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OFFICE OF THE SECRETARY  
REGULATORY AND ADJUDICATIONS  
ADJUDICATIONS

Risk-Informing Special Treatment Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Nuclear Regulatory Commission (NRC) is considering promulgating new regulations that would provide an alternative risk-informed approach for special treatment requirements in the current regulations. This action is a result of the Commission's continuing efforts to risk-inform its regulations. The NRC invites comments, advice, and recommendations from interested parties on the contemplated approach for this rulemaking.

*May 17, 2000*

DATE: Comment period expires (~~75 days from publication in the Federal Register~~). Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff.

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*Pub. on 3/3/00*

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking website through the NRC's home page (<http://ruleforum.llnl.gov>). This site provides the capability to upload comments as files (any format) if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415-5905; e-mail [cag@nrc.gov](mailto:cag@nrc.gov).

Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Thomas A. Bergman, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: (301) 415-1021; e-mail: [tab@nrc.gov](mailto:tab@nrc.gov).

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## I. Background.

On August 16, 1995 (60 FR 42622), the Commission published a policy statement entitled "Use of Probabilistic Risk Assessment (PRA) Methods in Nuclear Regulatory Activities." Since then, the Commission has issued guidance<sup>1</sup> on the use of risk information for reactor license amendments. This guidance is currently being used in processing license amendment applications that use risk information as part of their technical justification. However, fundamental reactor regulations remain largely deterministic. In addition, in meetings between the Commission and various stakeholders, a concern was expressed that the NRC is not placing enough emphasis on risk-informing its reactor requirements with the results of risk assessments. The Commission's current reactor regulatory framework (based largely upon design-basis events rather than on core-damage-accident scenarios) results in reasonable assurance of adequate protection to public health and safety but, in some cases, also results in unnecessary regulatory burden. In a staff requirements memorandum (SRM) dated September 14, 1998, the Commission requested the NRC staff to present a set of options to make the requirements in the Commission's regulations risk-informed. The Commission expects that making the regulations risk-informed would result in a reduction of unnecessary regulatory burden while maintaining safety because there will be a better focus of the NRC's and industry's resources on the more safety significant structures, systems, and components (SSCs) and, therefore, address the expressed concern.

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<sup>1</sup> To date, this guidance includes Standard Review Plan (SRP) Chapter 19 and related Regulatory Guide (RG) 1.174 on risk-informed decision making; SRP Section 3.9.7 and related RG 1.175 on risk-informed inservice testing; SRP Section 16.1 and related RG 1.177 on risk-informed technical specifications; RG 1.176 on risk-informed graded quality assurance; and SRP Section 3.9.8 and related RG 1.178 on risk-informed inservice inspection.

In SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - 'Domestic Licensing of Production and Utilization Facilities,'" dated December 23, 1998, the NRC staff proposed three high-level options for making the NRC's regulations risk-informed. In an SRM dated June 8, 1999, the Commission approved the NRC staff's recommendations.

One of the options presented in SECY-98-300 was to make special treatment requirements (e.g., quality assurance, environmental qualifications, technical specifications, reporting) risk-informed. Special treatment as used here may be defined as --

*Current requirements imposed on structures, systems, and components (SSCs) that go beyond industry-established requirements for equipment classified as "commercial grade" that provide additional confidence that the equipment is capable of meeting its functional requirements under design basis conditions. These additional special treatment requirements include additional design considerations, qualification, change control, documentation, reporting, maintenance, testing, surveillance, and quality assurance requirements.*

This definition does not encompass functional design requirements; that is, an SSCs functional design requirement is not considered a special treatment requirement. This definition applies, hereafter, when the term "special treatment" is used.

This advance notice of proposed rulemaking presents the approaches that the Commission is contemplating to risk-inform special treatment requirements. Several public meetings have been held to obtain comments on the NRC's efforts related to this task. Comments and suggestions obtained from these meetings have been incorporated, to the extent possible, into these approaches.

## II. Rulemaking Plan.

### A. Vision

Develop alternative regulations in 10 CFR Part 50 (and other applicable parts) that would modify the requirements for special treatment to focus on those SSCs that have been identified as important to protect public health and safety by using a risk-informed approach.

### B. Strategies

Increase the use of risk-informed approaches to modify the special treatment requirements imposed on SSCs under existing Part 50 requirements (and those of other applicable parts).

Maintain overall safety provided by the existing Part 50 while reducing unnecessary burden associated with these requirements for licensee operational and licensing activities and for NRC oversight and licensing activities.

Risk-inform the special treatment requirements imposed on SSCs under Part 50 (and other applicable parts) in a manner that encourages public participation and results in public confidence in the product and process.

### C. Objectives

Establish the criteria for acceptable methods for determining the SSCs that require special treatment in the regulations of Part 50. These criteria should be sufficiently clear and robust such that if a licensee's program meets the criteria there is not a need for prior NRC review and approval of the plant-specific program.

Assign priorities to the rules to be modified, taking into consideration the maintenance of safety, the reduction of unnecessary burden for industry, the effect on NRC efficiency and effectiveness, public confidence, and the complexity of modifying each rule.

Ensure that the categorization process has been evaluated under a pilot program to verify that the requirements and their associated guidance can be implemented by industry, and that the results of licensee implementation provide reasonable assurance that public health and safety is maintained.

Issue a proposed rule for the initial set of rules to be modified within 1 year of the Commission's approval of the rulemaking plan, and a final rule within 1 year of the completion of the associated pilot program.

The proposed risk-informed regulatory alternatives should reduce unnecessary burden so that licensees with more than 10 years remaining on their license would find it beneficial to voluntarily implement the risk-informed alternative requirements.

D. Selection of Candidate Rules

The Commission believes that the set of rules to be considered in this effort must be identified early so that rule-specific issues can be identified and addressed. Also, because implementation of any rules resulting from this effort is optional, the Commission does not intend to expend resources to modify rules that industry does not expect to implement, unless the modifications are necessary to maintain safety. However, the Commission notes that the set of rules included in this effort should be chosen such that implementation of the rules will require little or no exemptions. Therefore, rules that may require exemptions before a licensee can implement changes in other rules (e.g., 10 CFR 50.59) should be considered in this rulemaking effort.

The NRC has developed and applied a systematic approach to identify the rules that should be included in this rulemaking effort. A scoping review of all the regulations in 10 CFR Parts 21, 50, 52, 54, and 100 identified a set of potential candidate rules that could be included. Screening criteria and a logic for applying these criteria were then developed to identify the

subset of rules to which risk-informed changes can be made consistent with the intent of this effort. The screening criteria were based on the following elements: maintaining safety, improving NRC staff efficiency and effectiveness, reducing unnecessary regulatory burden, and increasing public confidence. In addition, and because this effort is focused solely on special treatment requirements, the NRC limited its selection to those rules that include special treatment requirements. Rules which would have to be modified in order to efficiently implement other rules included this effort were also included. The criteria and logic were then applied to the set of potential candidate rules identified by the scoping review. The screening process and results are illustrated in Figure 2. The results of the evaluations of the rules against each of the screening criteria are presented in the attached Table. As a result of this screening process, the NRC has identified the following candidate rules for inclusion in this effort:

10 CFR Part 50 - Sections 50.34, 50.36, 50.44, 50.48, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.65, 50.71, 50.72, and 50.73

10 CFR Part 50 - Appendix A (GDCs 1, 2, 3, 4, 37, 40, 42, 43, 45, and 46), Appendix B, Appendix J, Appendix R, and Appendix S

10 CFR Parts 21, 52, 54, 100, and Appendix A to Part 100

E. Rulemaking Alternatives

The NRC has evaluated alternatives to rulemaking and has concluded that, if sufficient industry interest exists, rulemaking is the most effective tool for implementing the type of generic changes encompassed by this effort. If sufficient interest does not exist, review and approval of a limited number of exemptions under 10 CFR 50.12 would be more efficient. Assuming industry interest does exist as has been indicated in public meetings, the NRC has evaluated several rulemaking alternatives to accomplish this task. These alternatives are discussed below.

