

10 CFR 50.69
“RISK-INFORMED CATEGORIZATION AND TREATMENT
OF STRUCTURES, SYSTEMS AND COMPONENTS FOR NUCLEAR
POWER REACTORS”

REGULATORY ANALYSIS

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Regulatory Analysis for §50.69

I. Statement of Problem and NRC Objectives

(a) History

The Nuclear Regulatory Commission (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. 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 and analyzed set of events as “design basis events.” This approach has employed the use of safety margins, operating experience, accident analysis, and qualitative assessments of risk, as defense-in-depth philosophy. One element of this defense-in-depth approach is the imposition of special treatment requirements on structures, systems, and components (SSCs) that are important to safety to provide a reasonable assurance that such SSCs will continue to function during the postulated design basis conditions. Special treatment requirements are imposed on nuclear reactor applicants and licensees through a number of regulations that have been promulgated since the 1960's. These requirements specify different levels of special treatment requirements for equipment depending on the specific regulatory concern.

As part of moving the Agency toward a more risk-informed regulatory body, in 1995, the Commission published a Policy Statement on the Use of Probabilistic Risk Assessment (PRA). To implement this Commission policy, the staff has developed guidance (Regulatory Guide (RG) 1.174 “An Approach for using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” RG 1.175 “Risk-informed Inservice Testing,” RG 1.176 “Graded Quality Assurance,” RG 1.177 “Risk-informed Technical Specifications,” and RG 1.178 “Risk-informed Inservice Inspection”) on the use of risk information for reactor license amendments. In this respect, the Commission has been successful in developing and implementing a regulatory means for considering risk insights into the current regulatory framework. One such risk-informed application, the South Texas Project (STP) submittal on graded quality assurance, is particularly noteworthy.

In March 1996, STP Nuclear Operating Company (STPNOC) requested that the NRC approve a revised Operations Quality Assurance Program (OQAP) that incorporated the methodology for grading quality assurance (QA) based on PRA insights. The STP graded QA proposal was 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 10 CFR Part 50 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. Subsequent to NRC's approval, STPNOC identified implementation difficulties associated with the graded QA program. Despite the reduced QA requirement applied for a large number of SSCs in which the licensee judged to be of low safety significance, other regulatory requirements such as environmental qualification, the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, or seismic continue to impose substantial burdens. As a result, the replacement of such a low safety-significant component needs to also satisfy other special requirements during a procurement process. These requirements prevented STPNOC from realizing the full potential reduction in unnecessary regulatory burden for SSCs judged to have little or no safety importance. In an

effort to achieve the full benefit of the graded QA program (and in fact go beyond the staff's previous approval of graded QA), STPNOC submitted a request, dated July 13, 1999, asking for an exemption from the scope of numerous special treatment regulations (including 10 CFR 50 Appendix B) for SSCs categorized as low safety-significant or as non-risk-significant. STPNOC's exemption was ultimately approved by the staff in August 2001.

Under Option 2 of SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - 'Domestic Licensing of Production and Utilization Facilities,'" dated December 23, 1998, the NRC staff recommended that risk-informed approaches to the application of special treatment requirements be developed as one application of risk-informed regulatory changes. Option 2 (also referred to as RIP50 Option 2) addresses the implementation of changes to the scope of SSCs needing special treatment while still providing assurance that the SSCs will perform their design functions. Changes to the requirements pertaining to the design of the plant or the design basis accidents are not included in Option 2. These technical risk-informed changes are addressed under Option 3 of SECY-98-300. The Commission approved proceeding with Option 2 in a staff requirements memorandum (SRM) dated June 8, 1999.

The stated purpose of the "Option 2" rulemaking was to develop a voluntary, alternative regulatory framework that enables licensees, using a risk-informed process for categorizing SSCs according to their safety significance (i.e., a decision that considers both traditional deterministic insights and risk insights), to reduce unnecessary regulatory burden for SSCs of low safety significance by removing these SSCs from the scope of special treatment requirements. As part of this process, those SSCs found to be of risk-significance would be brought under a greater degree of regulatory control through the requirements being added to the rule designed to maintain consistency between actual performance and the performance considered in the assessment process that determines their significance. As a result, both the NRC staff and industry should be able to better focus their resources on regulatory issues of greater safety significance.

The Commission directed the staff to evaluate strategies to make the scope of the nuclear power reactor regulations that impose special treatment risk-informed. SECY-99-256, "Rulemaking Plan for Risk-Informing Special Treatment Requirements," dated October 29, 1999, was sent to the Commission to obtain approval for a rulemaking plan and issuance of an Advance Notice of Proposed Rulemaking (ANPR). By SRM dated January 31, 2000, the Commission approved publication of the ANPR and approved the rulemaking plan. The ANPR was published in the *Federal Register* on March 3, 2000 (65 FR 11488) for a 75-day comment period, which ended on May 17, 2000. In the rulemaking plan, the NRC proposed to create a new section within Part 50, referred to as § 50.69, to contain these alternative requirements.

