



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 25, 2015

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-15-0050

TITLE: CUMULATIVE EFFECTS OF REGULATION PROCESS
ENHANCEMENTS AND RISK PRIORITIZATION INITIATIVE

The Commission acted on the subject paper as recorded in the Staff Requirements Memorandum (SRM) of August 25, 2015.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

A handwritten signature in black ink, appearing to read "Annette Vietti-Cook", written over a horizontal line.

Annette L. Vietti-Cook
Secretary of the Commission

Enclosures:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Burns
Commissioner Svinicki
Commissioner Ostendorff
Commissioner Baran
OGC
EDO
PDR

VOTING SUMMARY - SECY-15-0050

RECORDED VOTES

| | APRVD | DISAPRVD | ABSTAIN | NOT PARTICIP | COMMENTS | DATE |
|------------------|-------|----------|---------|-----------------|----------|---------|
| CHRM. BURNS | X | X | | | X | 6/30/15 |
| COMR. SVINICKI | X | X | | | X | 7/15/15 |
| COMR. OSTENDORFF | | X | | | X | 6/18/15 |
| COMR. BARAN | X | X | | | X | 5/27/15 |

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Burns

SUBJECT: SECY-15-0050: Cumulative Effects of Regulation
Process Enhancements and Risk Prioritization
Initiative

Approved Disapproved Abstain

Not Participating

COMMENTS: Below Attached None



SIGNATURE

30 June 2015

DATE

Entered on "STARS" Yes No

Chairman Burns Comments on SECY-15-0050
Cumulative Effects of Regulation Process Enhancements and Risk Prioritization Initiative

In SECY-15-0050, the staff presents four options for addressing the cumulative effects of regulation (CER) and the risk prioritization initiative (RPI). The staff recommends that the Commission approve Option 2 which would augment existing regulatory processes with a risk-informed prioritization method and permit the staff to explore using an internal expert panel to use risk information to further enhance regulatory decision-making. The staff also recommends that the Commission approve a pilot of Option 3 which would offer a voluntary opportunity for power reactor licensees to submit a plant-specific implementation plan when the NRC develops a rule.

The Commission's deliberations on the staff proposals in SECY-15-0050 have occurred at the same time as its deliberations on SECY-15-0015, "Project Aim 2020 Report and Recommendations." I see significant overlap in these two initiatives and, therefore, cannot view the staff's proposals in SECY-15-0050 outside of the context of Project Aim, as discussed further below.

I approve the first part of Option 2 to augment current regulatory processes by allowing licensees to use a risk-informed prioritization method as the basis to request schedule changes for initial compliance and implementation dates for regulations and orders. The staff should ensure that the associated guidance adequately addresses the prioritization of security, emergency preparedness, radiation protection, and beyond-design-basis regulatory requirements.

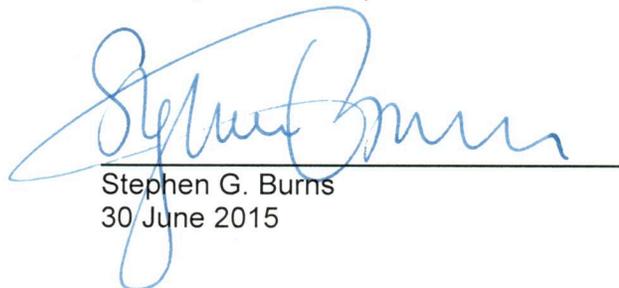
I disapprove pursuing the second part of Option 2 under the banner of CER/RPI. This proposal would allow staff to pilot an expert panel that would use risk insights and other relevant technical information as part of NRC's generic process. Although I am supportive of this proposal in concept, I believe that such an effort is more appropriately addressed in response to the Commission's direction regarding Project Aim. In the staff requirements memorandum (SRM) for SECY-15-0015, the Commission directed the staff to "identify and consider additional opportunities to apply more broadly risk insights to enhance our decision-making beyond traditional technical issues" and to "develop a common prioritization process with a supporting add/shed procedure that integrates all work activities across the agency and includes external mandates." In addition, as the ACRS noted in its letter on this topic, "[t]he staff should explicitly include risk information as an input to decisions and priorities for proposed regulatory actions regardless of the Commission's decisions about specific options or approaches presented in this SECY paper." I wholeheartedly agree. The staff should address any additional consideration of the concept proposed under the second part of Option 2 in its efforts to address the Commission's direction on Project Aim in the SRM for SECY-15-0015.