1. Define New Term

This alternative would entail the definition of a new term in 10 CFR 50.2 (e.g., "safety-significant") that describes, for the purposes of special treatment requirements, which SSCs are safety-significant and, therefore, need to be within the scope of the special treatment requirements. This new term would then be incorporated into each rule that contains special treatment requirements to allow licensees to voluntarily revise the scope of SSCs that are subject to special treatment requirements. To determine which SSCs are safety significant, the Commission would issue a new Part 50 appendix that contains the requirements governing the categorization of SSCs consistent with the new term defined in §50.2. Alternatively, the Commission could issue a regulatory guide that contains the SSC categorization guidance.

Regulatory treatment requirements in addition to the special treatment requirements currently in the regulations may be necessary as a result of the risk categorization processes. These additional requirements would have to be added to the regulations and, therefore, additional changes to each affected rule may be required to ensure that the new regulatory treatment requirements are appropriately captured in the regulations. Because this alternative would result in duplicate changes to multiple rules, the NRC did not choose this alternative.

2. Redefine Current Terms

This alternative would expand the definition of the term “safety-related” in 10 CFR 50.2, or as an alternative, define the term “important to safety” such that the redefined term would contain a portion that allows special treatment requirements to be risk-informed. Licensees could then elect to risk-inform the scope of SSCs that are subject to special treatment in all the applicable rules. This approach would expand the definitions of the current terms (which reside in the existing rules) so there is no need to add new terms to the governing regulations. However, a significant effort would be required to review all the regulations to ensure that the Commission has not unintentionally revised any non-special treatment rules and to make appropriate changes to preclude such occurrences. In a similar fashion to the “new term” approach, this approach would also need to be supplemented with either a new Part 50 appendix that contains the requirements governing the risk-informed categorization of SSCs, or a regulatory guide that contains the SSC categorization guidance.

This alternative would introduce unnecessary complications and confusion in the application of the terms at plants that choose to implement the new scope for a subset of the special treatment requirements covered in this effort, or for some systems and not others. Such a situation would result in the use of similar language with different meanings in the licensee’s licensing basis documents and in the associated plant implementation documents. Furthermore, regulatory treatment requirements, in addition to those currently in the regulations, may be necessary as a result of the risk categorization processes. These requirements would have to be added to the regulations. Therefore, changes to other rules may still be required. The NRC did not choose this alternative.

3. Issue New Rule

This approach entails the development of a new rule that would be added to Part 50. The rule would “list” the provisions that contain special treatment requirements that may have their scope risk-informed in accordance with the methodology requirements contained in either a new appendix that would also be added to Part 50, or in guidance contained in a regulatory guide (similar to above two alternatives in this respect). In addition to identifying which rules can be risk-informed for special treatment, the new rule would address rule specific issues resulting from this effort and contain new requirements concerning the type of regulatory treatment that SSCs would receive.

The NRC believes that this alternative is the simplest and most efficient regulatory approach because it appears to not require defining new terms which in turn requires subsequent revisions to each affected rule. In addition, this alternative has the benefit of integrating all the affected special treatment requirements into one rule which would make it easier for licensees and the NRC to implement. Therefore, the NRC has decided to proceed with this alternative.

4. Comprehensive vs. Phased Rulemaking

The NRC considered whether it should proceed with a comprehensive rulemaking covering all special treatment requirements or a phased approach. The NRC’s objective is to proceed with a comprehensive rulemaking. However, the NRC recognizes that this approach may prove problematic. Because of the uniqueness of the special treatment requirements, the potentially different effects that may result from modifying these requirements, and the inconsistencies that currently exist between the various special treatment requirements, the NRC notes that the comprehensive rulemaking approach would be a large and complex task. The comprehensive rulemaking approach appears to have a greater potential for delay because

of the time required to review each of the affected requirements and the potential for issues to arise that can have impacts on the schedule. A comprehensive rulemaking must address all affected requirements and issues before the rulemaking may be completed. Consequently, this might delay implementation of some rules due to complications with others. If complications do arise, the NRC may elect to proceed with a phased approach that allows the NRC to issue some revised rules while continuing to address issues that arise on others.

F. Implementation

1. New Appendix vs. Regulatory Guide

Each of the alternatives discussed in Section E include either the development of a new Appendix to Part 50 or the issuance of a regulatory guide that would contain the requirements governing the categorization of SSCs. The NRC has considered these two alternatives (a new appendix vs. a regulatory guide) and concluded that a new appendix approach is preferred because it would provide a more stable and predictable regulatory framework. Such a framework should result in the least burden on NRC and industry resources both from the standpoint of any prior NRC review that is required and from the standpoint of the staff's inspection of this task. If an appendix can be constructed that when implemented by licensees yields consistent, objective, enforceable, and inspectable results, then this regulatory approach should allow for implementation of the resulting risk-informed special treatment requirements with little or no NRC review. On the other hand, putting categorization guidance into a regulatory guide would require that the staff review and approve licensee submittals prior to implementation because of the flexibility inherent in a regulatory guide. The NRC expects the pilot plant program to enable it to determine if development of an appendix in lieu of a regulatory guide is sufficient to support a no prior NRC review regulatory approach. If the pilot

plant program reveals that development of the appendix does not minimize the need for NRC review, the NRC will reconsider whether an appendix remains the best approach.

2. Additional Guidance

In addition to either an appendix or a regulatory guide, the Nuclear Energy Institutes (NEI) has indicated that it will submit an implementing document for this effort. The NRC intends to review this implementing document. The objective of this review will be to reach agreement with NEI concerning the implementation of risk-informed special treatment, and to be able to endorse the NEI guidance in a regulatory guide. Consequently, the Commission does not currently plan to develop draft regulatory guidance to implement this rulemaking. Additional NRC efforts would be required to update current regulatory guides that address the current SSC categorization approach, as appropriate.

G. Pilot Plant Program

The Commission believes that the pilot plant program is an essential component of this rulemaking effort. The purpose of this program would be to demonstrate the viability of the requirements contained in the resulting rule and appendix before final rulemaking and the viability of the proposed NEI guidance for the implementation of the resulting rule and appendix. The program will also help the NRC identify the special treatment requirements that industry believes should be addressed.

The most important aspect of the pilot plant program will be to demonstrate the viability of risk categorization processes to establish alternative risk-informed special treatment requirements. These processes must be based on the requirements in the resulting rule and appendix in order to provide meaningful feedback on the rulemaking effort. In addition, the categorization processes must be evaluated against the set of special treatment requirements

they are applied to so that critical attributes are appropriately evaluated. The categorization processes must also be applied to a variety of plant systems, including mechanical (active and passive), fluid, and electrical systems, and safety-related and nonsafety-related systems, so that technical aspects of the categorization processes and their implementation can be thoroughly exercised. The Commission may explicitly exclude any attributes that are not exercised by the pilot plant program from consideration in this effort.

The pilot plant program must be integrated with the rulemaking plan. It must agree on overall and plant-specific schedules and the rules to be piloted. Pilot plant program participants must commit to meet the resulting rulemaking requirements and proposed NEI guidance for categorization and implementation. In addition, pilot program submittals should address how design basis functions will be preserved when special treatment for safety-related SSCs is reduced as a result of the risk categorization processes. The discussion should address how these SSCs will be treated by the licensee's design control and corrective action programs. Similarly, licensees should discuss how critical attributes identified by the risk categorization processes will be identified and controlled. This applies to safety-related and non-safety-related SSCs that are found to be significant as a result of the risk categorization processes. The processes established should be capable of reflecting changes to the facility and categorizing new and modified equipment as these changes are made.

#### H. South Texas Exemption Request

In addition to the pilot plant program, the Commission notes that South Texas Project Nuclear Operating Company has submitted an extensive exemption request related to a number of special treatment requirements. This submittal was developed before initiation of this effort, and so was not coordinated with the development of the rulemaking plan. Presently, the NRC expects to complete review of this submittal before the proposed rulemaking stage of

the effort would begin. The NRC believes that, if approved, the South Texas exemption request will serve as a proof-of-concept prototype which will provide useful information and experience when the rulemaking for this effort is developed.