The Commission received more than 200 comments in response to the ANPR. The staff sent the Commission SECY-00-194 "Risk-Informing Special Treatment Requirements," dated September 7, 2000, which provided the staff's preliminary views on the ANPR comments and additional thoughts on the preliminary regulatory framework for implementing a rule to revise the scope of special treatment requirements for SSCs. The comments from the ANPR are further discussed in Section IV.1.0 of SECY-02-0176 "Proposed Rulemaking to Add New Section 10 CFR 50.69, 'Risk-Informed Categorization and Treatment of Structures, Systems, and Components'" dated September 30, 2002 (ADAMS accession number ML022630007).

The staff prepared a proposed rule package and provided it to the Commission in SECY-02-176 dated September 30, 2002. The Commission approved issuance of proposed 10 CFR 50.69 for public comment in an SRM dated March 28, 2003. Consistent with Commission direction, the staff subsequently published proposed 10 CFR 50.69 for public comment in the *Federal Register* on May 16, 2003 (68 FR 26511). The Commission received 26 sets of comments comprising more than 250 individual comments in response to the proposed rule. The comments are discussed in section II of the final rule *Federal Register* notice.

(b) Objective for Rulemaking

As discussed above, the current scope of SSCs covered by the special treatment requirements governing commercial nuclear reactors is deterministically based and stems primarily from the evaluation of design basis events, as described in updated final safety analysis reports (UFSARs). This regulatory framework provides reasonable assurance of adequate protection (no undue risk) to the health and safety of the public. However, advances in technology, coupled with operating reactor experience, have suggested that an alternative approach, one that continues to maintain reasonable assurance of public health and safety and common defense and security, while reducing unnecessary regulatory burden, is possible and the utilization of such an approach could increase regulatory effectiveness. The new approach embodied in the rule uses a risk-informed process to evaluate the safety significance of SSCs and establish the appropriate level of special treatment requirements for SSCs. It is important to note that this rule is a voluntary rule (it is not being imposed on licensees) that is intended only to ensure that the scope of special treatment requirements imposed on SSCs is risk-informed. The rule, however, does not allow SSC functional requirements to be eliminated, 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 rule enables licensees who elect to implement its provisions, and the NRC, to focus its resources on SSCs with significant contributions to plant safety. Conversely, for SSCs that do not significantly contribute to plant safety, this approach maintains SSC functionality, albeit at a reduced level of assurance.

II. Analysis Of Alternative Regulatory Strategies

A number of rulemaking strategies were considered for risk-informing the special treatment requirements. Those strategies considered most viable were evaluated in the rulemaking plan attached to SECY-99-256. The evaluation of those strategies has been updated based on additional information obtained since the issuance of SECY-99-256. The updated discussion is provided below. The NRC continues to conclude that adding a new section to 10 CFR Part 50 is the appropriate approach for risk-informing the special treatment requirements and hence this is the approach taken for the rule. However, a significant change regarding the regulatory approach is being taken for the rule in lieu of what was concluded in SECY-99-256. As discussed below (in section II.f) and as a result of additional interactions with stakeholders, the NRC no longer concludes that the best regulatory approach is to include an appendix to 10 CFR Part 50 that provides categorization requirements as part of the regulatory approach.

Alternative regulatory approaches for risk-informing special treatment requirements were discussed in the ANPR (attached to SECY-99-256). For example, the NRC discussed use of exemptions if only a limited number of plants were interested in this approach, as well as several variations for proceeding with rulemaking (e.g., including within each special treatment requirement any alternative requirements). The NRC did not receive ANPR comments that

disagreed with the NRC's suggested approach to add a new section to Part 50. However, negative comments from stakeholders were received with regards to the use of a detailed appendix (i.e., Appendix T) to support a proposed new CFR section (refer to section II.f for a summary of these ANPR comments).

(a) No Action or Exemption Alternative

This alternative describes what would occur without the rule. One way to risk-inform special treatment requirements is to do it without a rulemaking, and instead to process exemptions per 10 CFR 50.12. Such an approach was followed for STPNOC who filed an exemption request (from numerous special treatment requirements) which was then subsequently reviewed and approved by the NRC. This exemption review for STPNOC was a "proof-of-concept" of the categorization and adjustment in special treatment concept. While other plant-specific exemptions could be processed, when there is sufficient industry interest, rulemaking is the most efficient means for implementing the type of generic changes encompassed by this effort. Rulemaking, when compared to the exemption process, also provides an opportunity for input from all stakeholders about the requirements that the NRC is considering to promulgate for the contemplated risk-informed process. If only a small number of facilities are interested in risk-informing special treatment requirements, then review and approval of a limited number of exemptions under 10 CFR 50.12 would probably be more efficient. Based on the industry's response to the ANPR, and subsequent industry participation in this rulemaking effort to date, the NRC continues to conclude that there is sufficient industry interest in this initiative to warrant the NRC continuing to expend its resources to develop the rule. For these reasons, the NRC did not choose this alternative.

