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MEMORANDUM TO: Ho K. Nieh, Director
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SUBJECT: LOW SAFETY SIGNIFICANCE ISSUE RESOLUTION RECOMMENDATION 5

Purpose

The purpose of this memorandum is to provide the Low Safety Significance Issue Resolution (LSSIR) Recommendation 5 (Rec 5) working group's assessment and recommendations for the resolution of low safety significance (LSS) issues[1] that are within the licensing basis. The LSSIR Rec 5 working group, in developing this assessment and the associated recommendations, coordinated with both internal and external stakeholders and benefited from the support of the EMBARK Venture Studios. Consistent with the overall LSSIR effort, this assessment and the associated recommendations are intended to improve U.S. Nuclear Regulatory Commission (NRC) processes so that LSS issues are promptly resolved without an excessive use of resources, thereby enabling the NRC staff and licensees to better focus resources on issues of greater safety significance. These recommendations do not represent official agency policy, and their implementation would not alter any regulatory requirement.

Summary

This memorandum outlines the LSSIR Rec 5 working group recommendations on establishing more efficient means for resolving LSS issues that are within the licensing basis, enabling the

[1] Existing regulatory processes use differing terminology with respect to safety significance because the processes were developed at different times, by different working groups, serving different purposes, and involving differing numbers of categories that needed descriptions. In this memorandum, LSS is generally intended to mean a level of safety significance where the agency would be least likely to take further regulatory action or require additional assurance. For example, relative to processes that use a binary description of safety significance (e.g., Section 50.69 of Title 10 of the *Code of Federal Regulations*), this would be the lower categorization (i.e., safety-related and nonsafety-related structures, systems, and components that perform low safety significant functions. Relative to processes that use a tertiary (or higher) description of safety significance (e.g., Inspection Manual Chapter 0609, "Significance Determination Process," or Office of Nuclear Reactor Regulation (NRR) Office Instruction LIC-504, "Integrated Risk-Informed Decisionmaking Process for Emergent Issues"), LSS would be the lowest of these categorizations (i.e., findings of very low safety significance and issues of clearly low safety significance).

NRC staff and licensees to focus available resources on matters of greater safety significance. Accordingly, these recommendations address the first category of LSS issues that were identified in the LSSIR recommendation memorandum, "Low Safety Significance Issue Resolution Working Group Recommendations," dated February 5, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19260G224). As noted in that memorandum, when there is a compliance issue that is clearly within a plant's licensing basis, licensees may choose to perform corrective actions; request exemptions; or change their licensing basis either through a license amendment request under Section 50.90 of Title 10 of the *Code of Federal Regulations* (10 CFR) or through the 10 CFR 50.59 process. Therefore, the LSSIR Rec 5 working group concluded that at a high level, LSS issues can be more efficiently resolved through either: (1) providing greater flexibility or authority to enable changes to the licensing basis under the existing change control regulations (e.g., 10 CFR 50.59), or (2) providing for more efficient review of LSS issues that require an NRC licensing action (i.e., a request for an exemption or license amendment).

The LSSIR Rec 5 working group developed a proposal, referred to as the Risk-Informed Process for Evaluations (RIPE), to achieve more efficient review of LSS license amendments and exemption requests. RIPE leverages previous risk informed initiatives (i.e., Technical Specifications Task Force (TSTF) Traveler 505, "Provide Risk-Informed Extended Completion Times – RITSTF [Risk-Informed TSTF] Initiative 4b," 10 CFR 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors," and TSTF-425, "Relocate Surveillance Frequencies to Licensee Control - RITSTF Initiative 5b") to help evaluate regulatory issues consistent with the key principles of integrated decision making in Regulatory Guide (RG) 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk Informed Decisions on Plant-Specific Changes to the Licensing Basis" (ADAMS Accession No. ML17317A256). Using those principles, staff can ensure the level of effort of the staff's review is commensurate with the issue's safety significance.

As discussed in more detail below, the LSSIR Rec 5 working group held several meetings to solicit feedback on the RIPE process from internal and external stakeholders. Feedback from all stakeholders was reviewed and considered prior to developing the final recommendation. Specifically, public meetings on RIPE were held on May 14, 2020 (ADAMS Accession No. ML20161A040), and August 13, 2020 (ADAMS Accession No. ML20252A211). The LSSIR Rec 5 working group received comments from industry (ADAMS Accession No. ML20245E157). The LSSIR Rec 5 working group did not receive feedback from members of the public.