I. Schedule

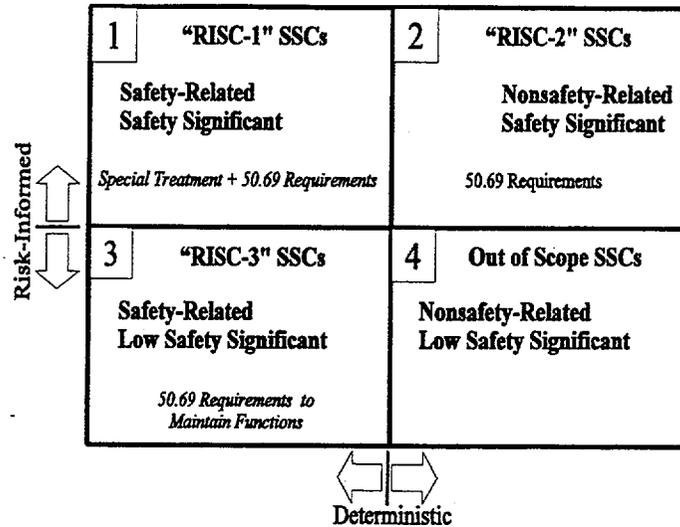
The NRC has developed a schedule covering the following activities which influence this rulemaking: (1) the South Texas exemption request, (2) development and issuance of this advanced notice of proposed rulemaking, (3) the pilot plant program, (4) NRC review of the NEI implementation guidance, (5) development and issuance of the proposed rulemaking, and (6) development and issuance of the final rulemaking. The NRC estimates that a final rule can be issued by March of 2002. This rulemaking includes milestones that depend significantly on NEI to develop implementation guidance and pilot plant program participants to develop and implement categorization processes.

III. Specific Proposal

A. Approach

To effect the described changes, the Commission is considering an approach that consists of issuing a new rule (10 CFR 50.69) and a new appendix (Appendix T to 10 CFR Part 50). The new rule and appendix would allow licensees, for purposes of special treatment requirements, to categorize SSCs with regard to their importance to plant safety. The result of such a rulemaking, when combined with the current deterministic design basis, would result in SSCs being classified in two different manners. One would be consistent with the safety-related/non-safety-related philosophy that exists today for the deterministic design basis. The other would be consistent with a risk-informed philosophy. A graphical depiction of the results of the contemplated changes is illustrated in Figure 1. The figure is only intended to provide a conceptual understanding of the new SSC categorization process. The NRC's thinking on this

Figure 1: Diagram of Categorization and Treatment



matter is continuing to evolve. The NRC will explore the idea of more than two levels of safety significance. The NRC is requesting stakeholder feedback on the safety significance categories in question C.3 of Section V of this notice. The figure depicts the current safety-related versus nonsafety-related SSC categorization scheme on the horizontal axis with an overlay of the new risk-informed categorization on the vertical axis. The risk-informed categorization would group SSCs into one of the four boxes.

Box 1 of Figure 1 contains safety-related SSCs that a risk-informed categorization process concludes are significant contributors to plant safety. These SSCs are termed risk-informed safety class 1 (RISC-1) SSCs. SSCs in this box would continue to be subject to the current special treatment requirements. In addition, it is possible that some of these SSCs may have some additional requirements concerning reliability and availability if attributes that cause the SSC to be safety significant are not sufficiently controlled by current special treatment requirements. However, the NRC is not currently aware of any examples of this situation.

Box 2 of Figure 1 depicts the SSCs that are nonsafety-related, and that the risk-informed categorization concludes make a significant contribution to plant safety. These SSCs are termed RISC-2 SSCs. Examples of RISC-2 SSCs could include the station blackout emergency diesel generator, the startup feedwater pump for pressurized water reactors (PWRs), and SSCs used for “feed and bleed” operations at PWRs. For RISC-2 SSCs, there will probably need to be requirements to maintain the reliability and availability of the SSCs consistent with the PRA. It is currently envisioned that the new rule would contain the requirements regarding reliability and availability of RISC-1 and RISC-2 SSCs.

Box 3 of Figure 1 depicts the currently safety-related SSCs that a risk-informed categorization process determines are not significant contributors to plant safety. These SSCs are termed RISC-3 SSCs. The rulemaking effort would revise 10 CFR Part 50 to contain alternative requirements such that RISC-3 SSCs would no longer be subject to the current special treatment requirements. For RISC-3 SSCs, it is not the intent of this rulemaking to allow such SSCs to be removed from the facility or to have their functional capability lost. Instead, the RISC-3 SSCs will need to receive sufficient regulatory treatment such that these SSCs are still expected to meet functional requirements, albeit at a reduced level of assurance. The NRC may determine that this level of assurance can be provided by licensees’ commercial grade treatment programs. It is envisioned that the new rule would contain the regulatory treatments requirements for RISC-3 SSCs (e.g., the new rule may require commercial treatment for RISC-3 SSCs).

Box 4 of Figure 1 depicts SSCs that are nonsafety-related and continue to be categorized as not being significant contributors to plant safety. These SSCs are out of scope of both the current special treatment regulations and of the new rule. The functional performance of these SSCs would be controlled under the licensee’s commercial grade program (no change from the current requirements).

B. New Rule for Part 50

The Commission expects that the new rule that would (1) identify the special treatment requirements in the current regulations whose scope could be modified consistent with the requirements resulting from this effort, (2) address rule-specific issues that arise as a result of the new scope by, for example, specifying, on a rule-by-rule basis, the applicability of the new scope, (3) specify all additional regulatory requirements that would result from this effort, and (4) reference the new appendix as providing the requirements governing the categorization of SSCs.

C. New Appendix to Part 50

The Commission expects that the new appendix would contain the elements discussed below. The discussion consists of NRC expectations of the SSC categorization process and is not presented as proposed rule language. When finalized, the appendix would establish minimum requirements for the process and decision criteria for use in the categorization of SSCs into two groups — those that have safety significance and those that have low safety significance. This is consistent with the process to categorize SSCs into RISC classes as discussed above in which the safety significant and low safety significant categorization is used in the vertical axis.

**Appendix T to Part 50 - Categorization of SSCs into Risk-Informed Safety Classes**

The principal activity required for the categorization of structures, systems and components (SSCs) into risk-informed safety classes is the categorization of the SSCs according to safety significance. Treatment requirements for SSCs will be dependent on this

safety classification. This appendix establishes minimum requirements for the process and decision criteria for use in the categorization of SSCs.

### Process for Categorization

The determination of safety significance of SSCs must be performed as part of an integrated decision-making process which uses both risk insights and traditional engineering insights. In categorizing SSCs, it must be demonstrated that the defense-in-depth philosophy is maintained, that sufficient safety margin is maintained, and that increases in risk (if any) are small.

To accomplish these objectives, the process to categorize SSCs should consist of the following elements:

- (1) Identification of current treatment requirements for SSCs.
- (2) Assessment of the capability of the plant-specific Probabilistic Risk Assessment (PRA) to support the categorization process.
- (3) Use of the PRA to determine the relative importance of modeled SSCs to accident prevention and mitigation.
- (4) Use of an integrated decision-making panel (IDP) to determine the safety significance of SSCs. The categorization of SSCs as either safety significant or low safety significant must include considerations of:
  - a. Results of the PRA importance evaluation.
  - b. Deterministic and other traditional engineering analyses.
  - c. Maintenance of the defense-in-depth philosophy.
  - d. Maintenance of safety margins.

- (5) Evaluation of the change in risk resulting from reclassifying SSCs.
  - a. Determination of treatment requirements for SSCs based on their initial safety significance categorization.
  - b. Evaluation of the overall change in plant risk as a result of changes in treatment requirements, and readjustment (if necessary) of the categorization of SSCs based on this estimation of change in risk.
- (6) Documentation of the process and the decision criteria used for the categorization of SSCs.
- (7) Monitoring of the impact of the change in treatment requirements.

The remainder of this appendix discusses requirements and decision criteria for the above elements in more detail.

