

December 23, 1998

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: OPTIONS FOR RISK-INFORMED REVISIONS TO 10 CFR PART 50 - "DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES"

PURPOSE:

This paper proposes high-level options for modifying regulations in [10 CFR Part 50](#) to make them risk-informed and to delineate associated policy issues for Commission consideration. The staff seeks guidance on the Commission's preferred approach in order to develop a detailed rulemaking plan.

SUMMARY:

The staff has proposed a high level approach for incorporating risk-informed attributes into the Part 50 regulations, and is seeking Commission approval to proceed with a phased implementation strategy. After receiving Commission guidance, the staff will develop a rulemaking plan which includes more complete resource and schedule estimates. Two primary objectives of this effort are to develop a risk-informed regulatory framework that will enhance safety as well as reducing unnecessary staff and licensee burden. To initiate this phased effort, the staff is recommending (Option 2) changes to the regulatory scope of SSCs needing special treatment in such areas as quality assurance, environmental qualification, Technical Specifications, [10 CFR 50.59](#) and ASME code. This will be accomplished, in part, by developing risk-informed definitions for safety-related and safety important SSCs. While this approach would allow "grading" of special treatment requirements on SSCs based upon their risk importance, system functional capabilities would not be removed. Rather, the SSC functional capabilities (for low risk important SSCs) would remain in the plant and be expected to perform their design function but without additional margin, assurance or documentation associated with high safety significant SSCs.

The staff is also planning to undertake a study (Option 3) to explore changes to the body of the Part 50 regulations, to incorporate risk-informed attributes. These changes could involve such actions as developing a new set of design-basis accidents, adding provision to Part 50 allowing for risk-informed alternatives to the present requirements, revising specific requirements to reflect risk-informed considerations, or deleting unnecessary or ineffective regulations. After the completion of this study, the staff will make recommendations to the Commission on any specific regulatory changes that should be pursued, and the corresponding schedules and resource needs.

In addition, the staff has identified four policy issues for Commission consideration and guidance. Direction with respect to these issues would be needed to proceed with a risk-informed Part 50 program. The staff has recommended that: 1) Licensee conformance with a modified Part 50 should be voluntary rather than mandatory, 2) Industry pilot studies with selected exemptions to Part 50 should be utilized as part of the risk-informed development process, 3) The scope of the maintenance rule should be changed as an early part of the risk-informed program, and 4) The staff should develop clarification of its authority for applying risk-informed decision making in areas beyond those associated with licensee initiated risk-informed licensing actions.

BACKGROUND:

In 1995, the Commission published a Policy Statement on the Use of Probabilistic Risk Assessment (PRA). Since then, the staff has developed guidance on the use of risk information for reactor license amendments and is currently processing license amendment applications that use risk information as part of their technical justification. However, the fundamental reactor regulations remain largely deterministic. In addition, in recent meetings between the Commission and various stakeholders, the concern was expressed that the NRC is not placing enough emphasis on risk-informing its reactor requirements with the results of risk assessments. It is generally believed that our current reactor regulatory framework (based largely upon design-basis events rather than on core-damage-accident scenarios) results in sufficient safety regulation but in some cases also results in unnecessary regulatory burden. In its September 2, 1998, briefing to the Commission on the status of the PRA Implementation Plan, the staff discussed this issue with the Commission and proposed the development and assessment of various options for making requirements in 10 CFR Part 50 risk-informed. In a staff requirements memorandum dated September 14, 1998, the Commission asked the staff to present a set of options that contain an assessment of the implications of each option, and to also present resource impacts and the role pilot studies would play in the development of new or modified requirements.

In developing the options discussed below, the staff met with the public, the Nuclear Energy Institute (NEI), nuclear utilities, and other representatives of industrial groups on several occasions, including a 2-day public workshop⁽¹⁾, for the purpose of discussing the objectives of revising Part 50, different approaches for incorporating risk information into the regulations in Part 50, and issues that the staff should consider in evaluating the options for the Commission. These stakeholder activities produced significant information for developing the implementation options given below. A general consensus was also reached regarding the overall objectives of risk-informed modifications to Part 50. These include the following:

- Enhance safety by focusing NRC and licensee resources in areas commensurate with their importance to health and safety.
- Provide NRC with the framework to use risk information to take action in reactor regulatory matters.
- Allow use of risk information to provide flexibility in plant operation and design, which can result in burden reduction without compromising safety.

This paper discusses options and a phased approach for their implementation such that, when completed, the staff envisions that Part 50 would have the following characteristics:

- In concert with other NRC regulations, it would continue to provide reasonable assurance of adequate protection of public health and safety.
- It would contain requirements on specific attributes of nuclear power plant design and operations commensurate with their safety significance. This safety significance would be assessed using principles of risk-informed regulation including the following:
 - consistency with the defense-in-depth philosophy
 - maintenance of sufficient safety margins
 - consistency with the intent of the Safety Goal Policy Statement
- The requirements would be written in a manner that would accommodate the plant-specific nature of the safety significance of design and operational attributes.
- It would provide a clear, consistent, and coherent set of requirements that would also facilitate consistency in treatment among the assessment, inspection and enforcement programs.
- It would provide a regulatory basis for all NRC reactor-related activities, including licensing, inspection, enforcement, and assessment.
- It would be performance-based to the extent practical.
- It would be practical to implement for both licensees and the NRC.

These characteristics reflect the long term holistic vision for a risk-informed Part 50.

DISCUSSION:

High-Level Options

As a result of our preliminary assessments and stakeholder activities, the staff has identified the following three options for risk-informed modifications of 10 CFR Part 50: (1) make no changes to current Part 50, (2) make changes to the overall scope of systems, structures, and components (SSCs) covered by those sections of Part 50 requiring special treatment (such as quality assurance, technical specifications, environmental qualification, and 50.59 by formulating new definitions of safety-related and important-to-safety SSCs)⁽²⁾, and (3) make changes to specific requirements in the body of regulations, including general design criteria (GDCs). Options 2 and 3 could be implemented individually or in combination, since in many aspects they are complementary. The three options are discussed next.

Option 1.

