UNITED STATES NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR REACTOR REGULATION

16.1 RISK-INFORMED DECISIONMAKING: TECHNICAL SPECIFICATIONS

INTRODUCTION

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

Licensee-initiated TS changes that are consistent with currently approved staff positions [e.g., regulatory guides, standard review plans, branch technical positions, or the Standard Technical Specifications (STS) (Refs. 3-7)] are normally evaluated by the staff using traditional engineering analyses. A licensee would not be expected to submit risk information in support of the proposed change. 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 set forth in Regulatory Guide 1.177, "An Approach for Plant-Specific Risk-Informed Decisionmaking: Technical Specifications" (Ref. 8). A licensee may be requested to submit supplemental risk information if such information is not provided in the original submittal by the licensee. If risk information on the proposed TS change is not provided to the staff, the staff will review the information provided by the licensee to determine whether the application can be approved based upon the information provided using traditional methods and will either approve or reject the application based upon the review.

Section 182a of the *Atomic Energy Act* requires that applicants for nuclear power plant operating licenses 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," (Ref. 9), the Commission established its regulatory requirements related to the content of TS. In doing this, the Commission emphazed matters related to the prevention of accidents and the mitigation of accident consequences; the Commission noted that applicants were expected to incorporate into their TS those items that are directly related to maintaining the integrity of the physical barriers designed to contain radioactivity. Pursuant to 10 CFR 50.36, TS are required to contain items in 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 controls.

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

In its July 22, 1993, final policy statement on TS improvements (58 FR 39132) (Ref. 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.

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

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

In August 1995, the NRC adopted the policy statement, including the following, regarding the expanded use of PRA (Ref. 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 and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy.

- 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 associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Where appropriate, PRA should be used to support the proposal of additional regulatory requirements in accordance with 10 CFR 50.109 (Backfit Rule) (Ref. 12). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. It is, of course, understood that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised.

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

- The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments on need for proposing and backfitting new generic requirements on nuclear power plant licensees.

In its approval of the policy statement, the Commission articulated its expectation that implementation of the policy statement will improve the regulatory process in three areas: foremost, through safety decisionmaking enhanced by the use of PRA insights; through more efficient use of agency resources; and through a reduction in unnecessary burdens on licensees.

Regulatory Guide 1.177 (Ref. 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 discussed in Regulatory Guide 1.177. Licensees should identify how chosen approaches and methods (whether they are quantitative or qualitative, and traditional or probabilistic), data, and criteria for considering risk are appropriate for the decision to be made.

REVIEW RESPONSIBILITIES

Primary responsibility for evaluating the technical bases for TS changes resides with the lead technical branch, as specified in SRP Chapter 16, "Technical Specifications." Other branches with review responsibility for risk-informed TS change requests include the Probabilistic Safety Assessment Branch, the Technical Specifications Branch, and the appropriate Project Directorate.

I. AREAS OF REVIEW

NRC Standard Review Plan (SRP) Chapter 19 (Ref. 13) describes a four-element approach for evaluating risk-informed regulatory changes. The individual elements are described in detail in Section I, "Areas of Review," of SRP Chapter 19. The areas of review for each of these elements as they relate to TS changes are discussed below.

Element 1: Define the Proposed Change

The reviewer should confirm that the licensee has explicitly identified the particular TS that are affected by the proposed change and has identified available engineering studies (e.g., topical reports), methods, codes, and PRA studies that are related to the proposed change. The licensee should also determine how the affected systems, components, or parameters are modeled in the PRA and should identify all elements of the PRA that the change impacts. This information should be used collectively to provide a description of the TS change and to outline the method of analysis. The licensee should describe the proposed change and how it meets the objectives of the Commission's PRA Policy Statement, including enhanced decisionmaking, more efficient use of resources, and reduction of unnecessary burden. Section III.A provides a description of the review process for Element 1.

