June 8, 1999

COMMISSION VOTING RECORD

DECISION ITEM: SECY-98-300

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

The Commission approved the subject paper with two exceptions as recorded in the Staff Requirements Memorandum (SRM) of June 8, 1999.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commissioners, and the SRM of June 8, 1999.

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Annette Vietti-Cook
Secretary of the Commission

Attachments: 1. Voting Summary
2. Commissioner Vote Sheets
3. Final SRM

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR
DCS

VOTING SUMMARY - SECY-98-300

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. JACKSON	X				X	2/14/99
COMR. DICUS	X				X	3/11/99
COMR. DIAZ	X				X	2/8/99
and	X				X	4/14/99
COMR. McGAFFIGAN	X				X	3/24/99
COMR. MERRIFIELD	X				X	2/8/99

In their vote sheets, the Commission approved the staff's recommendations and provided some additional comments with the following exceptions:

Chairman Jackson, although she preferred mandatory conformance with a risk-informed 10 CFR Part 50, she was in agreement with Commissioners McGaffigan and Merrifield that the recommendation to not allow selective implementation of a voluntary approach was prematurely before the Commission and disapproved the recommendation at this time.
Commissioner Dicus, Diaz and Merrifield disapproved the staff's recommendation that the current rulemaking initiatives associated with paragraph (a)(3)/(a)(4) of 10 CFR 50.65 (maintenance rule) continue as planned. Commissioner Diaz, in his vote on February 8, recommended a two step process to risk inform the scope of the maintenance rule in the short term and long term. Commissioner Dicus agreed with Commissioner Diaz. Commissioner Merrifield recommended suspending the rulemaking and including it in a later rulemaking package with scope changes. Commissioner Diaz supplemented his vote on April 14, 1999, which supported the expeditious revision of 50.65(a)(3)/(a)(4) if the requisite ("should" to "shall") assessment of plant configuration is restricted to risk-significant structures, systems, and components; and, the requisite assessment is conducted using the methods stated in the Staff Requirements Memorandum (SRM) for SECY-97-173. Commissioners Dicus and Merrifield agreed with Commissioner Diaz' approach. Subsequently, the Commission held a public meeting on May 5, 1999. Specific Commission direction regarding the rule language and development of the regulatory guidance was provided in the SRM on the Maintenance Rule Commission briefing of May 5, 1999, which was issued on May 13, 1999. Regarding the overall scope of the Maintenance Rule (50.65), the Commission approved changing the existing scope to conform to the risk-informed regulatory framework being developed as part of Option 2. Commissioner Diaz disagrees with the draft SRM language regarding Policy Issue 3 but recognizes that there is a majority. As stated in COMNJD-99-003, although Commissioner Diaz continues to believe NRC has a regulatory framework which provides adequate protection, the Advisory Committee on Reactor Safeguards (ACRS) raised questions that have implications for adequate protection and backfit. Therefore, he believes that as a matter of prudence, the Commission should await ACRS and Office of General Counsel analyses, and conduct further open consideration before the final direction is provided to the staff.

Subsequently, the comments of the Commission were incorporated into guidance to staff as reflected in the SRM issued on June 8, 1999.

Commissioner Comments on SECY-98-300

Chairman Jackson

Having commented on the need for a risk-informed and performance-based approach to regulation for over 3 years, I am a strong advocate of focusing NRC and licensees resources on areas commensurate with their health and safety significance. In my vote on SECY-97-205, I approved the staff's proposal to develop a framework for risk-informed regulatory processes. In particular, I called for the staff to develop a series of milestones by which the Commission could "chart its course in its move to more risk-informed regulatory processes." Additionally, I promoted the idea of promulgating a new regulation in 10 CFR Part 50, that would make clear how the Commission uses risk information in its decision-making and regulation. Consequently, I commend the staff for the substantial progress that they have made in developing the proposed options for risk-informing the regulations of Part 50.

I endorse the staff's proposed Option 2 (develop risk-informed definitions, processes, and scope changes to systems, structures, and components needing special treatment in terms of quality) with the following modifications and comments:

(1) I agree with the staff proposal to modify, in a risk-informed manner, the scope of SSCs needing special operations and qualification treatment in 10 CFR Part 50 (e.g., Quality Assurance, Environmental Qualification, Technical Specifications, 50.59, ASME code, 50.72, and 50.73). The rulemaking associated with these scope changes should be mandatory, unless the staff finds through a regulatory analysis, that the backfit provisions cannot be met. However, I would add that determining the appropriate "scope" for a particular rule is only a first step in risk-informing a rule. A second, and more important, step involves determining how the items within the scope of a rule should be treated. It is at this point where true risk-informing takes place. Any treatment of "scope" must acknowledge two important facts: (1) not all items within a given scope should be treated equally, and (2) the relative importance of the items is subject to change over time. Therefore, the scope of a particular rule should remain broad enough to encompass both the items known to be important at the time of application of the rule and those items which may become important over time (due, for example, to changes in the design or new risk insights gained from operational experience).
(2) I disagree with the staff proposal regarding selective implementation, as it is premature. If the regulatory analysis demonstrates a case for a mandatory risk-informed Part 50, then selective implementation is not an issue (i.e., the new requirements are mandatory). In the absence of mandatory requirements, I do not believe that, at this time, the staff can, or should, preclude licensees from choosing to apply risk-informed applications on a program level. To do so otherwise would strongly discourage cooperation on pilot projects, and frustrate the process of risk-informing Part 50. Therefore, selective implementation on a program level should be allowed, if the risk-informed changes are voluntary.
(3) I agree with the staff proposal to develop risk-informed definitions for "safety-related" and "important to safety" SSCs.
(4) I agree with the staff proposal to solicit pilot plants to assist in the development of risk-informed scope and definition changes to Part 50. The staff should issue exemptions, where justified, in accordance with 10 CFR 50.12 to the pilot plants to allow implementation of the risk-informed changes prior to the completion of the final rulemakings. The exemptions authorizing each pilot plant should include a provision requiring the plants to comply with the requirements in the final rulemakings. The number of pilot plants should be limited to prevent (what could be considered to be) a *de facto* change to the regulatory requirements in Part 50. The staff should assess the benefits to the agency, the public, and our licensees of the pilot plant studies, evaluate progress against the filters established in the Planning, Budgeting, and Performance Management system, and allow elimination of fees where justified in accordance with long-standing NRC fee policy.
(5) I agree with the staff proposal to study additional changes to the body of the Part 50 regulations to incorporate risk-informed attributes,

such as development of a new set of risk-informed design-basis accidents, adding provisions to Part 50 allowing for risk-informed alternatives, revising specific requirements to reflect risk-informed considerations, and deleting unnecessary regulations. The staff should periodically inform the Commission on progress made in this study. The staff should forward promptly for Commission consideration additional regulatory changes, as they are identified, that could be undertaken in a step-wise (evolutionary) manner, rather than accumulate the changes for a period and rolling them into a large rulemaking plan.

(6) I agree with the staff proposal to proceed unimpeded with the ongoing rulemakings for revised source term, 50.59, 50.65, 50.72, 50.73, and 50.55a.

(7) The staff should continue the timely review and approval of plant-specific risk-informed initiatives submitted in accordance with the recently developed Standard Review Plans and Regulatory Guides. Consistent with item (4), the staff should issue plant-specific exemptions, where justified, in accordance with 10 CFR 50.12 to allow implementation of the risk-informed initiatives.

(8) I agree with the staff proposal that, following the current rulemaking on the Maintenance Rule (10 CFR 50.65), the staff should evaluate whether a scope change is appropriate to this rule or whether, as I have discussed previously, a change in the treatment of those items under the scope of the rule is preferable. The current 50.65 rulemaking need not be delayed, since the staff has the necessary flexibility to ensure that regulatory guidance appropriately limits unnecessary burden associated with assessments.

Additionally, regarding the policy issues in the staff's paper, I have the following comments:

1. *Voluntary vs. Mandatory Conformance with Modified 10 CFR Part 50*
   As I indicated above, the rulemaking associated with the scope changes should be mandatory, unless the staff finds through a regulatory analysis, that the backfit provisions cannot be met.
2. *Industry Pilot Studies with Selected Exemptions to Part 50*
   As indicated above, I endorse the staff's recommendation to use a limited number of pilot studies with selected exemptions to Part 50 as part of the risk-informed development process.
3. *Modification of Scope of the Maintenance Rule*
   The staff has recommended that the scope of the Maintenance Rule (10 CFR 50.65) be risk-informed as an early part of the risk-informed program. I provided my views on a potential modification to the scope, or preferably, the treatment of SSCs within the scope of the Maintenance Rule above. I agree that the staff should address the Maintenance Rule as an early part of the risk-informed program.
4. *Clarification of Staff Authority for Applying Risk-Informed Decision Making*
   The staff has recommended clarifying its authority for applying risk-informed decision-making in cases that do not involve licensee initiated risk-informed licensing actions. I support the staff's intention to issue guidance, but do not believe that the current proposed guidance is adequate. For those licensing actions that are not submitted as risk-informed licensing actions, the staff has indicated that the "test" as to whether the staff could request risk information is whether a specific license change or proposal would "not ensure adequate protection." This appears to be too high a threshold. I am concerned that the proposed staff position may unnecessarily restrict the staff and cause important risk questions not to be asked (the answers to which may impact on adequate protection or significantly affect the "margin" to such).
   For example, as the Commission heard during the briefing by the ACRS on February 3, 1999, it may be appropriate to question the risk-implications of hi-burnup fuel, even though all the regulatory requirements may be met. The ACRS indicated that the impact on severe accident core degradation and source term release of hi-burnup fuel is uncertain, and as such, the risk implications should be known before the use of such fuel is authorized. In addition, although not an exact parallel, the NRC inspection staff is encouraged to question and evaluate the risk-implications of plant activities and configurations under the context of the Maintenance Rule. Furthermore, the NRC enforcement staff considers risk-implications in determining the severity level of violations issued. The NRC licensing staff should be allowed similar latitude (i.e., greater than that associated with questioning adequate protection, but far short of becoming commonplace) to request information and understand risk implications in licensing actions that are not submitted within the context of a "risk-informed" licensing action. The staff should evaluate what changes are necessary to allow such latitude, and develop the necessary guidance documents to promote discipline and consistency in its application.

