October 8, 1999 (1:39PM)

RISK-INFORMING SPECIAL TREATMENT REGULATIONS

RULEMAKING PLAN

10 CFR PART 21, 10 CFR PART 50, 10 CFR PART 100, 10 CFR PART 54

1.0 Regulatory Issue

1.1 Problem Statement

In Option 2 of SECY-98-300 "Options for Risk-Informed Revisions to 10 CFR Part 50 - Domestic Licensing of Production and Utilization Facilities," the staff proposed making changes to the scope of structures, systems, and components (SSCs) requiring special treatment. The staff did not define the phrase "special treatment," but rather chose to provide some insight into the meaning of this terminology by using specific examples of regulations. The current scope of SSCs covered by the special treatment regulations governing commercial nuclear reactors[1] is deterministically based and stems primarily from the evaluation of selected design basis events, as described in updated final safety analysis reports (UFSARs). This regulatory framework provides reasonable assurance of no undue risk to the health and safety of the public. However, recent advances in technology, coupled with operating reactor experience, have suggested that an alternative approach, one that maintains safety with a reduction in unnecessary burden, is possible. The new approach would use a risk-informed process for evaluating SSC safety significance, that would, in turn, result in a more focused determination of which SSCs should receive special treatment requirements. This revised regulatory framework should allow both NRC staff and industry to focus resources on issues that are important to plant safety.

1.2 Background

As directed by a staff requirements memorandum (SRM) of June 8, 1999, the staff is implementing Option 2 of SECY-98-300. Specifically, the Commission directed the staff to evaluate strategies to make the scope of the commercial nuclear reactor regulations that impose unique requirements identified in this discussion as "special treatment requirements," risk-informed. For the purposes of this rulemaking effort, the staff has defined special treatment requirements broadly as requirements imposed on 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. Typically, the regulations establish the scope of SSCs that receive special treatment using one of three different terms: "safety-related ," "important to safety," or "basic component." The terms "safety-related " and "basic component" are defined in the regulations, while "important to safety" (used principally in the general design criteria of Appendix A to 10 CFR Part 50) is not explicitly defined.

[1]These regulations reside in 10 CFR Part 21, 10 CFR Part 50, 10 CFR Part 54, and 10 CFR Part 100.

The risk-informed approach discussed in this plan for establishing an alternative scope of SSCs subject to special treatment requirements is intended to complement the NRC's traditional deterministic approach. The risk-informed approach will be consistent with the defense-in-depth philosophy, will maintain sufficient safety margins, will provide reasonable assurance that all necessary safety functions will be performed, will ensure that any increase in core damage frequency or risk is small and consistent with the safety goal policy statement, and will ensure that a performance measurement strategy is employed.

It is important to note that, consistent with SECY-98-300, this rulemaking effort, while intended to ensure that the scope of special treatment requirements imposed on SSCs is risk-informed, is not intended to allow for the elimination of SSC functional requirements, or to allow equipment that is required by the deterministic design basis to be removed from the facility. Instead, by restructuring the regulations to allow an alternative risk-informed approach to special treatment, this rulemaking should enable licensees and the staff to focus their resources on SSCs that make a significant contribution to plant safety. Conversely, for SSCs that do not significantly contribute to plant safety, this approach should allow a reduced level of assurance that these SSCs will meet functional requirements.

The following describes the staff's vision, strategies, and objectives for this rulemaking effort. The staff believes that they have been developed in a manner that is consistent with the agency's performance goals:

Vision Develop alternative regulations in 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 using a risk-informed approach.

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 preferentially utilizes change processes that encourage public participation (e.g., rulemaking, license amendments) and result in public confidence in the product and process.

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 staff review and approval of the plant-specific program.

Assign priorities to the rules to be modified, taking into consideration the reduction of unnecessary burden for industry, the effect on staff efficiency

and effectiveness, and 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.

2.0 Existing Regulatory Framework

The NRC has established a set of regulatory requirements for commercial nuclear reactors to ensure that a reactor facility does not impose an undue risk to the health and safety of the public, thereby providing reasonable assurance of adequate protection to public health and safety. The current body of NRC regulations and their implementation are largely based on a "deterministic" approach. Requirements were devised on the basis of a defined set of events that are analyzed as "design basis events." This approach has employed the use of safety margins, operating experience, accident analysis, and qualitative assessments of risk, relying on the application of a defense-in-depth philosophy. One element of this defense-in-depth approach is the imposition of "special treatment" requirements on SSCs important to safety to provide reasonable assurance that such SSCs will meet functional requirements during postulated design basis conditions. Special treatment requirements are imposed on nuclear reactor applicants and licensees through numerous regulations that have been promulgated since the 1960's. These requirements specify different scopes of equipment for different special treatment requirements depending on the specific regulatory concern.

Against this deterministic regulatory backdrop, the Commission published a Policy Statement on the Use of Probabilistic Risk Assessment (PRA) in 1995. To implement this Commission policy, the staff developed guidance on the use of risk information for reactor license amendments issuing Regulatory Guide (RG) 1.174 and its daughter regulatory guides: RG 1.175 (Risk-informed Inservice Testing), RG 1.176 (Graded Quality Assurance), RG 1.177 (Risk-informed Technical Specifications [TSs]), and RG 1.178 (Risk-informed Inservice Inspection). Currently, the staff is processing applications that use risk information as part of their technical justification utilizing the referenced regulatory guidance. In this respect, the Commission has been successful in developing and implementing a regulatory means for factoring risk insights into the current regulatory framework. One such risk-informed submittal, the South Texas Project (STP) submittal on graded quality assurance, is particularly noteworthy.

In March 1996, STP Nuclear Operating Company requested that the NRC staff approve a revised Operations Quality Assurance Program (OQAP), incorporating the methodology for

graded quality assurance (QA), that was based on PRA insights. The STP graded QA proposal was essentially an extension of the existing regulatory framework. Specifically, the STP approach continued to use the traditional safety-related categorization, but allowed for gradation of safety significance within the "safety-related " categorization (consistent with Appendix B) through use of a risk-informed process. Following extensive discussions with the licensee and substantial review, the staff approved the proposed revision to the OQAP on November 6, 1997. In its letter and the accompanying safety evaluation, the staff concluded that for the proposed graded QA approach the licensee's methodology for determining the relative safety significance of plant SSCs was acceptable, that appropriate QA controls had been defined for the established categories of SSCs, that adequate feedback mechanisms had been established to adjust the graded QA program if operational performance indicated such a need, and that all pertinent regulatory requirements continued to be satisfied.

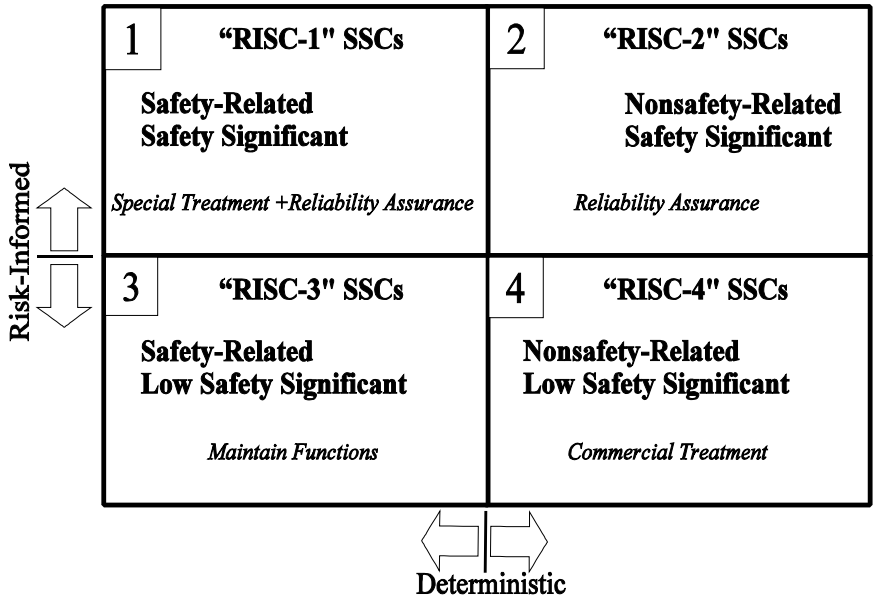
Subsequent to NRC's approval, the licensee identified implementation difficulties associated with the graded QA program. For a large number of SSCs that the licensee judged to be of low risk significance, and for which the licensee reduced the QA requirement, other regulatory requirements such as environmental qualification, the American Society of Mechanical Engineers Boiler and Pressure Vessel Code, or seismic requirements continue to impose substantial requirements. Therefore, if the licensee needs to replace such a component, there is still a need to meet all such special requirements when procuring the replacement even though the SSC in question may have been determined to be of low safety significance and QA controls have been reduced. These "special treatment" requirements have prevented the licensee from realizing the full potential reduction in unnecessary regulatory burden for SSCs judged by the licensee to have little or no safety importance. In an effort to achieve the full benefit of the graded QA program, the licensee submitted a request, dated July 13, 1999, asking for an exemption from the scope of numerous special treatment regulations for SSCs categorized as of "low safety significance" or as "nonrisk significant." This proposal is currently being reviewed by the staff.

As already mentioned, SECY-98-300 was sent to the Commission on December 23, 1998, to obtain the Commission's agreement on a list of three options for ensuring the governing commercial reactor regulations are risk-informed. As described in SECY-98-300, "Option 2" which pertains to this rulemaking effort was to risk-inform the scope of regulations which impose special treatment requirements. By SRM dated June 8, 1999, the Commission directed the staff to implement Option 2 of SECY-98-300. Thus, the staff has initiated the rulemaking effort described in this plan.