Element 2: Perform Engineering Analysis

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

The licensee should also perform risk-informed evaluations of the proposed change to determine the impact on plant risk. The evaluation should explicitly consider the specific plant equipment affected by the proposed TS changes and the effects of the proposed change on the functionality, reliability, and availability of the affected equipment. The necessary scope and level of detail of the analysis depends upon the particular systems and functions that are affected, and it is recognized that there will be cases for which a qualitative, rather than quantitative, risk analysis is acceptable.

The licensee should provide the rationale that supports the acceptability of the proposed changes by integrating probabilistic insights with traditional considerations to arrive at a final determination of risk. The determination should consider continued conformance to applicable rules and regulations, the adequacy of the traditional engineering evaluation of the proposed change, and the change in plant risk relative to the acceptance guidelines. All these areas should be adequately addressed before the change is considered acceptable. Section III.B provides a description of the review process for Element 2.

Element 3: Define Implementation and Monitoring Program

The reviewer should confirm that the licensee has consiPdered implementation and performance monitoring strategies formulated to ensure (1) that no adverse safety degradation occurs because of the changes to the TS and (2) that the engineering evaluation conducted to examine the impact of the proposed changes continues to reflect the actual reliability and availability of TS structures, systems, and components (SSCs) that have been evaluated. This will ensure that the conclusions that have been drawn from the evaluation remain valid. Section III.C provides a description of the review process for Element 3.

Element 4: Submit Proposed Change

The final element involves documenting the analyses and submitting the license amendment request. Section III.D provides a description of the documentation guidelines for Element 4.

II. ACCEPTANCE GUIDELINES

For each TS application, the reviewers should ensure that each of the five key principles of the staff's philosophy of risk-informed decision making is met. These principles are described in Section B, "Discussion," of Regulatory Guide 1.177 (Ref. 8). General acceptance guidelines for meeting these principles for all risk-informed regulatory applications can be found in SRP Chapter 19, Section II. Additional guidance as to how these acceptance guidelines relate to TS change requests is provided here.

A. Traditional Engineering Guidelines

1. Defense-in-Depth

The engineering evaluation conducted by the licensee should evaluate whether the impact of the proposed TS change is consistent with the defense-in-depth philosophy. The intent is to ensure that the philosophy of defense in depth is maintained, not to prevent changes in the way defense-in-depth is achieved. The defense-in-depth philosophy has traditionally been applied in reactor design and operation to provide multiple means to accomplish safety functions and prevent the release of radioactive material. It has been and continues to be an effective way to account for uncertainties in equipment and human performance. When a comprehensive risk analysis can be done, it can be used to help determine the appropriate extent of defense in depth (e.g., balance among core damage prevention, containment failure, and consequence mitigation) to ensure protection of public health and safety. When a comprehensive risk analysis is not or cannot be done, traditional defense-in-depth considerations should be used or maintained to account for uncertainties. The evaluation should consider the intent of the general design criteria, national standards, and engineering principles such as the single failure criterion. The evaluation should consider 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. As stated earlier, the licensee should select the engineering analysis techniques, whether quantitative or qualitative and 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 a number of elements as summarized below. These elements can be used as guidelines for assessing defense in depth. Other equivalent acceptance guidelines may also be used.

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

a. A reasonable balance among prevention of core damage, prevention of containment failure, and consequence mitigation is preserved, i.e., the proposed change in a TS has not significantly changed the balance among these principles of prevention and mitigation, to the extent they are required to meet 10 CFR 50.36 (Ref. 9). TS change requests should consider whether the anticipated operational changes associated with a TS change could introduce new accidents or transients or could increase the likelihood of an accident or transient (as is required by 10 CFR 50.92) (Ref. 14).