Make No Change to Current Part 50

This option would terminate staff action to develop comprehensive risk-informed changes to the current Part 50. Risk-informed approaches specified in Regulatory Guide (RG) 1.174, and associated application-specific RGs would continue to be implemented subject to existing regulatory limitations. One example of these limitations is in the area of graded quality assurance (GQA), where requirements other than those that govern QA (10 CFR 50.54 and Appendix B to Part 50 directly govern QA) limit the degree to which the risk informed process can be implemented. See [Attachment 1](#) regarding the Graded QA implementation experiences at South Texas project (STP). This impediment could, if the Commission agrees, be eliminated by granting 10 CFR 50.12 exemptions on the basis of risk information. This approach, however, would be very resource intensive in the long term, assuming that many exemptions would be requested.

Under Option 1, ongoing Part 50 rulemaking activities, which have risk informed elements, would continue on their current schedules rather than be subsumed into an overall Part 50 revision process. These would include ongoing activities related to [50.65](#), [50.59](#), [50/72.50.73](#) and [50.55a](#) as well as the revised source term rulemaking that will, if approved, create a new Section [50.67](#). Currently, the staff is going forward with each of these programs separately from the proposed Part 50 process.

Meetings with stakeholders have indicated the industry's desire that ongoing activities proceed on their current schedule, with the exception of the Maintenance Rule ([10 CFR 50.65](#)) rulemaking where the Nuclear Energy Institute (NEI) has indicated it will respond to proposed rulemaking with comments suggesting broader changes to the Rule's scope as part of current rulemaking. Discussions on various Maintenance Rule approaches, with associated advantages and disadvantages, are presented as a policy issue in a later section of this paper. The assessment of the advantages and disadvantages of risk-informing the Maintenance Rule (in [Attachment 4](#)) also addresses the possibility of developing more risk-informed guidance on application of the Maintenance Rule within the context of the existing rule without further modifications to the rule itself.

Ongoing rulemaking activities associated with 50.59 will provide increased clarity and implementation stability by defining a minimal (but non-zero) threshold for licensees to make changes to their facility without prior staff review and approval. The changes to the reporting requirements in 50.72 and 50.73 are intended to provide a better safety and risk focus to the reporting process and avoid unnecessary burden. The ongoing Inservice Inspection (ISI) code case endorsement process will incorporate staff guidance directly into the ASME code cases, allowing for more efficient implementation. The proposed 50.67 would enable operating reactors to voluntarily implement a more representative source term that would be used in assessing design-

basis accident response against revised dose acceptance criteria. (A similar change in 50.34 in January 1997 enabled the use of revised source terms by applicants for Construction Permit, Combined Operating License, or Design Certification.) These alternative source terms reflect the release of fission products during design-basis accidents more accurately than does the current source term, making it possible for operating reactors to implement cost-beneficial plant modifications, thereby reducing unnecessary regulatory burden.

None of the ongoing revisions are anticipated to be inconsistent or incompatible with future Part 50 risk informed revisions. However the more extensive Part 50 revision process identified in Options 2 and 3 below, would likely identify additional refinements in some of the above regulations. For example, more specific risk-informed decision criteria may be developed for 50.59. Allowing these separate efforts to continue could necessitate revisiting some of the above regulations at a later date.

Option 2. Make Changes to the Scope of Systems, Structures, and Components Covered by Those Sections of Part 50 Requiring Special Treatment

The current scope of SSCs covered by most sections of Part 50 is based primarily on the evaluation of selected design-basis events, as described in final safety analysis reports (FSARs). These postulated events represent a small fraction of the potential accident sequences treated in risk assessments. As the primary part of this option, risk-informed definitions of "safety-related" and "important to safety" could be developed. This would lead to changes in the scope of what receives special operational and qualification treatment.

This option only addresses implementing changes to the regulatory scope for SSCs needing special treatment in terms of quality (e.g., quality assurance, environmental qualification, Tech Specs, 50.59, ASME Code). It does not address changing the design of the plant or the design-basis accidents, which establishes the physical complement of plant systems included in the design. Under this option, SSCs of low safety significance (from a risk-informed assessment) would move from "special treatment" to normal industrial (sometimes called "commercial" treatment), but would remain in the plant and be expected to perform their design function but without additional margin, assurance or documentation associated with high safety significant SSCs.

As discussed in Option 1, one area that the industry has identified for early consideration of a revised regulatory scope is the Maintenance Rule ([10 CFR 50.65](#)). Revisions to the scope of this rule could be undertaken as part of Option 2 activities, or could be undertaken as part of the ongoing 50.65 rulemaking, which currently only address the 50.65(a)(3)/(a)(4) pre-maintenance safety assessment process. It should be noted however, that applying such changes would modify the original scope of the rule as intended by the Commission. A discussion on the intent and implications of the present Maintenance Rule scope is provided in [Attachment 2](#). The question of whether the scope of the Maintenance Rule should be revised is discussed below as a Commission policy issue, as is consideration of alternative approaches that could reduce unnecessary burden without a rule revision.

Under implementation of Option 2, there could be extensive changes to treatment of SSCs, as those with low risk importance have their regulatory requirements reduced and others not currently regulated have requirements added. To prevent excessive industry and staff burden, it is essential that an efficient regulatory process be employed as part of any implementation process. That process should be structured to eliminate unnecessary prior staff review and approval as licensees implement the operational changes allowed by the changes in Part 50 scope. Therefore, as part of this option, the staff could place specific regulatory requirements in a revised Part 50 (and associated guidance in a regulatory guide) on what provisions and criteria should be utilized by licensees to implement these changes without having to submit them to the staff for prior review and approval. Since changes to requirements in the revised regulations would apply to those SSCs of low risk importance, it is anticipated that such an approach could be accomplished with no significant safety impact. However, as part of this process, the staff would have to ensure that the licensee had appropriate assessment and feedback programs in place to reflect SSC performance degradation back into the PRA and to modify SSC risk importance as necessary.