#### Requirements and Decision Criteria

##### Element (1): Identification of Current Treatment Requirements for SSCs.

All safety-related as well as non-safety-related SSCs in the plant are within the scope of this categorization process. For each SSC where changes to the treatment requirements are considered, current requirements must be identified and documented so that the effect of the changes can be more easily understood.

##### Element (2): Assessment of the Capability of the PRA to Support the Categorization Process.

**PRA scope.** At a minimum, a PRA modeling the internal initiating events at full power operations must be used for SSC importance analysis and determination of change in risk from the application. The PRA must be capable of quantifying core damage frequency (CDF) and

large early release frequency (LERF). When categorizing SSCs, the licensee shall also consider external event initiators, as well as the shutdown and low-power modes of operation, either by PRA modeling or by the integrated decision-making process. Element (4)(b) discusses the requirements for cases when PRA modeling is not available.

**PRA quality.** The PRA should conform to the consensus ASME/ANS PRA Standard documents as endorsed by the NRC. In addition to the technical requirements, the PRA shall conform to the requirements in the areas of documentation, configuration control, quality assurance, and peer review. Where elements of the Standard are not met, justification of why these elements are not important to the results must be documented and available for NRC review.

**PRA updates.** The PRA must reflect the as-built and as-operated plant. When used for SSC categorization, and as long as regulatory requirements are being dictated by this categorization, the PRA must be updated on a periodic basis, that is, annually or within six months after each refueling outage provided the interval between successive updates does not exceed 24 months. These updates are mandatory before implementation of changes to plant design or procedures if these changes affect the categorization of SSCs. A PRA update is also required upon receipt of new PRA information which would invalidate the results of the categorization process. Upon the completion of the PRA update, the SSC categorization shall be revisited in accordance with Elements 3 through 5 of this process with a focus on the impact of the changes on SSC categorization.

Element (3): Determination of Relative Importance of SSCs Using the PRA.

Relative importances of SSCs modeled in the PRA should be determined using PRA importance measures. The results of this process together with results of sensitivity studies will be used as inputs to the integrated decision-making process for the categorization of SSCs.

**Risk metrics and importance measures.** SSC importances must be determined based on both CDF and LERF. Importance measures should be chosen such that results can provide the IDP with information on the relative contribution of an SSC to total risk. Examples of importance measures that can accomplish this are the Fussell-Vesely (F-V) importance and the Risk Reduction Worth (RRW) importance. Importance measures should also be used to provide the IDP with information on the safety margin available should an SSC fail to function. The Risk Achievement Worth (RAW) importance and the Birnbaum importance are example measures that are suitable for this purpose.

**Screening criteria.** Importance measures do not directly relate to changes in the absolute value of risk. Therefore, the criteria for categorizing SSCs into the safety significant and the low safety significant categories shall be based on an assessment of the overall impact of SSC re-categorization and a comparison of this impact to the acceptance criteria for changes in CDF and LERF, see Element (5)(b). However, in the initial screening stages, an SSC with  $F-V < 0.005$  based on either CDF or LERF, and  $RAW < 2$  based on either CDF or LERF can be considered as potentially low safety significant. Elements 4 and 5 must be carried out to confirm the low safety significance of these SSCs.

**Truncation limit.** The truncation value used for PRA model quantification must be set to a value that is sufficiently low so that the resultant minimal cutsets contain the significant contributors to risk and that at least 95 percent of the CDF and LERF is captured in the final solution.

**Sensitivity analyses.** The sensitivity of SSC importances to uncertainties in the parameter values for component availability/reliability and human error probabilities should be evaluated. Results of these sensitivity analyses should be provided to the IDP for deliberation.

**Combining models for different initiating events and plant operating modes.** The PRA models for external initiating events (e.g., events initiated by fires or earthquakes), and for low power and shutdown plant operating modes may be conservative with respect to those for internal initiating events. Use of conservative models can influence the calculation of importance measures by moving more SSCs into the low safety significance category. Therefore, when PRA models for external event initiators and for the low power and shutdown modes of operation are available, the importance measures shall be evaluated for each analysis separately, as well as integrally. Results of the analyses should be provided to the IDP for deliberation.

Element (4): SSC Categorization by the Integrated Decision-Making Panel.

An integrated decision-making panel, for example, an Expert Panel similar to the one used in implementing 10 CFR 50.65, must be used to determine the safety significance of SSCs. The categorization of SSCs as either safety significant or low safety significant must consider: results of the PRA importance analysis; deterministic and other traditional engineering analyses; maintenance of the defense-in-depth philosophy; and maintenance of safety margins. Elements (4)(a) through (4)(d) describe these requirements in more detail. Element (6) describes the requirements of the IDP process, and the documentation required of this process.

Element (4)(a): Use of PRA Insights.

Results of the PRA importance analysis, including results from sensitivity studies, and results from the external initiating events and the low power and shutdown modes of operation when available, should form the initial inputs to the categorization process:

- (i) For screening, an SSC with  $F-V < 0.005$  based on either CDF or LERF, and  $RAW < 2$  based on either CDF or LERF can be considered as potentially low safety significant.
- (ii) Results of sensitivity analyses shall be used to show that SSC categorization will not change for the expected range of values of SSC reliability/availability and human error probabilities.
- (iii) When PRA models are available, the importance measures for external event initiators and for the low power and shutdown mode of operation shall be evaluated for each analysis separately, as well as integrally, and only when an SSC is low safety significant for each of these analyses will it be assigned to the low safety significant category.

Application of the above guidelines will yield a list of SSCs that are determined to be safety significant by the PRA. These SSCs shall not be re-categorized as low safety significant by the IDP process.

**Verification of Low Safety Significance for SSCs Implicitly Modeled in the PRA.**

For SSCs which have not been identified as safety significant by PRA importance measures, the IDP must verify that these SSCs are not implicitly depended upon in the PRA.

The IDP must determine if:

- (i) Failure of the SSC will significantly increase the frequency of an initiating event, including those initiating events originally screened out in the PRA.

- (ii) Failure of the SSC will fail a safety function, including SSCs that are assumed to be inherently reliable in the PRA (e.g., piping and tanks) and those that may not be explicitly modeled (e.g., room cooling systems, and instrumentation and control systems).
- (iii) The SSC supports operator actions credited in the PRA.
- (iv) Failure of the SSC will result in failure of safety significant SSCs (e.g., through spatial interactions).

If any of the above conditions are true, the IDP should use a qualitative evaluation process to determine the impact of relaxing requirements on SSC reliability and performance. This evaluation should include identifying those failure modes for which the failure rate may increase, and those for which detection could become more difficult. The IDP can justify low safety significance of the SSC by demonstrating one or more of the following:

- The reclassification is consistent with the defense-in-depth philosophy and sufficient safety margin is maintained.
- Relaxing the requirements will have minimal impact on the failure rate increase.
- Historical data show that these failure modes are unlikely to occur.
- Such failure modes can be detected in a timely fashion.

Element (4)(b): Use of Deterministic and Other Engineering Analyses.

For SSCs identified in Element (4)(a) as low safety significant by the PRA as well as those SSCs outside the scope of the PRA, the IDP must verify low safety significance based on deterministic and other engineering analyses and insights, operational experience, and information from licensing basis documents and design basis accident analyses.

### **Initiating Events and Plant Operating Modes not Modeled in the PRA**

When initiating events with frequencies of greater than  $10^{-6}$  per year are not modeled in the PRA, or when the low power and shutdown plant operating modes are not modeled, the IDP shall demonstrate that the relaxation of regulatory requirements will not unacceptably degrade plant response capability and will not introduce risk vulnerabilities for the unmodeled initiating events or plant operating modes. For these unmodeled events, the IDP assessment must consider whether an SSC has an impact on the plant's capability to:

- (i) Prevent or mitigate accident conditions;
- (ii) Reach and/or maintain safe shutdown conditions;
- (iii) Preserve the reactor coolant system pressure boundary integrity;
- (iv) Maintain containment integrity; and
- (v) Allow monitoring of post-accident conditions.