3.0 How the Regulatory Issue Will Be Addressed By Rulemaking

The purpose of this rulemaking is to develop an alternative regulatory framework that enables licensees, using a risk-informed process for categorizing SSCs according to their safety significance (i.e., a judgment that considers both traditional deterministic insights and risk insights), to reduce unnecessary regulatory burden for SSCs of low safety significance by reducing the amount of special treatment required. In the process, both the NRC staff and industry should be able to better focus their resources on regulatory issues of greater safety significance. This should improve regulatory effectiveness and efficiency and contribute to

Figure 1: **Diagram of Categorization and Treatment**



enhanced plant safety. To accomplish this, it is necessary to amend the governing regulations. The current regulations use terms such as "safety-related," "important to safety," and "basic component" to identify the groups of SSCs and supporting activities that require "special treatment." This rulemaking will build into the regulations an alternative that offers licensees the flexibility of utilizing a risk-informed process to evaluate the need for special treatment. This risk-informed process will ensure that risk insights will be used in a manner that complements the NRC's traditional deterministic approach. The risk-informed approach will be consistent with the defense-in-depth philosophy, will maintain sufficient safety margins, will ensure that any increase in core damage frequency or risk is small and consistent with the safety goal policy statement, and will ensure that a performance measurement strategy is employed.

A graphical depiction of the changes that are expected to result from a risk-informed re-categorization of SSCs is illustrated in Figure 1. The figure depicts the current safety-related versus nonsafety-related SSC categorization scheme with an overlay of the new risk-informed categorization. The figure groups SSCs into one of 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, these SSCs may have some additional requirements concerning reliability and availability of SSCs if the SSC is determined to be safety significant due to its contribution in beyond design basis events.

Box 2 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. For RISC-2 SSCs, there will probably need to be requirements to maintain the reliability and availability of the SSCs consistent with assumptions made in the PRA (i.e., these SSCs will typically be important only for beyond design basis events and current regulations generally only have meaning for design basis events and therefore would not impose any new requirements on such SSCs).

Box 3 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. A significant portion of the rulemaking effort would be to revise the rules that contain special treatment requirements to create alternatives such that these RISC-3 SSCs would no longer be subject to the current special treatment requirements. However, 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 requirements defeated. 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.

Box 4 depicts SSCs that are nonsafety-related and continue to be categorized as not being significant contributors to plant safety. These SSCs are termed RISC-4 SSCs, and the assurance of their functional performance is controlled under the licensee's commercial grade program (no change from the current requirements).

4.0 Rulemaking Alternatives

This section:

(1) Evaluates various alternative rulemaking strategies (Section 4.1);
(2) Describes the selection of rules (that contain special treatment requirements) rules which are being considered for inclusion into the rulemaking effort (Section 4.2);
(3) Discusses unique considerations for specific rules that contain special treatment requirements (Section 4.3); and
(4) Evaluates the best approach for implementation of the rulemaking (Section 4.4).

4.1 Selection of the Optimal Rulemaking Approach

Section 4.1 evaluates various alternative rulemaking strategies. The agency's performance goals (i.e., maintain safety, reduce unnecessary regulatory burden, increase efficiency and effectiveness, enhance public confidence) are used as criteria to judge each regulatory approach.

Numerous rulemaking strategies were considered for implementing this risk-informed initiative. The strategies judged to be most viable are:

1. New Term: This approach entails the definition in 10 CFR 50.2 of a new term (i.e., "safety-significant SSCs") that describes for the purposes of special treatment requirements which SSCs are safety-significant and therefore need to be within the scope of the rules containing special treatment requirements. This new term would then be incorporated into the scope of each rule that contains special treatment requirements

to allow licensees to voluntarily revise the scope of SSCs that are subject to special treatment requirements (i.e., only SSCs that are safety-significant would need to receive special treatment). To determine which SSCs are safety significant, the staff 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, or alternatively the staff could issue a regulatory guide that contains the SSC categorization guidance.

2. Redefine Current Terminology: This approach 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 expands the meaning of the current terms (which reside in the existing rules) so there is no need to add new terms to the governing regulations. However, there would need to be a significant effort to go through all the regulations to make sure that the staff did not unintentionally revise any non-special treatment rules and make appropriate changes to preclude such occurrences. In a similar fashion to the "new term" approach described above, 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 alternatively the staff could issue a regulatory guide that contains the SSC categorization guidance.

3. New Rule: This approach entails the development of a new rule to Part 50 (currently the rule would be 10 CFR 50.69) that would "list" the rules that contain special treatment requirements that may have their scope risk-informed in accordance with the methodology requirements contained in either an appendix to Part 50, or guidance contained in a regulatory guide (similar to above two approaches in this respect). It is not clear at this point whether this approach of "listing" the rules is practical and efficient, or whether it is better to revise the scope of each special treatment rule to reference §50.69 for additional requirements concerning the alternative approach. In addition to identifying which rules can be risk-informed for special treatment, the new rule would contain some new requirements concerning the type of regulatory treatment that SSCs would receive. RISC-1, RISC-2, and RISC-3 SSCs (i.e., boxes 1, 2, and 3 of figure 1) would receive some type of regulatory treatment. For example, it is expected that the new rule will include a requirement that RISC-3 SSCs (formerly safety-related SSCs that are determined to be of low safety significance) would have their functionality maintained through the use of commercial practices and standards. The new rule could also specify that RISC-1 and RISC-2 SSCs (either formerly safety-related or nonsafety-related) that are determined to be significant contributors to plant safety for events that are beyond the design basis of the facility shall have their reliability and availability maintained such that the assumptions of the PRA continue to be valid. For the purposes of this discussion, this regulatory treatment is referred to as a Reliability Assurance Program.

After comparing these alternatives, the staff eliminated alternative 2. The staff decided not to define or redefine the existing terms (i.e., "safety-related" or "important to safety") primarily because this approach was judged to be relatively inefficient and ineffective from a regulatory standpoint. The staff concluded that the use of the same terms having two different meanings would unnecessarily complicate and confuse the existing regulations governing power reactors. The potential level of confusion could be significant considering the potential for licensees to elect to implement the risk-informed alternative for only for a subset of revised rules, resulting in the use of similar language with different meanings in the licensee's licensing basis documents

and in the associated plant implementation documents. In fact, this type of confusion would be unavoidable during the time period when licensees are phasing in the new approach at their facilities as they re-categorize the SSCs in various plant systems. Both the terms "safety-related " and "important to safety" have a long regulatory history that has established their meaning and interpretation in both a technical and regulatory sense. The staff concludes that it is better to avoid the potential for reopening previous debates concerning these terms (and the associated resource drain for both the NRC staff and industry).

Regarding the remaining two alternatives, the staff judges alternative 3 to be the simplest approach requiring fewer staff resources to implement since it appears to avoid the need to develop and incorporate a new definition into the regulations. This approach avoids the consequential need to revise the scope of each regulation containing special treatment requirements to insert the newly defined term. However, as already mentioned the staff may still need to revise the scope of each rule to refer to §50.69, if the staff concludes that this course of action is the most efficient and coherent approach. Alternative 3 has the benefit of grouping or integrating all the risk-informed requirements into one rule. This contributes to regulatory clarity and makes it easier for both licensees and the staff to implement the regulation (as opposed to having risk-informed requirements incorporated into each regulation). Additionally, the new rule approach enables the staff to "cleanly" identify in one place what the regulatory treatment requirements will be for each SSC "box" (see figure 1). Specifying these types of regulatory treatment requirements for the alternative 1 approach would be more difficult and confusing because it would require changing the specific regulations that were intended only for "design basis" events to RISC-2 and RISC-3 SSCs. In the case of RISC-2 SSCs, this would mean revising the current Part 50 regulations which have a design basis focus to address SSCs that are important for beyond design basis events. In the case of RISC-3 SSCs, this would mean revising the current Part 50 regulations to maintain design basis function but with less assurance. From a regulatory perspective, to revise the Part 50 regulations to address RISC-2 and RISC-3 SSCs is a difficult task. More importantly, it appears that it would confuse the Part 50 regulations with respect to what it means to be within the design basis and what it means to be functional. On the other hand, the new rule alternative enables the staff to address these two difficult issues in a separate, stand-alone regulation which has the least impact on existing regulations. From this perspective, the new rule approach appears to be a more coherent regulatory approach.

Since alternative 3 would incorporate into Part 50 new requirements concerning the regulatory treatment for SSCs categorized as RISC-2 and RISC-3, it is not simply a "scope" approach to special treatment. It could therefore be viewed as going beyond the Commission's June 1999 SRM to implement option 2 of SECY-98-300. However, in this regard, the staff concludes that the new rule alternative is consistent with the Commission's directive and SECY-98-300 because the alternative only expands the "scope" approach as necessary to facilitate a sound technical and regulatory approach for risk-informing special treatment requirements. For example, without some additional requirements placed into the §50.69, RISC-2 SSCs that are "scoped" into the new rule would have no requirements placed on them since the current regulations do not generally have applicability for beyond design basis events. It is in those events that RISC-2 SSCs make a significant contribution to plant safety.

Regarding whether alternative 3 should be supported with an appendix to Part 50 or with a regulatory guide, the staff concludes that an appendix is the preferable approach. A regulatory approach that is supported with a Part 50 appendix has the potential to be constructed such that it supports implementation of risk-informed alternative without the need for prior NRC review and approval of licensees' risk-informed categorization methodologies or resultant equipment lists (i.e., use of a regulatory guide would require NRC staff review and approval).

Incorporation of categorization methodology requirements into an appendix in the regulations minimizes the interaction required with licensees to implement the new regulatory approach, provides greater regulatory stability and predictability, and is judged to result in the least burden on staff and industry resources. This conclusion assumes that the staff can construct an appendix that contains regulatory criteria that maintain safety and are sufficiently clear to both the staff and industry so that there is consistent implementation of the criteria and the staff can conclude that safety is maintained without the need for prior review and approval of the licensee's SSC categorization methodology. The staff recognizes that this will be a difficult task from both a technical and legal perspective. It involves a new type of regulatory approach that requires an explicit, detailed appendix. It is not clear at this point in time whether such an approach can be developed. Therefore, it is possible that the ultimate regulatory approach may involve staff review that relies on a less detailed and explicit appendix.