Additionally, in the time period before the Part 50 scope changes take final form, the staff believes that the current provisions of [50.12](#) would permit the Commission to approve regulatory exemptions that allow for early implementation of risk-informed reductions to operational and qualification requirements. An exemption to operational requirements that involve, *in toto*, no change or a decrease in risk could be granted pursuant to paragraph (a)(2)(iv) of Section 50.12. An exemption that involves an increase in risk could potentially be granted under paragraph (a)(2)(vi) if the Commission were able to find that quantitative risk information was not considered in the establishment of the regulatory requirement which is the subject of the exemption. The rationale for granting an exemption under paragraph (a)(2)(vi) would be that quantitative risk information constitutes a "material circumstance" not considered when the regulation was adopted. The grant of limited exemptions to a limited number of plants for purposes of pilot testing does not pose any special problems but the repeated issuance of a large number of exemptions which, considered together, represent a fundamental alteration of the conceptual nature of the licensing basis, to more than a limited number of plants essentially constitutes a generic change to the regulatory requirements in Part 50. Such generic changes should be adopted through rulemaking, rather than the case-by-case approach inherent in the regulatory approach embodied in the issuance of exemptions. Similarly, the granting of a large number of exemptions to a single plant, should not be so extensive that the validity of the original license is called into question (i.e., grant wholesale exemptions to all GDC, and regulations for an extensive subset of SSCs).

Option 3. Changes to Specific Regulatory Requirements

Under this option, changes would be made to the body of the Part 50 regulations to include risk-informed attributes in the requirements. Approaches to revising the body of the regulations could include the following:

- adding provisions to Part 50 allowing the staff to approve risk-informed alternatives to current regulations,
- revising specific requirements to reflect risk-informed considerations,
- deleting unnecessary or ineffective regulations.

This approach could be as broad as a complete rewrite of 10 CFR Part 50, or it could be more limited in scope, focusing on the regulations that have the most significant potential for improving safety and efficiency and reducing unnecessary burden. A process that results in a comprehensive reassessment of the Part 50 requirements would offer the ability to develop a coherent risk-informed regulatory framework that can be propagated throughout the regulations. It is especially important that the process results in consistent requirements among the assessment, inspection, and enforcement programs. In addition to benefits to currently operating reactors, such a framework would be of benefit for future reactors, and potential impact on Part 52 should be considered in developing this option.

Changes to specific design provisions of the general design criteria (GDCs) in [Appendix A to 10 CFR Part 50](#) or development of a revised set of design-basis events based upon risk significance are potential areas for action under this option. The changes envisioned under Option 3 would be necessary to accomplish the long term vision for a risk-informed Part 50 discussed earlier in this paper. Changes of this magnitude would involve extensive public comment and participation. Use of industry pilot programs would be helpful for selecting, prioritizing, and implementing such changes.

Assessment of Benefits/Impacts For Various Options

The staff has assessed each of the options for risk-informing Part 50 with respect to the following factors to determine the implications of pursuing them:

- potential for improving safety decisions and increasing public confidence
- potential for reducing unnecessary licensee and NRC burdens
- the anticipated complexity of changes
- NRC resources needed for putting changes in place
- licensee resources needed for putting changes in place
- calendar time for full implementation⁽³⁾ (NRC and licensee)

These assessments are, for the most part, qualitative, although preliminary estimates or estimated ranges have been made for resources, burden reduction, and an implementation schedule. In addition, magnitudes of the impacts of the other factors have been judged in relative terms as either high, moderate, or low. The results of the staff's assessment are summarized below and presented in both a narrative and tabular form in [Attachment 3](#).

RECOMMENDATIONS:

The staff recommends adopting a phased approach to making 10 CFR Part 50 more risk-informed by proceeding initially with Option 2. However, the staff acknowledges that the options developed here have not had the benefit of full internal and external stakeholder involvement and that additional discussions on the formulation of these issues and their costs and benefits are needed in the process of developing a rulemaking package for the Commission. A phased approach appears to be consistent with comments received from stakeholders and would allow for achieving meaningful benefits in the early stages, while additional study is conducted to identify where additional risk-informed insights can be factored into more extensive regulatory changes in later phases. The staff also recommends that the current rulemaking activities identified in Option 1 continue unimpeded.

The staff also recommends that pilot plants be solicited (1) to assist in the development of scope and definition changes to Part 50 and (2) to test proposed changes during the development and comment period. The staff seeks guidance from the Commission on whether the scope of the Maintenance Rule should be revised and included as an early part of Option 2 (see associated issue under "Policy Issues" below). With Commission approval (see associated issue under "Policy Issues" below), the staff would consider exemption requests from pilot plants related to risk-informed scope modifications for such operational and qualification requirements that could be justified by applying the guidelines of RG 1.174 or supplemental criteria developed as part of the rulemaking effort.

The staff additionally recommends that Option 3 be studied further and that the industry and staff continue with such pilot programs as the NEI Whole Plant study, to identify specific requirements meriting change and possible risk-informed alternatives to the body of Part 50. At the conclusion of this study, the staff would make recommendations to the Commission on any specific regulatory changes that should be pursued and the corresponding schedules and resource needs. During this study phase, the staff would be receptive to identifying specific regulatory changes that provide very beneficial risk-informed enhancements. These could include identifying requirements that are not risk- or safety-effective (for deletion consideration) as well as identifying areas in which very well-focused revisions could significantly enhance safety and/or effectiveness. When such issues are identified, they will be brought to the Commission's attention on a priority basis along with staff recommendations for action.

POLICY ISSUES:

The policy issues for Commission consideration include the following:

- (1) voluntary vs. mandatory conformance with modified 10 CFR Part 50,
- (2) industry pilot studies with selected exemptions to Part 50,
- (3) modification of scope of the Maintenance Rule,
- (4) clarification of staff authority for applying risk-informed decision making.

An assessment of the advantages and disadvantages of these issues is discussed in detail in [Attachment 4](#) to this paper.

In summary, (1) the staff recommends that risk-informed implementation of Part 50 should be voluntary for licensees; (2) the staff recommends

allowing pilot plants to implement changes using exemptions, because it will provide a significant benefit to the process of developing risk-informed revisions to Part 50; (3) the staff recommends that the current rulemaking initiatives associated with paragraphs (a)(3)/(a)(4) of 50.65 continue and that the scope of the Maintenance Rule be revised to one that is risk-informed and that this activity be an early activity in support of the overall Part 50 revision process; and (4) the staff recommends that additional guidance be developed, such as in a regulatory guide, to provide clarification on staff authority for applying risk-informed processes in regulatory activities beyond risk-informed licensing actions.