Finally, the staff should: 1) continue to work with our stakeholders in risk-informing Part 50; 2) provide sufficient staff resources and management oversight to these high priority initiatives to ensure effective development of the risk-informed regulatory structure and timely completion of pilot plant applications; and 3) bring policy issues promptly to the attention of the Commission.

Commissioner Dicus

The staff is to be commended for its efforts in developing a foundation for a comprehensive risk-informed Part 50. This effort represents an important step of our commitment towards risk-informing all of our regulations. The process of completely risk-informing Part 50 will require careful and thoughtful consideration of pertinent issues, and stakeholder input, as well as a recognition that completion of an effort of this magnitude and complexity will take time.

I approve the ongoing rulemaking actions identified in Option 1.

I approve implementation of Option 2 which provides a phased approach to risk-informing 10 CFR 50, and the use of industry pilot studies and exemptions to Part 50 as needed for the pilot efforts.

I agree that the Maintenance Rule can be used as a pilot effort in the implementation of Option 2, but I do so with a great deal of caution. During the January 11, 1999, Commission briefing, a number o f issues pertaining to Option 2 were raised. For example, questions were raised regarding implementation (including approach and methodology), quality of PRAs, impact on license renewal, resources needed for development and implementation of Option 2, and pros and cons of using the Maintenance Rule as a pilot vs. addressing all applicable regulations at one time in an

integrated fashion. The staff should address the issues raised during the Commission briefing as it prepares to implement the Maintenance Rule pilot effort.

I approve a study of Option 3, and agree with Commissioner Merrifield that the study should proceed in an aggressive fashion. Such a study should determine how best to proceed with risk-informing the remaining sections of Part 50.

I approve the development of regulatory guides, including clarification guidance with respect to staff authority for applying risk-informed processes in regulatory activities beyond risk-informed licensing actions.

I agree that risk-informed implementation of Part 50 should be voluntary for licensees. I also believe, at this time, that once the risk-informed alternative has been chosen by the licensee, it do so in its entirety; selective implementation within the risk-informed alternative should not be permitted. The Commission, as well as its stakeholders, recognized early in the process that the use of risk-informed approaches could result in a reduction in requirements for certain SSCs that were determined to be of low risk significance, but may also result in additional requirements for SSCs that were determined to be of high risk significance. The intent of a risk-informed regulatory approach was not to provide an avenue to utilize risk-informed regulation only where it resulted in significant savings or reduction in burden, but to provide a mechanism to utilize and integrated, comprehensive, risk-informed approach to operation and regulation.

I support staff's recommendation to continue with the present rulemaking effort on 10 CFR 50.65, consistent with the short-term actions delineated in Commissioner's Diaz's vote. It is my belief that the effect of a reduction in the scope of the rule as articulated in Commissioner Diaz's Short-term Action 2(b) can be achieved in the short-term via changes to guidance documents or minor scope revision, followed in the longer term by a rulemaking that addresses final scope revisions to the Maintenance Rule.

Finally, while moving towards a risk-informed regulatory framework, the staff should keep in mind that the use of quantitative risk analyses may not be appropriate for all applications, and therefore, should not be force-fit into areas that are not amenable to such an approach.

Commissioner Diaz

Background and Rationale

A rational, informed, state-of-the-art definition of adequate protection of public health and safety for reactors requires the establishment of an operational safety envelope. Because of its complex nature, the operational safety envelope cannot be defined by a line or a threshold. The operational safety envelope must be composed of necessary elements of the defense-in-depth philosophy as well as robust risk-informed components in order to provide sufficient safety margins and be consistent with both the NRC's Safety Goal Policy Statement and the PRA Policy Statement.

