POLICY ISSUE
(Notation Vote)

September 14, 2010 SECY-10-0121

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: MODIFYING THE RISK-INFORMED REGULATORY GUIDANCE FOR NEW REACTORS

PURPOSE:

Since the U.S. Nuclear Regulatory Commission (NRC) published its probabilistic risk assessment (PRA) policy statement in 1995, the NRC staff has developed or endorsed many guidance documents to support risk-informed changes to the licensing basis and the Reactor Oversight Process (ROP). The purpose of this paper is to request Commission approval of the staff's recommendation to modify the risk-informed regulatory guidance to (1) recognize the lower risk profiles of new reactors[1] and (2) prevent a significant decrease in the enhanced levels of safety provided by new reactors.

SUMMARY:

In early 2009, the staff provided the Commission with a memorandum and white paper that identified potential issues with applying the current guidance for risk-informed changes to the licensing basis (including operational programs such as risk-managed technical specifications) and the ROP to new reactors with lower risk estimates. In the memorandum, the staff informed the Commission about the staff's intent to engage external stakeholders in the development of potential options to modify risk-informed regulatory guidance for new reactors.

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[1] For the purpose of this paper, the term "new reactor" refers to large light-water reactors (LWRs) that have been certified or are under review as standard designs by the NRC.

This paper defines several options for consideration by the Commission. The NRC staff recommends an option in which the NRC staff, together with stakeholders, identifies appropriate changes to the existing risk-informed guidance for changes to the licensing basis, including operational programs, and to the ROP.

BACKGROUND:

For both operating and new reactors, regulatory interactions in the areas of licensing and oversight rely upon a number of regulatory processes and guidance, some of which are risk-informed. The current framework that supports risk-informed regulation for reactors consists of guidance that can be grouped into four major categories:

(1) *Guidance for changes to a licensee's approved licensing basis without prior NRC approval.* In this category, the NRC's endorsement of Nuclear Energy Institute (NEI) 96-07, "Guidelines for 10 CFR 50.59 Evaluations," in Regulatory Guide (RG) 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," supports implementation of Title 10 of the *Code of Federal Regulations* (10 CFR) 50.59, "Changes, Tests and Experiments."

(2) *Risk-informed guidance to support changes to a licensee's approved licensing basis, including operational programs, with prior NRC approval.* In this category, RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," and associated guidance (e.g., RG 1.177, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications") provide a risk-informed integrated decisionmaking framework.

(3) *Guidance to support implementation of risk-informed regulations.* In this category, NRC endorsement of Nuclear Management and Resources Council 93-01, "Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," in RG 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," and RG 1.182, "Assessing and Managing Risk Before Maintenance Activities at Nuclear Power Plants," supports implementation of the Maintenance Rule (10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants").

(4) *Guidance to support implementation of the ROP.* Management Directive (MD) 8.13, "Reactor Oversight Process," dated June 19, 2002, documents the staff's oversight process under the ROP. The NRC Inspection Manual describes the implementation of specific aspects of the ROP.

Given Commission guidance on its expectations about enhanced safety for new reactor designs, implementing the above guidance when reviewing applications under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," presents several challenges. In its policy statement, "Severe Reactor Accidents Regarding Future Designs and Existing Plants," dated August 8, 1985 (50 *Federal Register* (FR) 32138), the Commission stated that it "fully expects that vendors engaged in designing new standard (or custom) plants will achieve a higher standard of severe-accident safety performance than their prior designs." The policy statement, "Regulation of Advanced Nuclear Power Plants," dated July 8, 1986 (and restated July 12, 1994; 59 FR 35461), further states that "the Commission expects that advanced

reactors will provide enhanced margins of safety and/or utilize simplified, inherent, passive, or other innovative means to accomplish their safety functions." This policy is effectively implemented by design certifications, which codify in rules the severe-accident enhancements in the new reactor designs, and by environmental reviews, which consider severe-accident mitigation design alternatives based on the lower risk profile estimates of the new reactor design.

In the staff requirements memorandum dated February 15, 1991, for SECY-90-377, "Requirements for Design Certification under 10 CFR Part 52," dated November 8, 1990, the Commission approved a process similar to that in 10 CFR 50.59 for making changes to Tier 2 information between issuance of a combined license (COL) and authorization for operation. The Commission stated that "the staff should ensure that this process requires preservation of the severe accident, human factors, and operating experience insights that are part of the certified design." Under 10 CFR Part 52, the process for changes to and departures from each certified reactor design appears in Section VIII of the appendix that contains its design certification rule.