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

c. 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 following items should be considered by the licensee.

   i. Whether there are appropriate restrictions in place to preclude simultaneous equipment outages that would erode the principles of redundancy and diversity,

   ii. Whether compensatory actions to be taken when entering the modified AOT for pre-planned maintenance are identified,

   iii. Whether it is specified that voluntary removal of equipment from service should not be scheduled when adverse weather conditions (or other situations when the plant may likely be subjected to abnormal conditions) are predicted, and

   iv. Whether the impact of the TS change on the safety function should be taken into consideration. For example, what is the impact of a change in the AOT for the low-pressure safety injection system on the overall availability and reliability of the low-pressure injection function?

d. 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 associated with a change in an AOT or STI could introduce any new common cause failure modes not previously considered.

e. Independence of physical barriers is not degraded, e.g., TS change requests should address a means of ensuring that the independence of barriers has not been degraded by the TS change (e.g., when changing TS for containment systems).

f. Defenses against human errors are maintained, e.g., TS change requests should consider whether the anticipated operation changes associated with a change in an AOT or STI could change the expected operator response or introduce any new human errors not previously considered, such as the change from perfoming maintenance during shutdown to performing maintenance at power when different personnel and different activities may be involved.

g. The intent of the General Design Criteria in Appendix A to 10 CFR Part 50 (Ref. 15) is maintained.

2. Safety Margins

The engineering evaluation conducted should assess whether the impact of the proposed TS change is consistent with the principle that sufficient safety margins are maintained (Principle 3). An acceptable set of guidelines for making that assessment are summarized below. Other equivalent decision guidelines are acceptable.

Sufficient safety margins are maintained when:

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

b. 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, e.g., the proposed TS AOT or STI change does not adversely affect any assumptions or inputs to the safety analysis, or, if such inputs are affected, justification is provided to ensure sufficient safety margin will continue to exist. For TS AOT changes, an assessment should be made of the effect on the FSAR acceptance criteria assuming the plant is in the AOT (i.e., the subject equipment is inoperable) and there are no additional failures. Such an assessment should result in the identification of all situations in which entry into the proposed AOT could result in failure to meet an intended safety function.

3. Need for and Adequacy of Change

The licensee has demonstrated that the change is needed and will ensure adequate reliability and availability of significant safety systems.

4. Justification

The licensee has provided the justification for the change based on the guidance in Section III.A.

B. Probabilistic Guidelines

The guidelines discussed in Sections 2.2.4 and 2.2.5 of Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Current Licensing Basis," (Ref. 16) are applicable to TS change requests. Risk-acceptance guidelines are presented in those sections as a function of the result of the licensee's risk analysis in terms of total core damage frequency (CDF) predicted for the plant and the change in CDF and large early release frequency (LERF) predicted for the TS change requested by the licensee. In addition, those sections discuss cases when the scope of the licensee's PRA does not include a Level 2 (containment performance) analysis, and when, according to the guidelines presented in Regulatory Guide 1.177 and in Regulatory Guide 1.174, such an analysis is needed. TS submittals for changes to AOTs should also be evaluated against the risk acceptance guidelines presented in this section, in addition to those in Regulatory Guide 1.174. Application of all of the risk acceptance guidelines to individual proposals for TS modifications will be done in a manner consistent with the fundamental principle that changes to TS result in small increases in the risk to the health and safety of the public (Principle 4, as described in the "Discussion" section of Regulatory Guide 1.177) (Ref. 8). General guidance for evaluating the risk impact from TS and other types of changes can be found in SRP Chapter 19, Section II.

TS change evaluations may involve some small increase in risk as quantified by PRA models. Usually, it is argued that such a small increase is offset by the many beneficial effects of the change that are not modeled by the PRA. The role of numerical guidelines is to ensure that the increase in risk is small, and to provide a quantitative basis for the risk increase based on aspects of the TS change that are modeled or quantified.

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

As discussed previously, the numerical guidelines are used to ensure that any increase in risk is within acceptable limits; traditional considerations are used to ensure that the change satisfies rules and regulations that are in effect; practical considerations judge the acceptability of implementing the change; and lessons learned from past experience ensure that mistakes are not repeated.

Using the risk measures discussed in Regulatory Guide 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 changed case, additional changes to be implemented as part of the change can be credited. For example, in seeking an STI change, if the test strategy is also to be changed, the effect of this should also be incorporated in the risk evaluation.