PRA methodology and - more importantly - its application, is fundamentally an integral process, more so than the deterministic models that make up most of the NRC's regulations. They both have errors and uncertainties; however, PRA has the advantage for risk decision-making since errors are less important when relative values are used. The long standing complaint that the benefits of 25 years of investing ratepayers' money in PRA has not paid off is due, I believe, to the failure to integrate risk methods into our regulatory fabric, and to the lack of a commitment on our part to apply the risk-informed results - a chicken and egg proposition. In other words, for risk-informed applications to "succeed" fully (i.e., enhance safety and/or reduce unnecessary burden), they need to be integral components of the dominant regulatory process.

Undoubtedly, over the past 25 years, there have been singular successes (e.g., ATWS, SBO, Generic Issue Prioritization and recent risk-informed license amendments). However, I submit that these successful but limited efforts yielded few benefits because they were isolated; and that they were few because they were driven by our need to respond to acute single issues. Until recent years, the state of the "know-how" and the state of the regulations did not support the propagation of risk-informed methods throughout the regulatory fabric: they now do. I believe we have an historic opportunity to employ a more holistic regulatory approach using established methodologies and processes to provide the regulatory basis for risk-informed decision-making that will yield substantial benefits both in terms of enhanced safety and reduction in unnecessary burden. This is a "win-win" situation not only for the industry and the NRC, but for the ratepayers and the nation as well.

Safety performance of the structures, systems and components (SSCs) is the focus of baseline regulatory requirements for design, operation, testing and maintenance. Robust risk-informed reactor analyses and rules are also focused on the assessment of "risk," and the inferred "safety" of SSCs' performance. The staff concludes in SECY-98-300 that, to risk inform Part 50, it is first necessary to establish the definitions of "safety," their relationship to "risk" and to make changes to the overall scope of SSCs "requiring special treatment." I agree; however, as outlined below, I propose to add specificity to these efforts.(1)

Specific Comments

I offer the following concurrences, changes and specific recommendations regarding the proposals in SECY-98-300:

1. Policy Issues

   - I agree that risk-informed implementation of Part 50 should be voluntary and that selective implementation within the new risk-informed rules should not be allowed. However, this should not preclude the use of risk-informed alternatives in the existing regulations. The staff should provide recommendations on potential alternatives in implementing risk-informed Part 50 without complicating NRC's oversight.

- I support utilization of industry pilot plant studies with selected exemptions to Part 50.
- I agree to modifying the scope of the Maintenance Rule, as outlined under Requested Actions below, as a first and necessary step to risk-inform all of Part 50.
- I agree that the staff should provide clarification of its authority for applying risk-informed approaches in regulatory activities beyond risk-informed licensing actions. This clarification should be submitted for Commission approval.

2. Requested Actions

- I approve continuation of the rulemaking actions identified in Option 1, with the exception of the treatment of 50.65 (see below).
- The Maintenance Rule (50.65) rulemaking should be made risk-informed, consistent with present "know-how", with the following components:

Short term actions

a) Change the 50.65 (a)(4) paragraph in the proposed rule (SECY-98-165) to conform exactly with the SRM for SECY-97-173 by deleting the added, ambiguous phrase, "or configurations that would degrade performance of safety functions to an unacceptable level." Define "risk-significant configurations" consistent with the use of the term in Section 2.3 in RG 1.177, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications," and more specifically, as it pertains to the Configuration Risk Management Program outlined in Section 2.3.7.1 in RG 1.177.

b) Reduce the scope of the rule, using a risk-informed approach that focuses on safety, by eliminating those SSCs clearly at or below "low risk-significance." The staff should interact with stakeholders to identify those SSCs that can be easily eliminated.

The significance of this activity should not be underestimated because risk-informing the scope of the Maintenance Rule is essential to risk-informing Part 50 and should be completed prior to any other scoping of SSCs. Risk-informing the scope of the Maintenance Rule will send a clear and credible message that the Commission is committed, on a priority basis, to risk-informing those regulations that are amenable to risk assessment and are most pertinent to the creation of a risk-informed Part 50.

The staff should present a proposed rule for Commission approval on a) and b) above by May 28, 1999.

Final scope revisions

c) The staff should submit to the Commission a Rulemaking Plan(2) to finalize the revision of the Maintenance Rule scope. To provide proper risk-informed treatment of the SSCs, the Rulemaking Plan should address three categories of risk significance: those "high risk-significant" SSCs requiring highest levels of performance goals and monitoring and those "medium risk-significant" SSCs requiring graded level of monitoring and preventive maintenance. These two categories of SSCs should be captured in the Maintenance Rule. The third category, the "low risk-significant" SSCs requiring no monitoring, should be kept outside the scope of the Maintenance Rule.
I believe that the truly "high risk-significant" and "low risk-significant" SSCs can be easily identified. Those "medium risk-significant" SSCs comprise the difficult choices; these can only be risk-ranked within the context of a more rigorous examination of SSCs.