With respect to Option 3, I support the concept of offering the ability for power reactor licensees to submit a plant-specific implementation plan for the NRC's review and approval. However, I am concerned with the staff's proposal to allow licensees to submit, during the comment period of a proposed NRC regulation, a proposed plant-specific schedule to be codified in the text of the final regulation. In my view, such an approach is over-complicated and rife in the potential for error. For instance, I believe that codifying plant-specific implementation plans in a regulation is highly likely to result in licensees seeking exemptions from their own implementation schedule codified in the final rule. Further, as part of the rulemaking process, final rules often vary to some significant degree from the proposed rule. Yet, under the staff's

proposal, licensee's proposed implementation plans that would ultimately be codified in the final rule would be based on assumptions licensees made from the proposed rule. I also do not support the staff's other Option 3 proposal to codify the key attributes of NRC guidance on plant-specific schedule relief for implementation dates (developed in Option 2) in the language of each regulation for which the NRC wishes to offer schedule relief. This also has the potential to significantly complicate rulemaking and it isn't clear why it is necessary to codify such guidance. Therefore, I disapprove the staff's Option 3 proposal. A much simpler, tried and true option is available to support plant-specific implementation schedules: i.e., including in regulations a provision that requires licensees to submit proposed implementation schedules for the NRC's review and approval within a certain time after the effective date of a final rule. This has been used in the past, for example, in the station blackout rule, 10 CFR 50.63(c), and the cyber security rule at 10 CFR 73.54. I support the continued use of such an approach to ensure that new requirements are implemented in a timely manner, but with the necessary flexibility to licensees to appropriately prioritize work. In using an implementation plan approach, staff should consider including in the rule a "no later than" compliance date (similar to what the NRC imposed in the post-Fukushima orders issued to reactor licensees) and also publishing guidance to licensees on acceptable implementation plans.

Finally, I disapprove Option 4 under which the NRC would issue a standalone "RPI Rule," based on the implementation concerns outlined by the staff in SECY-15-0050. This rule would establish a voluntary prioritization process enabling each licensee to make site-specific schedule changes for NRC regulations in accordance with the process established in the rule without requesting an exemption. I also agree with the ACRS that implementation of Option 4 would be premature at this time.

Though I have disapproved some of the specific proposals recommended by the staff, I continue to strongly support the agency's efforts to address the cumulative effects of regulation. I encourage the staff to continue to look for new and innovative ways to address these challenging issues. The staff should not view my vote on this matter as discouraging such efforts. In my view, the Commission sent a strong message in its direction on Project Aim that the agency must continue to examine its regulatory decision-making to ensure that it remains focused on the issues most important to our core safety and security mission. As such, the staff should continue to pursue its improvement efforts in this regard earnestly.



Stephen G. Burns
30 June 2015

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-15-0050: Cumulative Effects of Regulation
Process Enhancements and Risk Prioritization in
Initiative

Approved XX In Part Disapproved XX In Part Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached XX None ___



SIGNATURE

07/15/15

DATE

Entered on "STARS" Yes No _____

Commissioner Svinicki's Comments on SECY-15-0050
Cumulative Effects of Regulation Process Enhancements and Risk Prioritization Initiative

I approve the continuation of agency initiatives to address the cumulative effects of regulation (CER) described under the staff's Option 1. I do not necessarily agree with the staff that the structure of options laid out in the paper is one where each option "builds upon the previous option(s)," nor do I find that Options 2 through 4 represent the exclusive set of alternatives or a necessary or exclusive bundling of the described activities. Consequently, I disapprove the other options and in lieu of any of them, I propose, or join my colleagues in supporting, a set of actions that are clearly meritorious and should be pursued, continued, or expanded.