In determining the importance of SSCs for each of these functions, the following factors must be considered:

- Safety function being satisfied by SSC operation.
- Level of redundancy existing at the plant to fulfill the SSC's function.
- Ability to recover from a failure of the SSC.
- Performance history of the SSC.
- Use of the SSC in the Emergency Operating Procedures or Severe Accident Management Guidelines.
- Cumulative impacts of combinations of SSC unavailability which could impact an entire system or critical safety function.

### **Risk Indices Outside the Scope of the PRA**

In addition to being safety significant in terms of CDF and LERF, SSCs can also be safety significant in terms of other risk metrics. Therefore, when an SSC is not identified as safety significant by the PRA, the IDP must verify low safety significance by determining if:

- (i) The SSC is a part of a system that acts as a barrier to fission product release during severe accidents;
- (ii) The SSC is depended upon in the Emergency Operating Procedures or the Severe Accident Management Guidelines; and
- (iii) Failure of the SSC will result in unintentional releases of radioactive material even in the absence of severe accident conditions.

If any of the above conditions are true, the IDP should use a qualitative evaluation process to determine the impact of relaxing requirements on SSC reliability and performance. This evaluation should include identifying those failure modes for which the failure rate may increase, and those for which detection could become more difficult. The IDP can justify low safety significance of the SSC by demonstrating one or more of the following:

- The reclassification is consistent with the defense-in-depth philosophy and sufficient safety margin is maintained.
- Relaxing the requirements will have minimal impact on the failure rate increase.
- Historical data show that these failure modes are unlikely to occur.
- Such failure modes can be detected in a timely fashion.

Element (4)(c): Maintaining the Defense-in-Depth Philosophy.

When categorizing SSCs as low safety significant, the IDP must demonstrate that the defense-in-depth philosophy is maintained. Defense-in-depth is considered adequate if the overall redundancy and diversity among the plant's systems and barriers is sufficient to ensure the risk acceptance guidelines provided in Element (5)(b) are met, and that:

- Reasonable balance is preserved among prevention of core damage, prevention of containment failure or bypass, and mitigation of consequences of an offsite release;
- System redundancy, independence, and diversity is preserved commensurate with the expected frequency of challenges, consequences of failure of the system, and associated uncertainties in determining these parameters;
- There is no over-reliance on programmatic activities and operator actions to compensate for weaknesses in the plant design; and
- Potential for common cause failures is taken into account.

Element (4)(d): Maintenance of Safety Margins.

When categorizing SSCs as low safety significant, the IDP shall demonstrate that there is sufficient safety margins to account for uncertainty in the engineering analysis and in the supporting data. Safety margin shall be incorporated when determining performance characteristics and parameters (e.g., component, system, and plant capability) or when defining mission success criteria (e.g., the number of system trains required to mitigate an initiating event or the ability of an SSC to perform in a certain environment). The amount of margin should depend on the uncertainty associated with the performance parameters in question, the availability of alternatives to compensate for adverse performance, and the consequences of failure to meet the performance goals. Demonstration of available safety margins shall be

accomplished by use of data from plant operations or research studies, or by use of analyses using established engineering codes and standards or NRC-approved alternatives.

Element (5): Evaluation of the Change in Risk Resulting from Reclassifying SSCs.

The change in risk from reclassifying SSCs shall be quantified. Elements (5)(a) and (5)(b) provide the requirements for this quantification.

Element (5)(a): Determination of Treatment Requirements Based on Safety Significance.

Where regulatory requirements are to be relaxed for SSCs categorized as low safety significant or where regulatory requirements are increased for SSCs categorized as safety significant, the IDP must document the functional requirements for the SSCs and describe the process to assure that these requirements are preserved. Based on the revised requirements, the IDP must document and justify the target SSC reliability and availability.

Element (5)(b): Assessment of the Change in Risk.

The potential impact of relaxing treatment requirements on SSCs must be evaluated in an integrated manner. Changes in CDF and LERF must be estimated by calculations where the failure likelihood of SSCs is changed to the level corresponding to the failure likelihood for the revised treatment requirements.

Changes to CDF and LERF must be small. Plants with total baseline CDFs of  $10^{-4}$  per year or less will be permitted CDF increases of  $10^{-5}$  per year, and plants with total baseline CDFs greater than  $10^{-4}$  per year will be permitted CDF increases of  $10^{-6}$  per year. Plants with total baseline LERFs of  $10^{-5}$  per year or less will be permitted LERF increases of  $10^{-6}$  per year, and plants with total baseline LERFs greater than  $10^{-5}$  per year will be permitted LERF increases of  $10^{-7}$  per year.

If a PRA model is not available to evaluate the change in risk from an external initiating event or plant operating mode, the IDP must provide justification, on the basis of bounding analyses or qualitative considerations, that the risk will not be significantly impacted.

Subsequent changes to the categorization of SSCs for the purpose of further modifying regulatory requirements must be performed in such a manner where plant performance and previous changes to the licensing basis are taken into account. There must not be a pattern of systematic increases in risk as a result of repeated applications of the SSC categorization process.

Element (6): Documentation of the Integrated Decision-Making Process and the Decision Criteria Used.

**Requirements of the Integrated Decision-Making Panel**

Plant procedure: The IDP shall be described in a formal plant procedure which includes:

- (i) The designated chairman, panel members, and panel alternates;
- (ii) Required training and qualifications for the chairman, members and alternates;
- (iii) Requirements for a quorum, attendance records, agendas, and meeting minutes;
- (iv) The decision-making process;
- (v) Documentation and resolution of differing opinions; and
- (vi) Implementation of feedback/corrective actions.

Membership: There shall be at least five experts designated as members of the IDP. Expertise in the following fields shall be represented on the IDP: plant operations, design

engineering, systems engineering, safety analysis engineering, quality assurance, plant licensing, and probabilistic risk assessment. Members may be experts in more than one field, however excessive reliance on any one member's judgement should be avoided.

**Expertise:** The licensee shall establish and document specific requirements for ensuing adequate expertise levels of IDP members, and shall ensure that expertise levels are maintained. There shall be at least three members of the IDP with a minimum of five years experience at the plant, and there shall be at least one member of the IDP who has worked on the modeling and updating of the plant-specific PRA for a minimum of five years.

**Training:** The IDP shall be trained in the specific technical aspects and requirements related to the categorization process. Training shall address, at a minimum --

- (i) The purpose of the categorization;
- (ii) Present treatment requirements for SSCs including requirements for design basis events;
- (iii) PRA fundamentals;
- (iv) Details of the plant-specific PRA including the modeling scope and assumptions;
- (v) The role risk importance measures including the use of sensitivity studies;
- (vi) The assessment of SSC failure modes and effects;
- (vii) The role of and the use of risk thresholds; and
- (viii) The defense-in-depth philosophy and requirements to maintain this philosophy. Each of these topics must be covered to the extent necessary to provide the IDP with a level of knowledge sufficient to evaluate and approve SSC categorization using both probabilistic and deterministic information.

Decision-making: IDP decision criteria for categorizing SSCs as safety significant or low safety significant shall be documented. Decisions of the IDP shall be arrived at by consensus. Differing opinions shall be documented and resolved, if possible. If a resolution cannot be achieved concerning the safety significance of an SSC, then the SSC shall be classified as safety significant.

Feedback and corrective actions: SSC categorization shall be revisited by the IDP when the PRA is updated or when the other criteria used by the IDP are affected by changes in plant operational data or changes in plant design or plant procedures.

#### **Documentation of the IDP Process**

The following shall be documented and available for NRC review:

- Results of the relative risk importance of SSCs modeled in the PRA including the results of sensitivity analyses. This should include separate SSC importances for the external events initiators and for low power and shutdown operations when these events are modeled in the PRA.
- Results of the final SSC categorization including a summary of IDP deliberations for each SSC classified as low safety significant and each non-safety-related SSC classified as safety significant. Decision criteria in terms of qualitative assessments, assessments for initiating events and plant operating modes not modeled in the PRA, defense-in-depth, and safety margins must be included. Technical basis documents used to support the categorization shall also be available.
- Functional requirements for each SSC receiving revised treatment, the original treatment requirements for these SSCs, the revised requirements for these SSCs, target

values for SSC reliability and availability, and the process that will be used to assure these functional requirements and target values will be preserved/met.

