Expansion and Use of Risk-Informed Process for Evaluations

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Abstract: The Risk-Informed Process of Evaluations (RIPE) can be used to defer or eliminate compliance issues that have a minimal safety impact using existing regulations. The Nuclear Regulatory Commission (NRC) approved this initiative that utilizes licensee's previously approved risk-informed initiatives to inform licensing actions in January 2021. The initiative leverages current regulations and uses risk information to identify low safety significant issues that US licensees can use to submit plant-specific regulatory actions. These issues would support a streamlined review by the NRC using existing programs and processes that are consistent with Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-specific Changes to the Licensing Basis" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML100910006). The NRC expanded the use of RIPE to include other risk-informed initiatives and to allow for technical specification changes. In addition, the first application using the RIPE process was submitted involving the diverse feedwater actuation requirement in 10 Code of Federal Regulations 50.62, "Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants." This paper will discuss the expansion of RIPE and the first use of the initiative and lessons-learned from that submittal.

1. INTRODUCTION

In January 2021, the NRC approved the Risk-Informed Process for Evaluations via memorandum [1], which allowed licensees to utilize the NRC "Guidelines for Characterizing the Safety Impact of Issues" [2] and developed internal draft guidance [3] on how NRC staff would process a RIPE submittal. RIPE is available to licensees that have a robust probabilistic risk assessment (PRA) and a robust integrated decisionmaking panel (IDP) demonstrated by a reviewed and approved Technical Specification Task Force (TSTF) Traveler 505 "Risk Initiative 4b - Risk Informed Completion Times" application [4] and a robust IDP, as demonstrated by an approved 10 CFR 50.69 "Risk-informed Categorization and Treatment of Systems, Structures and Components of Nuclear Power Plants" application [5] or equivalent. The licensees can use the safety impact categorization process to determine if the issue has a minimal safety impact and thus is of very low safety significance. As part of those deliberations, the licensee's IDP would evaluate any risk management actions that would be appropriate and commensurate with the risk significance of the issue. The licensee would also track the cumulative impact of the requested licensing action, consistent with RG 1.174 [6]. Once the IDP is completed with their evaluation, the licensee would document their results and use those results as supporting documentation for their licensing request. The NRC would then review the licensee's application using a streamlined process that confirms the low safety significance of the issue and either approve or deny the request.

Recognizing the benefits of the RIPE process, NRC staff continue to work with industry, to identify further ways to expand the process to include more licensees and more license amendments. In addition, the first-of-a-kind application using the RIPE process was submitted to the NRC in January 2022 for review, involving the diverse feedwater actuation requirement in 10 Code of Federal Regulations 50.62, "Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants," also known as the ATWS rule [7]. The RIPE exemption request was reviewed and approved by the NRC in March 2022. From that review, several lessons-learned were gleaned that will be shared in this paper.

2. BACKGROUND

2.1. Expansion

After approving the RIPE process in January 2021, NRC staff began to work with industry to determine if there were ways to expand the process to allow more licensees to be able to utilize the streamlined review. In early 2022, only 27 units out of the 93 units in operation had a reviewed and approved TSTF-505 program or 10 CFR 50.69. Therefore, licensees who had not adopted these initiatives were unable to benefit from the RIPE process. However, all US operating units had a reviewed and approved TSTF-425 "Relocate Surveillance Frequencies to Licensee Control-RITSTF Initiative 5b" [8]. Consequently, industry requested NRC to revisit the threshold that had been established to define the degree of PRA robustness required to support RIPE. Allowing licensees who have adopted TSTF-425 would enable more licensees to leverage that risk-informed initiative and be able to use the NRC "Guidelines for Characterizing the Safety Impact of Issues" to characterize the safety impact of an issue. Section 3.1 of this paper discusses some adjustments that needed to be made to account for the differences in scope of the two initiatives.

The RIPE process approved in January 2021 had excluded its use to license amendments that request NRC's approval for changes to technical specifications. However, based on additional discussions with staff and industry, it became apparent that some requests that were submitted to the NRC staff for exemptions or license amendments that could be very low safety significant could also include a change to the technical specifications. For example, a licensee requesting an exemption from the regulations for a system, structure, or component (SSC), may also need to apply for a license amendment, if that SSC has applicable technical specifications. Thus, by allowing technical specifications changes, a licensee could apply for both the exemption and license amendment under RIPE, using one regulatory action, which would result in time and resource savings, thus allowing both the NRC and licensees to focus their resources and time on more safety significant issues. Both the expansion of RIPE to include TSTF-425 and technical specification changes are discussed in more detail in sections 3.1 and 3.2 of this paper.