As Chairman Burns outlined in his vote, there is significant overlap between the matters we are considering here and the improvements the agency seeks to make in its performance under Project Aim 2020. As he notes, the Commission has directed the staff, under Project Aim 2020, to "identify and consider additional opportunities to apply more broadly risk insights to enhance our decision-making beyond traditional technical issues" and to "develop a common prioritization process . . . that integrates all work activities across the agency." This direction is central to our goal of developing regulatory requirements and other generic communications that are truly risk-informed, performance-based, and promulgating only those mandates whose safety significance merits their implementation.

As noted by Commissioner Ostendorff, this objective is nothing new for the NRC. Our Principle of Good Regulation of Efficiency demands of us that "[r]egulatory activities should be consistent with the degree of risk reduction they achieve" and "[w]here several effective alternatives are available, the option which minimizes the use of resources should be adopted." Our structure and processes are set up to achieve this. Careful consideration of our work on CER, and the Risk Prioritization Initiative (RPI) pilots especially, however, may be giving us pause as to whether our current implementation of these processes is yielding the kind of continued adherence to the Principles that we hope always to be demonstrating.

On this question, I conclude – from the paper, from my engagements with the NRC staff and managers over the course of the paper's development, from my review of the report on the results of the RPI pilots, from conversations with plant personnel who participated in the pilots, from the Commission meeting we held, and from deliberations with my fellow Commissioners – that beneficial insights have clearly been gained from all of this exploration of the issue and that specific actions are needed in response.

First and foremost, as the Advisory Committee on Reactor Safeguards observed in its letter report, and I agree: "The staff should explicitly include risk information as an input to decisions and priorities for proposed regulatory actions regardless of the Commission's decisions about specific options or approaches." Although this action is already required of the staff under existing Commission policy, I believe this direction should be repeated in the staff requirements memorandum resulting from Commission action on this paper.

I agree with Commissioner Ostendorff that the NRC's regulatory framework already provides flexible and appropriate mechanisms for relief such as exemption requests under 10 CFR 50.11 and license amendments under 10 CFR 50.90. Under these mechanisms, the staff applies risk-informed decision making in reviewing licensee requests. I do not approve the design and establishment of agency processes for risk-informed relief when they already exist. This does not mean, however, that our execution of these processes is uniformly flawless. If the staff's execution of these processes could be improved through the use of a standardized risk

prioritization method or template, the staff should explore with the regulated community what form(s) of guidance would improve these processes and should report back to the Commission on proposed actions. Although concerns have been raised by the staff about “perpetual deferral” of mandated actions, the Commission needs to remember that the Commission itself is the ultimate backstop against this happening. The Commission has the sole and principal obligation always to ensure that: 1) necessary regulatory actions are promulgated but 2) only those regulatory actions that can be appropriately justified are imposed.

I also agree with Commissioner Ostendorff’s framing of the “problem set” here as one intended to address how we make sure that any new requirements are justified with a robust regulatory analysis, are respectful of the backfit rule, and take into account the impacts and other feedback from stakeholders. The staff should not limit such considerations to the rulemaking process, however, nor should NRC’s CER activities be confined to power reactor activities. The NRC’s CER work is quite mature at this point and should continue to be expanded to include other agency generic regulatory communications, tools, and processes, as well as formally expanded to include fuel cycle facilities and other materials licensees. While the staff concludes that many of these processes “already reflect elements of CER process enhancements,” it is too ad hoc for my liking. A more structured approach and more thorough consideration can and should be put into place.

This brings me to the staff’s recommendation that the Commission approve the piloting of an expert panel that would use risk insights and other relevant technical information to consider proposed rules, orders, and generic communications early in the development stages consistent with CER process enhancements. The panel would make recommendations to prioritize, schedule, or eliminate, where appropriate, proposed rules, orders, and generic communications across the Operating Reactor business line.

I think I was not the only member of the Commission surprised to hear that this simply was not happening at NRC. Whether or not we are surprised to hear it, our staff has informed us of this deficiency and it must be addressed. I do not approve the establishment of a new panel, however. Rather, the staff should return to the Commission with a paper discussing the current mechanisms that exist, such as the Committee to Review Generic Requirements (CRGR), the Common Prioritization of Rulemaking, and others, describing what they are intended to address, pointing out gaps and overlaps, and proposing revisions to the overall structure – including the elimination or combining of groups and activities, and the revision of group charters, as necessary – to achieve the objective of making “recommendations to prioritize, schedule, or eliminate, when appropriate, proposed rules, orders, and generic communications” across all business lines (not just Operating Reactors). This should not require the establishment of a new panel and could perhaps even be achieved by the EDO using his line management structure and authorities, supplemented by advice from other bodies such as CRGR.