However, it should be noted that this SRP, Regulatory Guide 1.177, and Regulatory Guide 1.174, are applicable only to permanent (as opposed to temporary, or "one time") changes to TS requirements. TS AOT changes are permanent changes, but because AOTs are entered infrequently and are temporary by their very nature, the following TS acceptance guidelines specific to AOT changes are provided for evaluating the risk associated with the revised AOT, in addition to those acceptance guidelines given in Regulatory Guide 1.174.

1. 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 considered small for a single TS AOT modification. An incremental conditional large early release probability (ICLERP)[4] of 5.0E-8 or less is also considered small. Also, the ICCDP contribution should be distributed in time such that any increase in the associated conditional risk is small and within the normal operating background (risk fluctuations) of the plant (Tier 1).

2. The licensee has demonstrated that there are appropriate restrictions on dominant risk-significant configurations associated with the modification (Tier 2).

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

In the context of the integrated decisionmaking, the acceptance guidelines should not be applied in an overly prescriptive manner. They are intended to provide an indication, in numerical terms, of what is considered acceptable. As such, the numerical values above are approximate values that provide an indication of the changes that are generally acceptable. The intent in making the comparison of the PRA results with the acceptance guidelines is to demonstrate with reasonable assurance that Principle 4, discussed in the "Discussion" section of Regulatory Guide 1.177 (Ref. 8), is being met. This decision must be based on a full understanding of the contributors to the PRA results and the impacts of the uncertainties, both those that are explicitly accounted for in the results and those that are not.

There may be situations in which a non quantitative assessment of risk (either alone or accompanied by quantitative assessment) is sufficient to justify TS changes. The licensee is expected to use judgment on the acceptability (to support regulatory decisionmaking) of the risk argument being considered, including the appropriate blend of quantitative and qualitative assessments.

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

[3] The ICCDP acceptance guideline of 5.0E-7 is based upon the hypothetical situation in which the subject equipment at a representative plant is 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 conditionally increase 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 existing 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).

III. REVIEW PROCESS

Licensees are expected to provide strong technical bases for any TS change. The technical bases should be 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 give proper attention to the integration of considerations such as conformance to Standard Technical Specifications, generic applicability of the requested change if it is different from Standard Technical Specifications, operational constraints, manufacturer recommendations, and practical considerations for test and maintenance. Standard practices used in setting AOTs and STIs should be followed, e.g., AOTs normally are 8 hours, 12 hours, 24 hours, 72 hours, 7 days, 14 days, etc. STIs normally are 12 hours, 7 days, 1 month, 3 months, etc. Using such standards greatly simplifies implementation, scheduling, monitoring, and auditing. Logical consistency among the requirements should be maintained, e.g., AOT requirements for multiple trains out of service should not be longer than that for one of the constituent trains.

A. Define the Proposed Change

The reasons for requesting the TS change or changes should be stated in the submittal, along with information that demonstrates that the extent of the change is needed. Generally, acceptable reasons for requesting TS modifications fall into one or more of the categories below.

1. 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 a reduction in occupational exposure of plant personnel in complying with the requirements.

2. 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 in a plant or to reflect equipment reliability improvements that make a previous requirement unnecessarily stringent or ineffective. TS may be changed to establish consistently based requirements across the industry or across an industry group. It must be ensured that the risk resulting from the change remains acceptable.

3. Reduce Unnecessary Burdens

The change may be requested to reduce unnecessary burdens in complying with current TS requirements, based on the operating history of the plant or industry in general. For example, 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, result in unnecessary equipment wear, result in excessive radiation exposure to plant personnel, or place unnecessary administrative burdens on plant personnel that are not justified by the safety significance of the surveillance requirement.

In some cases, the change may provide operational flexibility; in those cases, the modification might allow an increased allocation of the plant personnel's time to more safety-significant aspects.

In some cases, licensees may determine there is a common need for a TS change among several licensees and submit the request as a group rather than individually. Group submittals can be advantageous when the SSCs being considered in the change are similar across all plants in the group. Plant specific information with regard to the engineering evaluations described in Section III.B must still be provided. However, the group may be able to draw generic conclusions from a compilation of the plant-specific data. In addition, there will be benefits from cross-comparison of the results of the plant-specific evaluations.