2.2. First-of-a-Kind Application of RIPE

On March 23, 2022, the NRC successfully issued its first exemption using RIPE. The licensee submitted a request on January 14, 2022, for an exemption from 10 CFR 50.62(c)(1), to remove the diverse auxiliary feedwater actuation system from the licensing basis for all units. The ATWS rule includes the following three requirements in 50.62(c): (1) the diverse auxiliary feedwater actuation system (DAFAS), (2) diverse turbine trip, (3) diverse reactor scram system as well as the existing safety-related actuation of auxiliary feedwater and the reactor protection system reactor/turbine trip under the conditions of an ATWS. The RIPE submittal requested partial exemption for the diverse auxiliary feedwater actuation system requirement. The NRC staff completed its "no technical objection" (NTO) review on January 31, 2022, thereby accepting the exemption under the RIPE process. Consistent with the streamlined review process of RIPE for issues characterized as having a minimal safety impact, the NRC staff successfully completed its review and issued the staff approval of the RIPE request on March 23, 2022, and completed the review within the NRC staff's timeliness goal for RIPE submittals of 13 weeks. As part of the evaluation, the staff identified several lessons-learned from this first-of-a-kind review and identified and implemented best practices for future reviews of applications submitted under RIPE. Both those lessons-learned and best practices are discussed in more detail below.

3. EXPANSION OF RIPE

3.1. Expansion to Allow TSTF-425

During the development of the RIPE process, the NRC received feedback from industry suggesting that the NRC staff consider allowing licensees that have only adopted TSTF-425 (or Nuclear Energy

Institute (NEI) 04-10, "Risk-Informed Technical Specifications Initiative 5B, Risk-Informed Method for Control of Surveillance Frequencies" [9]), "Relocate Surveillance Frequencies to Licensee Control-RITSTF Initiative 5b," to be able to use RIPE. The staff's concern with this proposal was that staff had accepted PRAs with varying degrees of scope under TSTF-425 to approve changes to their license. Like TSTF-505, TSTF-425 is a broad scope licensing process that requires review of all applicable hazards and open facts and observations (F&Os). However, applications to adopt TSTF-425 reached a peak in industry adoption during a phase when licensees and staff practices relating to PRA acceptability were undergoing various changes. Therefore, staff were not confident that licensees PRAs under TSTF-425 would allow for the same efficiencies in RIPE as in TSTF-505 PRAs.

NEI and industry conducted several public meetings [10, 11] with the NRC staff to discuss a methodology for expanding RIPE to include licensees that have approved TSTF-425 applications. The interaction was principally aimed at addressing the NRC concerns regarding the technical acceptability of the TSTF-425 PRAs including issues such as unresolved F&Os and the lack of a consideration of external events PRA such as internal fires when they could influence the results associated with the application. Any new process would need to be structured and aligned with the RIPE attributes in terms of the PRA aspect of the process and determination of PRA acceptability. The new process would need to include a way to address open F&Os and to address any applicable external events. Staff and industry converged on a process where a licensee desiring to implement RIPE with a TSTF-425 PRA would need to have very few, or no, open F&Os which could be addressed using the industry's F&O closure process. Additionally, there would need to be a previously reviewed PRA for external events, or otherwise the very low safety significant issue would need to be shown to not be impacted by external events. Accordingly, following these meetings NRC's general feedback was that the industry proposal for including TSTF-425 within RIPE appeared reasonable and staff would review the NEI guidance that addressed the inclusion of TSTF-425.

On March 22, 2021, the NEI provided a draft of this guidance document in the form of draft NEI 21-01 "Industry Guidance to Support Implementation of NRC's Risk-Informed Process for Evaluations" [12] to the NRC staff for its consideration and feedback, which included much of the adjustments discussed above. The staff reviewed the NEI guidance and held several additional outreach sessions with internal stakeholders to discuss the expansion of RIPE and obtain feedback on those charges. These sessions also supported required revisions to the internal NRC staff guidance that is used to conduct the streamlined reviews submitted under RIPE. Based on its review and these sessions, the staff provided additional feedback to NEI on April 13, 2021 [13]. After these interactions, staff revised the process and completed the expansion of RIPE to include TSTF-425 and issued the final memorandum, which included the updated internal guidance and safety impact characterization guidance [14, 15, 16] in June 2021.