The staff should submit this Rulemaking Plan to the Commission by December 10, 1999.

- I approve a combined Option 2 and 3 for risk informing Part 50, with a phased-in approach closely

resembling the staff recommendations, with the specific changes outlined below.

Short term actions

a) Consistent with the staff recommendations outlined in Option 2, the staff should establish an "Action Plan"[3], with appropriate milestones, to issue a new Appendix to Part 50 -- "Risk-informed Regulatory Criteria" -- capturing in one document those changes to the scope of systems, structures and components requiring special treatment in Part 50. The staff should address in this Plan those changes to Part 50, including portions of Appendices A and B, proposed by NEI on August 28, 1998, (under the Risk-informed, Performance-based Pilot Project) and subsequently presented by the staff to the Commission in the September 2, 1998, Commission meeting.

   This new Appendix would establish an alternative risk-informed regulatory regime, and provide a clear choice to licensees: keep the treatment of SSCs as in the original Part 50 or, voluntarily, use all the risk-informed SSC criteria in the new Appendix, plus the remaining requirements of Part 50. This Plan should embody the concepts of the seven cornerstones of the new inspection, assessment and enforcement processes and thereby provide a solid regulatory foundation for those processes.

The staff should submit this Action Plan to the Commission by May 28, 1999, with a rulemaking plan to follow by December 10, 1999.

Final Part 50 modifications

b) As proposed under Option 3, the staff should provide recommendations to the Commission on how to modify all the pertinent components of Part 50 that can and should be risk-informed for consistency with the regulatory framework being established. The staff should ensure that their recommendations resolve any inconsistencies with other provisions of our regulations, especially Parts 52 and 54. The staff should include in its package the recommended approach to develop a revised set of design-basis events based on risk significance. In this regard, the staff should also recommend how best to implement the voluntary risk-informed regulatory regime, thus satisfying the needs of the stakeholders.

The staff should submit the recommendation package to the Commission by January 28, 2000, a rulemaking plan by June 30, 2000, with expected final implementation of a fully risk-informed Part 50 by June 28, 2002.

Since the above is an ambitious program, I recommend that the work outlined in a) and b) be accomplished by a dedicated NRC task force focused on risk-informing Part 50 and meeting the proposed milestones.

I recommend that the Commission separately determine how to allocate the resources for this work because resource availability and its efficient use is a key question. A holistic approach may be more resource intensive at first, but it should achieve substantial savings in the long term, and it is a more effective use of resources when compared to a piecemeal, protracted program.[4]

The course set out above with its recommended schedule is a demanding yet practical roadmap to implement the cornerstones of risk-informed reactor regulation within 25 years of the TMI accident and its lessons. It will establish an enhanced safety focus that is consistent with risk-informed regulation and will provide the requisite operational margins. It will also assure adequate protection of public health and safety without undue burden for the present and for a new generation of advanced nuclear power plants.

Commissioner Diaz (Additional Comments)

I am supplementing my vote of February 8, 1999, on the Maintenance Rule rulemaking activities. Since issuance of SECY-98-300 (December, 1998),

[5]

additional significant information has been received from the staff, stakeholders, and from individual Commissioner's deliberations. This information has added focus and definition to the SRM for SECY-97-173 (December, 1997), and SECY-98-300.

The scope of the assessment requirement proposed under paragraph 50.65(a)(4) needs to be restricted to risk-significant structures, systems or components (SSCs). An unbound scope would not be compatible with our on-going risk-informed oversight and other activities. It would divert licensee and NRC resources to areas with little risk-significance and could actually be deleterious to the protection of public health and safety.

Therefore, I approve continuation of the expeditious revision of 50.65 (a)(3)/(a)(4), if and only if:

- the requisite ("should" to "shall") assessment of plant configurations is restricted to risk-significant structures, systems or components; and
- the requisite assessment of plant configurations is conducted using the methods stated in the SRM for SECY-97-173 [(6)]. The assessment should be performed "commensurate with complexity of the maintenance configuration."[(7)]

If the conditions provided above are not adopted, I cannot support the proposed configuration assessment requirement to be effected by changing "should" to "shall".

Regarding the scope of the rule, I approve changing the existing scope of 50.65 to conform to the risk-informed regulatory framework advocated by the Commission. In the near term, the staff should develop a rulemaking plan to risk-inform the scope of the Maintenance Rule on an aggressive schedule. This rulemaking should be a priority activity and should give due consideration of the Commission objectives and policies, including those recently reaffirmed in testimony to the U.S. Senate. The proposed rulemaking plan should be submitted to the Commission no later than September 15, 1999.

All other statements in my vote of February 8, 1999 remain unchanged.