Further, the Statement of Considerations of the standard design certification for the Advanced Boiling Water Reactor (ABWR) design (62 FR 25800, 25810; May 12, 1997) highlights the Commission's position on the change process as it relates to the PRA and severe accidents:

> The Commission recognizes that the ABWR design not only meets the Commission's safety goals for internal events, but also offers a substantial overall enhancement in safety as compared, generally, with current generation of operating power reactors. The Commission recognizes that the safety enhancement is the result of many elements of the design, and that much but not all of it is reflected in the results of the probabilistic risk assessment (PRA) performed and documented for them. In adopting a rule that the safety enhancement should not be eroded significantly by exemption requests, the Commission recognizes and expects that this will require both careful analysis and sound judgment, especially considering uncertainties in the PRA and the lack of a precise, quantified definition of the enhancement which would be used as the standard.

The Statement of Considerations also includes the following Commission statement:

> The Commission on its part also has a reasonable expectation that vendors and utilities will cooperate with the Commission in assuring that the level of enhanced safety believed to be achieved with this design will be reasonably maintained for the period of the certification (including renewal). This expectation that industry will cooperate with NRC in maintaining the safety level of the certified designs applies to design changes suggested by new information, to renewals, and to changes under section VIII.B.5 of the final rule. If this reasonable expectation is not realized, the Commission would carefully review the underlying reasons and, if the circumstances were sufficiently persuasive, consider the need to reexamine the backfitting and renewal standards in Part 52 and the criteria for Tier 2 changes under section VIII.B.5.

On February 12, 2009, the staff provided the Commission a memorandum with an enclosed white paper, "White Paper on Options for Risk Metrics for New Reactors" (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML090150636 and ML090160004, respectively) (Enclosure 1) that identified potential issues with applying the current guidance for risk-informed changes to the licensing basis (including operational programs such as risk-managed technical specifications) and the ROP to new reactors with lower risk estimates. In the memorandum, the staff informed the Commission about the staff's intent to engage external stakeholders in the development of potential options. As discussed below, the staff held many dialogues with external stakeholders on the issues raised in the 2009 white paper.

DISCUSSION:

With the implementation of an enhanced level of severe-accident prevention and mitigation design capability being confirmed through the review of applications for design certification for new LWRs, the staff is identifying potential issues that may arise with the transition to operations and the use of the existing risk-informed framework. Although RG 1.174 and the current ROP have no specific provisions precluding their application to new reactor designs, the NRC experience with implementing both RG 1.174 and the ROP has only involved currently operating plants. As discussed in the 2009 white paper, the staff identified a number of potential issues posed by the lower risk estimates of new reactors using the current risk-informed guidance that could potentially allow for a significant erosion of the enhanced safety of new reactors as originally licensed. As a result, the staff is considering whether changes to RG 1.174 and the ROP are needed in light of the differing risk profiles and the 10 CFR Part 52 process (e.g., design certification rulemaking on enhanced severe-accident features per Section VIII.B.5 discussed above). The staff is currently reviewing one application for risk-informed technical specifications initiatives 4b and 5b (on completion times and surveillance test intervals, respectively) as part of the U.S. Advanced Pressurized-Water Reactor design certification. In addition, other industry representatives have expressed interest in pursuing risk-informed inservice inspection of piping for new reactors, and the staff expects additional risk-informed applications for new reactors in the future.

Risk-Informed Changes to the Licensing Basis and Operational Programs

RG 1.174 provides an approach for using PRA in risk-informed decisions on plant-specific changes to the licensing basis for current reactors. This guide provides the basis for many other risk-informed programs (e.g., risk-informed inservice testing, risk-informed inservice inspection of piping, and risk-managed technical specifications).

RG 1.174 describes five principles for making risk-informed decisions. Specifically, the proposed change should be shown to do the following:

- Meet current regulations, unless the change is explicitly related to a requested exemption.
- Be consistent with the defense-in-depth philosophy.
- Maintain sufficient safety margins.

- Result in an increase in core damage frequency (CDF) or risk that is small and consistent with the intent of the Commission's safety goal policy statement.

- Include monitoring that uses performance measurement strategies.

Figures 3 and 4 of RG 1.174 provide acceptance guidelines for what constitutes "small changes" in both CDF (ΔCDF) and large early release frequency (ΔLERF). In RG 1.174, the acceptance guidelines for "small" and "very small" are defined relative to the Commission's safety goal policy statement and not to the specific plant's risk profile. For most new LWRs, which have baseline CDF estimates at or substantially below 10^{-6} per year, a ΔCDF of 10^{-6} or even 10^{-7} would not constitute a "small change" on a relative basis to the plant's risk profile. A change that is considered a "small increase" for current reactors under RG 1.174 may not have the same ramifications when applied to new reactors. Furthermore, RG 1.174 does not explicitly consider the impact of changes on the enhanced severe-accident safety features included in new reactor designs, which could result in the increased levels of safety achieved by these enhanced features being significantly reduced during operations unless specific guidance is developed to maintain these enhanced levels. RG 1.174 also does not address whether changes in large release frequency, which is used in new reactor licensing, should be considered when evaluating "small changes."