3.2. Inclusion of Technical Specification Changes

The initial NRC "Guidelines for Characterizing the Safety Impact of Issues" issued in January 2021 specifically excluded the allowance of technical specification changes under RIPE. NRC staff's initial rational was that any items included in the technical specification could not be of low safety significance. In addition, staff were concerned that expanding the scope of RIPE too quickly would hamper its initial issuance and delay its implementation. After discussing with staff internally and based on interactions with industry and other interested parties, it became apparent that there may be a subset of issues that could necessitate a change to the technical specifications and that could have a minimal safety impact. Staff proceeded to conduct several outreach sessions with the technical specifications branch to gather feedback and to identify an acceptable approach for issues involving technical specification license amendments using RIPE. Based on those interactions, the staff identified very minor changes to RIPE that could allow for a licensee to leverage the process. Most changes involved the internal staff guidance used to process RIPE submittals. The staff will be issuing updated guidance to expand RIPE to include technical specifications in June 2022.

Under RIPE initially, traditional engineering staff would be asked to only provide a NTO during the acceptance review phase of the RIPE review. The NTO was added to ensure technical staff did not identify any issues precluding the streamlined review. The issues of concerns would be any challenge to the safety impact characterization that would negate the minimal safety impact determination as it relates to defense-n-depth, safety margins, and performance monitoring. Once the submittal is accepted for review, a qualified reactor technical reviewer would conduct the final streamlined review. With the expansion of RIPE to include technical specifications, the technical specification branch staff would now be included in both the acceptance review and final streamlined review. This would ensure any issue related to technical specifications is reviewed by a qualified and experienced technical specification reviewer. The internal staff guidance was revised to include those changes and the inclusion of the technical specification reviewer. The final memorandum, which included the updated internal guidance and safety impact characterization guidance for technical specifications was issued in mid-2022 [17, 18, 19].

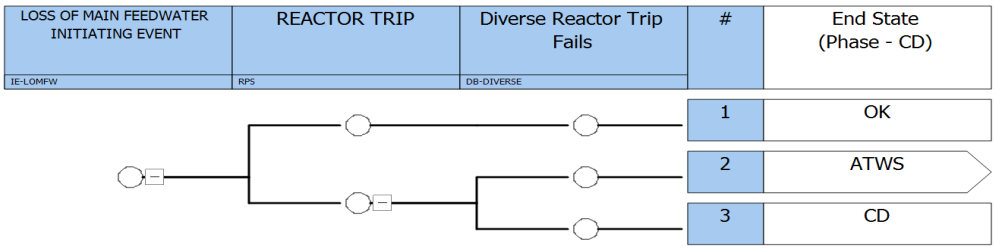
4. IMPLEMENTATION AND LESSONS-LEARNED

4.1. Implementation

The NRC staff became aware of the licensee's intent to submit an exemption using RIPE in the fall of 2021. The exemption requested partial exemption for the diverse auxiliary feedwater actuation system requirement of the ATWS rule. The staff conducted a presubmittal meeting in September 2021 to discuss the key aspects of the request and to ensure the issue fell within the scope of RIPE. In addition, staff conducted several internal alignment meetings to refresh staff's understanding of RIPE and the details of the internal RIPE guidance as it pertains to an actual review. Staff were also allowed to observe the deliberations of the IDP in October 2021 as it reviewed the issue to better understand the process and to become familiar with the robust nature of the IDP evaluation. From those interactions, staff requested a followup presubmittal meeting to ensure any key items discussed during the IDP were included in the exemption request the licensee was planning to submit in January 2022.

