilities)] x (duration of single AOT under consideration).

be distributed in time so any increase in conditional risk is small and within the normal operating background (risk fluctuations) of the plant (Tier 1).

B. The licensee has demonstrated appropriate restrictions on dominant risk-significant configurations of the modifications (Tier 2).

C. The licensee has a risk-informed plant configuration control program with procedures to utilize, maintain, and control it (Tier 3).

In the context of integrated decision-making, application of the acceptance guidelines should not be overly prescriptive. They are intended to indicate, in numerical terms, what is acceptable. The numerical values are approximate and indicate changes generally acceptable. The intent in comparing PRA results to the acceptance guidelines is to demonstrate with reasonable assurance that Principle 4, addressed in the "Discussion" section of RG 1.177 (Reference 8), is met. The decision must be based on a full understanding of the contributors to the PRA results and the impacts of the uncertainties, both those explicitly considered in the results and those not.

A nonquantitative assessment of risk (either alone or accompanied by quantitative assessment) may suffice to justify TS changes. The licensee is expected to use judgment on the acceptability (to support regulatory decision-making) of the risk argument, including the appropriate blend of quantitative and qualitative assessments.

III. REVIEW PROCEDURES

The reviewer will select and emphasize material from the procedures described below, as may be appropriate for a particular case.

These review procedures are based on the identified SRP acceptance criteria. For deviations from these acceptance criteria, the staff should review the applicant's evaluation of how the proposed alternatives to provide an acceptable method of complying with the relevant NRC requirements identified in Subsection II.

Licensees are expected to provide for any TS change strong technical bases rooted in traditional engineering and system analyses. TS change requests based on PRA results alone should not be submitted for review. TS change requests should integrate such considerations as compliance with STSs, generic applicability of the requested change if different from STSs, operational constraints, manufacturer recommendations, and test and maintenance practicalities. Standard practices for setting AOTs and STIs should be followed (*e.g.*, AOTs normally are eight hours, 12 hours, 24 hours, 72 hours, seven days, 14 days, etc., STIs normally 12 hours, 7 days, one month, three months, etc.). Such standards greatly simplify scheduling, monitoring, and auditing. Logical consistency among requirements should be maintained (*e.g.*, AOT requirements for multiple trains out of service should not be longer than for one of the constituent trains).

1. Define the Proposed Change

The reasons for requesting the TS change or changes should be stated with information demonstrating that the extent of the change is needed. Generally, acceptable reasons for requesting TS modifications fall into one or more of the following categories:

A. Improvement in Operational Safety. The reason for the TS modification may be to improve operational safety; that is, a reduction in the plant risk or in occupational exposure of plant personnel complying with the requirements.

B. Consistency of Risk Basis in Regulatory Requirements. The TS modifications requested can be supported on their risk implications. TS requirements can be changed to reflect improved design features or equipment reliability improvements that make a previous requirement unnecessarily stringent or ineffective. TSs may be changed to establish consistent requirements across the industry or an industry group. The risk from the change must remain acceptable.

C. Reduce Unnecessary Burdens. The change may be requested to reduce unnecessary burdens of compliance with TS requirements based on plant-specific or industry operating history. In specific instances, the repair time needed may be longer than the AOT defined in the TS. The required surveillance may lead to plant transients, unnecessary equipment wear, excessive radiation exposure to plant personnel, unnecessary administrative burdens not justified by the safety significance of the surveillance requirement.

The change may increase operational flexibility or allow an increased allocation of plant personnel time to more safety-significant aspects. In some cases, several licensees may determine there is a common need for a TS change and submit the request as a group. Group submissions can be advantageous when the SSCs considered in the change are similar across all plants in the group. Plant-specific information as to the engineering evaluations described in Section III.2 of this SRP section still is required; however, the group may be able to draw generic conclusions from a compilation of the plant-specific data. In addition, there are benefits from cross-comparison of the results of the plant-specific evaluations.