Assuming that a "no prior staff approval" appendix approach can be developed, the staff will need to make its safety determination principally based on the conclusion that the appendix ensures sufficient fidelity of the categorization process to support the more general conclusion that plant safety is maintained. Performance monitoring of re-categorized equipment (RISC-3 SSCs) appears to have significant limitations. For RISC-3 SSCs, there is likely to be limited capability for meaningful monitoring of these SSCs because, in many cases, the original special treatment requirements were the principal means for providing increased assurance that such SSCs would function under design basis conditions. For instance, the SSC can not be tested under design basis conditions and so additional requirements like §50.49 and 10 CFR 50 Appendix B were imposed on the SSC to provide greater assurance that such SSCs would satisfy functional requirements under design basis conditions. The staff expects that the experience gained from the pilot plants will help it resolve whether a regulatory approach that does not involve prior NRC review and approval is feasible.

If the staff concludes that it must review to some extent the licensee's categorization of SSCs, then the staff will reconsider which regulatory approach to pursue. The conclusion above is based primarily on the judgement that the burden is less for both the staff and industry for the "no prior approval" appendix approach. The basis for this conclusion is that the net impact on staff resources is less when this activity is regulated through the performance of risk-informed inspections (performed consistent with the regulatory oversight process) that inspect the licensees' implementation of the new SSC categorization process rather than regulating this activity as both a licensing action (i.e., prior review and approval) and as an inspection task. This inspection activity has potential to be resource intensive (under the assumption that the staff will not be reviewing and approving the licensee's re-categorization methodology) for both the staff and industry unless such inspections are well defined, focused, and both staff inspectors and licensees clearly understand what it means to comply with the new regulatory approach for classifying SSCs. Therefore, the appendix must contain clear, unambiguous regulatory criteria on what is acceptable. The staff currently believes that it is possible to establish such an inspection framework. It is also important to note that any regulatory approach which requires prior NRC review and approval of the re-categorization methodology or the resultant equipment lists, may be viewed by industry as having too much uncertainty regarding what will be acceptable, and being too unpredictable regarding the potential costs to implement the regulatory alternative. Consequently, the staff believes that under a "prior NRC review and approval" approach, licensees would be less likely to pursue this risk-informed regulatory alternative.

Conclusion The "new rule" alternative, for the reasons stated above, is judged to be the best regulatory approach assuming that it can be implemented without the need for extensive prior NRC review and approval of licensees' risk-informed categorization approaches and assuming

that the approach does not become too unwieldy (i.e., which means that the staff may need to revise the scope of each rule to refer to §50.69). The staff will rely, in part, on the pilot plant experience to determine whether such a regulatory framework can be constructed, or whether there will be a need to structure the regulatory framework to require some level of prior staff review and approval of licensee's SSC risk-informed categorization effort. The key elements that would be contained in a new rule and supporting appendix to implement this preferred regulatory alternative are provided in Attachment 2 to the SECY paper (the ANPR) that transmits this rulemaking plan to the Commission.

4.2 Rulemaking Implementation/Selection of Special Treatment Rules

A detailed discussion of the screening of the regulations containing special treatment requirements is provided as Attachment 3 to the SECY paper that forwards this rulemaking plan to the Commission. Section 4.2 provides an overview of this rule screening effort. The regulations governing commercial reactors were screened using the five criteria and associated measures identified below, to identify the list of special treatment regulations that should be considered in this rulemaking effort:

Criterion 1 The rule includes special treatment requirements.

Measure 1 For the purposes of identifying special treatment regulations for possible inclusion in this rulemaking, the staff defines "special treatment" as follows:

Special treatment requirements are requirements imposed on 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. Any rule that specifies such broadly defined requirements is considered a special treatment rule.

Criterion 2 The rule needs to be included in the rulemaking effort because risk-informing the special treatment requirements will improve internal efficiency and effectiveness.

Measure 2 The staff judged that the internal review and inspection effort could be reduced for the subject rule if its special treatment requirements were risk informed (while maintaining safety)

Criterion 3 The rule needs to be included in the rulemaking effort since risk-informing of its special treatment requirements will reduce unnecessary burden on licensees or applicants or it needs to be included to maintain safety.

Measure 3 The staff made a preliminary analysis to assess whether risk-informing the special treatment requirements of the subject rule would reduce unnecessary burden. Industry input on benefits/costs associated with rules should weigh heavily in the final decision. Identification of pilot plants interested in modifying a specific requirement should be considered as sufficient evidence that a rule reduces burden.

Criterion 4 The rule needs to be included in the rulemaking effort to minimize the need for exemptions, or the rule needs to be included to facilitate rulemaking for another rule.

Measure 4 The staff assessed whether the subject rule needed to be addressed or revised in the rulemaking effort to avoid the need for exemptions once the special treatment rulemaking is implemented (i.e., to avoid the problem that STP encountered with graded QA).

Criterion 5 The rule needs to be included in the rulemaking effort to ensure that the licensing basis is appropriately documented and controlled (e.g., FSAR updates, documentation of methodology used for implementing risk informed changes, staff or licensee reviews related to implementation of risk informed changes).

Measure 5 The staff assessed whether the rule contained requirements that relate to the documentation and control of the licensing basis.

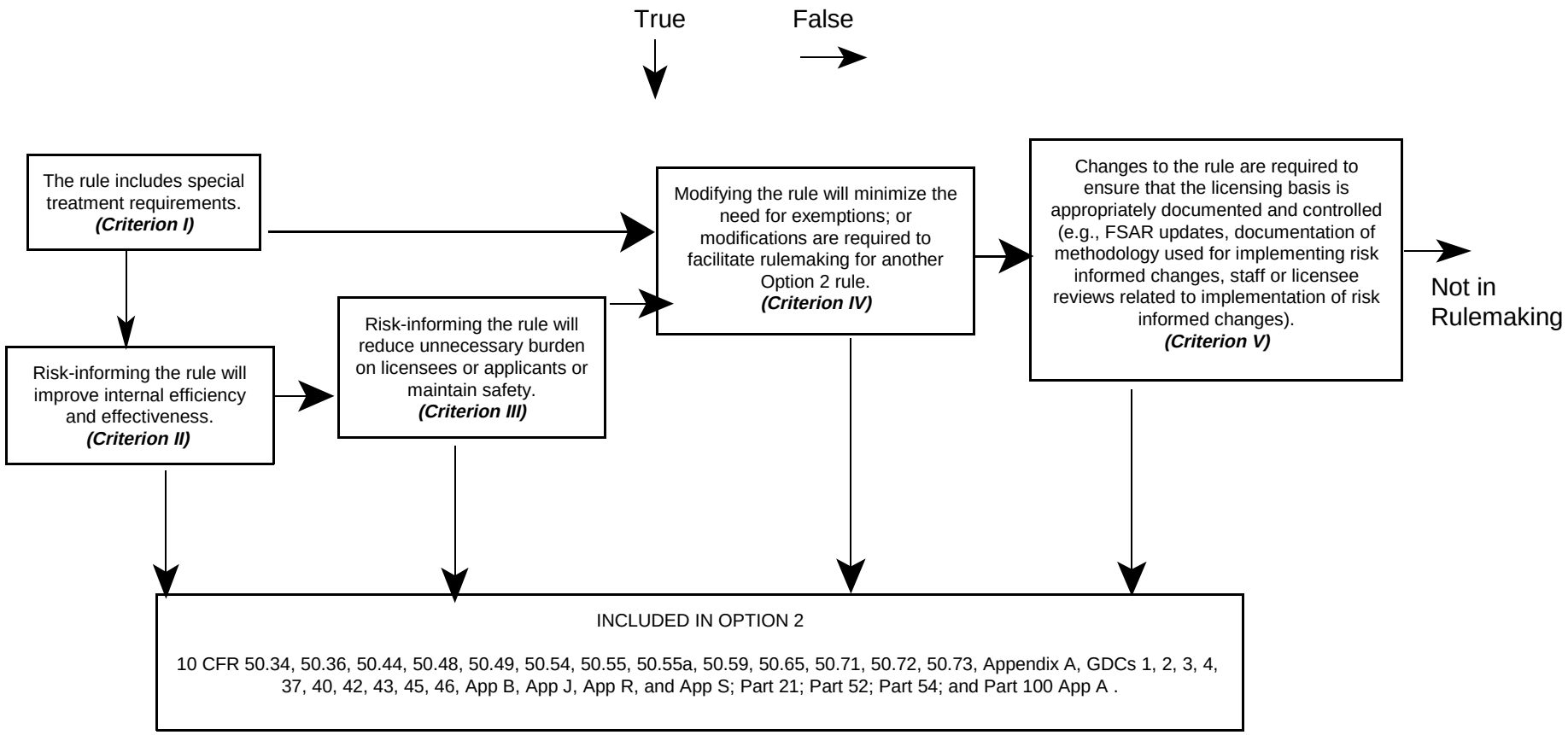
Figure 2 depicts how the screening criteria were utilized to screen the regulations. Refer to Attachment 3 (i.e., the Advance Notice of Proposed Rulemaking [ANPR]) of the SECY paper that transmits this rulemaking plan to the Commission for a detailed summary of the results of the screening process.

As a result of the staff's rule screening effort, the staff concluded that the following rules containing special treatment requirements should be considered as part of the rulemaking effort:

1. 10 CFR 50.34
2. 10 CFR 50.36
3. 10 CFR 50.44
4. 10 CFR 50.48
5. 10 CFR 50.49
6. 10 CFR 50.54(a)(3)
7. 10 CFR 50.55
8. 10 CFR 50.55a
9. 10 CFR 50.59
10. 10 CFR 50.65
11. 10 CFR 50.71(e)
12. 10 CFR 50.72
13. 10 CFR 50.73
14. 10 CFR Part 50 Appendix A General Design Criteria 1, 2, 3, 4, 37, 40, 42, 43, 45, and 46
15. 10 CFR Part 50 Appendix B
16. 10 CFR Part 50 Appendix J
17. 10 CFR Part 50 Appendix R
18. 10 CFR Part 50 Appendix S
19. 10 CFR Part 21
20. 10 CFR Part 52
20. 10 CFR Part 54
21. 10 CFR Part 100, Appendix A

At present, the above list of rules does not contain 10 CFR Part 19, 10 CFR Part 55, or 10 CFR 50.120. It is possible that the staff's efforts to risk-inform the special treatment requirements could result in the need to make conforming changes to these regulations.