The staff should also assess, and report to the Commission in the paper, on whether the “value-impact assessment technique” – the development of which was outlined in SECY-99-143, “Revisions to Generic Communication Program” but subsequently abandoned by the staff – would now be of utility in light of Project Aim 2020 goals and the agency’s CER efforts. One way or another, such a basic organizational function as priority setting must start being effectively performed at NRC, if it is not being done now. And the Commission, as a body that truly looks across all agency functions and activities, needs to play its part, fully and actively, which may include more active engagement in the review of rulemaking plans and/or the review and approval of the Common Prioritization of Rulemaking.

At bottom, the NRC should carry forward and continue to build on what is a solid set of CER activities. The work on RPI provided many beneficial insights and was clearly not a wasted effort. I commend the industry volunteers and the NRC staff for their efforts in generating these insights, which have the potential to further strengthen our regulatory program.



Kristine L. Svinicki 07/15 /15

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: SECY-15-0050: Cumulative Effects of Regulation Process Enhancements and Risk Prioritization in Initiative

Approved _____ Disapproved X Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached X None ___

W. Ostendorff
SIGNATURE

6/18/15
DATE

Entered on "STARS" Yes X No ___

**Commissioner Ostendorff's Comments on SECY-15-0050:
"Cumulative Effects of Regulation Process Enhancements and Risk Prioritization
Initiative"**

I thank the staff for their efforts in responding to the Commission direction in SRM-COMGEA 12-0001/COMWDM-12-0002, and in working with industry to pilot the use of risk-informed prioritization. I also thank the Advisory Committee for Reactor Safeguards (ACRS) for their thoughtful review of the staff's proposal. After careful consideration of the staff's proposal, I approve Option 1, the status quo.

I have been a strong supporter of agency efforts to address the cumulative effects of regulation. The staff originally provided its plan to address cumulative impact in SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process." Over the past four years, the staff has made great strides in this area.

Separately, in SRM-COMGEA 12-0001/COMWDM-12-0002, the Commission approved an initiative to further explore the idea of enhancing safety by applying probabilistic risk assessment (PRA) to determine the risk significance of current and emerging reactor issues in an integrated manner and on a plant-specific basis. This is the so-called risk prioritization initiative (RPI). Subsequently, for convenience, the Commission approved combining CER and RPI deliverables into one SECY paper. However, in my view, these are separate and distinct activities, with the CER enhancements well understood and well underway.

One of the key objectives of RPI, as directed by the Commission in 2012, was to incentivize licensees to develop and maintain high-quality and full-scope PRAs. As stated in SRM-COMGEA-12-0001/COMWDM-12-0002, licensees would be "required to develop site-specific Level 1 and 2 PRAs addressing all initiating events (including natural hazards) and plant modes as supported by NRC endorsed consensus standards in order to participate in the voluntary risk-prioritization initiative." The risk-prioritization process presented to the Commission does not fulfill this objective because there is no industry agreement to develop full-scope PRAs nor is there a regulatory basis upon which the NRC can mandate them.

In response to SRM-COMGEA 12-0001/COMWDM-12-0002, the staff provided SECY-15-0050 with four options for risk prioritization activities. The first option maintains the status quo, which includes the current CER enhancements. The next three options augment current regulatory processes or propose changes to regulatory processes by incorporating risk insights to prioritize initial compliance and implementation dates for regulations and orders on a plant-specific basis for operating power reactors.

When approaching decisions such as these, I always ask "what problem are we trying to solve and what is the best approach to address it?" In this case, the underlying issue is to make sure that any new requirements are justified with a robust regulatory analysis, and that the impacts on stakeholders are considered during the rulemaking process. The agency has undertaken several enhancements to its rulemaking process to ensure this is the case. Some of these enhancements have been completed as part of the CER initiative, including:

- Developing and implementing outreach tools that allow the NRC to consider the overall impacts of regulatory actions on licensees and their ability to focus effectively on items of greatest safety importance, in a comprehensive manner.
- Interacting with external stakeholders during the development of the regulatory basis and draft guidance in the rulemaking process.