- The overall change in plant risk as a result of changes in treatment requirements, including the baseline CDF and LERF and the change in this CDF and LERF. Changes to plant risk from all previous changes to treatment requirements shall also be included.
- Requirements for the IDP including, the plant procedure, expertise, membership, training, and decision-making guidelines. Meeting minutes should also be included.
- The PRA used and the supporting analyses, together with a description of conformance of this PRA to the PRA Standards documents.

Element (7): Monitoring of the Impact of the Change in Requirements.

A performance monitoring and corrective action program must be implemented so that early indication of SSC degradation can be obtained, and corrective actions can be implemented. This program shall include safety significant SSCs and safety-related SSCs classified as low safety-significant. A mechanism for changing SSC categorization based on operating experience must be included in the program. SSC performance must be consistent with the level of performance allocated in the risk analysis or credited in the integrated decision-making process. Monitoring of the safety-significant SSCs is expected to be addressed by the Maintenance Rule as described in 10 CFR 50.65.

Results of the monitoring program must be documented and available for NRC review. Results of the monitoring program must also be incorporated into the PRA update process described in Element (2).

#### IV. Issues.

##### A. Selective Implementation

“Selective implementation” is defined as implementing the changes resulting from this effort for a subset of the affected special treatment requirements or implementing the changes for a subset of SSCs at a facility, or both. The NRC is considering the argument that selective implementation would tend only to reduce unnecessary regulatory burden and would not yield safety benefits where the risk importance of SSCs had not been recognized by the current regulatory framework. However, selective implementation may be possible and even necessary to some degree.

The South Texas Project experience with the Graded Quality Assurance program has demonstrated that implementation of the resulting changes for only 10 CFR 50, Appendix B, is not beneficial from a burden reduction perspective without exemptions from other regulations. The South Texas Project experience has further shown that implementation for a minimum set of rules, in combination with 10 CFR 50, Appendix B, must occur before sufficient benefits are realized. The NRC believes that this feedback applies to most of the current set of regulations. However, even with the experience that South Texas Project had with 10 CFR 50, Appendix B, the licensee did not request exemption from the full set of regulations identified as candidates for this effort. In addition, none of the potential pilot plant program participants have expressed interest in implementing the full set of rules being considered. As a result, the NRC currently believes that a sufficient amount of burden reduction can be achieved with selective implementation.

The NRC intends to make rule changes so that exemptions will not be required for licensees wishing to implement the risk-informed regulatory regime that would result from this effort. Therefore, the NRC currently believes that it should not issue exemptions to allow for selective implementation after final rulemaking.

With regard to safety, the NRC believes that, if the exemption request submitted by South Texas Project can be found acceptable, the NRC would have, in effect, determined that an adequate level of safety could be preserved without having to adopt all changes resulting from this effort. Therefore, the NRC will depend, in part, on the results of the South Texas exemption effort to decide this issue.

Selective implementation of alternative regulatory treatment requirements would introduce additional complexity into the regulatory process and the NRC will need to assess the practicality of the approach. In addressing this issue, the NRC will need to establish an implementation approach which recognizes all of the NRC's outcome oriented goals, not just reducing unnecessary regulatory burden. The NRC is continuing to evaluate this issue and is seeking stakeholder feedback in Section V.F. of this advance notice of proposed rulemaking.

Another selective implementation issue is whether licensees should be allowed to implement the alternative for certain systems and not others. The NRC expects that licensees would look at a comprehensive set of systems and components as it applies any individual risk-informed regulation. If a comprehensive scope of equipment is not considered, the NRC does not believe that licensees can develop an appropriate risk-ranking process or identify risk-significant characteristics of equipment which may warrant additional control. For example, licensees would be expected to review systems and components outside current safety-related boundaries to identify the need for additional equipment qualification for risk-significant SSCs at the same time that it reviews the current equipment qualification scope for relaxation opportunities. The NRC does recognize, however, that implementation would take place through a phased approach by licensees.

The NRC recognizes that licensees may elect to exclude certain systems from the detailed risk-ranking process based on their prior understanding of the importance of those systems to overall safety. Some systems, such as the reactor protection system, can be shown

to be very important without an extensive risk evaluation. Other systems may not be relevant to facility safety at all. Licensees may determine that there is little benefit from a detailed risk categorization process for such systems. However, to ensure that this effort is implemented correctly, such systems may still need evaluation to assess the risk-significant attributes from a risk-informed perspective.

The Commission is continuing to evaluate this issue and is seeking stakeholder feedback on this issue in Section V.F. of this advance notice of proposed rulemaking.

B. Impact on Other Regulations

The NRC has determined that implementation of risk-informed alternatives in Part 50 may affect implementation of other regulations. For example, the NRC has determined that changes to Part 54 may be required to accommodate license renewal for a facility that had implemented risk-informed changes encompassed by this effort. The scope of Part 54 is explicitly defined using the traditional deterministic approach. Therefore, Part 54 does not, without change, accommodate the alternative the risk-informed scope that would result from this effort. The goal of the license renewal program is to establish a stable, predictable, and efficient license renewal process. The NRC believes that a revision to Part 54 at this time would have a significant effect on the stability and consistency of the processes being established for preparation of license renewal applications and for NRC review. Allowing a voluntary alternate scoping criteria would necessitate the development of an alternate license renewal process. Guidance would need to be developed regarding format and content of a renewal application, NRC review criteria, and inspection guidance for conducting onsite scoping inspections.

In other cases, such as operator licensing (Part 55), rule changes may not be necessary. Nevertheless, licensees may need to make changes to programs implementing these regulations in order to ensure compliance.

The Commission would like to identify all such impacts early in this effort and is, therefore, seeking stakeholder input on this issue in Section V.G. of this advance notice of proposed rulemaking.

C. Need For Prior NRC Review

The preferred approach for this effort is to avoid the need for prior NRC review and approval of either the licensee's categorization process or the results of that process. The Commission intends on achieving this by issuing a detailed and enforceable appendix which would yield consistent, objective, and inspectable results. This appendix is being developed, in part, from existing guidance such as RG 1.174 and from experience gained by review of the South Texas Graded Quality Assurance methodology. Several significant aspects of the proposed categorization technique rely upon subjective and qualitative judgement. For example, it is expected that an expert panel will consider defense-in-depth and margin of safety as part of the assessment of the significance of SSCs. However, these terms are often defined only in a qualitative, not quantitative, sense. These terms are difficult to translate into enforceable regulations yielding consistent, objective, and inspectable results. Therefore, use of these concepts within an appendix creates a significant challenge to the NRC. If the NRC cannot develop criteria which result in consistent, objective, and enforceable results, some level of NRC review and approval will be necessary.

No prior NRC review of a licensee's categorization process may affect the public participation process concerning the implementation. With no prior NRC review, public participation would be limited to the rulemaking process. For example, the public could

participate by providing input on this advanced notice of proposed rulemaking, on the notice of proposed rulemaking, in public meetings, etc. However, public participation allowed by the licensing amendment process (i.e., for implementation), including hearing rights on the licensing action, would not be part of the implementation of this effort because no licensing action would need to take place.

The Commission is seeking comment on this issue in Section V.H. of this advance notice of proposed rulemaking.

D. Identification and Control of Attributes Requiring Special Treatment

The NRC anticipates some SSCs that are not presently subject to special treatment requirements to be identified as significant to plant safety (i.e, RISC-2 SSCs). The NRC further anticipates to find that the existing special treatment requirements do not fully address some risk-significant characteristics of SSCs that are significant to plant safety (RISC-1 and RISC-2 SSCs). This is anticipated to occur because the risk-informed categorization processes will address some severe accident concerns that are not currently addressed by the special treatment requirements. The Commission expects to develop regulatory controls for RISC-1 and RISC-2 SSCs to ensure risk-significant characteristics of these SSCs are adequately preserved.