2. Perform Engineering Analysis

A. Traditional Engineering Evaluation

(i) Compliance with Current Regulations. In evaluating proposed TS changes the licensee must ensure that the current regulations, orders, and license conditions are met, consistent with Principle 1 of risk-informed regulation. The NRC TS regulations are stated in 10 CFR 50.36, "Technical Specifications." Additional information as to NRC TS policies is in the "NRC Final Policy Statement on Technical Specification Improvements for Nuclear Power Reactors" (58 FR 39132) of July 22, 1993 (Reference 10). These documents define the main TS elements and state criteria for items to be included in the TS. The final policy statement and the statement of considerations for 10 CFR 50.36 (60 FR 36953) of July 19, 1995, (Reference 11), also address probabilistic approaches to TS improvement. Regulations of application for and issuance of license amendments are in 10 CFR 50.90 (Reference 17), 10 CFR 50.91 (Reference 18), and 10 CFR 50.92 (Reference 14). In addition, the licensee should ensure that any discrepancies between the proposed TS change and licensee commitments are considered in the evaluation.

(ii) Evaluation of Defense-in-Depth Attributes & Safety Margins. The engineering evaluations should show that the fundamental safety principles for the plant design are not compromised. Design-basis accidents, a combination of postulated challenges and failure events against which plants are designed with features for adequate and safe response, play a central role in nuclear power plant design. During the design process, plant response and safety margins are evaluated by assumptions intended to be conservative. National standards and engineering considerations like defense-in-depth attributes and the single-failure criterion also influence plant design and operation. Margins and defenses for these considerations may be affected by the proposed TS change and, therefore, should be re-evaluated for a requested TS change. In this reevaluation, the impact of the proposed TS change on affected equipment functionality, reliability, and availability is determined. The engineering evaluation should assess whether the proposed TS change is consistent with the defense-in-depth philosophy and maintains sufficient safety margins. The reviewers should confirm whether the acceptance criteria of subsection II of this SRP section are met as to the principles of defense in depth and safety margins.

B. Probabilistic Engineering Evaluation

(i) Risk Evaluation for AOTs. The staff has a three-tiered approach to evaluate the risk of proposed TS AOT changes. Tier 1 evaluates the impact on plant risk of the proposed TS change as expressed by the change in CDF (ΔCDF), the ICCDP, and, where appropriate, the changes in LERF (Δ LERF) and the ICLERP. Tier 2 evaluates the process for addressing potentially high-risk configurations if equipment in addition to that affected by the change were taken out of service simultaneously or if other risk-significant operational factors like concurrent system or equipment testing also were involved. The objective of this part of the review is to ensure that appropriate restrictions on dominant risk-significant configurations of the change are in place. Tier 3 evaluates the overall configuration risk management program for whether adequate programs and procedures are in place to compensate for other configurations of lower probability but nonetheless risk-significant from maintenance and other operational activities. If the Tier 2 evaluation demonstrates, with reasonable assurance, that there are no risk-significant configurations for the subject equipment, the application of

Tier 3 may not be necessary to the proposed AOT. Although defense in depth is protected to some degree by most current TSs, the three-tiered approach to the evaluation of risk-informed TS modifications addressed in the following subsection adds assurance that defense in depth will not be impacted significantly by such changes to the licensing basis.

(1) <u>Tier 1: PRA Capability and Insights</u>. The first tier evaluates the impact of the proposed TS change on CDF, ICCDP, and, where appropriate, on LERF and ICLERP. Two aspects must be considered, (a) the validity of the PRA and (b) the PRA insights and findings. The depth of the staff review at this stage depends on the extent to which the licensee demonstrates that its PRA is valid for assessing the proposed TS changes and overall impact on plant risk.

(2) <u>Tier 2: Avoidance of Risk-Significant Plant Configurations for TS AOT Changes</u>. The licensee's assessment also should provide reasonable assurance that risk-significant plant equipment outage configurations will not occur when specific plant equipment is out of service after the proposed TS AOT change. An effective assessment evaluates equipment according to its contribution to plant risk (or safety) while the equipment affected by the proposed AOT change is out of service. Evaluation of such combinations of equipment out of service against the Tier 1 ICCDP acceptance guideline is one appropriate method of identifying risk-significant configurations. With plant equipment risk contribution evaluated, the licensee can assess whether TS or procedure enhancements are required to avoid risk-significant situations. In addition, compensatory actions that can mitigate any corresponding increase in risk (*e.g.*, backup equipment, increased surveillance frequency, or procedural and training upgrades) should offset the risk with certain configurations. These compensatory actions should be evaluated in the first tier where practical. In addition, Tier 2 for TS changes should be reviewed for whether the guidance of RG 1.177, Position 2.3.6, is followed.