(b) New 10 CFR 50.2 Definition Approach

This alternative rulemaking approach would entail the development and incorporation of a new definition into 10 CFR 50.2. This new definition (e.g., define a new term such as "safety-significant") would describe, for the purposes of the special treatment requirements within Part 50, which SSCs are safety-significant and, therefore, need to be within the scope of the special treatment requirements. To implement this approach, this new term would need to be incorporated into each special treatment rule, thereby enabling the scope of these special treatment rules to be revised per the new definition such that SSCs that are not "safety-significant" would no longer be subject to the special treatment provisions of the applicable rules. Licensees could voluntarily revise the scope of SSCs that are subject to special treatment requirements by implementing a risk-informed categorization process that determines which SSCs are safety-significant. To determine which SSCs are safety-significant, the Commission could issue a new Part 50 appendix or new section that contains the requirements governing the categorization of SSCs, or alternatively, a regulatory guide could be issued that contains the SSC categorization guidance.

A significant problem with this approach is that unless new requirements are placed into Part 50 to address the low safety significant SSCs (no longer subject to special treatment requirements) and ensure that their design basis functions are maintained (once special treatment is removed from these SSCs), the design basis functional capability could be lost. This is not consistent with the ground rules for this rulemaking. For this approach to work and meet the rulemaking objective of preserving the design basis, it would appear that these additional requirements (to maintain the design basis functions for low safety significant SSCs) would either need to be incorporated into each and every special treatment requirements

section, or be incorporated into a separate section. In this later case this approach becomes very similar to the approach selected for the rule. This rulemaking alternative appears to require duplicate changes to multiple rules, and it is less coherent when compared to an approach that combines all the relevant requirements into one section. Relative to the preferred rule change, this alternative is disadvantaged because the changes to NRC regulations are more extensive, and thus the NRC rulemaking effort should be more time consuming and costly than the recommended alternative. In addition, as a vehicle to risk-inform the regulations, it is likely to be less effective than the recommended rule change because it would be more confusing and less coherent to licensees. For these reasons, the NRC did not choose this alternative.

(c) Expand a § 50.2 Definition or Define a Currently Used Part 50 Term

This alternative is a variation of the approach just described above, but instead of using new language (define a new term in § 50.2), it would expand the definition of a currently defined term such as “safety-related,” or it could define another term currently used (but not defined) in Part 50 such as “important to safety.” This approach has one advantage over the “new definition” approach discussed above such that this approach uses the same terminology as already exists in each of the special treatment requirements. Therefore, it would not be necessary to change the language in any of the special treatment rules. However, a significant effort would be required to review all the regulations to ensure that inadvertent revisions to any non-special treatment rules will not occur and to make appropriate changes to preclude such occurrences. In a similar fashion to the “new term” approach, this consideration would also need to be supplemented with a new Part 50 appendix or section that contains the requirements governing the risk-informed categorization of SSCs. This approach has the problem of the previously described approach (new definition approach) in that a separate section would be required to contain the requirements needed to maintain the design basis of SSCs removed from the scope of special treatment requirements (in which case this approach becomes very similar to the approach selected for the rule) or the requirements would need to be incorporated into each and every special treatment requirements section. This alternative would introduce unnecessary complications and confusion in the application of the terms at plants that choose to implement the new scope for a subset of the special treatment requirements covered in this effort, or for some systems and not others. Such a situation would result in the use of similar language with different meanings in the licensee’s licensing basis documents and in the associated plant implementation documents. For these reasons, the NRC did not choose this alternative.

(d) New Section in Part 50 Approach (10 CFR 50.69)

This alternative rulemaking approach is the approach taken for the rule, and entails the development of a new rule that would be added to Part 50 that licensees could voluntarily adopt. The rule contains the categorization requirements (supported by a regulatory guide). Additionally, the rule contains the new “treatment” requirements that apply to SSCs based on their associated risk-informed safety class (RISC) categorization.