The Commission expects some SSCs that are presently subject to special treatment requirements to be identified as being of low significance to plant safety (i.e, RISC-3 SSCs). However, it is not the intent of this effort to redefine the design basis events that a plant must analyze to demonstrate compliance with the regulations. Therefore, this effort will not allow for elimination of these components from the plant. In addition, these components must remain functional to meet the design basis. Accordingly, the Commission expects to develop regulatory controls for RISC-3 to ensure that they would be maintained functional.

The Commission is considering how to identify the risk-significant attributes for RISC-1 and RISC-2 SSCs and what regulatory controls to establish for them to ensure that they are adequately preserved. The Commission is also considering what regulatory controls to establish for RISC-3 SSCs to ensure that they would be maintained functional. The Commission is seeking comment on this issue in Section V.E. of this advance notice of proposed rulemaking.

#### V. Specific Questions

Comments, advice, and recommendations on a proposed rule reflecting the features presented above and any other pertinent points are invited from all interested persons. Particularly, comments and supporting reasons are requested on the following questions arranged by topic:

##### A. Approach

- A.1. If the NRC elects to pursue a phased rulemaking approach, how should the rules identified be prioritized/phased?
- A.2. Proceeding with changes to special treatment requirements before establishing a risk-informed design basis (establishment of a risk-informed design basis is being addressed by a separate task) may create inconsistencies between the treatment of SSCs and the functions they serve for the deterministic design basis. Are there any detrimental effects (licensing or otherwise) associated with changing the special treatment requirements before changing the design basis? Please provide a discussion of the detrimental effects that you believe would result.

- A.3. (a) What should the proposed rule state in order to clearly identify the scope of SSCs in each special treatment requirement for which the rule provides a regulatory alternative?
- (b) If the Commission should decide to impose alternative requirements to the special treatment requirements and/or if the Commission should decide to impose risk requirements on RISC-1, RISC-2, and/or RISC-3 SSCs, how should the proposed rule be constructed in order to clearly identify the scope of SSCs for which the alternative requirements apply?
- A.4. If the Commission should decide to impose alternative requirements to the special treatment requirements and/or if the Commission should decide to impose risk requirements on RISC-1, RISC-2, and/or RISC-3 SSCs, how should the alternative requirements be expressed to ensure clarity (please provide examples of how the requirements should be phrased)? Should the alternative requirements be expressed prescriptively or in a performance-based approach? Should the alternative requirements be placed in each specific special treatment regulation for which an alternative is being provided, or should the alternative requirements be included in the proposed new rule?
- A.5. Please provide an estimate of the expected costs and benefits of implementing risk-informed special treatment requirements.
- A.6. Please comment on the benefits of risk-informing 10 CFR 50.36?

B. Screening

- B.1. Are the screening criteria reasonable and have the rules that have been evaluated (see the attached Table) been screened correctly against the screening criteria? Please provide rule-specific comments on reduction of unnecessary burden and the need to modify a rule in order to maintain safety (Criterion III).
- B.2. Are there any other rules, in addition to those that have been evaluated, that should be considered as part of this effort? Please provide specific comments identifying any rules that you believe should be considered and the reasons for recommending their inclusion.
- B.3. Are there any rules that have been identified for inclusion that should not be included? Please provide specific comments identifying those rules and the reasons for recommending their exclusion.

C. Categorization Methodology

- C.1. Are the elements identified for the appendix appropriate and adequate for establishing a risk-informed process to categorize SSCs with respect to their significance to safety?
- C.2. Is the appendix written at a level sufficient to support a no prior NRC review approach? Are there specific areas that warrant additional requirements?
- C.3. The approach described in this ANPR would define two levels of safety significance. Would it be better to define more than two levels? For example, South Texas uses a

four level approach where they categorize equipment as having high safety significance, medium safety significance, low safety significance, and no safety significance. (Note however, that South Texas is not proposing to apply four different types of treatment for the four levels of significance.) What are the benefits of using an approach where more than two levels of safety significance are defined? Would it be better to define more than two levels in this rulemaking?

- C.4. Importance measures are strongly affected by the scope and quality of the PRA. For example, incomplete assessments of risk contributions from low-power and shutdown operations, fires, and human performance will distort the importance rankings. What should be the requirements for assuring PRA quality? What should the scope of the PRA be in terms of initiating events and plant operating modes? If modeled in a PRA, how should the contributions from external event initiators and low power and shutdown operating modes be factored into the results (taking into account that modeling for these events is usually not as complete as that for the internal events)?
- C.5. Even with a full-scope, high quality PRA, the importance measures have limitations. How should these limitations be addressed in Appendix T? What is the role of sensitivity and uncertainty analyses? What is the role of delta risk measures and absolute risk measures?
- C.6. It is essential that the implementation of 10 CFR 50.69 and Appendix T be scrutable and auditable. What requirements are needed to ensure that this is the case? What documents should be available for NRC inspection (e.g., the risk assessment, technical

bases documents, inputs to and deliberations of the expert panel)? Please provide a discussion to support your comments.

- C.7 Does the proposal provide adequate guidance on the use of expert judgement in the form of the integrated decision-making panel to ensure consistent categorization of SSCs across the industry?

D. Pilot Plant Program

- D.1. How should the pilot plant program be constructed and implemented in order to adequately pilot the elements in the appendix?
- D.2. Please comment on the need or lack of need to pilot each of the rules affected by this effort.

E. Identification and Control of Special Treatment Attributes

- E.1. How should the special treatment requirements for SSCs that are currently safety-related for one reason but found to be safety significant for a different reason be modified? Should special treatment of safety-related SSCs be modified to address risk-significant attributes that are identified as a result of a risk-informed categorization process? If so, how should treatment be identified and controlled?
- E.2. What regulatory treatment should be applied to safety-significant SSCs which are not currently safety-related?

- E.3. Explain whether the design control and procurement requirements in Appendices A and B of 10 CFR Part 50 should apply to safety-significant SSCs which are not currently safety-related (i.e., RISC-2 SSCs).
- E.4. (a) Should 10 CFR Part 21 requirements be imposed upon vendors who supplied safety-related components to licensees who subsequently select the new regulatory approach? If not, what regulatory basis would there be for not imposing such requirements on those vendors? Would the failure to impose Part 21 requirements on such vendors be inconsistent with the underlying statutory basis for Part 21, viz., Section 206 of the Energy Reorganization Act of 1974, as amended? What regulatory provisions are necessary to assure that the underlying purpose of Section 206 and 10 CFR Part 21 are fulfilled under the alternative regulatory approach?
- (b) If such requirements are imposed, what difficulties would such vendors experience in fulfilling their Part 21 responsibilities and how could these difficulties be addressed in this rulemaking? What specific rule provisions are necessary in order to fairly impose Part 21 vendors who supply basic components to licensees who at some point decide to adopt the alternative approach?
- (c) Discuss whether the alternative regulatory approach, with respect to the new categories, is inconsistent with the definition of basic component in Section 223.b of the Atomic Energy Act (which imposes criminal liabilities for knowing and willful violations of NRC rules, regulations orders and license conditions that result, or if undetected could have resulted in significant impairment of a "basic component"). If there is an

inconsistency, does it have any adverse effects on licensees? What rulemaking provisions could eliminate or minimize such adverse effects?

- E.5. What regulatory treatment requirements are necessary to ensure the functional capabilities of SSCs that are safety-related because of the plant's deterministic licensing basis but found to be of low safety significance are maintained?
- E.6. To what degree should severe accidents be incorporated into the licensing basis under the regulatory effort to risk-inform special treatment requirements?

F. Selective Implementation

- F.1. What are the potential advantages and disadvantages of selective implementation with regard to selection of rules and selection of systems?
- F.2. What bounds should be set on the scope of SSCs evaluated under a risk-informed regulatory framework? Should all systems be evaluated, or can some subset be considered?
- F.3. What limits should be placed on the set of rules for implementation? Should licensees be required to implement all risk-informed rules? If not, what limitations are appropriate?
- F.4. How can the NRC ensure that additional attention is given to risk significant components if selective implementation is allowed?