IMPLEMENTATION ISSUES:

The modification of 10 CFR Part 50 to make it more risk-informed requires the resolution of a set of implementation issues as well as the policy issues identified previously in this paper. These implementation issues are described in [Attachment 5](#), and are provided for the Commission's information at this time. Resolution of these issues will be addressed during the development of the rulemaking process.

REQUESTED COMMISSION ACTION:

The staff requests that the Commission (1) approve implementation of Option 2 (including additional early internal and external stakeholder discussion) with utilization of industry pilot studies, and allow ongoing rulemaking actions identified in Option 1 to continue unimpeded; (2) note that the staff will initiate a study of Option 3; (3) approve the use of industry pilot studies involving the use of exemptions to assist in the development of the Part 50 modifications; (4) endorse using the Maintenance Rule (10 CFR 50.65) as part of the Option 2 effort, as an initial step in revising the scope to be risk-informed and to facilitate scope revisions being developed for other Part 50 operational requirements (Option 2); (5) approve work to develop regulatory guide or other staff guidance clarifying staff approaches for applying risk-informed decision making; and (6) provide guidance on the remaining policy issues discussed in [Attachment 4](#).

After the Commission issues its guidance, the staff will develop another Commission paper (including a Rulemaking Activities Plan, as appropriate) to address in more detail a plan of action for implementing the guidance provided by the Commission.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

RESOURCES:

On the basis of experience with developing such programs as standard technical specifications, Maintenance Rule, and risk-informed regulatory guidance, the staff has made some preliminary estimates of NRC resources needed to implement the various options. These estimates, which the staff believes are the best possible at this point in time, are shown in [Attachment 3](#). Also provided are preliminary estimates of the potential benefits from the various options with respect to decision making and burden reduction. Although these estimates vary among options, in all cases they are considered substantial in an environment of declining resources. Current Operating Plan budgets for FY 1999 and FY 2000 do not reflect the resources (dollars or FTE) needed to pursue Options 2 or 3 or the study of Option 3. Therefore, implementing these options would necessitate reprogramming resources from other activities from within the NRR and RES budgets. More specifically, this would have implications for the NRR operating plan and budget for undertaking rulemaking and review of exemptions, and the RES operating plan and budget for support of the development of technical bases and study of Option 3 alternatives. The staff proposes to make more refined resource estimates and identify adjustments in office operating plans after receiving guidance and direction from the Commission regarding specific options. The staff's initial judgment is that the resource requirements for the recommended options could be accommodated without compromising the high priority issues of risk-informed licensing actions and risk-informing the inspection, assessment and enforcement processes.

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- Attachments:
- 1. Insights From Graded Quality Assurance Implementation at South Texas
 - 2. Supplementary Information on Maintenance Rule Scope
 - 3. Preliminary Assessment of Impacts of Various Options for Risk-Informing Part 50
 - 4. Discussion of Policy Issues
 - 5. Implementation Issues for Risk-Informing 10 CFR Part 50

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**INSIGHTS FROM GRADED QUALITY ASSURANCE IMPLEMENTATION
AT SOUTH TEXAS PROJECT (STP)**

In March 1996, the STP licensee asked NRC to approve a revised Operations Quality Assurance Program (OQAP) for STP, incorporating the methodology for graded quality assurance (QA), which was also based on probabilistic safety assessment (PSA) risk insights. Following extensive discussions with the licensee and substantial review, the staff approved the proposed revision to the OQAP by letter dated November 6, 1997. In its letter and accompanying safety evaluation, the staff concluded that the licensee's methodology for determining the relative safety significance of plant structures, systems, and components (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 approval, the licensee has identified implementation difficulties associated with the graded QA program. For a number of low-risk-significant SSCs, for which the licensee has reduced the QA requirement, other regulatory requirements such as environmental qualification and American Society of Mechanical Engineers Code seismic requirements continue to impose substantial requirements. This has prevented the licensee from reducing additional burdens on these SSCs that have low importance.

The licensee has indicated its desire to solicit additional regulatory relief, to achieve its originally envisioned graded QA program benefits. As discussed with the staff at several meetings, the licensee would propose exemptions to [10 CFR 50.2](#) and [10 CFR 50.59](#), so that some components currently considered as "safety-related" or "important to safety" could be reclassified as non-risk-significant and low-risk-significant components, consistent with the NRC-approved graded QA process. This STP initiative could reduce the complexity and resources required for routine maintenance and replacement for specifically identified systems or components by removing them from the scope of specific regulations, such as those governing seismic and other qualification requirements. Commission approval of the policy issue allowing risk-informed exemptions would clarify the staff's ability to proceed with this pilot.

SUPPLEMENTARY INFORMATION ON MAINTENANCE RULE SCOPE

Scope Issues Related to Risk-Informing the Maintenance Rule

The staff has received comments from the Nuclear Energy Institute (NEI) that the industry intends to propose narrowing the Maintenance Rule ([10 CFR 50.65](#)) scope as part of the current Maintenance Rule revision.⁽⁴⁾ It should be noted that the scope of the Maintenance Rule was intentionally broader than the scope of other regulations. In 1991, when the rule was written, the Commission specifically included non-safety-related structures, systems, and components (SSCs) in order to apply the NRC's authority to take action against poor maintenance practices in the balance of plant. The purpose of the Maintenance Rule is to "provide reasonable assurance that (1) intended safety, accident mitigation, and transient mitigation functions of the SSCs [in scope via (b)(1) and (b)(2)(I)] can be performed, and (2) failure of SSCs [in scope via (b)(2)(ii) and (b)(iii)] will not occur which prevent the fulfillment of safety-related functions, and failures resulting in scrams and unnecessary actuation of safety-related systems are minimized." The staff's current thinking on a risk-informed Part 50 is in conflict with the present scope of the Maintenance Rule, in that SSCs whose failures could result in transients and scrams are currently captured but would not necessarily be captured by a risk-informed scope. Also, equipment that is used to mitigate accidents and transients as well as equipment whose failure could prevent a safety-related SSC from fulfilling its intended function would not necessarily (dependent on their risk importance) remain in a risk-informed scope. Since risk-informing Part 50, including the Maintenance Rule, would change a previous Commission policy, a related policy issue has been included in the "Policy Issues" section of this paper. This policy issue addresses whether a scope change on the Maintenance Rule should be implemented, and possible alternatives to a rule change that offer potential reductions in implementation burden.