The “new rule section” approach embodied in 10 CFR 50.69 has the benefit of grouping and 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 section” rule approach enables the NRC to identify in one place what the regulatory treatment

requirements will be for each risk-informed safety class (RISC)¹. RISC-1 and RISC-2 SSCs will continue to meet applicable special treatment requirements and will also have requirements that ensure that key categorization assumptions that relate to credited performance in beyond design basis scenarios are technically valid, and updated consistent with the process feedback requirements in the rule. RISC-3 SSCs will have requirements that maintain with reasonable confidence the capability of performing their safety-related functions under design basis conditions. RISC-4 SSCs will be removed from any applicable special treatment requirements and have no additional requirements imposed by § 50.69 (recognizing that any technical/functional requirements continue to apply unless they are changed via the normal design change process including § 50.59). This approach of utilizing a separate section in Part 50 to contain the revised special treatment requirements is a significantly more coherent regulatory approach than any of the previously described approaches. Revising each specific special treatment rule, as suggested by the other alternatives, would be more difficult and confusing because it involves changing each specific regulation, and in addition each of these specific special treatment requirements would need to be modified to address RISC-2 and RISC-3 SSCs. Given that these requirements were structured for "design basis" events, this would be a difficult task. 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 with respect to the special treatment requirements, and replacing these requirements with similar, but less extensive treatment requirements. The potential for increased confusion is significant for such an approach. Further, since 10 CFR 50.69 is a voluntary alternative to existing requirements, changing the individual sections could potentially be confusing for those licensees who elect not to implement the new alternative requirements. These considerations led to the decision to develop a separate section to contain the new requirements. As already noted, the stakeholder comments agreed with this portion of the suggested regulatory approach.

(e) Categorization Requirements

The NRC considered two alternative approaches for incorporating the categorization requirements into the new regulatory framework: 1) adopting a rule (i.e., a new appendix) that sets forth in significant detail, objective, nondiscretionary criteria governing the categorization that licensees could implement without prior NRC review and approval or 2) placing higher-level, less-detailed categorization requirements in the rule with the need for NRC to review and approve a submittal prior to implementation of § 50.69.

Incorporating the categorization requirements into an appendix, such that a no prior review approach could be pursued, would require the appendix to contain a sufficient level of detailed requirements such that the NRC would be able to determine, in an objective, non-discretionary manner involving no substantial professional judgement on the part of NRC staff reviewers, that a § 50.69 licensee complies with the appendix categorization requirements. This "appendix"

¹Safety-related SSCs that a risk-informed categorization process determines are significant contributors to plant safety are termed RISC-1 SSCs. Nonsafety-related SSCs that the risk-informed categorization determines to be significant contributors to plant safety are termed RISC-2 SSCs. Safety-related SSCs that a risk-informed categorization process determines are not significant contributors are termed RISC-3 SSCs. Finally, nonsafety-related SSCs that a risk-informed categorization process determines are not significant contributors to plant safety are termed RISC-4 SSCs.

regulatory approach was the approach the NRC originally concluded was the best approach (see SECY-99-256 and the ANPR). This approach appears to have the following advantages:

- Provides a stable and predictable regulatory framework.
- Reduces and potentially eliminates NRC and industry resources that would be expended on a submittal and associated review.
- Simplifies inspection and enforcement.

The disadvantages of the appendix approach were pointed out in the ANPR comments as follow:

- Incorporating detailed requirements into the regulations can, and has in the past (e.g., Appendix R), resulted in numerous exemption requests from licensees who wish to pursue alternative approaches. The review and approval of these exemption requests is very resource intensive.
- Incorporating detailed requirements into the regulations stifle new creative approaches (i.e., forces licensees to pursue exemption requests for alternatives which can be costly) and ultimately can cause licensees to not pursue these new creative approaches, which may be technically superior.
- It appears that there would be a need for the NRC to review some aspects of the PRA to determine its acceptability for application to § 50.69 under any circumstance. As such, a true “no-prior-review” type of approach simply does not appear to be technically feasible at this time. As a result, some level of prior review and approval appears to be needed, and this in turn removes much of the attractiveness of contemplated Appendix T “no prior review” approach.

As evidenced in the ANPR comments, stakeholders generally did not support the detailed appendix approach. In response to the proposed rule, two comments were provided on this issue. Both comments were from industry owners groups, and both did not support putting more detailed categorization requirements back into the regulatory framework. Since this is a voluntary rulemaking initiative, and since it was clear that industry would not utilize the appendix approach, it was not appropriate, nor an efficient use of NRC resources, to continue to develop the appendix approach. Accordingly, the NRC elected to incorporate less detailed categorization requirements into the rule, and to require licensees to provide a license amendment submittal for NRC review and approve prior to implementation of § 50.69. This approach (regarding the incorporation of more high level categorization requirements into the rule versus a detailed appendix) is supported by industry based on the comments on the proposed rule.

(f) Conclusion Regarding Alternative Strategies

The NRC concludes that:

1. Rulemaking is the most effective tool for implementing the type of generic changes encompassed by this effort. This conclusion is based on the industry’s continued support for the rulemaking as evidenced with their ongoing development of implementation guidance, their

continued participation in pilot activities, and the fact that no major impediments to wide industry use were identified in the proposed rule comments.