(3) <u>Tier 3: Risk-Informed Configuration Risk Management for TS AOT Changes</u>. Tier 3 focuses on licensee programs for whether the risk impact of out-of-service equipment is appropriately evaluated prior to and during any maintenance activity. A viable program can uncover risk-significant plant equipment outage configurations promptly during normal plant operation by quantitatively evaluating the impact on plant risk of, for example, equipment unavailability, operational activities like testing or load dispatching, or weather conditions. The need for a third tier stems from the difficulty in ascertaining in Tier 2 all possible risk-significant configurations encountered over extended periods of plant operation. In addition, Tier 3 should review TS changes for whether the guidance of RG 1.177, Position 2.3.7, is followed.

(ii) Risk Evaluation for STIs. The reviewer should ensure that the licensee identifies the STIs to be evaluated; determines the risk contribution of the subject STIs; determines the risk impact from the change to the STIs; and evaluates the sensitivities and uncertainties in the STI evaluations. Additional detailed guidance on the evaluation of proposed STI changes is in the following subsections.

(iii) Risk Evaluation for All TS Changes. The scope and the level of PRA necessary for the evaluation of a TS change fully depend on the type of TS change sought; however, in some cases, a PRA of sufficient scope may not be available and qualitative arguments, bounding analyses, or compensatory measures must compensate for this lack.

(1) Breadth and Depth of PRA Review. The breadth and depth of the PRA review should be addressed in the review for TS changes. The breadth and depth of the review depend on several factors:

(a) The emphasis placed on traditional analysis as opposed to PRA in the basis for the TS change.

If the justification for the change is based on well founded traditional arguments easily supported by PRA insights, only a limited PRA review may be warranted; however, if a TS change is supported primarily by complex PRA arguments with limited traditional bases, the breadth and depth of the PRA review are substantially greater.

(b) The safety significance of the SSC under consideration.

The level of redundancy, diversity, and need for operator recovery actions will impact the safety significance of any proposed TS change. The reliance on operator actions for safety functions under high-stress conditions requires greater scrutiny of the human reliability than of the automatic systems analysis.

(c) The validity of the PRA.

An initial evaluation of the PRA is needed for confidence in the PRA validity. The confidence necessary depends on the application. PRA validity for the decision-making process can be established by evaluating:

- Consistency of the PRA methodology with acceptable methods and practices.

- Robustness of the results through sensitivity studies.

- Consistency of the PRA findings as to the plant's design and operational characteristics.

- Modeling detail and scope necessary to support the decision-making activity.

- Representation of the as-built, as-operated plant.

- Discussion of peer review, industry certification, or cross-comparisons presented by the licensee as evidence of PRA quality.

(d) The consistency of the TS change with other TSs approved by the NRC.

If there is a baseline for approving similar TS changes for similar plants, only differences between previously accepted submissions and that under review need be assessed.

The need to validate the PRA independently in the context of the TS proposal is based on the need to establish a defensible probabilistic basis for approving the TS change. The basis depends on the PRA role in the decision-making process

(2) PRA Review Considerations. The PRA review covers the areas presented here; therefore, the application must have sufficient detail for evaluation. General review guidance is in SRP Section 19.1. Additional guidance specific to the review of TS changes is here.

(a) Quality of the PRA.

The reviewer should consider the quality and validity of the PRA during the review of the licensee's submission for the TS change.

Has the PRA been reviewed previously by the NRC? Did the NRC safety evaluation report (SER) on the individual plant examination (IPE) or other NRC reviews of the PRA find any shortcomings? Have any shortcomings been addressed and resolved by the licensee if relevant to the proposed TS change?

The quality of the PRA must be compatible with the safety implications of the requested TS change and with the PRA role in justifying that request. The greater the potential change in risk, the uncertainty in that risk, or both from the requested TS change, the more rigor must go into ensuring PRA quality. One approach to ensure quality is a peer review of the PRA. The submission should document the review process, the qualifications of the reviewers, a summary of the review findings, and resolutions for these findings when applicable. Industry PRA certification programs and PRA cross-comparison studies also may help ensure appropriate scope, level of detail, and PRA quality. A program or study description, including the approach and standard or guidelines to which the PRA is compared; the depth of the review; and the make-up and qualifications of the personnel involved should be submitted for NRC review. Based on the findings of the peer review or other certification process the licensee should explain why the PRA is adequate for the TS application in scope and quality. A peer review, certification, or cross-comparison would not replace a staff review but the more confidence the staff has in the licensee's PRA the less rigorous may be the staff review. For most TS reviews, demonstration of PRA quality by an industry certification or cross-comparison process combined with a focus-scoped staff review, should be sufficient. Cross-comparisons are most appropriate when the system designs are similar across the plants compared. Some licensees may elect to use the PRA underlying their IPE to analyze the risk impact of requested TS changes. The staff's review of the IPE alone is not an adequate review for TS applications.