PRELIMINARY ASSESSMENT OF IMPACTS OF VARIOUS OPTIONS FOR RISK-INFORMING PART 50

	Option 2 Change Scope of SSCs Requiring Special Treatment	Option 3 Change Specific Safety Requirements
Improved safety decisions and public confidence	High	Moderate to High
Implementation costs NRC⁽⁵⁾	25 to 50 NRR FTE over 4 to 8 years; NRR	100 RES/NRR FTE over not less than 5 years; RES tech.

	tech. assistance \$250K/yr 2 to 3 Research FTE and 500K/yr for approximately 2 to 3 years	assistance of \$1 million/yr ⁽⁶⁾
Implementation costs licensees	High	High
Burden reduction NRC	Moderate ⁽⁷⁾	Less than Option 2 but dependent upon specific changes implemented
Burden reduction licensees	Very High ⁽⁸⁾	Potentially high
Complexity	Moderately high	High
Time to full implementation	4 to 8 years	Not less than 5 years after completion of Option 3 study

Assessment of the Implications of Pursuing Various Options

The staff has made a very preliminary assessment of each of the options for risk-informing Part 50 with respect to the following factors to determine the implications of pursuing them:

- potential for improving safety decisions
- potential for reducing unnecessary licensee and NRC burdens
- the anticipated complexity of changes
- licensee and NRC resources needed for putting changes in place
- calendar time for full implementation⁽⁹⁾ (licensee and NRC)

Although the assessments are, for the most part qualitative, some preliminary estimates have been made for NRC resources, burden reduction on the part of NRC and licensees, and the schedules for implementation. In addition, magnitudes of the impacts of the other factors have been judged in relative terms as either very high, high or moderate, or low.

The results of the staff's assessment are discussed below and summarized in the table on the preceding page.

Option 2. Changing the Scope of SSCs Requiring Special Treatment

Changing the scope of SSC operational and qualification treatment requirements to be risk-informed would lead to better safety decisions in one of the most important areas with respect to safety at nuclear power plants-plant operations. Indeed, operating experience, research, and analyses of severe accidents have shown plant designs to be generally robust; also, with the completion of the individual plant examinations, plant-specific design vulnerabilities have been addressed. Consequently, the risk at plant sites is controlled on a day-to-day basis by decisions pertaining to operations. For this reason, the staff believes that this option would have the highest safety impact with respect to the regulatory decision making process, as well as offering the greatest potential for reducing unnecessary burden.

Changing the scope of operational and qualification treatment involves fundamental changes to a significant number of diverse requirements that would lead to many changes in procedures and practices for the licensees and NRC. Because of this, the staff believes that NRC and its licensees would face a significant number of complex issues in implementing this option. Along with resolving difficult issues, significant effort by both the NRC and licensees would be required to make changes to their respective "infrastructures" (e.g., procedures, training, regulatory guides) dictated by this option. Consequently, the staff expects that this option would require significant resource commitments from the NRC and licensees to develop and implement the option fully. The staff estimates 25 to 50 direct FTE expended over a 4-8 year period and \$250K per year would be needed to implement this option. At the public workshop on risk-informing Part 50, industry representatives also expressed their expectation that this option could lead to significant reductions in operating costs (burden), especially when the changes lead to reductions in occupational exposure to radiation. The staff believes that a 1 percent to 10 percent reduction in current operations and maintenance (O&M) costs per plant per year following implementation of the option (\$100 million to 1 billion/year for the entire population of operating plants) is a reasonable figure to use for the purpose of considering options. This estimate is consistent with the views of senior nuclear industry executives. In a November 10, 1998 e-mail to Annette L. Vietti-Cook, Mr. Harold B. Ray, Executive Vice President, Southern California Edison Company, submitted information in preparation of the planned November 13, 1998 Stakeholders meeting. In that e-mail, Mr. Ray stated in response, "In contrast, savings of at least 1 percent of annual O&M should certainly be achievable over the long term, and far more than this would be a reasonable goal. On another basis, only a few hours of avoided, market-based revenue loss per year, as a result of fully risk-informed regulation, would offset the assumed cost of plan implementation by any one unit. In our experience, this should certainly be achievable."

In regard to schedule, one licensee representative at the workshop who is a participant in the NEI Whole Plant initiative on Part 50 expressed his belief that this option could be fully implemented in approximately 5 years. Given the time it has taken to develop the Maintenance Rule and put it in place, and the lessons learned from Maintenance Rule implementation, the staff believes that a reasonable estimate is on the order of 4-8 years.

Option 3. Changes in Safety Requirements

Changes to safety requirements can vary substantially in cost and burden reduction, depending on the number of requirements being changed, the nature of each specific requirement being changed, and the complexity of the change being made to the regulation. Fundamental and far-reaching

changes to cornerstone safety requirements such as 10 CFR 50.46 (emergency core cooling) or 10 CFR Part 50, Appendix A (General Design Criteria) would have a cost and schedule much higher than that associated with changes that simply permit licensees to propose an alternative risk-informed method for satisfying an existing Part 50 requirement. Resources needed on the part of the NRC and licensees to make substantive changes to safety requirements are expected to be large. In many cases such changes would include changes in codes, standards, NRC regulatory guides, NRC standard review plans, FSARs, and design-basis documents that implement the requirements in Part 50. For this reason, the staff believes this option would be the most difficult, most expensive, most time-consuming (no fewer than 5 years) to implement. The staff's preliminary estimate for NRC resources needed to implement this option is a total of 100 direct FTE with technical assistance of \$1 million/yr. This estimate will be refined after the Option 3 study is finished. These are preliminary estimates for full Option 3 implementation, including rulemaking. The estimated resources to conduct the study of Option 3 are approximately 5 direct FTE spread over 2-3 years and technical assistance of \$500k/yr.