There were many discussions related to the risk significance of the proposed change discussed in the submittal and the level of defense-in-depth necessary to support the review and to ensure adequate defense-in-depth was maintained per RG 1.174. The exemption in question requested the diverse feedwater actuation system be retired in place. The licensee decided to request the exemption due to the unreliability of the system and lack of vendor support in maintenance and replacement parts due to obsolescence issues. The ATWS rule requires licensees to install a diverse system to actuate feedwater in the event of an ATWS to prevent steam generator dry out and over pressurization of the reactor. Using the Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE) software [20] and the plant-specific Standardized Plant Analysis Risk (SPAR) model, an analysis is performed to illustrate the risk significance of the issue. The current SPAR models do not model the diverse reactor trip system and only calculate the failure of the reactor protection system. Therefore, the existing model was modified to add the failure of the diverse reactor trip breakers. The analysis also used the loss of main feedwater initiating event, which would be the most limiting case for this exemption. A simplified event tree, Figure 1 below, was developed to calculate the risk significance. The sequence of interest is sequence 3, which models the loss of main feedwater, the failure of the reactor protection system, and the failure of the diverse reactor trip system. No further modeling was performed, and we assumed the sequence terminates at core damage. The resultant core damage frequency (CDF) for this scenario is approximately 1E-10 per year. This assumed no other mitigating actions such as emergency boratian or other actions that could mitigate the consequences of the accident but would not preclude core damage.

Figure 1: Simplified Loss of Main Feedwater Initiating Event Tree with ATWS



The above does not fully capture the issue related to the partial exemption of the diverse feedwater actuation system. If the diverse reactor trip system is successful, failure of the auxiliary feedwater system can also lead to core damage. Concerns were also raised that common-cause failures that could fail the reactor protection system could also fail the actuation of the auxiliary feedwater system. In the current SPAR models, no credit is given to diverse feedwater actuation. In modifying the fault trees for the auxiliary feedwater system, an operator action was added to the fault tree and the model assumed failure of the normal automatic feedwater actuation system. The resultant core damage probability, assuming failure of the reactor protection system, successful actuation of the diverse reactor trip system, and failure of the operators to actuate auxiliary feedwater system given the failure of the automatic system, was approximately 8E-11 CDF/year. While the risk significance of the issue was clearly very low, staff still needed to ensure that adequate defense-in-depth was maintained.

The question of adequate defense-in-depth is addressed in RG 1.174's seven considerations and "the maintenance of sufficient defense in depth and margins, among other things, is reasonably assured." Furthermore, "the proposed licensing basis change is considered to maintain consistency with the defense-in-depth philosophy if the integrated assessment demonstrates no significant impact on a single consideration (i.e., the intent of each defense-in-depth consideration is met) or there is not a significant impact collectively across all seven considerations." However, the regulatory guide does not define significant impact, nor does it describe a process that assess the level of defense-in-depth needed in relation to the proposed change. Instead, the regulatory guide relies on informed judgment of cognizant technical staff. Consequently, considerable dialogue and interactions occurred related to this consideration and led to several lessons-learned that will be discussed later in this paper.

After, the exemption request was submitted, staff conducted the acceptance review and identified several requests for confirmation of information. After receiving the information, the staff was able to successfully complete the acceptance review and the safety evaluation of the exemption request ahead of schedule. The number of staff-hours spent on the review was also significantly less than the hours expended on staff reviews done on similar requests that do not use the RIPE process. The submittal, safety evaluation, and the exemption can be found in the NRC's ADAMS using the information is listed in Table 1 below.

Table 1: Regulatory Documents Related to First RIPE Submittal

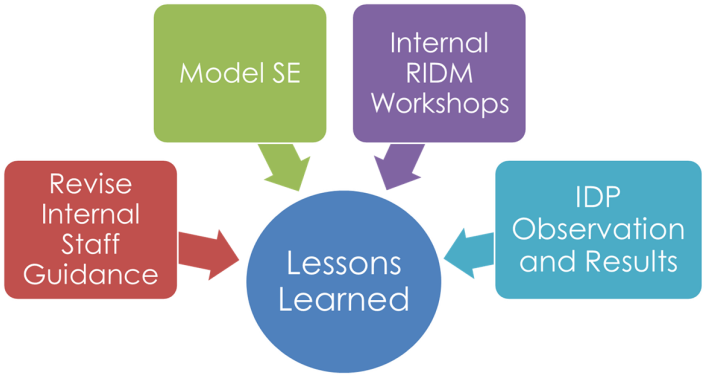
	ADAMS Accession No.
RIPE Exemption Submittal	ML22014A415
RIPE Exemption Letter and Safety Evaluation	ML22054A005
RIPE Exemption	ML22054A006