2. Adding a new section to Part 50 that contains the necessary requirements, but without a supporting appendix as initially suggested in the ANPR, is the best approach for rulemaking. The final rule reflects this decision.

III. Estimate and Evaluation of Values and Impacts

(a) Overview

The NRC's chief concern in moving forward with this regulatory approach is ensuring that sufficient requirements have been incorporated into the new regulation to maintain adequate protection of public health and safety (please refer to section III of the statement of considerations supporting the rule for a discussion of the technical basis for § 50.69). Once the NRC has satisfied itself that the new regulation will maintain adequate protection, then the NRC's next concern is whether the regulatory approach is cost-beneficial. Since implementation of this rulemaking is voluntary, it is not in the NRC's interest to continue developing a regulatory approach that would not be adopted by industry. Hence from this perspective, the NRC's interest in estimating the values and impacts of the regulatory approach is to determine whether the approach is likely to prove cost-beneficial. If the approach should prove not to be cost-beneficial, then the NRC will not expend additional resources on development of the rulemaking since it would not be utilized by industry.

Available cost information has been utilized in this regulatory analysis. However, some of this analysis is qualitative with regard to the potential values and impacts of the rulemaking. It is not possible to develop a more quantitative regulatory analysis that has a reasonable level of certainty for this rulemaking. The NRC requested cost and benefit information as part of the ANPR, but did not receive the requested information. However, the nuclear power industry, through the efforts of the Westinghouse Owners Group (WOG), was able to generate some cost and benefit information as a result of a detailed examination of the costs and benefits for implementing § 50.69 based on its understanding of § 50.69 (then in draft form). This information has been incorporated into this regulatory analysis. No additional information involving costs and benefits for implementing § 50.69 was received in response to the proposed rule request for comment, and as a consequence, there has been no adjustments made to the previous estimates for costs and benefits that were provided in the draft regulatory analysis that supported proposed § 50.69.

It should be recognized that the costs and benefits of implementing § 50.69 will vary widely for licensees dependent on facility design, vintage, and licensing history. A further complicating factor is that § 50.69 is really a "process approval." Licensees will not know the actual cost savings until they begin implementing the new process (categorizing SSCs, revising treatment, replacing SSCs) at their facilities. As a result, the only facility that has developed real cost information is South Texas (whose exemption request was approved in August 2001). South Texas represents the bounding, cost benefit situation since the facility has the greatest potential to realize the greatest cost savings from risk-informing special treatment requirements. South Texas is a more recent facility, with a complex design (three train), large safety-related equipment list (i.e., list of equipment which receives special treatment), and a large number of applicable regulations. However, some cost benefit information was provided by Dominion from their Surry pilot activities. This information is incorporated into this regulatory analysis.

Additionally, based on the § 50.69 categorization pilot efforts, the staff developed rough estimates of the costs (in terms of days and number of people involved) associated with categorizing SSCs on a system basis.

In addition to facility design, vintage, and licensing history, the specific issues addressed below (as impacts) will also influence whether § 50.69 is a cost beneficial endeavor for licensees.

(b) Impacts to Licensees

Licensees that wish to implement § 50.69 will, at a minimum, incur the following impacts:

- PRA: The licensee will need to address PRA 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 a quality standard (RG 1.200), and is up-to-date. Depending on the state of the licensee's PRA, this activity could involve a significant commitment in resources. NRC notes that many licensees have already made investments in development of a PRA and having the PRA peer-reviewed for use in various applications, such as implementation of section 50.65(a)(4). Those licensees who choose to implement this risk-informed alternative would be likely to already have incurred many of these costs, and would be interested in additional opportunities for using the PRA. Another key factor is the NRC's requirements for submittal of PRA information and the resultant level of resources that § 50.69 licensees need to expend to provide the requested information (i.e., the effort to address the NRC's issues associated with NEI 00-02).
- Infrastructure for Categorization: The licensee will need to develop the infrastructure to support the risk-informed categorization of SSCs to determine safety significance. At a minimum, this involves the development of procedures governing the risk-informed SSC categorization process (e.g., for Palo Verde's pilot activities, procedure 70DP-ORA04 "Component Risk Significance Determination" was developed based on the NEI 00-04 guidance), establishment of the integrated decision-making panel (IDP), training of the IDP, and establishment of a supporting working group that provides the IDP with the relevant information to enable the IDP to make the categorization decisions. Some of this infrastructure may already exist from previous categorization efforts to meet maintenance rule monitoring and for other purposes (e.g., risk-informed Inservice Inspection (ISI) applications may have categorized the passive components in the system). Training, based on the pilot experience, is estimated to take at least one day for the IDP members. This training would be to familiarize the IDP with the PRA and the IDP decision-making process.
- Performing the Categorization: The licensee will need to expend significant resources in evaluating the SSCs to determine safety significance, both for the working group to complete the initial work of developing and gathering the relevant information on SSC/function significance and for the IDP to convene and make the decision regarding SSC categorization. This will be an ongoing cost and it is a function of the number of systems the licensee decides to