B. Perform Engineering Analysis

1. Traditional Engineering Evaluation

a. Compliance with Current Regulations

In evaluating proposed changes to TS, the licensee must ensure that the current regulations, orders, and license conditions are met, consistent with Principle 1 of risk-informed regulation. The NRC regulations specific to TS are stated in 10 CFR 50.36, "Technical Specifications." Additional information with regard to the NRC's policies on TS is contained in the "NRC Final Policy Statement on Technical Specification Improvements for Nuclear Power Reactors" (58 FR 39132), of July 22, 1993 (Ref. 10). These documents define the main elements of TS and provide 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 (Ref. 11), also discuss use of probabilistic approaches to improve TS. Regulations regarding application for and issuance of license amendments are found in 10 CFR 50.90 (Ref. 17), 50.91 (Ref. 18), and 50.92 (Ref. 14). In addition, the licensee should ensure that any discrepancies between the proposed TS change and licensee commitments are identified and considered in the evaluation.

b. Evaluation of Defense-in-Depth Attributes & Safety Margins

One aspect of the engineering evaluations is to show that the fundamental safety principles on which the plant design was based are not compromised. Design basis accidents (DBAs) play a central role in nuclear power plant design. DBAs are a combination of postulated challenges and failure events against which plants are designed and design features that ensure adequate and safe plant response. During the design process, plant response and associated safety margins are evaluated using assumptions which are intended to be conservative. National standards and other considerations such as defense-in-depth attributes and the single failure criterion constitute additional engineering considerations that influence plant design and operation. Margins and defenses associated with these considerations may be affected by the licensee's proposed TS change and, theRefore, should be reevaluated to support a requested TS change. As part of this evaluation, the impact of the proposed TS change on affected equipment functionality, reliability, and availability will be determined. The engineering evaluation conducted should evaluate whether the proposed TS change is consistent with the defense-in-depth philosophy. In addition, the engineering evaluation conducted should assess whether the proposed TS change maintains sufficient safety margins. The reviewers should confirm that the acceptance guidelines in Section II.A of this SRP are met with respect to the principles regarding defense-in-depth and safety margins.

2. Probabilistic Engineering Evaluation

<u>Risk Evaluation for AOTs</u>

The staff has identified a three-tiered approach for licensees and the staff to evaluate the risk associated with proposed TS AOT changes. Tier 1 is an evaluation of the impact on plant risk of the proposed TS change as expressed by the change in core damage frequency (Δ CDF), the ICCDP,[2] and, where appropriate, the change in large early release frequency (Δ LERF) and the ICLERP.[4] Tier 2 is an evaluation of the process used to address potentially high- risk configurations that could exist if equipment in addition to that associated with the change were to be taken out of service simultaneously, or other risk-significant operational factors such as concurrent system or equipment testing were also involved. The objective of this part of the review is to ensure that appropriate restrictions on dominant risk-significant configurations associated with the change are in place. Tier 3 is an evaluation of the overall configuration risk management program to ensure that adequate programs and procedures are in place to identify and compensate for other potentially lower probability, but nonetheless risk-significant, configurations resulting from maintenance and other operational activities. If the Tier 2 assessment demonstrates, with reasonable assurance, that there are no risk-significant configurations involving the subject equipment, the application of Tier 3 to the proposed AOT may not be necessary. Although defense in depth is protected to some degree by most current TS, the three-tiered approach to the evaluation of risk-informed TS modifications discussed in the following section provides additional assurance that defense in depth will not be significantly impacted by such changes to the licensing basis.

a. Tier 1: PRA Capability and Insights

The first tier assesses the impact of the proposed TS change on CDF, ICCDP, and where appropriate, on LERF and ICLERP. Two aspects need to be considered: 1) the validity of the PRA, and 2) the PRA insights and findings. The depth of the staff review at this stage will depend on the extent to which the licensee has demonstrated that its PRA is valid for assessing the proposed TS changes and the overall impact of the TS change on plant risk.