Figure 2. Screening Process and Results



4.3 Rulemaking Implementation/Rule-specific Approaches and Considerations:
Section 4.3 discusses unique considerations for specific rules that were screened for inclusion in this rulemaking effort.

10 CFR 50.34
10 CFR 50.34 identifies the required information that applicants must provide in preliminary and final safety analysis reports. It, therefore, is a rule that contains special treatment requirements in the form of documentation requirements for certain SSCs. This regulation may need to be revised to ensure that future applicants properly document the categorization of SSCs with regard to special treatment. Given that this requirement applies to future applicants, the priority for revising this rule is low.

10 CFR 50.36:
The staff determined that 10 CFR 50.36 is a rule that imposes special treatment requirements. It establishes operability, surveillance, limiting conditions of operation, and monitoring requirements on SSCs. Regarding 50.36, the staff makes the following observations:

1. The potential unnecessary burden reduction from risk-informing the scope of SSCs subject to TS requirements is judged to be minimal due in large part to the new standard TS effort, which resulted in a large percentage of TS requirements being relocated from the TS. A large percentage of the remaining SSCs would probably be judged to be safety significant (i.e., either RISC-1 or RISC-2 SSCs) and would retain their special treatment.

2. To implement changes to §50.36 (stemming from a revision to the regulation), licensees are required to submit TS amendments in accordance with 10 CFR 50.90. The §50.90 process also introduces an element of uncertainty due to the possibility that a hearing on the proposed TS change may be requested with the subsequent impact on costs. This possibility represents an additional burden on both licensees and the staff associated with changing this rule. As a result, it is possible that risk-informing the scope of special treatment for §50.36 could be a net burden increase.

3. There are ongoing activities that are successfully making different aspects of the current TS risk-informed within the current regulatory structure of 10 CFR 50.36 (i.e., consistent with Option 1 of SECY-98-300). As a result, the benefits of the risk-informed evaluation process (maintain safety while reducing unnecessary burden thereby leading to a better focus of staff and industry resources on safety) are being achieved without a rulemaking effort and therefore with less commitment in staff resources.

4. To make 10 CFR 50.36 risk informed is a very complex task that appears to require a fundamental change to the §50.36 regulatory criteria. This has ramifications for the underlying accident analyses and associated key assumptions. This type of effort appears to extend beyond the current rulemaking effort and perhaps is better considered as a potential Option 3 (per SECY-98-300) effort.

The staff will request input from stakeholders via the ANPR concerning the potential for reducing unnecessary burden associated with the special treatment requirements

imposed by this regulation. Depending on this feedback, the staff will determine whether 10 CFR 50.36 should remain part of this rulemaking effort.

10 CFR 50.44

Though not the focus of this rule, §50.44 includes special treatment requirements in the form of equipment qualification requirements. Specifically, for equipment located within containment, §50.44 requires that equipment to be capable of withstanding the consequences of a hydrogen-oxygen recombination without loss of safety function.

10 CFR 50.48, 10 CFR 50.55a, 10 CFR 50.72, 10 CFR 50.73–Ongoing Rulemakings

10 CFR 50.48 (including Appendix R to 10 CFR Part 50 and General Design Criteria [GDC] 3), 10 CFR 50.55a, 10 CFR 50.72, and 10 CFR 50.73 are rules containing special treatment requirements. In each case, there are ongoing rulemaking activities dealing with these rules, although none of the ongoing rulemakings involves risk-informing the scope of special treatment. The staff will coordinate its special treatment rulemaking activities with the appropriate technical groups to ensure that these regulations are revised when it is practical to do so consistent with ongoing efforts (i.e., such that it does not unduly delay the ongoing rulemaking). If it is not possible to take advantage of ongoing efforts, then the rule will be addressed in a manner similar to the other special treatment rules.

10 CFR 50.49

The current 10 CFR 50.49 provides a defined scope for electrical equipment items to receive special treatment. For 10 CFR 50.49, special treatment refers to required established measures and activities performed on electrical equipment items to ensure that these items perform their safety functions during and if necessary following exposure to harsh environmental service conditions resulting from design basis events. Electrical equipment important to safety and within the scope of 10 CFR 50.49 consist of three groups of equipment items. These three groups of equipment items important to safety and associated attributes are:

- Safety-related electric equipment (referred to as “Class 1E” equipment in Institute of Electrical and Electronics Engineers [IEEE] 323-1974) that is relied upon to remain functional during and following design basis events

- Nonsafety-related electric equipment whose failure under postulated environmental conditions could prevent satisfactory accomplishment of safety functions (or provide misleading information to the operators)

- Certain post-accident monitoring equipment as indicated in Revision 2 of RG 1.97, “Instrumentation for Light-Water-Cooled Nuclear Power Plants to Assess Plant and Environs Conditions During and Following an Accident.”

Consistent with the approach on other special treatment regulations, the objective of amending 10 CFR 50.49 would be to incorporate an alternative that allows for a risk-informed scope for SSCs that require qualification in accordance with §50.49. For SSCs re-categorized as having low safety significance, the functional requirements of the equipment would be maintained with less assurance.

10 CFR 50.54(a)(3)

This regulation is incorporated into this rulemaking effort because changes to this rule may be needed to facilitate the rulemaking. Specifically, 10 CFR 50.54(a)(3) requires

that changes to the QA program that reduce commitments receive prior NRC approval. As a result, this regulation may need revision to enable licensees to remove some of the re-categorized SSCs from quality controls without having to gain NRC approval for the subsequent changes. The basis would be that the changes were made consistent with the amended regulations (i.e., §50.69) and therefore it is not necessary that such QA plan changes be reviewed in accordance with §50.54.

10 CFR 50.59

In a similar fashion to §50.54(a)(3), 10 CFR 50.59 is included in this rulemaking effort since changes to the regulation may be needed to facilitate the rulemaking. The change to §50.59 is proposed to be limited to obviating the need for an evaluation of the change in special treatment for a safety-related SSC that is now categorized as RISC-3. Changes in functional capability for SSCs of low safety significance that are described in the FSAR will still require evaluation in accordance with §50.59. Currently, the staff concludes that RISC-3 SSCs that are re-categorized to enable special treatment requirements to be reduced or eliminated do not need to be subject to 10 CFR 50.59 because it is anticipated that categorization in accordance with the new appendix requirements will be essentially redundant to 10 CFR 50.59. This conclusion is clearly dependent on the ultimate structure and content of the new appendix. If this conclusion proves to be valid, then the staff will need to assess whether §50.59 needs revision to support this approach or whether the current rule can be interpreted to allow this approach.

For RISC-2 SSCs, the staff will need to assess whether such SSCs need to be described in the UFSAR in accordance with §50.71(e). If so, then future changes to RISC-2 SSCs would then be subject to 10 CFR 50.59. The staff recognizes that the §50.59 criteria may not make sense for these SSCs since these SSCs typically are safety-significant due to their functioning in events which are beyond the traditional design basis events. A possible solution is to evaluate future proposed changes to these RISC-2 SSCs such that a decrease in plant safety would require prior NRC review and approval consistent with the spirit of the §50.59 regulation. This possibility appears to require rulemaking. Another possible solution is to construct Appendix T to contain a requirement to maintain the reliability and availability of these RISC-2 SSCs consistent with the PRA assumptions. The staff needs to assess whether such a requirement would effectively supersede §50.59 and could constitute an acceptable change control mechanism.

10 CFR 50.65

The existing maintenance rule (MR) contains three areas that impose special regulatory treatment to sets of defined SSCs. These three scopes apply to maintenance at decommissioning status plants(§50.65(a)(1)), assessing the risk of maintenance at operating plants (§50.65(a)(4)), and monitoring the effectiveness of maintenance at operating plants (§50.65(b)(1)).

The staff recently revised §50.65(a)(4) to make it risk-informed. Under the current rulemaking effort, the objective for §50.65 would be to make its special treatment requirements risk-informed while preserving the recent §50.65(a)(4) change. Additionally, changes to §50.65 must be considered for the potential impact on license renewal. As stated in the Statements of Consideration (SOC) for the license renewal rule, the Commission determined that the license renewal rule should credit the existing maintenance activities and MR requirements for most structures and components as an aging management program. Recognizing that licensee activities associated with the

implementation of the MR will continue throughout the renewal period and that they are consistent with the first principle of license renewal is fundamental to establishing credit for the existing programs and the requirements of the MR.

10 CFR 50.71(e)

This regulation was screened into the rulemaking effort because it contains special treatment requirements that impose documentation and licensing basis control requirements on SSCs. Although the review to date indicates that the current rule is sufficient to support the current rulemaking effort, it has been included in the rulemaking effort because further evaluation is needed. It may be necessary to revise the rule to ensure that either the appropriate aspects of the licensees risk-informed categorization of SSCs is described in the UFSAR.

10 CFR 50 Part 50 Appendix A GDCs

The GDC of 10 CFR Part 50 Appendix A impose special treatment requirements on SSCs that are termed “important to safety.” In general, the staff has concluded that the GDCs do not need to be revised to implement the risk-informed special treatment rulemaking. Most GDCs simply require certain equipment to be provided in the facility design, or they require specific functional requirements to be part of the facility design.