categorize. Based on the pilot experience, it is estimated that the working group (estimated to be three people at a minimum) would need to spend about two weeks developing and preparing the information for presentation to the IDP. It is estimated that the IDP (estimated to be 5 members plus the 3 working group presenters) would need to spend an average of 3 days per system reviewing the information and making the categorization decisions. For less-complicated systems, these numbers would be much less, while for more involved systems, the estimates increase. Also, it is expected that over time, the process would become much more efficient, and these costs probably can be reduced, particularly if efficiencies are identified for categorizing groups of components.

- Implementation of § 50.69 Revised Treatment: Following categorization, the licensee will incur impacts that result from revised treatment. These include changes to 1) plant procedures to implement the revised approach (e.g., changes to procedures governing procurement, receipt inspection, testing), 2) equipment specifications, 3) plant data bases, and 4) training of plant personnel to implement the revised approach.
- Monitoring: To implement § 50.69, licensees will incur impacts that result from additional monitoring activities. It is expected that current maintenance rule monitoring efforts will address a significant portion of the § 50.69 monitoring requirements for RISC-1 and RISC-2 SSCs. However, monitoring activities must be expanded to consider all SSC performance issues (in addition to maintenance related issues) and include RISC-2 SSCs that may fall outside the scope of the maintenance rule in order to meet § 50.69 monitoring requirements. From a practical standpoint, licensees typically evaluate all failures for maintenance rule impact, therefore expanding the monitoring scope to consider failures other than those that are maintenance related can be readily addressed by current programs. Additionally, a level of monitoring is needed for RISC-3 SSCs to ensure that the condition and performance of SSCs is consistent with categorization sensitivity studies, and that design basis functions are being maintained per § 50.69(d)(2).
- Updating: To implement § 50.69, licensees will incur impacts that result from the need to periodically (every other refueling outage) update the PRA and categorization process to reflect the data collected from plant monitoring, or from industry, and to reflect any changes to plant configuration that impact categorization. Licensees have already developed much of this infrastructure in order to comply with the PRA quality guidance being implemented in support of the maintenance rule.
- Submittal Review and Approval: Licensees will incur an impact resulting from the need for the NRC staff to review and approve a submittal prior to implementing § 50.69. This impact includes the licensee's effort to develop a § 50.69 submittal, and the impact from the staff's review of the submittal including the need to support any requests for additional information from the staff.

The Westinghouse Owners Group (WOG) estimates that the total cost for implementation of § 50.69 at a single unit site is \$2,400,000. For a dual-unit site, with identical plants, the costs

are estimated at \$3,300,000. These are the total costs for program development, implementation and maintenance, and these costs include both utility and contractor support. All of the above costs are included within this estimate. Additionally, these costs were estimated for the categorization of 12 systems, and were assumed to occur over a three year period.

(c) Impacts to the NRC

- NRC would expend resources to review and approve § 50.69 submittals. If licensees adopt the NEI 00-04 guidance as endorsed by the RG 1.201, then review costs will be minimized (and this is the objective of this effort concerning the development of implementation guidance). This review effort will focus on the results of the PRA peer review, and the licensee's disposition of peer review findings. This impact is therefore a function of the number of licensees who choose to voluntarily implement § 50.69, the degree to which licensees adopt the RG (i.e., exceptions will require NRC review), and the number of key peer review findings (i.e., the size of the submittal). An estimate of this impact is that the staff will receive four (one per year) § 50.69 submittals and expend 400 staff-hours on each submittal for a total of 1600 hours of staff review time. This estimate could vary substantially if significantly more licensees implement § 50.69 than the estimate.
- There would also be additional resource impacts for adjusting inspection guidance or processes to take into account the existence of alternative requirements, and to perform an audit or inspection at some point in the future for some licensees following adoption of § 50.69 requirements. The initial effort to develop the inspection guidance is estimated to take 4-5 person weeks.

(d) Impacts to Other Stakeholders

- The NRC has not identified any impacts upon other stakeholders. Any costs of implementation will be borne by the licensees. The NRC does not expect licensees to implement § 50.69 unless they conclude it is cost-beneficial for their facility.