Changes in safety requirements that eliminate the need for some systems, structures, and components, or that allow substantial flexibility in such areas as reactor fuel design, would lead to a reduction in the unnecessary burden to licensees. The staff estimates a reduction that could be potentially high, but that there is more uncertainty regarding the potential benefit, which will be dependent upon what rule revisions are actually implemented.

ATTACHMENT 4

DISCUSSION OF POLICY ISSUES

The Commission is requested to provide guidance on the following policy issues in order to develop specific implementation approaches for the options discussed above. These include the following:

- voluntary vs. mandatory conformance with modified 10 CFR Part 50,
- industry pilot studies with selected exemptions to Part 50,
- modification of scope of the Maintenance Rule,
- clarification of staff authority for applying risk-informed decision making.

1. Mandatory versus Voluntary Implementation of Risk-informed Part 50

For any proposed risk-informed changes to Part 50, a fundamental policy question is whether all licensees would be required to implement the revised regulations, or whether the revised regulations would offer licensees an optional alternative set of requirements that each individual licensee can choose to adopt, (changes to the current Part 50) or not adopt (remain with the current Part 50). If the Commission directs that implementation of a risk-informed Part 50 modification be voluntary, a related policy question arises: can a licensee choose which elements of the revised Part 50 to follow, or does selection of the risk-informed track require utilization of the entire set of revised requirements.

Advantages of Mandatory Implementation

Requiring the mandatory implementation of a risk-informed Part 50 has a number of advantages. Regulatory clarity and stability would be enhanced since there would be a single set of regulatory requirements. The Commission's objective stated in the PRA Policy Statement, to increase use of PRA, would be furthered. The safety benefit and burden-reduction benefits of risk-informed regulation would be uniformly achieved throughout the industry as regulatory requirements would be more properly risk-focused. Problems inherent in having two classes of licensees, risk-informed and not risk-informed, would be avoided. The staff is currently committed to check on implementation of more than 500 safety enhancements identified by the IPE and IPPEE program and to consider the need for regulatory oversight of such safety enhancements to the extent that they meet the backfit rule. Under a mandatory, risk-informed program, important safety enhancements would receive appropriate regulatory oversight, reducing the need for staff IPE followup.

Disadvantages of Mandatory Implementation

Mandatory application of risk-informed changes to Part 50 could have a detrimental effect on the schedule, resources, and extent to which Part 50 could be risk-informed. This is because many in the nuclear industry oppose any mandatory application of risk-informed initiatives and would likely work to limit changes if they are mandatory. More fundamentally, it may be very difficult to show that the risk informed changes, in any form, either: (i) will result in a substantial increase in overall protection of the public health and safety or common defense and security, the initial backfit threshold finding; or (ii) are *necessary* for adequate protection. In the latter regard, it must be shown that the existing regulatory approach no longer provides reasonable assurance of adequate protection, such that mandatory imposition of the new regulatory scheme is necessary to provide such reasonable assurance. While there are several options open to the Commission with respect to addressing the Backfit Rule, it is likely that the industry would oppose Commission adoption of any of those options.

Also, licensees that have limited in-house PRA capability, and who may not have anticipated using the optional risk-informed approaches of RG 1.174, will have to expend start-up resources to ensure that they have adequate technical capability and an adequate quality PRA to properly implement the revised regulatory framework. Licensees that have shorter remaining license periods or those that anticipate early decommissioning would have less time to gain the benefits from a reduced regulatory burden. Also, the implications for those plants currently seeking license renewal would need to be determined.

Finally, current requirements have led to plants that are judged safe. Mandatory application of sweeping changes to Part 50 could send a signal that current plants are less safe than desired. If the risk-informed changes to Part 50 do represent an improvement, the staff expects that licensees would eventually change voluntarily.

If the Commission does direct the staff to proceed with risk-informed Part 50 revisions on a voluntary basis as the chosen option, the policy issue that remains is whether licensees that wish to use risk-informed options can implement selected elements, or whether they should employ the entire complement of risk-informed regulatory requirements. For example, could a licensee reduce quality assurance (QA), operational requirements, and equipment qualification requirements (EQ, and code class) on low risk important SSCs in the emergency ac power system, even though risk-important elements in non-safety-related gas turbine generators or startup feedpumps are not identified for additional attention?

This approach would allow licensees to be selective about what systems or programs are targeted for risk-informed implementation, thereby reducing implementation costs, and possibly allowing for earlier implementation, but in a more limited scope. However, partial implementation, sometimes known as "cherry picking" would tend to reduce burden in areas that are over regulated, but without the commensurate benefit of additional quality or performance requirements where SSC risk importance has not been fully recognized by the current regulatory framework. Such selective implementation is not compatible with the intent of risk-informed regulation.

Staff Recommendation

The staff recommends that implementation be voluntary, but that selective implementation not be allowed.

2. Industry Pilot Studies With Selected Exemptions to Part 50 in Advance of Rulemaking

The rulemaking process associated with a structured phased approach to risk-informing Part 50 would likely require several years before significant changes are issued. As the staff develops proposed regulatory revisions and works with pilot participants, the policy question arises as to whether pilot plant licensees may implement risk-informed alternatives through exemptions.

Advantages of Industry Pilot Studies With Exemptions

Industry pilot programs would be a very useful vehicle to develop and test approaches for risk-informed revisions to our regulatory requirements. They also would offer the opportunity to explore the detailed impact on design and operational requirements. Allowing exemptions in advance of final rulemaking would offer an incentive for industry pilot participants to justify the resource costs of pilot cooperation. This would serve to increase the potential pool of risk-informed pilot programs, which would benefit the risk-informing process. Even without formal pilot programs, stating the Commission's receptiveness to risk-informed exemption requests would demonstrate the agency's commitment to be forward-looking in allowing appropriate use of risk-informed approaches in the most timely manner. Additionally, Commission endorsement of this approach would clarify the ability of the staff to respond to the South Texas Project initiatives for resolving problems associated with Graded QA implementation (discussed in [Attachment 1](#)).