In addition, a number of important operational programs also have close ties to the current risk-informed regulatory framework. The extent to which these operational programs rely on quantitative risk metric guidelines varies. In risk-informed technical specifications initiative 4b, the derived completion times have a relationship to the PRA results, although they contain deterministic backstops consistent with the PRA policy statement that the PRA should complement the traditional deterministic approach and not replace it. In other cases, the analysis may be less quantitative and more qualitative in nature. For example, under 10 CFR 50.65(a)(4), the licensee "shall assess and manage the increase in risk that may result from the proposed maintenance activities" before performing the maintenance. The maintenance risk can be assessed using risk insights that are qualitative or quantitative in nature. Here again, the question of what constitute "small changes" in CDF and risk when applied to new reactors for these and other operational programs needs to be addressed. Without changes to the guidance documents for risk-informed changes to the licensing basis and operational programs, the Commission's expectations for new plants may not be met.

Reactor Oversight Process

The regulatory framework for reactor oversight is a risk-informed, tiered approach to overseeing plant safety. The framework has three key strategic performance areas: reactor safety, radiation safety, and security. Each strategic performance area has cornerstones that reflect the essential safety aspects of facility operation. Satisfactory licensee performance of the cornerstones provides reasonable assurance of safe facility operation and that the NRC's safety mission is being accomplished. Within this framework, the ROP provides a means of collecting information about licensee performance, assessing the information for its safety significance, responding to degraded licensee performance, and ensuring that licensees take appropriate corrective actions. Because there are many aspects of facility operation and maintenance, the NRC inspects licensee programs and processes on a risk-informed sampling basis to obtain representative information.

With regard to setting numerical thresholds, SECY-99-007, "Recommendations for Reactor Oversight Process Improvements," dated January 8, 1999, discusses a close link to RG 1.174:

> The concept for setting performance thresholds includes consideration of risk and regulatory response to different levels of licensee performance. The approach is intended to be consistent with other NRC risk-informed regulatory applications and policies as well as consistent with regulatory requirements and limits…(2) the thresholds should be risk informed to the extent practical, but should accommodate defense in depth and indications based on existing regulatory requirements and safety analyses; (3) the risk implications and regulatory actions associated with each performance band and associated threshold should be consistent with other NRC risk applications, and based on existing criteria where possible (e.g., Regulatory Guide 1.174).

Additionally, consistent with the principles of RG 1.174, SECY-99-007 provides the framework for meeting cornerstone objectives with minimal reduction in safety margin.

The ROP is designed to respond to declining performance, utilizing risk insights and other factors to focus inspections and regulatory response. Because the ROP is *risk-informed,* thresholds for regulatory engagement are largely based on quantification of ΔCDF and ΔLERF. And since a new reactor generally has a lower risk profile than currently operating reactors, applying the same thresholds used for the current reactors to licensee safety performance at a new reactor site could allow more significant *relative* degradation in performance before NRC engagement would be invoked by the ROP.

One of the staff's concerns is that the existing ROP may not provide for meaningful regulatory oversight for new reactors that can support the NRC's regulatory actions and inspection as performance declines. The current risk-informed baseline inspection program and risk-informed thresholds for performance indicators may not trigger a regulatory response before significant erosion occurs to the enhanced defense in depth and safety margins of the plant.

Interactions with Stakeholders

The staff developed an initial set of possible options for risk metrics for new reactors in early 2009. Through subsequent public meetings, the staff engaged stakeholders, including the Advisory Committee on Reactor Safeguards (ACRS), to further assess these options. Industry representatives expressed the opinion that new and currently operating reactors should be treated the same with respect to risk-informed changes to the licensing basis and the ROP (i.e., status quo). NEI issued its own white paper (Enclosure 2) describing why it believes that the current metrics are technically justified and appropriate for all plants, based on reasonable assurance of public health and safety, including operation at a prudent margin above adequate protection. A Union of Concerned Scientists representative expressed the opinion that it was premature to consider any options so far in advance of reactor construction and operation. The representative further stated that, although new reactors appear to be safer than the currently operating fleet, the public should get the benefit of this safety through the implementation of more stringent acceptance guidelines for licensing and thresholds in the ROP. Finally, the staff discussed the options presented in this paper with ACRS at a June 10, 2010, full committee meeting. In a letter to the Commission dated July 27, 2010 (ADAMS Accession

No. ML102000422) (Enclosure 3), ACRS agreed with the staff's position on the proposed framework as described in Option 2. The staff reviewed the ACRS letter and responded on August 25, 2010 (ADAMS Accession No. ML102210553) (Enclosure 4).