Commissioner McGaffigan

I want to join my fellow Commissioners in commending the staff for a well-drafted set of options for pursuing risk-informed revisions to 10 CFR Part 50. This is a difficult subject on which there is no obvious path forward. Some external observers, the General Accounting Office among them, seem to expect that we have all the answers now as to what a risk-informed redraft of Part 50 would look like and that we can simply schedule the necessary changes. In my view, quite the opposite is true. Every step is likely to require real invention. A thorough examination of detailed issues that will arise in each rulemaking will be necessary. It is too much to expect the staff and the Commission together with their stakeholders to invent on a schedule. This is especially true when the Union of Concerned Scientists (UCS) and others are raising fundamental issues about risk-informing Part 50. If the expectation is that everything will proceed on a schedule we can predetermine today, we are being set up for a guaranteed failure down the road.

A fair expectation of the staff and Commission is that we should continue as rapidly as we can to fulfill the promise of the PRA Policy Statement. This paper does that. It asks the Commission to make decisions on fundamental options and policy issues. It does not guarantee success on any individual option the Commission ultimately decides to pursue. Those who would hold us to schedules for inventing new rules should consider the experience the past two years in the 50.59 rulemaking, which through hard work on the NRC staff's and industry's part will come to fruition this spring. They should consider the experience with the long maintenance rule (a)(4) rulemaking, which I hope will come to a close this spring. Fundamental rule changes take time. Perhaps the early rulemakings under Option 2 of this paper will go smoothly and build momentum for the broader changes under Option 3. Perhaps, they will not. I hope our stakeholders and observers will allow for this latter possibility in formulating their success criteria for the Commission and its staff.

As to the paper itself, I approve implementation of Option 2, which provides a phased approach to risk-informing Part 50 and involves the use of industry pilot studies together with exemptions as needed for the pilot efforts. This option is most consistent with stakeholder comments received thus far. The scope changes being considered for various operational and qualification requirements under this option would focus NRC's attention on systems, structures and components which operational experience, engineering judgment or risk insights from PRA indicate are important to safety. There is no undue reliance on PRAs alone in the Nuclear Energy Institute's (NEI's) August 1998 scope proposals. Risk insights are but one of three elements that will go into a risk-informed decision as to whether a system, structure or component is important to safety. The heart of these scope rulemakings on Part 50 operational and qualification requirements is likely to be how to balance these three elements in making that decision. In a real sense the changes being made to the NRC's oversight process, with the involvement of both NEI and UCS, already are headed in the same direction as the proposed Option 2 scope rulemakings. Our inspection, assessment and enforcement processes are going to be more focused on risk-significant activities at the reactor sites. The Option 2 scope rulemakings, starting with the maintenance rule, should prove complementary to the oversight program changes and easier to carry out than the likely even more complex rulemakings under Option 3.

I approve the study of Option 3 on as aggressive a schedule as budgets will permit. I am particularly interested in the possibility of "deleting unnecessary or ineffective regulations." My sense is that the new oversight process with its risk-informed, performance-based focus will result in the de facto abandonment of rules that are unnecessary or ineffective either because they are overly prescriptive or unrelated to risk or both. An important part of risk-informing Part 50 may lie, not in studying what should replace double guillotine breaks with simultaneous loss of off-site power as a design basis accident, but instead in simply cleaning up Part 50 based on the operational experience and risk insights that have accumulated since the prescriptive, deterministic rules were drafted. This part of Option 3 potentially has the most synergy with the ongoing oversight process improvements and may require the least additional research.

With regard to the ongoing maintenance rule (a)(4) rulemaking, I want to proceed to conclusion without using it as the vehicle to address the maintenance rule scope issue. I am encouraged by NEI's latest letter to the effect that they are willing to work with the staff on a two-step process, although I have not formulated a position on the specific NEI proposal. This is not the SECY paper on which to vote on specific (a)(4) language. But I am

sure that, with good faith on both sides, rule language can be agreed to that is workable. A delayed implementation date may be required to allow the staff and NEI to develop necessary updates to NUMARC 93-01 and NRC Regulatory Guide 1.160. But given the staff findings on the lack of assessments of, and control for, risk-significant configurations at some licensee facilities while operating at full power, I do not think we should delay this rulemaking. On the other hand, we can simultaneously begin preparations for the scope change rulemaking under Option 2 now without waiting for the (a)(4) rulemaking to conclude.

I approve voluntary implementation of risk-informed changes to Part 50. I do so recognizing that this will complicate NRC's regulatory framework. I cannot imagine risk-informed changes to Part 50 passing the "substantial benefit" test in the backfit rule (50.109). We should also recognize that in choosing a voluntary approach we will be successful in risk-informing Part 50 only if there is broad acceptance on a voluntary basis of rule changes (as, for instance, there was with Option B in Appendix J on containment leak testing).