Disadvantages of Industry Pilot Studies With Exemptions

Since the rulemaking process would not have been fully completed when some exemptions would be issued, there is a possibility that details of a licensee risk-informed implementation might not be identical with the final rule. However, once the rulemaking process is completed, the pilot plants could be required to comply with the final rule(s) if the exemptions authorizing each plant's pilot approach include a provision requiring the plants to comply with the requirements in the final rulemaking(s).

Staff Recommendation

The staff recommends that industry pilot programs be undertaken in all appropriate areas including, but not limited to, the Maintenance Rule scope (see policy issue #3 below) and NEI Whole Plant study, and that exemptions be granted to pilot participants in cases in which the staff has determined that adequate risk-informed bases have been provided and the provisions of [10 CFR 50.12](#) are met.

3. Modification of Scope of the Maintenance Rule

As discussed in Attachment 2, the intent of the Maintenance Rule was that licensee's maintenance of important SSCs is effective to assure the functional capability of a broad range of plant SSCs and to reduce (or minimize) safety challenges such as reactor scrams. If the scope of the Maintenance Rule were to be modified in a risk-informed manner, much of the current scope could be eliminated since many of the SSCs currently monitored have little impact on core damage frequency or large early release frequency. One of the proposed risk-informed assessment program cornerstones includes all plant scrams regardless of their safety significance. The impact of modifying the rule on the regulatory basis for inspection and enforcement related to those initiators should be carefully assessed and considered. Modifying the scope of the Maintenance Rule could also impact the implementation of the license renewal rules in [10 CFR Part 54](#). If the Commission directs the staff to modify the scope of the Maintenance Rule, the remaining issue is: should the present rulemaking (requiring assessment prior to taking equipment out of service for maintenance) continue on its present schedule, or should this rulemaking be suspended, and its content included in a later rulemaking package which includes the scope changes. As an alternative for rulemaking to revise the scope of [10 CFR 50.65](#), the staff could revise its guidance to reduce the scope of non-safety-related SSCs and the implementation requirements for SSCs that are of low risk importance.

Advantages of Revising Maintenance Rule Scope

Modifying the scope of the Maintenance Rule along with other regulations to be risk-informed would result in a coherent and consistent scope of all operation-related requirements. In addition, the overall intent of risk-informing the regulations (i.e., to better focus NRC and licensee resources on issues commensurate with safety) would be better served. Having a common scope of all operationally oriented rules would also contribute to improved clarity and communications. The inspection and enforcement programs are clear areas that would benefit from a reduced Maintenance Rule scope by

more closely focusing on risk-significant SSCs and activities. Additionally, risk-informing the scope of the Maintenance Rule could relieve licensee burden without significantly affecting plant safety. The process would also provide the staff and industry with an excellent pilot activity that could serve as a basis for scope development for other rule revisions.

If the Commission does direct the staff to implement a revised scope to the Maintenance Rule, the remaining policy question is whether the current rulemaking should continue and the scope changes be conducted as an early part of Option 2, or should current 50.65 rulemaking be suspended and the proposed (a)(3)/(a)(4) changes be incorporated into a single rulemaking which includes the scope revisions.

The advantage of continuing with the current rulemaking is that it allows for earlier implementation of the requirement for licensees to assess the safety impact of taking equipment out of service for maintenance, which is voluntary in the existing rule.

The disadvantage of continuing with the current rulemaking activities is that it will necessitate two separate rulemakings, one dealing with the assessment requirement and a later effort directed towards the scope change. This would likely result in a small overall increase in staff resources, versus a single rulemaking effort that included both elements.

Disadvantages of Revising Maintenance Rule Scope

Modifying the scope of the Maintenance Rule would eliminate one mechanism for getting early predictive information on licensees' performance and on equipment reliability and availability; therefore, such scope changes would have to be assessed relative to their impact on the reactor assessment process currently under development to ensure design consistency. Also, the Commission's longstanding desire to reduce challenges, such as reactor scrams, could be eroded to some extent, especially as related to performance of balance-of-plant (BOP) systems.

The Maintenance Rule was credited (along with the entire regulatory process) in establishing the scope and objective of the license renewal rule in 10 CFR Part 54. Prior to changing the scope of the Maintenance Rule, the potential impact of the proposed changes on license renewal must be carefully considered.

If the Commission directs the staff not to revise the scope of the Maintenance Rule to be risk- informed, the remaining policy question is whether revised guidance should be issued to remove some less risk significant non-safety-related SSCs from scope and to allow less monitoring and assessment for those in-scope low risk standby SSCs which are of low risk importance. A revised regulatory guide could be developed which outlines such reductions in implementation burden for low importance SSCs.

The advantages of issuing such guidance is that it would provide some amount of burden reduction for licensees on an expedited basis, without requiring the staff resources necessary to conduct additional rulemaking on 10 CFR 50.65.

The disadvantage of utilizing regulatory guidance documents, rather than a rule change, is that some monitoring and assessment burden would still remain on low risk importance SSCs due to the current scope definition in the rule. Therefore, this approach would only partially improve the risk-informed focus of the Maintenance Rule.

Staff Recommendation

The staff recommends that the present rulemaking effort on 10 CFR 50.65 continue unimpeded. The staff also recommends that the scope of the Maintenance Rule be revised to be risk-informed and that this effort be conducted in an early stage of Option 2 implementation. If the Commission directs the staff not to revise the scope of the Maintenance Rule, then the staff recommends that implementation guidance be revised to reduce the monitoring and assessment requirements on low risk important SSCs.

4. Clarification of Staff Authority for Applying Risk-Informed Decision making

Commission guidance presented in the final risk-informed regulatory guidance e.g., RG 1.174 and standard review plans, documents the process and criteria for licensees to use in justifying licensee-initiated (voluntary) risk-informed licensing actions. Although the Commission's 1995 PRA Policy Statement indicated that the staff should increase the use of PRA in its regulatory activities, no specific requirement exists for licensees to perform risk analyses in support of licensing actions.