(b) Scope.

A full-scope (Level 3) PRA is not needed for TS evaluations and in most cases a Level 2 PRA with external events for all modes of operation is not required for TS change applications. As a minimum, for systems that prevent core damage (*i.e.*, most of the TS systems modeled in a PRA other than the containment systems), Level I evaluations are needed. For containment systems, Level 2 evaluations are likely to be needed at least to the point of assessing containment structural performance to estimate the LERF. When only a Level I PRA is available but additional Level 2 information is desirable, one acceptable method for approximating the needed information is proposed in NUREG/CR-6595, "An Approach for Estimating the Frequencies of Various Containment Failure Modes and Bypass Events" (Reference 19). The key areas for review of PRA considerations are addressed in the following subsections. The review of the PRA scope in evaluating a TS change should ensure that the guidance of RG 1.177, Position 2.3.2, is followed.

(c) Modeling Level of Detail.

The review of the PRA level of detail in a TS change evaluation should ensure that the guidance of RG 1.177, Position 2.3.3.1, is followed.

(d) Modeling of Initiating Events.

The review of PRA initiating event modeling in a TS change evaluation should ensure that the guidance of RG 1.177, Position 2.3.3.2, is followed.

(e) Screening Criteria and Truncation Limits.

The review of the PRA screening criteria and truncation limits a TS change evaluation should ensure that the guidance of RG 1.177, Positions 2.3.3.3 and 2.3.3.4, is followed.

(f) Assumptions in Applying PRA for TS Changes.

The review of the assumptions in the PRA application to a TS change should ensure that the guidance of RG 1.177, Position 2.3.4, is followed.

(g) Sensitivity and Uncertainty Analyses.

The review of any sensitivity and uncertainty analyses in a TS change evaluation should ensure that the guidance of RG 1.177, Position 2.3.5, is followed.

3. Define Implementation and Monitoring Program

A. Three Tiered Implementation Approach. As described in subsection III.2.B of this SRP section, the staff expects the licensee to use a three-tiered approach in evaluating the risk of proposed TS changes. Application of the three-tiered approach is in keeping with the fundamental principle that the proposed change is consistent with the defense-in-depth philosophy. Application of the three-tiered approach provides assurance that defense in depth is not impacted significantly by the proposed change.

B. Maintenance Rule Control. To prevent extension of a TS AOT or STI from degrading operational safety over time, when an SSC does not meet performance criteria, the licensee should include prior related TS changes in the scope of its evaluation required under the Maintenance Rule (10 CFR 50.65) (Reference 20). If the licensee concludes that the performance or condition of a

TS system or component affected by a TS change does not meet established performance criteria, it should take appropriate corrective action under the Maintenance Rule, including another TS change to shorten the revised AOT or STI or a more restrictive administrative limit if such factors are important in reversing the negative trend.

4. Submit Proposed Change

The evaluations justifying the proposed TS changes should be documented in the license amendment request. The documentation should include:

A. A description of the TS changes proposed and the reasons for the changes.

B. A description of the process for arriving at the proposed changes.

C. Traditional engineering evaluations performed.

D. Changes made to the PRA for the TS change evaluation.

E. Review of the applicability and quality of the PRA models for TS evaluations.

F. Description of the risk measures in evaluating the changes.

G. Data in addition to the plant PRA database.

H. Summary of the calculated risk measures including intermediate results.

I. Sensitivity and uncertainty analyses performed.

J. Summary of the risk impacts of the proposed changes and any compensatory actions proposed.

K. A tabulation of equipment outage configurations that could threaten the integrity of the safety functions of the subject equipment and that are or will be prohibited by the TS or plant procedures (Tier 2).

L. A description of the capability to assess contemporaneously the overall safety impact of proposed plant configurations, including an explanation of how this capability ensures that risk-significant plant configurations will not be entered and that appropriate actions will be taken when unforeseen events put the plant in a risk-significant configuration (Tier 3).

M. A marked-up copy of the relevant TS and bases. The level of detail in the TS bases should include adequate information about the technical basis for the revised AOT or STI.