- For each proposed rule published in the Federal Register, seeking and considering stakeholder feedback on the cumulative effects of regulation related to the proposed rule.
- Holding a public meeting on implementation of the rule during the final rulemaking stage to better understand and clarify the cumulative effects of rulemaking concerns and to structure the rule requirements and compliance dates appropriately.
- Using the recently revised common prioritization of rulemaking (CPR) process for prioritizing its rulemaking activities.

In addition to the CER enhancements, the staff is in the process of enhancing cost-benefit analysis guidance in response to SRM-SECY-12-0110. These activities will serve to make the NRC's rulemaking process even more robust. I believe the actions listed above go to the very heart of addressing CER concerns.

In SECY-15-0050, the staff recommends Option 2, to augment existing regulatory processes with a risk informed prioritization method and to permit the staff to explore using an internal expert panel to use risk information to further enhance regulatory decision-making. The staff also recommends a pilot under Option 3, which would offer a voluntary opportunity for power reactor licensees to submit a plant-specific implementation plan when NRC develops a rule.

With regard to the first part of Option 2, I disapprove this option. As stated in Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," the regulatory guide can be applied to "justify modifications to the plant's design, operation, or other activities that require NRC approval." As noted in the regulatory guide, these modifications could include items such as exemption requests under 10 CFR 50.11 and license amendments under 10 CFR 50.90. As such, under existing agency processes, the staff can already apply risk-informed decisionmaking in reviewing licensee exemption requests. Moreover, the proposed prioritization process proposed in Option 2 would still require licensees to submit extension requests to the NRC in order to change implementation schedules for regulatory requirements. Therefore, I do not approve establishing new agency processes for risk-informed exemption requests, since these processes already exist. Furthermore, licensee exemption requests should stand on their own merits. The comparative safety benefit of an NRC requirement should not be weighed against the potential licensee initiated plant safety enhancements that are beyond the NRC's regulatory authority.

With regard to the second half of Option 2, I disapprove this option. I fully support and encourage early consideration of risk insights when developing new requirements consistent with the Commission's long-standing principles of good regulation which states that "regulatory activities should be consistent with the degree of risk reduction they achieve and that there should be a clear nexus between regulations and agency goals and objectives." However, I do not approve the development of new agency processes to do so. Rather, risk insights can and should be considered through existing agency processes under the umbrella of CER and the common prioritization of rulemaking process.

With regard to Option 3, I disapprove this option. Consistent with the objectives of Project AIM, I do not support embarking on a new process that may unnecessarily complicate or lengthen the rulemaking process. Rather, the staff should continue to focus on implementation of the CER enhancements and on its ongoing efforts to enhance the NRC's cost-benefit-analysis capability. As discussed above, the CER process already includes consideration of the impacts of regulatory actions on licensees and their ability to focus effectively on items of greatest safety

importance. This is where I see the most opportunity to address concerns with the cumulative effects of regulations.

Lastly, I also disapprove Option 4. As discussed in the March 11, 2015, ACRS letter, "implementation of Option 4 would require a substantial commitment of staff time and resources, with as-yet unknown practical acceptance by the industry." I agree with the ACRS's conclusion that implementation of Option 4 is premature.

In conclusion, I approve Option 1, the status quo. The staff should maintain its focus on implementation of current CER enhancements and its efforts to enhance the NRC's cost-estimating capabilities. I also encourage the staff to apply risk-informed decision-making early in the development of new requirements and in the consideration of licensee exemption requests under existing agency processes.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: Commissioner Baran
SUBJECT: SECY-15-0050: Cumulative Effects of Regulation
Process Enhancements and Risk Prioritization in
Initiative

Approved XX (in part) Disapproved XX (in part) Abstain _____

Not Participating _____

COMMENTS: Below _____ Attached XX None _____



SIGNATURE

5/27/15

DATE

Entered on "STARS" Yes XX No _____

Commissioner Baran's Comments on SECY-15-0050, "Cumulative Effects of Regulation Process Enhancements and Risk Prioritization Initiative"

Before us is a staff paper focused on cumulative effects of regulation process enhancements and the risk prioritization initiative. I appreciate the staff's thoughtful consideration of a range of policy options, as well as the industry and staff's work over the past 18 months on the risk prioritization initiative demonstration pilots. The staff presents four policy options and recommends the Commission approve option 2 and a pilot for option 3.

