

MODIFYING THE RISK-INFORMED REGULATORY GUIDANCE FOR NEW REACTORS

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ABSTRACT

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). In September, 2010, the staff requested Commission approval of the staff's recommendation to modify the risk-informed regulatory guidance to (1) recognize the lower risk profiles of new, large light-water reactors (LWRs) and (2) prevent a significant decrease in the enhanced levels of safety provided by these new reactors.

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 Regulatory Guide (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 a 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 of appendices for each certified design). A number of industry representatives have expressed interest in pursuing risk-managed technical specifications and risk-informed inservice inspection of piping for new reactors, and the staff expects additional risk-informed applications for new reactors in the future.

Key Words: NRC, risk-informed regulation, changes to severe accident design features

1 INTRODUCTION

New reactors are expected to be exhibit higher levels of safety performance than the current fleet of operating reactors. One way to quantify this enhanced level of safety is through risk metrics such as core damage frequency (CDF) and large early release frequency (LERF). These two metrics are often used as surrogates for latent and early fatality risks, respectively, from the Commission's quantitative health objectives (QHOs) in the Safety Goal Policy Statement [1]. The use of these metrics to guide regulatory interactions in licensing and oversight has become increasingly widespread. Because CDF and LERF estimates for new reactors are typically one or more orders of magnitude lower than those of the current fleet,

questions have arisen as to the acceptability of the numeric thresholds associated with several categories of risk-informed activities. These categories, broadly stated, are:

- (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's¹ oversight process under the ROP. The NRC Inspection Manual describes the implementation of specific aspects of the ROP.

In the past, the Commission made several statements that provide insight into its expectations regarding the resolution of this issue. In its 1985 policy statement, "Severe Reactor Accidents Regarding Future Designs and Existing Plants," 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 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."

The Commission has also stated that changes to new reactors should consider the impact on severe accident performance and should maintain the enhanced level of safety that is believed to have been achieved by the new designs. For example, the Commission has approved a

¹ In this paper, the term "staff" refers to the NRC technical staff.

process similar to that in 10 CFR 50.59 for making changes to Tier 2² 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.” [2]

Furthermore, when the Commission approved the Advanced Boiling Water Reactor (ABWR) standard design certification, the Commission stated its 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 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. [2]

In 2009, the staff provided the Commission a memorandum with a 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 [3]. Specifically, the staff raised concerns that the application of the current risk-informed guidance might not ensure that the aforementioned Commission expectations would be met.

In October 2010, the staff presented SECY-10-0121³ to the Commission, which expanded upon the 2009 white paper and identified several options for resolution of this issue [4]. Following receipt of the SECY, the Commission held a public meeting to discuss this issue and

² Tier 2 information refers to those aspects of a certified reactor design that can be changed without NRC approval, provided that certain criteria are met.

³ A Commission paper or “SECY” is a written paper the staff submits to the Commission to inform them about policy, rulemaking, and adjudicatory matters.

to solicit feedback from external stakeholders such as NEI and the Union of Concerned Scientists. This paper provides a look at the current status of this issue and highlights some of the key challenges that the staff and external stakeholders are working on.

2 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 has identified 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 questioned 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-managed 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. This information was presented to the Commission in SECY-10-0121 [4].

2.1 Risk-Informed Changes to the Licensing Basis and Operational Programs

2.1.1 RG 1.174

RG 1.174 provides an approach for using PRA in risk-informed decisions on plant-specific changes to the licensing basis for current reactors [5]. 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). Many of these programs explicitly state that their numeric thresholds are based directly on RG 1.174.

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 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 (Δ CDF) and large early release frequency (Δ LERF). 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 Δ CDF 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.”

2.1.2 Changes to ex-vessel severe accident features

New reactors are designed with a number of features to prevent and mitigate ex-vessel severe accidents. These design features (e.g., corium spreading equipment) are described in the design control document of each certified design. Some aspects of these design features can be changed without prior NRC approval, provided that the change does not lead to a “substantial increase” in either the probability or consequences of an ex-vessel severe accident. The staff noted a parallel between the definition of “substantial” as it related to ex-vessel severe accidents and “small” as defined in RG 1.174. In both cases, the question of an absolute versus relative definition arises. The staff met with industry representatives in December 2010 to explore this issue. The participants discussed potential definitions of what might constitute a “substantial increase” in probability and public consequences of ex-vessel severe accidents. Qualitative and quantitative definitions were considered. For “substantial increase” in probability, one possible definition that was considered was along the lines of the rule language for the ABWR design certification in Part 52, i.e., “A particular ex-vessel severe accident previously reviewed and determined to be not credible could become credible.”

The design control documents (DCDs) or supporting topical reports on severe accidents provide the source of evaluations on which design features have rendered potential severe accident containment challenges as *not credible*, although the staff emphasized that these discussions in the DCDs were not centrally located, and that often the terms *practically eliminated*, *not physically feasible*, and *not relevant* may have been used in lieu of *not credible*. Both the staff and industry representatives agreed that it would be advantageous if each design center working group created a comprehensive list or table of these ex-vessel design features and the technical basis (quantitative and/or qualitative) for concluding why certain containment challenges from

severe accidents are deemed not credible. This would assist COL holders in determining which changes would require NRC approval.

For increases in public consequences, workshop participants discussed the possibility of using surrogate measures for “public consequences” such as containment failure probability or frequency and fission product release fractions as opposed to offsite dose calculations. Dose calculations require a level-3 PRA, which is not required by the regulations for new reactors. A combination of qualitative and quantitative criteria for what constituted a “substantial increase” in public consequences seemed to be advantageous, for example:

- Remove or significantly degrade an ex-vessel severe accident mitigation design feature
- A combination of relative increase (e.g., order of magnitude) and contribution of the change to total containment failure probability or release fraction

Both the NRC staff and industry participants agreed that additional dialogue and tabletop exercises will likely be needed to ensure progress on this issue.

2.1.3 Other programmatic areas with ties to RG 1.174

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-managed 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 [6]. 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 may need to be addressed.

2.2 Reactor Oversight Process

The ROP provides a risk-informed, tiered approach framework for 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 in each 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 discusses a close link to RG 1.174 [7].

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).

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 Δ CDF and Δ LERF. And since a new reactor generally has a lower risk profile than currently operating reactors, the staff has questioned whether 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.

In summary, one of the staff's concerns is whether the existing ROP would provide for meaningful regulatory oversight for new reactors that can support the NRC's regulatory actions and inspection if performance declines.

2.3 Development of Options for Modifying the Risk-Informed Regulatory Guidance

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 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 [8]. 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 2010 full committee meeting. In a letter to the Commission, ACRS agreed with the staff's position on the proposed framework as described in Option 2 [9].

In SECY-10-0121, the staff requested Commission direction on whether new guidance, if any, should be issued for the risk-informed programmatic areas discussed above. The staff stated that potential policy issues associated with the ROP and RG 1.174 should be linked so as to maintain consistency with other risk applications. In SECY-10-0121, the staff also requested 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.

SECY-10-0121 identified three options for resolution of this issue:

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 would 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 public comment 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.

3 CONCLUSIONS

The staff recommended Option 2 based on their position that Option 2 would meet the Commission's expectation of "no significant decrease in the level of safety" over the life of the new reactor design. The staff also felt that this option would also create 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. At the deadline for submission of this paper, the Commission had not yet reached a decision on this matter.

4 ACKNOWLEDGMENTS

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