Options for Modifying the Risk-Informed Regulatory Guidance

The staff is requesting Commission direction before the staff implements new guidance, if any, for the review of a number of industry-proposed risk-informed initiatives for new reactors. The staff believes that potential policy issues associated with the ROP for new reactors should be addressed at this time because of the link to RG 1.174 and the goal to maintain consistency with other risk applications. Specifically, the staff is requesting Commission direction on its expectations for enhanced severe-accident safety performance for new reactors. This direction will determine the staff's approach to risk-informed changes to the licensing basis that could be viewed as voluntary changes to the design or operational programs (e.g., risk-managed technical specifications and risk-informed inservice inspection of piping), as well as to the risk-informed elements of the ROP for new reactors.

Option 1: No changes to the existing risk-informed guidance for the ROP and for changes to the licensing basis, or status quo.

Under this option, the staff would continue to use the existing risk-informed framework for licensing changes and the ROP. This option could provide incentives to build reactors with enhanced severe-accident safety features; applicants and licensees who invest in and maintain additional safety features would have more flexibility to operate the plants with a reduction in regulatory interactions. However, Option 1 may not meet Commission expectations because it may not prevent significant decrease in enhanced safety through changes to the licensing basis and plant operations over plant life. In addition, Option 1 may not provide for meaningful regulatory oversight that supports the NRC's regulatory actions and inspection.

Option 2: Identify and implement appropriate changes to the existing risk-informed guidance.

Under this option, the staff would continue to work with stakeholders to (1) identify specific changes to the guidance for risk-informed licensing-basis changes that would prevent a significant decrease in the new reactor's level of safety over its life and (2) identify specific changes to the risk-informed guidance for the ROP to provide for meaningful regulatory oversight. This option would support the Commission's expectations for new plants. The implementation details would differ for changes to the guidance for risk-informing the licensing basis and changes to the ROP because of the differences in the scope of NRC and industry documents that would be affected and the general time frames for implementation of each process, as discussed below.

For changes to the licensing basis and operational programs, the staff would modify the risk-informed guidance to prevent a significant decrease in the level of safety provided by certified designs. Implementation of this option will support the Commission's expectation about the maintenance of the level of severe-accident safety performance of new designs. The staff would supplement the CDF and LERF acceptance guidelines to recognize the lower risk profiles

of new reactors, including revisiting the definition of "small" change when implementing RG 1.174. Specifically, the staff would do the following:

- Use stakeholder involvement in the evaluation and development of detailed changes to risk-informed regulatory guidance.

- Evaluate the merits of developing additional criteria (e.g., deterministic, defense in depth) to support the change process.

- Evaluate proposed changes to guidance to ensure that the changes do not create unintended consequences, such as creating disincentives for safer designs or allowing degradation of passive safety system performance. This would include developing guidance to implement Section VIII.B.5.c of the design certification rules.

For oversight, the staff would identify appropriate changes to the risk-informed elements of the ROP. These changes would reflect the enhanced level of severe-accident safety performance of new reactors while providing for meaningful regulatory oversight that supports the NRC's regulatory actions and inspection, recognizing that the staff will continue to independently assess licensee performance in the area of safety culture, which addresses common underlying factors that affect plant safety. Specifically, the staff would do the following:

- Use stakeholder involvement in the evaluation and development of changes to the guidance.

- Evaluate the criteria for plant placement in the action matrix to assess whether or not the current process would ensure that operational performance resulting in significant reductions in the level of safety provided by the certified design is fully understood by the licensee and the NRC and is effectively corrected.

- Evaluate the merits of developing additional criteria (e.g., deterministic, change in risk) to support the NRC's response to findings and performance trends.

- Evaluate any potential ROP changes to avoid unintended consequences, such as creating disincentives for safer designs, allowing degradation of passive safety system performance, or diverting the attention of NRC inspectors from issues of higher safety significance in currently operating reactors.

- Consider the need to risk-weigh or otherwise weigh findings associated with passive systems to reflect the difficulty of recognizing the degradation of passive systems.

- Evaluate maintaining or changing the current thresholds for green, white, yellow, and red risk-significant findings and performance indicators, given that low-risk designs may rarely, if ever, cross the current white threshold.