Advantages of Clarification of Staff Authority

This action would clarify the staff's authority to question the risk implications of, and potentially reject proposed changes to, the license or licensing basis for specific instances where risk considerations indicate the change would be unacceptable, (i.e., would not ensure adequate protection). This guidance would specifically state the staff's responsibilities to consider risk in regulatory decision making where the staff has information that leads it to question whether there is adequate protection. Section 182.a of the Atomic Energy Act of 1954, as amended (AEA) provides the NRC the authority to require the submission of information in connection with a license application (including an application for a license amendment) and this includes requesting risk information where NRC has reason to question adequate protection in a specific case. In cases where the risk information raises a concern with respect to adequate protection, the Commission could deny the application or condition its approval upon a showing that the applicant has addressed the risk information such that there is reasonable assurance of adequate protection. However, if the risk information does not raise a concern with respect to adequate protection, then the Commission could: grant the license subject to conditions or requirements beyond those required in the Commission's regulations if a backfit analysis pursuant to 10 CFR 50.109 were performed to demonstrate that the additional conditions or requirements represent a substantial increase in protection of public health and safety whose costs are justified in view of the increased level of protection. In either case, however, the NRC bears the burden of demonstrating that the additional conditions and requirements are justified.

Therefore, additional direct authority does not need to be stated in Part 50 itself. However, to provide clarity and consistency, additional guidance in such supporting documents as a regulatory guide could be established to assist the staff in identifying circumstances in which the relationship between meeting the regulation and demonstrating adequate protection should be further explored. The staff would utilize such guidance in deciding "if undue risk exists" (i.e., there is no adequate protection), even when all other regulatory requirements appear to be satisfied.

Disadvantages of Clarification of Staff Authority

Issuing staff guidance, rather than undertaking a rulemaking, to clarify the responsibility of the staff to apply risk-informed concepts in regulatory activities would rely upon our regulatory authority to take appropriate action whenever adequate protection is called into question. Absent rulemaking severe accident risk will be considered only in those instances where the staff believes adequate protection may be in question, or the backfit provisions of 50.109 can be satisfied. This sets a high threshold that the staff must achieve in pursuing severe-accident issues with licensees, who are not in the process of supporting risk-informed licensing actions. Pursuing the clarification approach discussed above would put the additional burden on the staff to demonstrate lack of adequate protection, where the staff would wish to take regulatory action based upon risk insights.

Staff Recommendation

The staff recommends that the Commission approve development of clarification guidance with respect to the staff's authority to use risk-informed approaches in appropriate regulatory activities. However, should the Commission decide to initiate rulemaking to go further and require licensees to consider severe accident risk in all licensing activities, the staff recommends that this issue be included into the scope of Option 3 for further study.

ATTACHMENT 5

IMPLEMENTATION ISSUES FOR RISK-INFORMING 10 CFR PART 50

Issue	Description
Metrics and acceptance guidelines	What metrics are needed for the traditional engineering and risk parts of specific risk-informed regulations? What are the associated acceptance guidelines? Should the categorization of SSCs with respect to safety importance be graded? How should currently "non-safety-related" SSCs that are risk-important be captured in the new categorization scheme?
Required NRC review and approval	What risk-informed decisions can be made by licensees without NRC advance review and approval? What decisions will require such advance approval?
PRA quality	What is the required scope, level of detail, and quality of risk information needed for using PRA to support decisions for specific regulations?
Required documentation	What documentation is needed on site and is submitted to NRC for plant design and operational changes made as a result of the modifications to Part 50? Should the PRA be required to be docketed? How do potential changes to Part 50 to make it more risk-informed affect the ongoing process to make FSAR updates risk-informed?
Conforming regulatory guide and standard review plan changes	What regulatory guides (RGs) and standard review plan (SRP) sections need to be modified to reflect changes to Part 50? Should these modifications be made in parallel with or subsequent to rule changes?
Integration with risk-informed oversight	How do changes to make the oversight process more risk-informed affect potential changes to Part 50? How do changes to Part 50 affect the oversight process?
Integration with ongoing rule changes	Which ongoing rule changes should be combined with potential rule changes to Part 50 to make it more risk-informed?

1. The transcript of the 10/27-28/98 Public Workshop on Risk-Informing Part 50 are available on the NRC public website (<http://www.nrc.gov>).

At the NRC public homepage (www.nrc.gov),

Click on **News & Info** Icon

Click on **Public Meetings**

Click on **Meeting Transcripts**

Click on **Public Meeting on Making 10 CFR Part 50 Risk-Informed**

To read the transcript, choose and click on either of the two days

2. Changes to these definitions will have to be carefully assessed with respect to potential impact on the underlying definition of "basic component," which have specific requirement imposed as provided in Section 223.10 of the Atomic Energy Act. Modifying the treatment of safety-related and safety important SSCs without necessitating a change to the Atomic Energy Act would be desirable.

3. Full implementation means that all NRC and licensee actions needed to make the option become part of day-to-day operations have been completed. This includes rule changes, guidance documents, staff and licensee program and procedure changes and training.
4. The current rulemaking is limited to the safety assessment (a)(3) recommendation; a separate proposed rule change (including scope revisions) would have to be issued for public comment.
5. Estimated direct FTE assuming that all policy issue recommendations are endorsed by the Commission. Industry implementation being mandatory or voluntary (i.e., policy Option 1) would not appreciably affect these estimates.
6. Preliminary estimates for full Option 3 implementation, including rulemaking. Resources to conduct the study of Option 3 are in addition to the full implementation costs and are estimated to be approximately 5 RES/NRR FTE spread over 2-3 years, and RES technical assistance of \$500k/yr.
7. Once fully implemented, this option is estimated to result in increased staff efficiencies in the area of licensing reviews, inspection and enforcement to correspond to a net reduction in staffing levels of approximately 10-20 direct FTE per year.
8. Reduction of 1 to 10 % of current operations and maintenance (O&M) cost assumed (~\$100 million to 1 billion/year).
9. Full implementation means all licensee and NRC actions needed to make the option become part of day-to-day operations have been completed.