b. Tier 2: Avoidance of Risk Significant Plant Configurations for TS AOT Changes

The licensee's assessment should also provide reasonable assurance that risk-significant plant equipment outage configurations will not occur when specific plant equipment is out of service consistent with the proposed TS AOT change. An effective way to perform such an assessment is to evaluate equipment according to its contribution to plant risk (or safety) while the equipment covered 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 could be one appropriate method of identifying risk-significant configurations. Once plant equipment risk contribution is evaluated, an assessment can be made as to whether certain enhancements to the TS or procedures 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 upgrading procedures and training) should be used to offset the risk associated with certain configurations. These compensatory actions should have been evaluated and incorporated into the first tier where practical to do so. In addition, the review of Tier 2 for TS changes should ensure that the guidance contained in Regulatory Position 2.3.6 of Regulatory Guide 1.177 is met.

c. Tier 3: Risk-Informed Configuration Risk Management for TS AOT Changes

Tier 3 focuses on licensee programs that ensure that the risk impact of out-of-service equipment is appropriately evaluated prior to and while performing any maintenance activity. A viable program is able to uncover risk-significant plant equipment outage configurations in a timely manner during normal plant operation. This can be accomplished by quantitatively evaluating the impact of, for example, equipment unavailability, operational activities like testing or load dispatching, or weather conditions on plant risk. The need for a third tier stems from the difficulty in identifying all possible risk-significant configurations under Tier 2 that will ever be encountered over extended periods of plant operation. In addition, the review of Tier 3 for TS changes should ensure that the guidance contained in Regulatory Position 2.3.7 of Regulatory Guide 1.177 is met.

<u>Risk Evaluation for STIs</u>

The reviewer should ensure that the licensee has identified the STIs to be evaluated; determined the risk contribution associated with the subject STIs; determined the risk impact from the change to the proposed STI; and performed sensitivity and uncertainty evaluations to address uncertainties associated with the STI evaluations. Additional detailed guidance on the evaluation of proposed STI changes is contained in the following sections.

<u>Risk Evaluation for All TS Changes</u>

The scope and the level of PRA necessary to fully support the evaluation of a TS change depend on the type of TS change being sought. However, in some cases, a PRA of sufficient scope may not be available. This will have to be compensated for by qualitative arguments, bounding analyses, or taking compensatory measures.

i. 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 will depend on several factors:

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

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

b) The safety significance of the structure, system or component 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 to perform a safety function under high stress conditions will, for example, require greater scrutiny of the human reliability analysis than of automatic systems.

c) The validity of the PRA.

   An initial evaluation of the PRA will be needed to obtain a degree of confidence in the validity of the PRA. The necessary level of confidence will depend on the application. Validity of the PRA with respect to the decision making process can be established by evaluating:

   i) consistency of the PRA methodology with acceptable methods and practices
   ii) robustness of the results through sensitivity studies
   iii) consistency of the PRA findings with respect to the plant's design and operational characteristics
   iv) modeling detail and scope necessary to support the decision making activity
   v) representation of the as-built, as-operated plant
   vi) 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 to other TS proposals approved by the NRC.

If there is a baseline for approving similar TS changes for similar type plants, then only differences between previously accepted submittals and the one under review would need to be assessed.

The need to independently validate the PRA 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 will depend on the extent to which PRA plays a role in the decision making process.

ii. PRA Review Considerations

The PRA review will cover the items presented below. TheRefore the licensee's application must contain sufficient detail to evaluate these items. General guidance for reviewing these items can be found in SRP Chapter 19, Section II.2.2, "Risk Assessment." Additional guidance specific to the review of TS changes is provided here.

a) Quality of the PRA

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

Has the PRA been previously reviewed by the NRC? Did the NRC SER on the IPE or other NRC reviews of the PRA identify any shortcomings? Have any identified shortcomings been addressed and satisfactorily resolved by the licensee, if they are relevant to the proposed TS change?

