

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:

a)

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

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.

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."