Option 2 has two elements. The first part proposes to augment current regulatory processes by allowing licensees to use a risk-informed prioritization method as the basis to request schedule changes for initial compliance and implementation dates for regulations and orders. I agree with the NRC staff that this approach "would facilitate the submittal, review, and regulatory determination of schedule change submittals, using risk information as a basis." I approve proceeding with this element of option 2, provided that the staff takes the following steps. First, in determining whether to endorse the NEI risk prioritization guidance, the staff should ensure that the guidance results in an appropriate and consistent prioritization of security, emergency preparedness, radiation protection, and beyond design basis regulatory requirements. Second, consistent with the staff paper, any regulatory requirement that the Commission determines is necessary for adequate protection or corrective actions for findings, violations, and degraded or nonconforming conditions adverse to quality should not be subject to the guidance. Third, the staff should establish a predetermined backstop with a firm implementation deadline to prevent the indefinite deferral of regulatory requirements. The staff should evaluate the length of the backstop and whether it should be the same for all regulatory requirements or commensurate with the risk significance of the regulatory requirement at issue. Fourth, this approach should not be extended to the initial licensee responses for generic letters, which already reflect recent process enhancements, or bulletins, which communicate an urgent NRC safety, environmental, or security concern.

The second element of option 2 proposes that the NRC staff pilot an internal expert panel consisting of senior managers and subject matter experts to consider proposed rules, orders, and generic communications across the operating reactor business line early in the development stages and make recommendations to prioritize, schedule, or eliminate the proposed regulatory actions. This concept is somewhat amorphous, and it is not clear why it is necessary or how it would differ from existing processes and committees. Additionally, authorizing such an expert panel to potentially repeatedly or indefinitely defer the development or implementation of a regulatory requirement approved by the Commission would represent a significant delegation of authority from the Commission to the staff. Therefore, I disapprove the second element of option 2.

Under option 3, licensees could submit, during the comment period of a proposed regulation, a proposed plant-specific implementation schedule (based on the risk prioritization initiative guidance) to be incorporated into the text of the final regulation. This option also contemplates incorporating the key attributes of NRC guidance on plant-specific schedule relief into the language of each NRC rule. Although I appreciate the staff's effort to expand opportunities for public comment on plant-specific implementation deadlines, I disapprove option 3. Many NRC rulemakings already take several years to complete. This proposal has the potential to significantly slow down important rulemakings by requiring the staff to address up to 99 proposed plant-specific implementation schedules for each regulatory requirement and the potentially voluminous public comments that these proposed schedules could generate. Moreover, at the proposed rule stage, licensees will not know the specifics of the ultimate

regulatory requirement, which likely would make it difficult to develop accurate plant-specific implementation schedules. This could result in licensees seeking exemptions to the implementation schedules incorporated in the final rule, which would eliminate any benefits of this initiative. In addition, this process raises transparency concerns. Because the agency would not be presenting its view on plant-specific implementation schedules in the proposed rule that is issued for public comment, the final rule would be the first time the public would be presented with the agency's thinking on this key aspect of the regulatory requirement. Furthermore, the NRC staff acknowledges that this approach could pose unnecessary challenges and resource disruptions for the agency's inspections and enforcement actions.

Option 4 proposes to initiate a risk prioritization initiative rulemaking to allow operating power reactor licensees to make site-specific schedule changes to the initial compliance date for regulatory requirements on their own without requesting an exemption from NRC. I agree with the NRC staff that option 4 should not be approved. Industry representatives have stated explicitly that they are not pursuing development of the probabilistic risk assessment capabilities that were the original predicate for this approach. More fundamentally, I do not support empowering licensees to defer implementation of Commission-established regulatory requirements without agency approval. The case has not been made for such a profound change in the roles of the regulator and regulated entities.