I do not approve at this time the staff proposal not to allow selective implementation of risk-informed changes to Part 50. This issue is prematurely before the Commission. A future Commission will be better able to judge the issue of selective implementation after rules are drafted and rulemakings provide comment on this issue as it affects that rule. In the ongoing source term rulemaking we are dealing with this issue in exactly this way and we should continue to do so rule by rule.

I also agree with Commissioner Merrifield that a "no selective implementation" approach will adversely affect our ability to solicit industry pilot participants. The very nature of the pilots will be a selective implementation by exemption of a risk-informed Part 50 option. A pilot participant should not be locked into a choice to take or leave the entire suite of risk-informed Part 50 rules (yet to be invented) having helped us develop one or more of them.

I approve the staff's recommendation that additional guidance be developed to provide clarification on staff authority for applying risk-informed processes in regulatory activities beyond risk-informed licensing actions. This clarifying guidance should be submitted for Commission approval.

Commissioner Merrifield

I commend the staff for the progress they have made in developing options for risk-informing 10 CFR Part 50. A risk-informed approach to our regulations should serve to enhance safety, reduce unnecessary regulatory burden on licensees, and allow for more effective utilization of NRC resources. It will allow the NRC and licensees to focus on areas that are of greatest risk significance and thus enhance our ability to protect public health and safety.

As we proceed with risk-informing Part 50, the staff should not underestimate the leadership, management, tracking, and resources that will be necessary to be successful. We owe it to our stakeholders to ensure that our efforts are technically sound, well-planned, and effectively carried out. The agency's Planning, Budgeting, and Performance Management process should be a useful tool in achieving this goal. I encourage the Executive Council to take an active leadership role on this issue and to ensure adequate resources are dedicated to it; as they have so successfully done on the issue of license renewal. The PRA Steering Committee should also provide an active leadership role in assisting the line organization with this risk-informing Part 50 effort. Finally, I encourage the staff to continue to work with our stakeholders to gain their insights into how to most effectively prioritize our efforts.

I endorse a modified version of the staff's proposed Option 2 as follows:

I **approve** the staff's recommendation of adopting a phased approach to making 10 CFR Part 50 more risk-informed by proceeding initially with Option 2. I agree with the staff that a phased approach appears to be consistent with comments received from stakeholders and would allow for achieving meaningful benefits in the early stages.

I encourage the staff to study Option 3 on an aggressive timetable to identify specific requirements meriting change and possible risk-informed alternatives to the body of Part 50. However, I cannot endorse studying Option 3 without appropriate assurances that this study will be carried out in a disciplined and aggressive manner, with firmly established milestones. Thus, the staff should in the near-term provide, for Commission approval, a proposed schedule for carrying out this study. During this study, if the staff identifies a regulatory requirement which warrants prompt revision because such a change would significantly enhance safety or significantly reduce unnecessary regulatory burden, the Commission should be notified and provided with a recommended course of action. Otherwise, once this study phase is completed, the staff should provide, for Commission approval, a detailed plan outlining its recommendations regarding specific regulatory changes that should be pursued.

I **approve** the staff's recommendation that the current rulemaking activities identified in Option 1 continue unimpeded, with the exception of rulemaking activities associated with the Maintenance Rule as discussed below.

I **approve** the staff's recommendation regarding the use of industry pilot studies involving the use of exemptions to assist in the development of the Part 50 modifications.

I **disapprove** the staff's recommendation that the current rulemaking initiatives associated with paragraphs (a)(3) / (a)(4) of the 10 CFR 50.65 (Maintenance Rule) continue. Instead, this rulemaking should be suspended and its content included in a later rulemaking package which includes scope changes. This approach will avoid two separate rulemakings and optimize the use of staff resources.

I **approve** using the Maintenance Rule 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 and qualification requirements (Option 2). Modifying the scope of the Maintenance Rule and other regulations to be risk-informed would result in a coherent and consistent scope of all operation-related requirements. I agree with the staff's assessment that 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. Also, risk-informing the scope of the Maintenance Rule could relieve licensee burden without adversely affecting plant safety.

I encourage the staff to expeditiously move forward with risk-informing the scope of the Maintenance Rule. Given the importance of this step in the agency's overall efforts to develop a risk-informed Part 50, it is essential that senior management provide the leadership and resources that are necessary to ensure success. In the near-term, I expect the staff to develop a rulemaking plan to risk-inform the scope of the Maintenance Rule on an aggressive schedule.