4.2. Lessons-Learned

Based on feedback from the NRC technical reviewers and the licensee's staff who submitted the application, staff identified several lessons-learned from this first-of-a-kind review and identified and implemented best practices for future reviews of applications submitted under RIPE. The licensee was appreciative of the continuous interactions from the staff in the form of presubmittal meetings and discussion related to the RIPE exemption. Staff also recognized the need to conduct just in time training to RIPE reviewers, given that these submittals may be infrequent and associated with unique requests. Initially, staff had some challenges to establish standards on the technical rigor needed to support a NTO review during the acceptance review process. Also, as discussed above, staff were concerned with the level of defense-in-depth needed to support a risk-informed review given the issue was shown to be low safety significant using RIPE. Further, there were also questions related to the level of detail needed in the safety evaluation. Given the low safety significance of the issue, staff asked for guidance on what level of detail would be needed for the safety evaluation?

The staff identified four key areas related to lessons-learned from the first-of-a-kind RIPE submittal and are illustrated by Figure 2, below.

Figure 2: Illustration of Key RIPE Lessons-Learned



A summary of those lessons-learned are provided below:

- The first was the need to ensure continuous dialogue with the licensee that is considering submitting an application under RIPE. Presubmittal meetings for regulatory actions are not required but are valuable when working with new or unique situations such as a RIPE submittal. One lessons-learned, is that the presubmittal meetings for the first RIPE review were critical to ensure efficient and effective review of the issue.

- Another was to better clarify the role of the technical reviewers as it relates to the NTO and to conduct just in time training on the role of the reviewer and the RIPE process. Staff also needed a better understanding of how to integrate risk insights into their review. As discussed above, staff had significant deliberations to reach alignment on the appropriate level of defense-in-depth commensurate with the safety significance of an issue. Therefore, a key lessons-learned was the need to conduct internal risk-informed decisionmaking workshops that leverage real world examples to illustrate how defense-in-depth could be adjusted based on risk insights and the significance of an issue.

- Staff will also sustain this effort by developing monthly knowledge management workshops that could address different topics or reviews that successfully used risk insights to inform the level of staff rigor.

- Staff also recognized that safety evaluations written to approve an application that uses the RIPE process cannot emulate the staff practices on safety evaluations written for typical license amendment or exemption requests. Given the issue has been determined to be low safety significant and given the nature of the streamlined reviewed and use of limited resources, the safety evaluation should be commensurate with those conditions. Therefore, staff plan to develop a model safety evaluation/template that will leverage the lessons-learned from the first review. Staff expects to develop a concise, focused, safety evaluation that would require limited resources, i.e., resources commensurate with the safety significance, to develop safety evaluations for future RIPE submittals.

- Another important lesson-learned from the first RIPE review was the observation of the IDP. The IDP deliberations provided staff with the key information necessary to support their review. For the first RIPE submittal, the results of the final IDP were not submitted nor made available to staff as part of the formal review process. For future RIPE reviews, NRC will encourage licensees to either formally submit the results or make the results available on a secure online portal that could then support staff requesting key confirmatory information formally as part of the request for confirmation of information.

All the information discussed above will be reviewed and the final recommendation used to update and revise the internal staff guidance for future reviews. Ensuring these lessons-learned are institutionalized and ready for the next RIPE submittal.

5. CONCLUSION

RIPE constitutes a significant step forward in NRC's endeavor to advance risk-informed decisionmaking for the NRC. Its development and continuous improvement and enhancement supports the agency's effort to be a modern, risk-informed regulator. It ensures staff focus their time, attention, and resources on the most safety significant issues thus ensuring the safe operation of the commercial operating reactors and thus protecting the health and safety of the public and the environment. The strength of the RIPE process is the development of an objective, repeatable, and scrutable framework that leverages a multidisciplinary team to evaluate risk insights and the other key engineering principles of risk-informed decision making against a fix set of criteria to determine if an issue is of low safety significance. With the successful implementation of the first RIPE review, NRC staff have demonstrated regulatory certainty and confidence in our regulatory processes and has paved the way for potentially more low safety significant issues to be reviewed in an effective and efficient manner consistent with the NRC's principles of good regulation [21].

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