(e) Values of the Rulemaking for NRC, Industry, and Other Stakeholders

- The NRC concludes that this regulatory approach can be accomplished while maintaining public health and safety. This rulemaking will allow licensees to remove RISC-3 and RISC-4 SSCs from the scope of special treatment requirements. This rulemaking will not allow SSCs to be removed from the facility, or for the design basis functional requirements of RISC-3 or RISC-4 SSCs to be changed or eliminated (i.e., for RISC-3 SSCs, design basis functional requirements are to be maintained, albeit at a reduced level of assurance, and in all cases, licensees must follow existing design change control requirements if they desire to change an SSC's design basis). Some SSCs are expected to be "scoped" into regulatory treatment (i.e., RISC-2 SSCs), and it is possible that these SSCs will receive enhanced attention thereby increasing the level of assurance that such previous "nonsafety-related"

SSCs will perform as expected (i.e., as required by § 50.69(d)(1)). This element of the rulemaking may contribute to enhancing safety. Importantly, the regulatory approach will include a "performance-monitoring" element, such that if the performance of equipment degrades substantially (to the extent that it is not reasonable to expect that the SSCs can meet functional requirements, or that the 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 (as required by § 50.69(e)).

- As an indication of the potential savings that could be achieved through a risk-informed special treatment approach, the following information was provided by the licensee for the South Texas Project (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 addresses the same set of special treatment requirements specifically involving 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 judged to be an upper bound on the potential savings that can be realized by a given licensee based on STP's unique three-train design, which results in a larger number of SSCs whose special treatment requirements can be relaxed and based on a comparison with WOG estimates provided below. Part of the cost savings would arise if replacement components could be procured with less-prescriptive (and thus less expensive) quality and administrative impacts.
- Table 1 has some examples of procurement savings for STP that have resulted from approval of their exemption request (this information comes from a presentation at the Tenth Annual International Conference on Nuclear Engineering in Arlington Virginia, from April 14-18, 2002). As of April 2002, STP had saved an estimated \$300,000 in labor and \$60,000 in parts as a result of being able to modify the scopes and frequencies of preventative maintenance for SSCs categorized as low safety-significant or nonrisk-significant (i.e., the equivalent of RISC-3 for § 50.69). In addition, STP noted that there are other less quantifiable benefits, such as reduced outage time (arising from not having to test certain isolation valves), and greater flexibility in maintenance (procedures and scheduling). In fact STP is modifying the scope and focus of post-maintenance testing to streamline the testing for low safety-significant SSCs while maintaining an adequate level of assurance.

Table 1: Some Examples of Procurement Savings for STP

Item	Safety-Related	Nonsafety-related
Spent Fuel Pool Heat Exchanger Outlet Valve flow guide	Quoted, safety-related/qualified price = \$34000 (for two)	Identical commercial guides = \$842 (for two)
Generic Purchase of 1" vent and drain valves for lot of 100 valves	\$2400/valve	\$500/valve –total savings for 100 valves =\$190,000
Flow switches used in 45 applications (18 safety-related and 27 nonsafety-related).	To buy all 45 switches safety-related costs \$9000/switch	Nonsafety-related cost \$1200/switch –changed out every 5 years – by purchasing all commercial and evaluating life savings on these switches = \$900,000

- The WOG estimated that the total cost savings for adopting \$ 50.69 on a per unit basis per year is approximately \$1,100,000. Based on the single unit costs (\$2,400,000 incurred over three years) and dual-unit costs (\$3,300,000 incurred over three years) the corresponding payback periods are approximately 2.2 year and 1.5 years respectively. Extending these savings to the entire fleet of Westinghouse plants (and assuming that all plants implement \$50.69 and have an average licensed-life to 2020 and extended life to 2040), and calculating a net present value results in the cost savings shown in Table 2. These savings are significant, and when considered for the entire fleet of 48 Westinghouse plants could potentially exceed 500 million dollars.

Table 2: WOG Estimate of Cost Savings

Average WOG Plant	Single Unit Site Net Present Value	Dual Unit Site Net Present Value
Licensed Life (2020)	\$6,800,000	\$14,800,000
License Renewed (2040)	\$11,200,000	\$23,400,000

- Additional information was provided by Dominion (shown in Table 3) during a public meeting held on Feb 21, 2002. See the notes for the table for an explanation of the information provided.

Table 3: Procurement Cost Comparison: Safety-Related vs Dedicated vs Nonsafety-related SSCs For Surry

Item	Safety-Related	Dedicated ²	Nonsafety-related
Relief Valve 1 ½" X2"	\$11,000	\$4400	\$3600
Operator (valve)	\$30,000	\$15,000	\$9900
Gate Valve 3" SS	\$7000	\$800	\$130
Butterfly Valve 36"	\$36,000	\$13000	\$9500
Operator (large bore)	\$70,000	\$23,000	\$18,000
Check valve	\$3200	\$1000	\$320
Ball Valve 2"	\$3500	\$1000	\$560
Gate Valve 6"	\$15,000	\$2600	\$600
Butterfly valve 20"	\$30,000	\$7000	\$5000