- Consider the advantages and disadvantages of applying any potential changes to the ROP to currently operating reactors.

A key advantage of Option 2 is that it would reaffirm the Commission's expectation of enhanced severe-accident safety performance for new reactors and the expectation that this level of enhanced safety will be reasonably maintained throughout plant life. The option addresses both plant design and operations, including licensing basis changes, operational programs, and oversight. Furthermore, Option 2 acknowledges that there are safety-margin and defense-in-depth considerations beyond the quantitative risk-informed thresholds. However, a disadvantage of Option 2 is the short time available to revise the guidance needed to support the staff's review of a number of risk-informed initiatives expected to be proposed by design certification and COL applicants, including risk-informed technical specifications initiatives 4b and 5b. Further, some stakeholders may view any change to thresholds that might be considered under Option 2 to be inconsistent with the underlying technical basis for the current thresholds that are derived from the Commission's safety goals and implemented in RG 1.174.

In addition to revising RG 1.174, Option 2 would necessitate changes to associated guidance for specific risk-informed applications. Changes to the ROP, including MD 8.13 and some Inspection Manual Chapters, would be necessary. Several industry documents endorsed by the staff may also be affected.

Option 3: Modify the risk-informed guidance to include a new risk metric for the ROP and changes to the licensing basis.

Under this option, acceptance guidelines for risk-informed changes to the licensing basis and/or numerical thresholds in the ROP would be lowered. Like Option 2, this option would reaffirm the Commission's expectation of enhanced severe-accident safety performance for new reactors and the expectation that this level of enhanced safety will be maintained throughout plant life. However, some internal and external stakeholders have indicated that this option goes beyond the Commission's expectation by essentially requiring that new reactors be measured against more stringent risk guidelines. Thus, they believe this option may be inconsistent with the NRC response to the comment by the North Carolina Waste Awareness and Reduction Network on the Commission's "Policy Statement on the Regulation of Advanced Reactors," dated October 14, 2008 (73 FR 60612) that advanced reactors need to be made safer, more robust and effective. The NRC's response says that the "policy statement does not state that advanced reactor designs must be safer than the current generation of reactors."

Option 3 would thus create a risk-informed framework that is, in effect, inconsistent with the underlying technical basis for the current thresholds that are derived from the Commission's safety goals and implemented in RG 1.174. This option may also have unintended consequences in that new reactors with enhanced safety features would have less operational flexibility than the current fleet of reactors; applicants who invest in additional safety features expect more flexibility to operate the plants with a reduction in regulatory interactions.

Option 3 would require major revision to RG 1.174 and associated guidance for specific risk-informed applications. Significant changes to ROP-related documents also would be necessary. Many industry documents endorsed by the staff would be affected.

RECOMMENDATION:

The staff recommends Option 2. The staff believes that Option 2 meets the Commission's expectation that there is "no significant decrease in the level of safety" over the life of the new reactor design. This option also creates a regulatory environment that encourages the design of new reactors with higher levels of severe-accident safety performance, including greater redundancy of safety systems, which may allow for greater operational flexibility. Stakeholder involvement in the development of the new guidance for changes to the licensing basis and in the identification of potential changes to the risk-informed elements of the ROP is a key feature of this option. If directed by the Commission to implement Option 2, the staff would keep the Commission apprised of progress in the development of such guidance.

RESOURCES:

Option 1 (no changes) would require no additional resources to carry out.

Option 2 (identify and implement appropriate changes to existing guidance) would require staff resources to engage stakeholders, evaluate proposed changes, and draft any needed updates to guidance documents. Based on recent experience with the development of risk-informed regulatory guidance, this effort is estimated to require no more than 1.0 full-time equivalent during fiscal year 2011. Although this activity is not specifically included in the fiscal year 2011 budget, resources for licensing support are available within the new reactors business line to complete this work.

Option 3 (modify guidance to include new risk metric) would require additional staff resources beyond those currently budgeted, depending on the extent of the changes needed to the guidance documents. Because the scope of these revisions is not yet known, resource estimates would be developed following stakeholder interaction, and appropriate adjustments would be made through the planning, budgeting, and performance management process.

COORDINATION:

This paper has been coordinated with the Office of the General Counsel, which has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. A copy of this paper in draft form was provided to ACRS on May 12, 2010. The staff discussed the options presented in this paper with ACRS at a June 10, 2010, full committee meeting.

/RA/

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Enclosures:
1. Memorandum to Commission and
   White Paper
2. NEI Letter - Transmission of Industry White Paper
3. ACRS Letter - Risk-Informed Regulatory Guidance
   for New Reactors
4. Letter to Dr. Said Abdel-Khalik, ACRS

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