However, several GDCs contain requirements that have been interpreted by the staff as requiring continued testing throughout the life of the facility. These GDCs as currently interpreted may need revision. GDCs 37, 40, 42, 43, 45, and 46 contain language that states “testing to assure,” which has been interpreted to mean that the subject GDC requires testing throughout the life of the facility for the specific SSCs of concern. An issue may arise where an SSC that was formerly “important to safety” may now be categorized as low safety significant (i.e., RISC-3 SSC). Even if the implementing regulation in Part 50 is revised to allow for the special treatment alternative approach, the GDC as currently written would still require testing unless the staff approves an exemption to that requirement. This is clearly not a desired condition.

In addition, the first five GDCs are broadly applicable GDCs that impose “special treatment” requirements. For GDC’s 1 - 4, unless some additional flexibility is incorporated into Appendix A (i.e., a change to the specific GDCs, a change to the introduction section of Appendix A, or both), the staff currently concludes that these GDCs would prohibit a licensee from removing the associated special treatment

requirements from SSCs categorized as RISC-3 SSCs[2]. For example, GDC 1 would continue to require QA treatment for SSCs that are "important to safety" even if the Appendix B special treatment requirements were risk-informed. In order to fully implement risk-informed alternative QA treatment, a licensee would need an exemption to GDC 1, unless that rule is modified.

10 CFR Part 50 Appendix B

QA requirements are special treatment regulations. These requirements are found in the following regulations:

- Requirements for a QA program: 10 CFR Part 50 Appendix A, GDC 1, and 10 CFR Part 50, Appendix B
- Requirements for administrative controls in Technical Specification: 10 CFR 50.36(c)(5) and 10 CFR 50.36(c)(6)
- Requirement to describe the QA: 10 CFR 50.34(b)(6)(ii)
- Requirements to control changes to the QA program description: 10 CFR 50.4(b)(7), 10 CFR 50.54(a), and 10 CFR 50.71(e)

This rulemaking will revise Appendix B (and associated QA requirements) to offer licensees an optional risk-informed approach to determine the scope of SSCs requiring QA controls, and the nature of those controls.

10 CFR Part 50 Appendix J

Appendix J was screened into this rulemaking as a special treatment rule because it imposes testing requirements on certain SSCs that are not imposed on commercial-grade SSCs. The staff judges that risk informing this appendix may lead to less testing and therefore would reduce unnecessary regulatory burden on the licensees. Although the 1995 revision to Appendix J was characterized as risk-informed, the changes were not as extensive as those expected in the risk-informed Part 50 effort. The revision primarily decreased testing frequencies, whereas risk-informing the scope of SSCs that are subject to Appendix J testing would remove some components from testing (i.e., to the extent that defense-in-depth is maintained in accordance with the risk-informed evaluation process).

10 CFR Part 21

Part 21 applies procurement and reporting requirements for SSCs delineated by the term "basic component," which is also used in the Atomic Energy Act of 1954, as amended (AEA). The current definition of "basic component" includes design, analysis, and consulting services associated with SSCs. This structure needs to be preserved under the new risk-informed approach. Revising the scope of 10 CFR Part 21 would serve as a vehicle for risk-informing this rule. A potential discrepancy between Part 21 and the AEA could arise if the Part 21 definition of "basic component" is revised. This refers to the situation where the staff establishes through this rulemaking a set of SSCs that are safety-significant (i.e., RISC-1 and RISC-2 SSCs) which are different than the set of SSCs that are "basic components" (i.e, safety-related SSCs) and for which the

[2]GDC 5 applies to sharing of SSCs between nuclear reactors at a single site, and is not considered to be in the scope of this rulemaking, as discussed in Section 4.2.

AEA provides criminal penalties. Under such a scenario, it appears inappropriate to have a criminal penalty associated with an SSC that is determined to be of low safety significance.

The staff will also evaluate whether the current Part 21 dedication process can be used to address RISC-2 SSCs that are brought into the scope of special treatment because of their safety significance. The current regulations, in general, do not recognize accidents that are beyond design basis. Therefore, bringing an SSC into the "scope" of a rule containing special treatment requirements is not meaningful because the rule typically will not apply, since the significance of these SSCs is derived from their function in events that are beyond the current design basis of the plant. The staff will assess whether the dedication process is a useful regulatory vehicle for addressing this situation.

There is also a possibility that revising the scope of "basic component" could have ramifications for Part 19 and Part 55, which may require that conforming changes to be made these parts.

10 CFR Part 52

Although this regulation was screened into the rulemaking effort as a candidate rule that may require revision as part of risk-informed special treatment rulemaking effort, the review performed to date indicates that this regulation does not require revision since it simply references other regulations (mostly Part 50) and does not impose any unique special treatment requirements.

10 CFR Part 54

The staff has determined that changes to Part 54 are required, if license renewal is sought for a facility that has revised its licensing basis to incorporate the alternative risk-informed approach to special treatment. These changes to Part 54 are required because 10 CFR 54.4 explicitly defines the scope of the license renewal rule using the traditional deterministic approach. Therefore, conforming changes should be made to the scope of Part 54 to ensure consistency with Part 50.

The use of risk in establishing the scoping criteria within Part 54 was addressed by the Commission in 1995 when amending Part 54. The Commission determined that the scope of the license renewal rule be deterministic in nature, consistent with the licensing basis of currently operating plants, and that risk should not be used to establish license renewal scoping criteria. A change in the definition of safety-related in Part 54 would, therefore, involve a policy change by the Commission.

The goal of the license renewal program is to establish a stable, predictable, and efficient license renewal process. The staff believes that a revision of Part 54 at this time will have a significant effect on the stability and consistency of the processes being established for of preparation of license renewal applications, and for NRC staff review. Allowing a voluntary alternate scoping criteria will necessitate the development of an alternate renewal process, and create inconsistencies between license renewal applications and the staff's review at a time when the license renewal process is just being established. Guidance would need to be developed regarding format and content of a renewal application, staff review criteria, and inspection guidance for conducting onsite scoping inspections.

Because of the as-yet undefined effects of risk-informing Part 50, it is questionable whether any licensee which is considering license renewal would seek to implement a risk-informed Part 50 first because of the uncertainty created in the license renewal regulatory framework. Therefore, it seems unlikely that there will be any interaction between these efforts within the next few years. The difference between deterministic and risk-informed scopes could be large, given the large numbers of components classified as low safety-significant and non-risk significant at STP (i.e., which would be comparable to the staff's designation of RISC-3 and RISC-4 SSCs).

As discussed in the section addressing §50.65, changes to the maintenance rule scope need to be considered for their potential impact on the underlying basis for the Part 54 rule. Specifically, the license renewal rule, as revised in 1995, narrowed the scope of SSCs subject to aging review in large measure due to the implementation of 10 CFR 50.65. If the staff further reduces the scope of SSCs subject to §50.65 (as a result of this rulemaking), then the staff needs to assess whether this impacts the license renewal basis for eliminating certain components from the scope of Part 54. This assessment needs to be incorporated into the statement of considerations accompanying the rulemaking or make the appropriate modifications to Part 54. The staff would need to minimize any confusion and uncertainty that could be introduced into the renewal process due to the effort to risk-inform Part 50 special treatment requirements.

10 CFR Part 100, Appendix A and 10 CFR Part 50, Appendix S

The seismic design requirements are special treatment requirements. These requirements, for current operating reactors, are incorporated into Appendix A to Part 100, which includes both seismological and geological siting and engineering design criteria. For new plant applications, the seismic design requirements (as a result of the recent rulemaking published on January 10, 1997) are set forth in Appendix S to Part 50. Appendix A to 10 CFR Part 100, Section VI, identifies which SSCs must meet the seismic design criteria utilizing the "safety-related " definition. Appendix S to Part 50 implements GDC 2 to require that SSCs "important to safety" be capable of withstanding the effects of natural phenomena such as earthquakes. The scope of both regulations can be made risk-informed through the current rulemaking.

4.4 Rulemaking Implementation/Phased Implementation of the Rulemaking

Two basic approaches for implementing this rulemaking have been identified: (1) a comprehensive "all regulations at once" approach or (2) a phased approach. The staff concludes that a phased approach to implementation of the rulemaking is the better approach. Risk-informing the scope of the entire body of "special treatment" regulations is a large and complex task. The scope and structure of the current special treatment regulations are not consistent. Therefore, revision of these regulations to incorporate an alternative risk-informed scope will require the staff to examine each regulation and could involve somewhat unique approaches for different rules. The staff needs to gain an understanding of the impact of the risk-informed scope change on each special treatment regulation (i.e., re-categorization of SSCs made under the new appendix and the resultant change in scope of special treatment) to support the staff's finding that reasonable assurance of no undue risk to the health and safety of the public is maintained following the rulemaking. Given the complexity of some of the regulations, from both a regulatory structure perspective in which it may be necessary for the staff to incorporate unique considerations into its new rule, and from a technical perspective where it may be difficult to assess the impact of less assurance of functional requirements for SSCs, it makes sense from a resource standpoint to implement this rulemaking in a phased

manner. This approach enables the staff to go forward with portions of the rulemaking in which there is the greatest potential for benefits in terms of the agency's performance goals.

The alternative is to make the entire scope of the special treatment regulations risk-informed at one time, requiring the staff to assess the impact of the rulemaking on all of the special treatment rules of Parts 21, 50, 54, and 100. This approach is judged to have a greater potential for delay in issuance of the final rulemaking, and to have a greater potential for problems to be identified with individual rules that then would require a subsequent rulemaking to fix the problem.

On the basis of available information, a phased regulatory implementation approach is judged to be a more effective regulatory approach. It should enable the staff to offer the benefits of a risk-informed scope approach to industry on a more expedited schedule, thus contributing to a reduced burden for licensees who choose to implement the approach. As the staff progresses in its work, it may determine that it is feasible and practical to implement the approach for all the rules at one time.

5.0 Alternatives to Rulemaking

Alternative approaches that are intended to accomplish the objective of risk-informing special treatment requirements and that do not involve rulemaking are limited two ways:

1. At best, such alternatives can enable licensees to "grade" the special treatment. However, this requires that the governing regulation incorporates the flexibility to allow for grading. One such regulation is 10 CFR Part 50, Appendix B. More importantly, without regulatory changes, licensees may not be able to remove SSCs from special treatment requirements even when a risk-informed evaluation concludes that the SSCs are not important contributors to plant safety.