The quality of the PRA must be compatible with the safety implications of the TS change being requested and the role that the PRA plays in justifying that change. That is, the more the potential change in risk or the greater the uncertainty in that risk from the requested TS change, or both, the more rigor that must go into ensuring the quality of the PRA. One approach a licensee could use to ensure quality is to perform a peer review of the PRA. In this case, the submittal should document the review process, the qualification of the reviewers, a summary of the review findings, and resolutions to these findings when applicable. Industry PRA certification programs and PRA cross-comparison studies could also be used to help ensure appropriate scope, level of detail, and quality of the PRA. If such a program or studies are to be used, a description of the program, 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 provided for NRC review. Based on the peer review or other certification process and on the findings from this process, the licensee should justify why the PRA is adequate for the present TS application in terms of scope and quality. A peer review, certification, or cross-comparison would not replace a staff review in its entirety, although the more confidence the staff has in the review that has been performed by or for the licensee, the less rigor should be expected of the staff review. For most TS reviews, demonstration of PRA quality by means of an industry certification or cross-comparison process, in combination with a focus-scoped staff review, should be sufficient. Cross-comparisons are most appropriate when the system designs are similar across the plants being compared. Some licensees may elect to use the PRA underlying their individual plant examination (IPE) to analyze the risk impact associated with requested TS changes. It should be noted that the NRC staff's review of the IPE submittal alone does not suffice as an adequate review for TS applications.

b) Scope

A full scope PRA (Level 3) is not needed for TS evaluations. Also, in most cases, a Level 2 PRA with external events for all modes of operation will not be required for TS change applications. As a minimum, for systems used to prevent core damage (i.e., most of the TS systems modeled in a PRA other than the containment systems), Level 1 evaluations should be performed. For containment systems, Level 2 evaluations are likely to be needed at least to the point of assessing containment structural performance in order to estimate the LERF. When only a Level 1 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" (Ref. 19). The key areas for review of PRA considerations are discussed in the following sections. The review of the scope of the PRA used in evaluating a TS change should ensure that the guidance contained in Regulatory Position 2.3.2 of Regulatory Guide 1.177 is followed.

c) Modeling Level of Detail

The review of the level of detail of the PRA used in evaluating a TS change should ensure that the guidance contained in Regulatory Position 2.3.3.1 of Regulatory Guide 1.177 is met.

d) Modeling of Initiating Events

The review of initiating event modeling of the PRA used in evaluating a TS change should ensure that the guidance contained in Regulatory Position 2.3.3.2 of Regulatory Guide 1.177 is met.

e) Screening Criteria and Truncation Limits

The review of the PRA screening criteria and truncation limits used in evaluating a TS change should ensure that the guidance contained in Regulatory Positions 2.3.3.3 and 2.3.3.4 of Regulatory Guide 1.177 is met.

f) Assumptions in Applying PRA for TS Changes

The review of the assumptions in applying the PRA to a TS change should ensure that the guidance contained in Regulatory Position 2.3.4 of Regulatory Guide 1.177 is met.

g) Sensitivity and Uncertainty Analyses

The review of any sensitivity and uncertainty analyses used in evaluating a TS change should ensure that the guidance contained in Regulatory Position 2.3.5 of Regulatory Guide 1.177 is met.

C. Define Implementation and Monitoring Program

1. Three-Tiered Implementation Approach

As described in Section III.B.2, the staff expects the licensee to use a three-tiered approach in evaluating the risk associated with 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 will not be significantly impacted by the proposed change.

2. Maintenance Rule Control

To ensure that extension of a TS AOT or STI does not degrade operational safety over time, the licensee should ensure, as part of its Maintenance Rule program (10 CFR 50.65) (Ref. 20), that when an SSC does not meet its performance criteria, the evaluation required under the Maintenance Rule includes prior related TS changes in its scope. 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, appropriate corrective action should be taken, in accordance with the Maintenance Rule. Such corrective action could include consideration of another TS change to shorten the revised AOT or STI, or imposition of a more restrictive administrative limit, if the licensee determines this is an important factor in reversing the negative trend.