G. Impact on Other Regulations

- G.1. What regulations may be affected by risk-informed changes to special treatment requirements in Part 50 and how are these regulations affected?
- G.2. For those licensees implementing the new regulatory approach: (a) what, if any, GDC will require exemptions? (b) If exemptions would otherwise be necessary, is there a way and/a regulatory basis for the rulemaking to exempt, in whole or part, compliance with those GDCs for those licensees choosing the alternative regulatory approach?
- G.3. Part 19 currently requires all licensees to post NRC Form 3. Would it be more or less confusing if all licensees posted a single, NRC-developed Form 3 that covered both licensees who remain with the existing regulatory regime as well as licensees that choose the alternative regulatory approach; or should an alternative Form 3 be developed, with the licensee required to post the applicable Form depending upon whether it chose to implement the alternative regulatory approach.
- G.4. If a licensee were to adopt the alternative regulatory approach, would there be any inconsistency or discrepancy created between the term "operability" as currently used in technical specifications' limiting conditions for operations (LCOs) and the concept of "functionality" as proposed for SSCs in RISC-3? Please describe any adverse effects in detail, and discuss the manner in which these adverse effects can be avoided or minimized.

- G.5. What changes should be considered to provide consistency between affected regulations and risk-informed scope of special treatment?
- G.6. Please comment on the need and appropriateness of applying a risk-informed scope to license renewal (i.e., Part 54)?

H. Need for Prior NRC Review

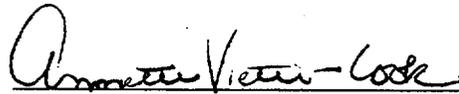
- H.1. Given that the means for public participation for this effort is through comment in response to this advanced notice for proposed rulemaking and in response to a proposed rulemaking, is there a need to have an NRC review process such that there will be additional public participation as part of the licensing amendment process?
- H.2. What level of NRC review is appropriate for a facility making the transition to a risk-informed regulatory regime?
- H.3. What regulatory controls need to be placed on licensees to implement risk-informed changes to special treatment without prior NRC approval?
- H.4. Please comment on the need for revising 10 CFR 50.59 to facilitate the risk-informed approach?

The preliminary views expressed in this document may change in light of comments received. In any case, there will be another opportunity for additional public comment in connection with any proposed rule that may be developed by the Commission.

The authority citation for this document is: 42 U.S.C. 2201; 42 U.S.C. 5841.

Dated at Rockville, Maryland, this 25<sup>th</sup> day of February, 2000.

For the Nuclear Regulatory Commission.

A handwritten signature in cursive script, reading "Annette Vietti-Cook", written over a horizontal line.

Annette L. Vietti-Cook,  
Secretary of the Commission.

Table - Rule Evaluation Matrix (Page 1 of 4)

RULE	TITLE	SCREENING CRITERIA					CANDIDATE RULES (I and II & III) & IV & V
		I	II	III	IV	V	
50.2	Definitions.						
50.4	Written communications.						
50.8	Information collection requirements: OMB approval.						
50.10	License required.						
50.34	Contents of applications; technical information.	x				x	x
50.35	Issuance of construction permits.						
50.36	Technical specifications.	x	x	x			x
50.44	Standards for combustible gas control system in light-water-cooled power reactors.	x	x	x	x		x
50.48	Fire protection.	x	x	x		x	x
50.49	Environmental qualification of electric equipment important to safety for nuclear power plants.	x	x	x	x	x	x
50.54	Conditions of licenses.		x	x	x	x	x
50.55	Conditions of construction permits.	x	x	x	x	x	x
50.55a	Codes and standards.	x	x	x		x	x
50.59	Changes, tests and experiments.	x	x	x	x	x	x
50.62	Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants.						
50.65	Requirements for monitoring the effectiveness of maintenance at nuclear power plants.	x	x	x			x
50.71	Maintenance of records, making of reports.	x				x	x
50.72	Immediate notification requirements for operating nuclear power reactors.	x	x	x			x
50.73	License event report system.	x	x	x			x

Table - Rule Evaluation Matrix (Page 2 of 4)

RULE	TITLE	SCREENING CRITERIA					CANDIDATE/RULES (I and (II or III) or IV or V)
		I	II	III	IV	V	
App. A Intro.	General Design Criteria for Nuclear Power Plants				x		x
GDC 1	Quality Standards and Records.	x	x	x	x	x	x
GDC 2	Design Bases for Protection Against Natural Phenomena.	x	x	x	x		x
GDC 3	Fire Protection.	x	x	x	x		x
GDC 4	Environmental and Dynamic Effects Design Bases.	x	x	x	x		x
GDC 5	Sharing of Structures, Systems, and Components.						
GDC 14	Reactor Coolant Pressure Boundary.	x					
GDC 16	Containment Design.						
GDC 17	Electric Power Systems.	x 1					1
GDC 18	Inspection and Testing of Electric Power Systems.	1					1
GDC 20	Protection System Functions.						
GDC 21	Protection System Reliability and Testability.	1					1
GDC 22	Protection System Independence.	x					
GDC 30	Quality of Reactor Coolant Pressure Boundary.	x					
GDC 32	Inspection of Reactor Coolant Pressure Boundary.	x 1					1
GDC 36	Inspection of Containment Heat Removal System.	1					1
GDC 37	Testing of Emergency Core Cooling System.	x 1 2	x	x	x		x 1 2
GDC 39	Inspection of Containment Heat Removal System.	1					1

Table - Rule Evaluation Matrix (Page 3 of 4)

RULE	TITLE	SCREENING CRITERIA					CANDIDATE RULES (I and II or III) or IV or V
		I	II	III	IV	V	
GDC 40	Testing of Containment Heat Removal System.	x 1 2	x	x	x		x 1 2
GDC 42	Inspection of Containment Atmosphere Cleanup Systems.	x 1 2	x	x	x		x 1 2
GDC 43	Testing of Containment Atmosphere Cleanup Systems.	x 1 2	x	x	x		x 1 2
GDC 44	Cooling Water.						
GDC 45	Inspection of Cooling Water System.	x 1 2	x	x	x		x 1 2
GDC 46	Testing of Cooling Water System.	x 1 2	x	x	x		x 1 2
GDC 52	Capability for Containment Leakage Rate Testing.	1					1
GDC 53	Provisions for Containment Testing and Inspection.	1					1
GDC 54	Systems Penetrating Containment.	1					1
GDC 55	Reactor Coolant Pressure Boundary Penetrating Containment.	x					
GDC 61	Fuel Storage and Handling and Radioactivity Control.	1					1
App. B	Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants	x	x	x	x	x	x
App. E	Emergency Planning and Preparedness for Production and Utilization Facilities						
App. J	Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors	x	x	x			x

Table - Rule Evaluation Matrix (Page 4 of 4)

RULE	TITLE	SCREENING CRITERIA					CANDIDATE RULES (I and (II or III) or IV or V)
		I	II	III	IV	V	
App. M	Standardization of Design; Manufacture of Nuclear Power Reactors; Construction and Operation of Nuclear Power Reactors Manufactured Pursuant to Commission License						
App. N	Standardization of Nuclear Power Plant Designs: Licenses to Construct and Operate Nuclear Power Reactors of Duplicate Design at Multiple Sites						
App. R	Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979	x	x	x		x	x
App. S	Earthquake Engineering Criteria for Nuclear Power Plants	x	x	x	x		x
Part 21	REPORTING OF DEFECTS AND NONCOMPLIANCE	x	x	x	x		x
Part 52	EARLY SITE PERMITS; STANDARD DESIGN CERTIFICATIONS; AND COMBINED LICENSES FOR NUCLEAR POWER PLANTS	x	x	x	x	x	x
Part 54	REQUIREMENTS FOR RENEWAL OF OPERATING LICENSES FOR NUCLEAR POWER PLANTS	x	x	x	x	x	x
Part 100 & App. A	REACTOR SITE CRITERIA	x	x	x	x		x

NOTES:

A.9 Includes requirements that components be designed to permit inspection and/or testing.

A.10 Includes requirements that components be designed to permit inspection and/or testing **to assure** the capability of the components. The staff has treated the words **to assure** as requiring actual periodic testing.

Figure 2. Screening Process and Results.