2. To remove SSCs from special treatment without a change to the governing regulations requires licensees to submit 10 CFR 50.12 exemption requests for staff review and approval. The review and approval of exemption requests can be resource intensive for both the staff and the industry. If the staff can approve such exemptions, and there is significant industry interest in risk-informing special treatment requirements, the more appropriate approach and the least resource-intensive approach in the long term is rulemaking.

On the basis of this information, the staff does not believe that there are alternative approaches as effective as rulemaking provided there is a reasonable level of industry interest in pursuing this risk-informed alternative. Otherwise, review and approval of a limited number of exemptions appears to be the more efficient approach.

6.0 Advance Notice of Proposed Rulemaking (ANPR)

The ANPR (which is Attachment 2 to the SECY paper that forwards this rulemaking plan to the Commission) will announce to the public the staff's intentions to revise the governing regulations that impose special treatment requirements on SSCs in nuclear power plants. requests that the public comment on: (1) the alternative new terminology and proposed criteria (the proposed Appendix T); (2) the staff's proposed approach for modifying the special

treatment requirements; (3) the staff's expectations with respect to conduct of the pilot program; (4) the staff's proposed activities and schedules for completion; and (5) certain policy and implementation issues. The staff believes that the ANPR provides the following benefits:

- It is consistent with the strategy in the mission statement to use processes that maximize the opportunity for public participation. The ANPR does not preclude the use of meetings and workshops, both of which are planned. The effectiveness of the meetings and workshops may be improved by providing preliminary staff positions in the ANPR.

- As a formal request for comments, the ANPR will receive high visibility within industry and from other external stakeholders and establishes a timetable by which comments must be received. The schedule assumes that this exchange of information will reduce the time required to address comments on the proposed rulemaking because many issues may be resolved on the basis of public comments received on the ANPR.

- By describing the contemplated new terminology and acceptance criteria for the proposed Appendix T, the ANPR would facilitate early implementation of the categorization pilot program and may encourage additional licensees to participate in this program.

- It provides an early basis for evaluating the draft NEI categorization guideline, which is expected to be submitted for staff review in December 1999.

- The ANPR does not commit the NRC to implement the contemplated rulemaking; it is only a mechanism for receiving stakeholder input. In the event the staff determined that this rulemaking was not feasible, the staff could discontinue its efforts and publish a document in the *Federal Register* withdrawing the ANPR.

7.0 Impacts on Licensees

Licensees that wish to implement a risk-informed approach to special treatment will, at a minimum, incur the following impacts:

- The licensee will need to address PRA completeness and quality issues. At a minimum licensees will need to have a PRA that reflects the current plant configuration, is sufficiently complete for the intended application, meets some quality standard (this is not yet defined and could range from an "industry peer review" to requiring the PRA to be reviewed by the staff), and is kept current. Depending on the state of the licensee's PRA, this activity could involve a significant commitment in resources.

- The licensee will need to develop the infrastructure to support the risk-informed evaluation of SSCs to determine safety significance. At a minimum, this task will probably involve the development of procedures governing the risk-informed SSC categorization process and will involve the establishment of a risk-informed expert evaluation team that systematically evaluates and documents the re-

categorization of SSCs. It is also likely that licensees will need to revise the training program, as well as other affected plant procedures .

- The licensee will need to expend significant resources in evaluating the SSCs to determine safety significance, and thus determine the need for special treatment. When the licensee completes this evaluation of SSCs, there should not be a significant additional impact on resources to complete the implementation for different rules. The special treatment rules would continue to apply to RISC-1 SSCs (i.e., not all RISC-1 SSCs have §50.49 requirements, only those that are in harsh environments). RISC-2 SSCs that are scoped into regulatory treatment would have to meet the requirements of §50.69.

- The licensee will need to have a performance monitoring program as part of the risk-informed regulatory alternative. This will be a continuing effort and represents an additional resource impact.

This description of impacts assumes that the rulemaking approach described in Section 4.1 is implemented, and that as a result there is not a need for the staff to review a licensee submittal prior to implementation (i.e., the staff would regulate the risk-informed alternatives principally through a risk-informed inspection consistent with the new regulatory oversight process). If this assumption is not valid and the staff needs to review a submittal, there is a substantial additional impact, including significant cost uncertainty, for licensees that wish to pursue this risk-informed approach, given the potential for such staff reviews to be lengthy. As previously mentioned, if such a regulatory framework is developed, this additional impact could be sufficient to discourage many licensees from pursuing this regulatory alternative.

8.0 Benefits

The staff currently concludes that this proposed regulatory approach can be accomplished while achieving the staff's most important objective: maintaining safety. This rulemaking will allow licensees to relax the special treatment requirements only for those SSCs that do not make more than a minimal contribution to plant safety (i.e., RISC-3 SSCs) . It is not intended that this rulemaking allow RISC-3 SSCs to be removed from the facility, or for the functional requirements for these SSCs to be defeated (i.e., functional requirements are to be maintained, albeit at a reduced level of assurance). The staff expects that some SSCs will be "scoped" into regulatory treatment (i.e., RISC-2 SSCs), and receive enhanced attention thereby increasing the level of assurance that such previous "nonsafety-related" SSCs will be perform as expected. This element of the rulemaking contributes to enhancing safety. Importantly, the regulatory approach will include a "performance monitoring" element, such that if the reliability of equipment degrades substantially (to the extent that it is not reasonable to expect the SSCs can meet functional requirements, or that the PRA assumptions that supported the SSC categorization are no longer valid), or if operational experience indicates that an SSC may be more important to plant safety than previously thought, consideration can be given to revising the SSCs categorization and associated treatment (recognizing that there are limitations associated with some aspects of performance monitoring as discussed in Section 4.1). Finally, this rulemaking effort should enable both the NRC and licensee to focus resources on issues having more importance to plant safety which contributes to enhancing plant safety.

While maintaining safety, the staff believes the following benefits would be realized as a result of this rulemaking.

8.1 Reduction Unnecessary Regulatory Burden

The benefits, in terms of unnecessary burden reduction, of implementing a risk-informed approach to special treatment will vary considerably with each licensee and are dependent on (1) the licensee's current plant programs (the more extenxive "special treatment" programs are, the more potential benefit), (2) the age of the plant (newer plants tend to be larger, more complex, have more SSCs with imposed special treatment requirements, and have a longer remaining lifetime for pay back from unnecessary burden relief, all of which add to a greater potential benefit), (3) the number of rules that the licensee implements (the more rules implemented, the more potential unnecessary burden relief) and (4) the amount of unnecessary burden reduction that licensees could realize is a direct function of the staff's requirements governing the risk-informed evaluation process. The more "restrictive" these requirements are in terms of classifying SSCs as "safety significant" (i.e., the more the process forces SSCs into the RISC-1 and RISC-2 boxes), and in terms of being costly to implement, the less potential benefit that licensees can ultimately realize in terms of unnecessary regulatory burden reduction.

The staff will request industry input on the issue of unnecessary regulatory burden reduction as part of the ANPR. One indication of the potential savings that could be achieved through a risk-informed special treatment approach was provided by the licensee for STP during a presentation to the Advisory Committee on Reactor Safeguards in July 1999. The STP licensee estimated that full implementation of its exemption request (which involves relief from §50.49; §50.34 and 10 CFR Part 100; §50.65; 10 CFR Part 50 Appendix B; 10 CFR Part 50 Appendix J; and 10 CFR Part 21) would result in several million dollars in savings a year at STP Units 1 and 2. This estimate is probably an upper bound on the potential savings that can be realized by a given licensee (given STP's unique three-train design, which results in a larger number of SSCs whose special treatment requirements can be relaxed).

8.2 Regulatory Efficiency and Effectiveness

This regulatory approach is judged to enhance the NRC staff's efficiency and effectiveness by permitting a better safety focus. Fewer regulatory resources would be focused on special treatment issues for equipment that does not have more than a minimal contribution to plant safety. As a result, available resources can be focused on safety issues of greater importance. Licensees should see a similar benefit because they would not be utilizing resources to respond to regulatory action on such equipment and could, therefore, better focus resources in areas that are more important to plant safety.

8.3 Public Confidence

A key element of this rulemaking effort is to keep the public informed and invite its participation. Accordingly, to date the staff has held several meetings open to public participation to discuss this regulatory initiative. In addition to the opportunity the public will have to comment on the proposed rulemaking package, the staff is planning to issue an ANPR to invite public comments on the staff's rulemaking approach. The staff is also considering development of an Internet Web site as another vehicle to disseminate information to the public in a timely manner. Ultimately, if the staff is successful in this regulatory approach, which specifically means that safety is maintained while the costs of operating and maintaining commercial nuclear reactors is reduced, the public will be the chief beneficiary.

9.0 OGC Legal Analysis

The proposed rulemaking would provide nuclear power plant licensees a voluntary alternative to complying with selected deterministic requirements in the Commission's regulations. These regulations currently set forth requirements with respect to design, quality assurance, construction and operation ("special treatment requirements") which are applicable to structures, systems, and components (SSCs) whose characteristics are defined in the selected regulations[3]. These SSCs are denoted as "safety-related" and "important-to-safety." The proposed rulemaking would permit licensees to redefine the scope of SSCs that are subject to the special treatment requirements, using risk-informed criteria as set forth in the amended rules. The staff expects that a significant number of SSCs currently deemed by licensees to be either "safety-related" or "important-to-safety" and therefore currently subject to special treatment requirements (RISC-3 SSCs) would not be "scoped in" under the alternative risk-informed criteria. Conversely, the staff expects that there would be a small number of SSCs currently not defined as "safety-related" or "important-to-safety," but would be "scoped in" under the alternative risk-informed criteria and therefore would be subject to special treatment requirements (RISC-2 SSCs).