D. Submit Proposed Change

The evaluations performed to justify the proposed TS changes should be documented and included in the license amendment request submittal. The documentation should include the following:

1. A description of the TS changes being proposed and the reasons for seeking the changes,
2. A description of the process used to arrive at the proposed changes,
3. Traditional engineering evaluations performed,
4. Changes made to the PRA for use in the TS change evaluation,
5. Review of the applicability and quality of the PRA models for TS evaluations,
6. Discussion of the risk measures used in evaluating the changes,
7. Data developed and used in addition to the plant's PRA database,
8. Summary of the risk measures calculated including intermediate results,
9. Sensitivity and uncertainty analyses performed,
10. Summary of the risk impacts of the proposed changes and any compensating actions proposed,
11. 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).
12. A description of the capability to perform a contemporaneous assessment of the overall impact on safety of proposed plant configurations, including an explanation of how these tools will be used to ensure 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).
13. A marked up copy of the relevant TS and Bases. The level of detail provided in the TS Bases should include adequate information to provide the technical basis for the revised AOT or STI.
14. All other documentation required to be submitted with a license amendment request.

IV. EVALUATION FINDINGS

Refer to SRP Chapter 19, "Use of Probabilistic Risk Assessment in Plant-Specific, Risk-Informed Decisionmaking: General Guidance," Section III, "Evaluation Findings," for guidance on this topic. In addition, the following items should be addressed in safety evaluations for TS changes.

A. Background and NRC review objectives (Input from PRA Policy statement and other Commission documents).

B. Breadth and depth of the review

The discussion of the breadth and depth of the review should consider the following factors:

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

2. The safety significance of the structure, system or component under consideration.

3. The validity of the PRA.

4. The consistency of the TS change to other TS proposals approved by the NRC.

V. IMPLEMENTATION

The following is intended to provide guidance to applicants and licensees regarding the NRC staff's plans for using this SRP section.

Except for those cases in which the applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the methods described herein will be used by the staff in its evaluation of conformance with Commission regulations.

VI. REFERENCES

1. USNRC, "Use of Probabilistic Risk Assessment Methods in Nuclear Activities: Final Policy Statement," *Federal Register*, 60 FR 42622, August 16, 1995.[5]

2. "Quarterly Status Update for the Probabilistic Risk Assessment Implementation Plan," SECY-97-234, October 14, 1997.[5]

3. USNRC, "Standard Technical Specifications, Babcock and Wilcox Plants," NUREG-1430 (latest revision).[6]

4. USNRC, "Standard Technical Specifications, Westinghouse Plants," NUREG-1431 (latest revision).[6]

5. USNRC, "Standard Technical Specifications, Combustion Engineering Plants," NUREG-1432 (latest revision).[6]

6. USNRC, "Standard Technical Specifications, General Electric Plants, BWR/4," NUREG-1433 (latest revision).[6]

7. USNRC, "Standard Technical Specifications, General Electric Plants, BWR/6," NUREG-1434 (latest revision).[6]

8. USNRC, "An Approach for Plant-Specific Risk-Informed Decisionmaking: Technical Specifications," Regulatory Guide 1.177, August 1998.[7]

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

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[5] Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

[6] Copies of NUREG-series documents are available at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-2249); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

[7] Single copies of regulatory guides, both active and draft, and draft NUREG documents may be obtained free of charge by writing the Reproduction and Distribution Services Section, OCIO, USNRC, Washington, DC 20555-0001, or by fax to (301)415-2289, or by email to GRW1@NRC.GOV. Active guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5285 Port Royal Road, Springfield, VA 22161. Copies of active and draft guides are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

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, "Use of Probabilistic Risk Assessment in Plant-Specific, Risk-Informed Decisionmaking: General Guidance," Standard Review Plan Chapter 19, July 1998.[7]

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," Regulatory Guide 1.174, July 1998.[7]

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.[7]

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.