Notes:

1. These are estimated procurement savings from actual SSCs (taken from purchase orders) procured at Surry, an older, Westinghouse designed, 3-loop plant.
2. The information is meant to estimate the potential savings for procuring a similar component as either safety-related, dedicated (for safety-related application), or nonsafety-related.
3. This information does not contain the increased cost due to § 50.69 regulations. But this is estimated to be approximately \$50–100 per component.
4. For valves procured as “ASME Section III” valves, it is estimated that the column 1 numbers would be a factor of 1.5 higher.
5. At Surry, the general practice is to “dedicate” safety-related equipment (this should be obvious from the substantial cost savings that are achieved)
6. Presumably, § 50.69 would enable cost savings for procurement to be similar to column 3 (close to nonsafety-related SSCs) with some additional costs associated with application of § 50.69 requirements

(f) Decision Rationale

This regulatory analysis is largely a qualitative analysis of the potential costs and benefits associated with § 50.69. This is due to the uncertainties that currently exist regarding implementation, as well as the major factors that can affect the costs and benefits associated with implementation of the rule (facility design, vintage, and licensing history). However, the NRC utilized all available cost information to inform the regulatory analysis where the

²This refers to licensee’s effort to qualify commercial equipment for safety-related applications. Refer to 10 CFR Part 21 for more information.

information was available. Because of the voluntary nature of this rule, the NRC is not attempting to justify implementation on the basis of cost information. With respect to values and impacts, the decision rationale that the NRC chose is whether there is reasonable expectation of a favorable value/impact from developing and implementing this rulemaking. Therefore, with respect to costs, efficiencies will be realized by incurring a one-time rulemaking cost in lieu of expending many of the repetitive costs of individual exemption requests. Relative to benefits, rulemaking is also preferable because it will add greater clarity and certainty to risk-informing the SSCs which in turn is likely to encourage more licensees to participate than would be the case if they had to rely on the vagaries of successfully receiving an exemption. Based on the available information, and noting the industry's continued interest in pursuing this rulemaking effort, it is the NRC's judgement that the values (including the cost savings and other benefits) described above outweigh the identified impacts. It was expected that better estimates of costs of implementation could be identified by the industry when they have had a chance to review the proposed rule, supporting SOC, and associated guidance in detail. However, no comments were provided on the regulatory analysis through the public input on the proposed rulemaking.

IV. Implementation

NRC is issuing a new rule section that defines the requirements and the process for transitioning from existing requirements to the new requirements. Implementation guidance will also be provided that discusses the categorization process requirements. The NRC is currently reviewing an industry-developed guidance document for categorization. The NRC plans to endorse the industry guidance document through a regulatory guide.

Section 50.69 requires licensees or applicants who wish to implement the requirements of § 50.69 to make a submittal to the NRC for approval of the categorization process prior to implementation. NRC plans a focused review of the PRA that undergirds the significance determination as well as of the integrated decision-making process. NRC has prepared review guidance to assist the staff in reviewing this submittal to determine whether the PRA is adequate for this application. Under the rulemaking approach, a licensee who implements the alternative rule requirements would not provide to NRC the actual list of specific SSCs and their new category per § 50.69 (i.e., RISC-1, RISC-2, RISC-3, RISC-4), nor would the licensee provide NRC with a description of the revised treatment applied to RISC-3 SSCs. Rather, NRC will review the categorization process before implementation begins (i.e., process approval), and following this approach, the licensee would proceed to categorize SSCs and to implement treatment processes that satisfy the rule requirements over time. Until SSCs are categorized per § 50.69 (i.e., categorized as RISC-1, RISC-2, RISC-3, or RISC-4 such that the treatment requirements associated with each category in § 50.69(d) can be applied), existing requirements remain in effect. NRC oversight of implementation would be through the routine inspection process.

Given the NRC's expectations that implementation guidance will be issued in conjunction with the final rule or shortly thereafter, the NRC expects that the final rule can be made effective immediately upon publication (or within a reasonably short period of time such as 30 days) in the Federal Register.

V. Conclusion

The risk-informed approach embodied in this rule for establishing an alternative scope of SSCs subject to special treatment requirements is a regulatory approach that maintains safety and is

consistent with the NRC's efforts to risk-inform its regulatory activities. The risk-informed approach 1) is consistent with the defense-in-depth philosophy, 2) provides reasonable assurance that necessary safety functions will be performed, 3) provides reasonable confidence that any increases in core damage frequency or large early release frequency (and therefore risk) are small, 4) is consistent with the safety goal policy statement, and 5) utilizes a performance measurement strategy. The overall value/impact of the rulemaking has been examined from a qualitative standpoint, and NRC concludes that the expected benefits outweigh the expected costs.