OGC has not identified any bases for legal objection to the contemplated rulemaking. The rulemaking provides an alternative method for assuring that the requirements of the Atomic Energy Act of 1954, as amended (AEA) are complied with, that there is reasonable assurance of adequate protection to public health and safety, that the operation of a nuclear power plant will not impose an undue risk to public health and safety, and that appropriate levels of protection are provided to minimize danger to life and property. Accordingly, OGC believes that Sections 103, 104, 161, 182 and 183 of the AEA provide the Commission with sufficient authority to promulgate the contemplated rule.

10.0 Category of Rulemaking

The proposed rulemaking would provide nuclear power plant licensees a voluntary alternative to complying with selected deterministic requirements in the Commission's regulations. This risk-informed regulatory alternative is judged by the staff to be a burden relief that would also minimize the need for exemptions.

11.0 Backfit Analysis

The Office of General Council has concluded (based on the available information) that the rulemaking will not constitute a backfit as defined in §50.109(a)(1). This is because each of the rules being modified in this rulemaking would provide a voluntary alternative to licensees who wish to utilize risk-informed methods for selecting the SSCs that are subject to the "special treatment requirements." Licensees who choose not to use risk-informed methods to select the applicable set of SSCs subject to the "special treatment requirements" can continue to rely upon their existing designations of "safety-related" and "important to safety" SSCs.

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[3]"Safety-related" structures, systems, and components (SSCs) are defined in 10 CFR 50.2. "Important-to-safety" SSCs are described in the introduction of 10 CFR Part 50, Appendix A.

12.0 Supporting Documents

Currently, the staff intends to review an implementing document that the Nuclear Energy Institute (NEI) has indicated will be submitted by the end of 1999. The objective is to reach agreement with NEI concerning the implementation of risk-informed special treatment and be able to endorse the NEI guidance in a regulatory guide. Consequently, the staff does not currently plan to develop draft regulatory guidance to implement this rulemaking. There will be some staff effort required to update, as appropriate, current regulatory guides that address the current SSC categorization approach. Currently, the staff believes this task will be limited to revising the subject regulatory guides to indicate that another risk-informed alternative exists with the appropriate reference.

13.0 Issuance of the Rule by the EDO

To date, the staff has communicated its recommendations regarding this regulatory effort to the Commission (SECY-98-300) and has received direction from the Commission in return. The staff concludes that this level of approval will continue to be needed for this rulemaking effort. Therefore, this rule will not be issued by the EDO.

14.0 Interoffice Management Steering Group

Two interoffice Committees (containing members of NRR, OGC, RES, and Region II) are involved in advising the staff concerning the development of this rulemaking as discussed below.

14.1 Risk-Informed Licensing Panel
The Risk-Informed Licensing Panel (RILP) provides management oversight and direction, resolves conflicts on technical issues, and ensures that proper interaction with other offices is maintained. The members of the RILP are the NRR and RES Division Directors, and a representative from OGC and Region II. The NRR/DSSA Division Director is the RILP chairman.

14.2 PRA Steering Committee
The PRA steering committee provides oversight and addresses policy issues. The PRA steering committee members are the office directors and senior OGC management. The Director of RES is the PRA steering committee chairman.

15.0 Participation by the Public and the Industry

There is significant public and industry interest in this rulemaking as evidenced in the public meetings held to date to discuss the staff's and the industry's efforts on this matter. The staff is considering the establishment of an Internet Web site for release of information in a more timely and convenient manner to the public to further facilitate public participation.

16.0 Organization

Figure 3 depicts the staff's organization for this rulemaking effort. This figure shows the NRR organization for the Option 2 rulemaking .

The members of the core team are Tom Bergman, Tim Reed, Mohammed Shuaibi, Tony Markley, Raj Auluck, Mike Cheok, Bob Palla, Goutam Bagchi, Pete Balmain, and Joe Williams.

Individuals who are providing support are S. Magruder, R. Young, S. Dinsmore, T. Eaton, F. Ashe, J. Knox, D. Fischer, E. McKenna, S. Ali, S. Hoffman, N. Gilles, and J. Pulsipher.

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OGC interface: G. Mizuno and J. Moore
OE interface: T. Reis
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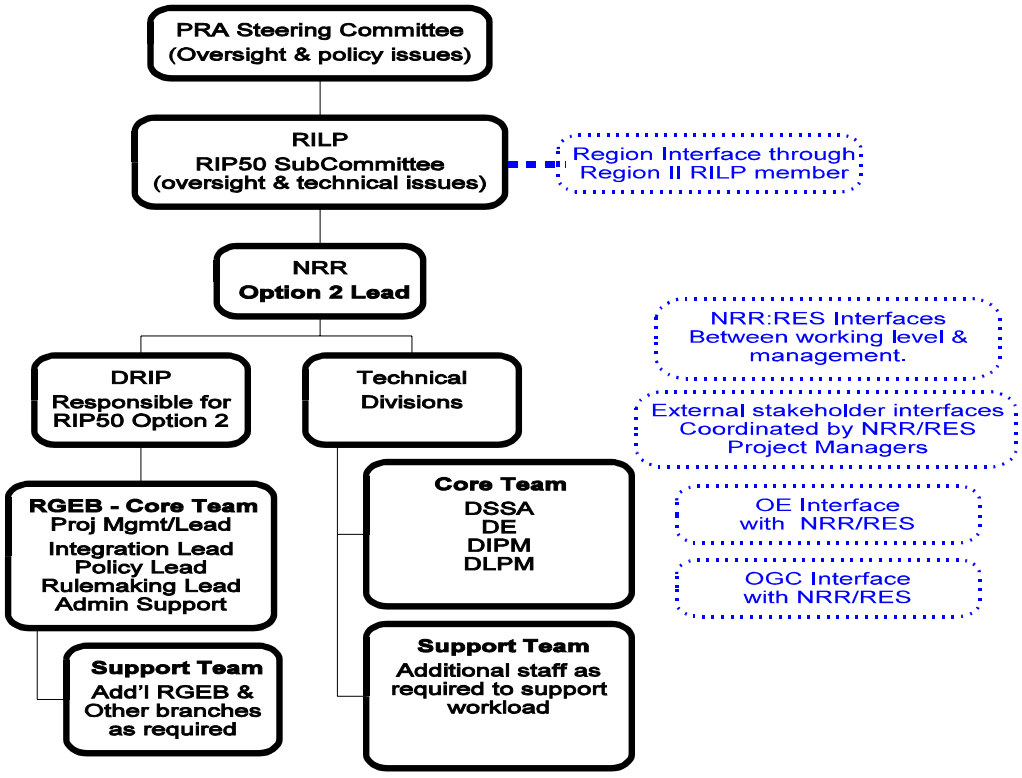
Figure 3: RIP50 Option 2 Organization



17.0 Schedule/Resources

The staff's proposed schedule is described below and is illustrated in Figure 4, "RIP50 Option 2 - Proposed Schedule PERT Chart" and Figure 5, "RIP50 Option 2 - Proposed Schedule Gantt Chart." Explanatory notes for these figures are provided in Figure 6. The proposed schedule includes six major efforts: (1) STP Exemption, (2) ANPR, (3) Categorization Pilot Program, (4) NEI Guideline Review, (5) Proposed Rulemaking, and (6) Final Rulemaking. Some of these efforts are currently underway. The staff estimates that a final rulemaking can be provided to the Commission for approval in October 2001. The total resources for this effort are expected to be 35 full-time equivalent positions (FTE) and **<TBD $>** contractor assistance.

1. STP Exemption: This effort ensures that the results of the exemption request review are factored into the proposed rulemaking package such that the two efforts are consistent. STP is not part of the categorization pilot program because it is too far ahead in implementation to effectively test the proposed Appendix T categorization method. However, if the exemptions can be granted, it will demonstrate that a risk-informed approach can be implemented, at least as far as the STP approach is concerned. In addition, some of the findings will be similar between the STP exemption and the basis for modifying the rules in Option 2.

The STP exemption is currently being reviewed, and the effort is currently projected to be completed in April 2000 and is expected to require about 3 FTEs. The tasks included in this effort are:

a. STP Exemption Request (Task STP.1): This task is a milestone (i.e., no associated NRC effort) reflecting that the STP exemption request was received on July 13, 1999.

b. Staff Evaluation of STP Exemptions (Task STP.2): This task includes the staff effort to review the STP exemptions and to resolve all technical and legal issues. It is estimated to require 39 weeks to complete. To ensure consistency between the exemptions and the proposed rulemaking, this task must be completed prior to completing the proposed rulemaking task (Task PRM.2). If completion of Task STP.2 is delayed by more than 11 weeks (mid-June 2000), it could become critical path work and delay the Option 2 rulemakings.

c. Issuance of STP Exemptions (Task STP.3): This task is a milestone to indicate completion of the STP exemption effort with respect to Option 2.

2. ANPR: This effort includes the issuance of the ANPR included as Attachment 2 to this Commission paper through the evaluation of public comments. The purposes of the ANPR include: (1) a description of the staff's proposed rulemaking approach, including draft regulatory text for the proposed Appendix T, and (2) early solicitation of public comments concerning rules considered for inclusion in the rulemaking effort, alternative regulatory approaches for accomplishing the same objectives, and issues associated with implementation of the rulemaking effort. The resolution of public comments received on the ANPR is expected to facilitate development of the proposed rulemaking package.

The ANPR has been developed and is scheduled to be issued in December 1999. The ANPR effort is scheduled to be complete in May 2000 and is estimated to require about 2 FTEs. In the event cumulative delays of the tasks in this effort exceed 5 weeks, the ANPR effort could become critical path work and impact the schedule for the final rulemaking.

a. Negative Consent to Issue ANPR (Task ANPR.1): this task is a milestone indicating initiation of the ANPR effort. It assumes that the Commission will provide its negative consent to proceed with publishing of the ANPR (mid-November 1999).

b. Publication of ANPR (Task ANPR.2): This task includes staff efforts to address Commission comments on the ANPR and have it published in the *Federal Register*. It is estimated to require 4 weeks to complete.

c. ANPR Comment Period (Task ANPR.3): This task reflects a 75-day comment period for the ANPR, and is expected to be completed in February 2000.

d. Staff Evaluation of ANPR Comments (Task ANPR.4): This task provides 13 weeks for the staff to review and incorporate public comments received on the ANPR, as appropriate.