I commend Commissioner Diaz for his efforts to improve and expedite the staff's proposed approach to risk-inform Part 50. His insights regarding risk-informed regulation have been invaluable to the agency and to me as a new Commissioner. However, I am not prepared to support a multi-step approach to reduce the scope of the Maintenance Rule. The issue of Maintenance Rule scope is not squarely presented by the facts of this paper. Consequently, I do not believe it would be appropriate to decide how to address the scope issue, in the context of a paper addressing risk-informing Part 50. I am also concerned about endorsing a multi-step approach without having the benefit of a fully developed assessment by the staff of its overall implications. While such an approach may result in some burden reduction for licensees in the short-term, I believe it could divert NRC resources away from the primary goal of developing a comprehensive, integrated rulemaking which makes the Maintenance Rule truly risk-informed. I also believe a multi-step approach could increase regulatory burden on licensees in that it would require them to change their infrastructure (program description, procedures, training) which supports implementation of the Maintenance Rule several times. It could have the same effect on the NRC's infrastructure in that inspection procedures, training, and regulatory guidance would have to be modified several times. While I generally support initiatives which expeditiously reduce unnecessary regulatory burden, I do not believe I have sufficient information to fully understand the implications of reducing the scope of the Maintenance Rule using the proposed multi-step approach. Thus, I cannot support such an approach at this time.

I **approve** the staff's recommendation that risk-informed implementation of Part 50 be voluntary for licensees. As the staff proceeds with its efforts to risk-inform Part 50, it should provide the Commission with additional information regarding how it will manage voluntary implementation.

I **disapprove** the staff's recommendation that selective implementation not be allowed. While I agree with the spirit of the no selective implementation recommendation, and agree that such selective implementation is not entirely compatible with the intent of risk-informed regulation, I cannot endorse such a inflexible position across the board. For instance, I agree with the staff that selective implementation within a program should not be allowed (i.e., decrease quality assurance requirements on low risk significant SSCs, but not increase quality assurance requirements on high risk significant SSCs). On the hand, the staff has recommended that the scope of the Maintenance Rule be changed as an early part of the risk-informing process. The staff's position would require all licensees who desire scope changes to the Maintenance Rule to implement the entire complement of risk-informed changes. I have no safety basis upon which to conclude that the licensees benefitting from a risk-informed Maintenance Rule of reduced scope should be limited to only those that adopt the entire complement of risk-informed regulatory requirements. There are likely other similar examples.

In addition, I question how the no selective implementation approach would affect our ability to solicit industry pilot participants. Specifically, I assume licensees that volunteer to be pilot plant participants have a vested interest in adopting the risk-informed revision to the particular regulatory requirement for which they are piloting. However, these licensees may be undecided as to whether they would be interested in adopting the entire complement of risk-informed regulatory requirements. With an inflexible no selective implementation approach, it would seem that only those licensees absolutely committed to adopting the entire complement of risk-informed regulatory requirements, a complement not yet defined, would volunteer to be a pilot plant participant.

Finally, if a no selective implementation approach is adopted, it is unclear how the staff intends to handle plants that have already been granted risk-informed initiatives.

In summary, I am opposed to the staff's broad recommendation that selective implementation not be allowed. However, I clearly recognize that the limits to selective implementation would have to be well-defined and carefully controlled by the NRC.

I **approve** the staff's recommendation that additional guidance be developed to provide clarification on staff authority for applying risk-informed processes in regulatory activities beyond risk-informed licensing actions. This clarifying guidance should be submitted for Commission approval.

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1. The GAO in its February 4, 1999, testimony before the Subcommittee on Clean Air, Wetlands, Private Property, and Nuclear Safety, Committee on Environment and Public Works, U.S. Senate, states that "[i]t is critical that NRC clearly articulate how the various initiatives will help achieve the goals set out in the 1995 policy statement."

2. As stated in NUREG/BR-0053, Rev.4, "Regulations Handbook," a rulemaking plan defines the regulatory problem that is to be resolved through rulemaking. It includes, among other considerations, a legal analysis, resource and schedule requirements, and the level of public participation.

3. As stated in NRR Office Letter 504, an action plan is appropriate for resolution of "safety significant and complex issues." It should include, but not limited to, a description of the issue, proposed actions, schedule and milestones, priority, and resources.

4. The GAO in its February 4, 1999, testimony before the Subcommittee on Clean Air, Wetlands, Private Property, and Nuclear Safety, Committee on Environment and Public Works, U.S. Senate, states, concerning implementation of a risk-informed approach, that "NRC has developed an implementation plan,...that is a catalog of about 150 separate tasks and milestones for their completion."

5. For example, I refer to the Commission briefing on January 11, 1999, and to the presentations to the ACRS on April 8, 1999.

6. "...[T]here can be several inputs to the determination of risk significance of plant configurations, including PRA, deterministic analysis, considerations

of defense in depth, and qualitative measures."

7. Staff presentation to the ACRS on April 8, 1999.