N. All other documentation required with a license amendment request.

IV. EVALUATION FINDINGS

The reviewer verifies that the applicant has provided sufficient information and that the review and calculations (if applicable) support conclusions of the following type to be included in the staff's SER. The reviewer also states the bases for those conclusions.

SRP Section 19.1, provides general guidance on this topic. In addition, the following items should be addressed in safety evaluations for TS changes.

1. Background and NRC review objectives (input from PRA policy statement and other Commission documents).

2. Breadth and Depth of the Review. The statement of the breadth and depth of the review should consider the following factors:

   A. The emphasis on traditional analysis as opposed to PRA in the basis for the TS change.

   B. The safety significance of the SSC under consideration.

   C. The validity of the PRA.

   D. The consistency of the TS change with other TS proposals approved by NRC.

V. IMPLEMENTATION

The staff will use this SRP section in performing safety evaluations of DC applications and license applications submitted by applicants pursuant to 10 CFR Part 50 or 10 CFR Part 52. Except when the applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the staff will use the method described herein to evaluate conformance with Commission regulations.

The provisions of this SRP section apply to reviews of applications docketed six months or more after the date of issuance of this SRP section.

VI. REFERENCES

1. USNRC, "Use of Probabilistic Risk Assessment Methods in Nuclear Activities: Final Policy Statement." *Federal Register,* 60 FR 42622, August 16, 1995.

2. "Quarterly Status Update for the Probabilistic Risk Assessment Implementation Plan," SECY-97-234, October 14, 1997.

3. USNRC, "Standard Technical Specifications, Babcock and Wilcox Plants," NUREG1430 (latest revision).

4. USNRC, "Standard Technical Specifications, Westinghouse Plants, NUREG-1431 (latest revision).

5. USNRC, "Standard Technical Specifications, Combustion Engineering Plants," NUREG1432 (latest revision).

6. USNRC, "Standard Technical Specifications, General Electric Plants, BWRI/4," NUREG1433 (latest revision).

7. USNRC, "Standard Technical Specifications, General Electric Plants, BWR/6," NUREG1434 (latest revision).

8. USNRC, "An Approach for Plant-Specific Risk-Informed Decisionmaking: Technical Specifications," Regulatory Guide 1.177, August 1998.

9. NRC, Statement of Considerations, "Technical Specifications for Facility Licensees; Safety Analyses Reports," *Federal Register,* 33 FR 18612, December 17, 1968.

10. USNRC, "Final Policy Statement on Technical Specifications Improvements for Nuclear Power Reactors," *Federal Register, 58* FR 39132, July 22, 1993.

11. USNRC,10 CFR 50.36, “Technical Specifications,”*Federal Register,* 60 FR 36953, July 19, 1995.

12. USNRC, 10 CFR 50.109, "Backfitting," *Federal Register*, 54 FR 15398, April 18, 1989.

13. USNRC, "Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," SRP Section 19.1.

14. USNRC, 10 CFR 50.92, "Issuance of Amendment," *Federal Register,* 51 FR 7767, March 6, 1986.

15. USNRC, Appendix A, "General Design Criteria for Nuclear Power Plants," of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," *Federal Register,* 52 FR 41294, October 27, 1987.

16. USNRC, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," RG 1.174, July 1998.

17. USNRC, 10 CFR 50.90, "Application for Amendment of License of Construction Permit," *Federal Register,* 51 FR 40310, November 6, 1986.

18. USNRC, 10 CFR 50.91, "Notice for Public Comment; State Consultation," *Federal Register,* 51 FR 40310, November 6, 1986.

19. W.T.Pratt et al., "An Approach for Estimating the Frequencies of Various Containment Failure Modes and Bypass Events," Draft NUREG/CR-6595, December 1997.

20. USNRC, 10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," *Federal Register,* 58 FR 33996, June 23, 1993.

21. NRC Inspection Manual Chapter IMC-2504, "Construction Inspection Program - Non-ITAAC Inspections," issued April 25, 2006.

SRP Section 16.1
Description of Changes

This SRP section affirms the technical accuracy and adequacy of the guidance previously provided in Revision 0, dated August 1998, of this SRP section. See ADAMS accession number ML042520260.

In addition, this SRP section was administratively updated in accordance with NRR Office Instruction LIC-200, Revision 1, “Standard Review Plan (SRP) Process.” The revision also adds standard paragraphs to extend application of this updated SRP section to prospective applicant submissions pursuant to 10 CFR Part 52.