3. Categorization Pilot Program: This effort includes the implementation and evaluation of the pilot plant program that will demonstrate that the risk-informed categorization of SSCs utilizing the proposed Appendix T requirements and proposed NEI guideline can be performed in an acceptable manner. Included in this effort are the review and issuance of the exemptions for the pilot plants participating in this program.

This effort is underway and is expected to be completed (i.e., exemptions issued) in July 2001 and require about 6 FTEs. Although not currently critical path, delays of more than 4 weeks in most tasks (exceptions noted below) would make them critical path and potentially delay the schedule.

a. Request for Pilot Plants (Task CPP.1): This task is a milestone indicating that the staff has requested that the pilot plants for this effort be identified. This request was in the form of a letter to NEI dated **<TBD>**.

b. Licensee Commitments to Pilot (Task CPP.2): This task is ongoing and assumes 13 weeks for licensees to commit to participating in the categorization pilot program. The appropriateness of this duration was discussed with NEI, which agreed it is reasonable. This task is expected to be completed in December 1999.

c. Staff Acceptance of Pilot Plants (Task CPP.3): This task provides 4 weeks for the staff to evaluate the proposals for pilot plant participation and determine if any limitations or changes need to be made to the program. This task is estimated to begin in December 1999 and to be completed in January 2000.

d. Pilot Plant Categorization Effort (Task CPP.4): This task assumes that licensees will need up to 52 weeks to complete the categorization of a number of systems to be included in their pilot effort. On the basis of discussions with NEI and some possible pilot program participants, this assumption appears reasonable, although the actual time required will vary among licensees. It also assumes that this task cannot begin until the ANPR is published so that licensees can review the staff's proposed Appendix T. This task is estimated to begin in January 2000 and to be completed in January 2001.

e. Submittal of Pilot Plant Exemptions (Task CPP.5): this task is a milestone to indicate that licensees will submit exemptions as they complete their categorization effort. It assumes that licensees will prepare the exemptions in parallel with the categorization.

Since review and approval of the exemptions is not necessary to proceed with rulemaking, delays in this task would not affect the rulemaking schedule. This milestone should occur in January 2001.

f. Staff Evaluation of Pilot Plant Categorization (Task CPP.6): This task provides the staff 52 weeks to evaluate the acceptability of pilot plant implementation of Appendix T and the associated NEI guideline. It can be accomplished in parallel with the categorization effort (Task CPP.4), but it is assumed that 26 weeks will be necessary for the staff to complete its review after the categorization efforts are complete. This task is expected to begin in July 2000 and to be completed in July 2001.

g. Staff Review of Pilot Exemptions (Task CPP.7): This task assumes that the staff can complete its review in 13 weeks, and that this review can be performed in parallel with the staff's review of the categorization effort (Task CPP.6) but cannot be completed before completion of that task. Task CPP.7 also cannot begin until the exemptions are submitted. Since completion of this task is not necessary to proceed with rulemaking, delays in completion of this task will not affect the schedule. This task is expected to begin in April 2001 and to be completed in July 2001.

h. Staff Issuance of Exemptions (Task CPP.8): This task is a milestone indicating that the categorization pilot program effort is expected to occur in July 2001.

4. NEI Guideline Review: This effort is to review an NEI guideline on the categorization of SSCs in a manner that will comply with the proposed Appendix T. This effort will factor in the experience of the categorization pilot program, which will utilize the NEI guideline. It also involves the development of a draft regulatory guide that would endorse the guideline and be part of the proposed rulemaking package.

This effort is on the critical path and therefore any delays may delay the entire schedule. NEI has already begun development of its guideline. This effort is projected for completion in July 2001, and is estimated to require about 3 FTE.

a. Development of Draft NEI Categorization Guideline (Task NEI.1): This task is a milestone to indicate that NEI has already begun development of this guideline.

b. NEI Submission of Draft to the Staff (Task NEI.2): This task is a milestone to indicate that NEI expects to submit the guideline at the end of December 1999. This milestone is on the critical path.

c. Staff Review of NEI Draft Guideline (Task NEI.3): This task includes the staff effort to review, resolve comments on the guideline, and prepare a draft regulatory guide that proposes to endorse the NEI guideline. It is estimated to begin in December 1999 and be completed in June 2000. This is a critical path task.

d. Categorization Approach Deemed Acceptable (Task NEI.4): This task is a milestone to capture the integration of the completion of the staff review of the guideline (Task NEI.3), Commission approval to publish the proposed rulemaking for comment (Task PRM.3), and completion of the staff's evaluation of the categorization pilot program (Task CPP.6). This milestone is estimated to occur in July 2001.

5. Proposed Rulemaking: This effort includes the development and issuance of the proposed rulemaking package for public comment. This effort includes resolution of all technical and

legal issues and development of the associated regulatory guidance necessary to implement the proposed §50.69, including modifications to existing regulatory guidance for rules included in Option 2 (except for the regulatory guide for Appendix T and the NEI guideline, which is included in the NEI guideline review effort).

This effort is on the critical path, and therefore any delays may delay the entire schedule. It is expected to begin in December 1999, and to be completed in December 2000, with a proposed rule to be submitted to the Commission in September 2000. Approximately 12 FTEs are estimated for this effort.

a. Initiation of Proposed Rulemaking (Task PRM.1): This task is a milestone indicating that the SRM for this Commission paper has been issued. It is estimated to occur in mid-December 1999; a delay of this milestone of more than 3 weeks (i.e., into January 2000) could delay the entire schedule.

b. Preparation of Proposed Rulemaking (Task PRM.2): This task includes staff effort to resolve technical and legal issues associated with the rulemaking, and to develop proposed rule language, regulatory analyses, and associated regulatory guidance. The output of this task is a proposed rulemaking package submitted for Commission approval. In order to complete this task, the staff must have resolved technical and legal issues in common with the STP Exemption (Task STP.2), identified the scope of the categorization pilot program (Task CPP.3), and completed the review (and preparation of draft regulatory guide) of the NEI draft guideline (Task NEI.3). Task PRM.2 is a critical path task, and is estimated to begin in December 1999 and be completed in September 2000.

c. Issuance of the SRM by the Commission for the Proposed Rulemaking (Task PRM.3): This task assumes that an SRM on the proposed rulemaking can be issued in 6 weeks. It is estimated to begin in September 2000 and be completed in November 2000. This is a critical path task.

d. Publication of the Proposed Rulemaking for Comment (Task PRM.4): This task includes the staff effort to resolve Commission comments on the proposed rulemaking and to publish it in the *Federal Register*. It assumes this goal can be completed in 4 weeks, which is only reasonable if the staff prepares a proposed rulemaking package that does not need substantive modification. This task is projected to begin in November 2000 and be completed in December 2000. This is a critical path task.

6. Final Rulemaking: This effort includes the development and issuance of the final rulemaking package, including resolution of public comments on the proposed rulemaking. To facilitate implementation, the final rulemaking should include final regulatory guidance as necessary to allow implementation of the rulemaking, in particular, regulatory guidance associated with §50.69, and Appendix T and the final NEI guideline.

This effort is estimated to begin in December 2000, have a final rulemaking package to the Commission in October 2001, and a final rule published in March 2002. This effort is estimated to require 7 FTEs. All tasks in this effort are on the critical path and any delays could delay issuance of the final rulemaking.

a. Initiation of Final Rulemaking (Task FRM.1): This task is a milestone to indicate completion of the proposed rulemaking effort and initiation of the final rulemaking effort. It is projected to occur in December 2000.

b. Comment Period (Task FRM.2): This task allows for a 75-day public comment period. It is estimated to begin in December 2000 and be completed in February 2001.

c. Evaluation of Public Comments (Task FRM.3): This task includes staff effort to resolve public comments, as appropriate, and modify the final rulemaking and associated guidance documents. Because the ANPR is expected to result in early identification of issues and reduction of the number raised as a result of the proposed rulemaking, it is assumed that only 13 weeks are necessary evaluate public comment at this point. This task is estimated to begin in February 2001 and be completed in May 2001.

d. Endorsement of NEI Guideline in Final Regulatory Guide (Task FRM.4): This task includes staff effort to resolve staff concerns and public comments received on the NEI guideline. It assumes that 26 weeks are necessary for this task. It can be accomplished in parallel with the evaluation of public comments (Task FRM.3), although it is assumed that 13 weeks will be needed after completion of Task FRM.3 to conduct public meetings to discuss comments and achieve resolution. This task is projected to begin in February 2001 and be completed in August 2001.

e. Preparation of Final Rulemaking (Task FRM.5): This task includes staff effort to refine the rulemaking package and associated regulatory guidance. It assumes that this effort will begin after public comments are evaluated (Task FRM.3) and partly in parallel with endorsement of the NEI guideline (Task FRM.4). The result of this task is a final rulemaking package for Commission approval. The task is estimated to require 26 weeks, beginning in April 2001 and ending in October 2001.

f. Issuance of the SRM by the Commission on the Final Rulemaking (Task FRM.6): This task assumes that an SRM on the final rulemaking can be issued in 6 weeks. It is estimated to begin in October 2001 and be completed in December 2001.

g. Publication of the Final Rule (Task FRM.7): This task includes staff effort to resolve Commission comments in the SRM and additional process considerations, such as an OMB clearance. It is assumed to require 13 weeks, and is projected to begin in December 2001 and be completed in March 2002. Upon completion of this task licensees may begin implementation of the revised rules, and the rulemaking effort would be complete.

In addition to the these efforts, the staff will also conduct public meetings and workshops, and briefings of the Committee to Review Generic Requirements, the Advisory Committee on Reactor Safeguards, and the Commission. These interactions are expected to require about 2 FTEs.