The LSSIR Rec 5 working group recommends that RIPE be adopted as an efficient way for NRC staff to review licensing actions that address LSS issues. As mentioned above, the LSSIR Rec 5 working group developed temporary staff guidance to allow for a streamlined NRC review process of license amendment and exemption requests that qualify for RIPE. If RIPE is adopted and the temporary staff guidance is successful, then the LSSIR Rec 5 working group will formalize the process by incorporating it into existing applicable office instructions or developing a standalone office instruction for RIPE, and will consider updating RG 1.174 to document the guidance for industry on characterizing the safety impact of the LSS issues. The implementation of these recommendations will enable more efficient use of agency resources and reduce unnecessary regulatory burden, consistent with the NRC's Principles of Good Regulation.

Background

Risk-informed and performance-based approaches provide for greater focus on items of the highest safety significance, enable more efficient use of agency resources, and reduce unnecessary regulatory burden. One of the goals of these approaches is to establish processes and procedures that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety. The objective of the LSSIR effort is to advance these goals. Additional background and history on the LSSIR effort is provided in the NRC LSSIR recommendations memorandum dated February 5, 2020. The recommendations provided in that memorandum, which included Rec 5 (the subject of this effort), were endorsed by the Director of the Office of Nuclear Reactor Regulation (NRR) in his February 7, 2020, memorandum, "Addressing Issues of Very Low Safety Significance" (ADAMS Accession No. ML20022A032).

Rec 5 Review Approach

The LSSIR Rec 5 working group focused on LSS issues that are clearly within the licensing basis, and as such, are addressed under existing regulatory processes (e.g., licensee corrective action programs and the NRC's licensing, inspection and enforcement processes). To address such issues, licensees may choose to perform corrective actions to restore compliance with its licensing basis, request an exemption, or consider changing their licensing basis through a license amendment request or through the 10 CFR 50.59 process. The LSSIR Rec 5 working group effort focuses on aligning NRR review resources for these LSS requests to reflect the safety significance of the issues involved. The LSSIR Rec 5 working group also notes that there is a separate ongoing effort within the agency to apply risk insights to the application of 10 CFR 50.59 criteria. This 50.59 effort may provide greater flexibility for licensees by enabling some LSS issues within the licensing basis to be addressed without the need for prior NRC review and approval.

Discussion

Several new developments support establishing RIPE. Foremost is the expanded use of risk-informed decision making and implementation of risk-informed initiatives by both licensees and the NRC. This has led to improvements in licensees' site-specific probabilistic risk assessment (PRA) information that can be leveraged to support a streamlined NRC review process. RIPE can be used to address regulatory issues with a minimal safety impact using existing regulations, such as 10 CFR 50.12, "Specific exemptions," and 10 CFR 50.90, "Application for amendment of license, construction permit, or early site permit."

RIPE leverages current regulations and risk initiatives to allow for a streamlined NRC review process of plant-specific exemption requests or license amendment requests. The streamlined process would be available to licensees that have a robust PRA and integrated decision-making panel (IDP), meaning that the licensee must have:

- adopted TSTF-505 (or NEI 06-09, "Risk-Informed Technical Specifications Initiative 4b, Risk Managed Technical Specifications (RMTS) Guidelines"), and

- adopted either 10 CFR 50.69 or a RIPE IDP, as documented in Nuclear Energy Institute (NEI) guidance, "NEI Guidelines for the Implementation of the Risk-Informed Process for Evaluations Integrated Decision-Making Panel" (ADAMS Accession No. ML20245E147). The RIPE IDP was developed to enable licensees that have not adopted 10 CFR 50.69

to use the RIPE process and establishes a structured mechanism to ensure risk-informed decision-making principles are appropriately considered in developing RIPE requests.

RIPE uses the IDP to assess the safety impact of issues using both quantitative and qualitative risk insights consistent with RG 1.174 and following NRC's Guidelines for Characterizing the Safety Impact of Issues (Enclosure 1). Once the plant-specific assessment is completed, the licensee would then submit the supporting information from the IDP to the NRC to support a streamlined review process. The NRC staff including the Division of Operating Reactor Licensing and applicable technical branches will be involved in the acceptance review to ensure that the RIPE submittal meets the RIPE criteria and that having the streamlined review principally limited to DRA is appropriate. The acceptance review would use a standard template, and the licensee would have to provide sufficient information to support the change and demonstrate how public health and safety are maintained. If the acceptance review determines the issue is within the scope of RIPE, is an LSS issue, and was appropriately evaluated by the IDP, then the NRC's Division of Risk Assessment (DRA) in NRR would conduct the substantive review of the licensee's request using the streamlined process. Under the streamlined review, as illustrated in the Temporary Staff Guidance (Enclosure 2), DRA staff would determine if the issue is well within the scope and capability of the licensee's PRA and evaluate the IDP results related to the other risk-informed key principles, such as defense-in-depth and safety margins.

The major benefits of this process enhancement include:

- NRC and licensee resources are focused on the most safety significant issues, and
- Licensing actions concerning LSS issues are reviewed in an efficient and predictable manner consistent with NRC's Principles of Good Regulation.

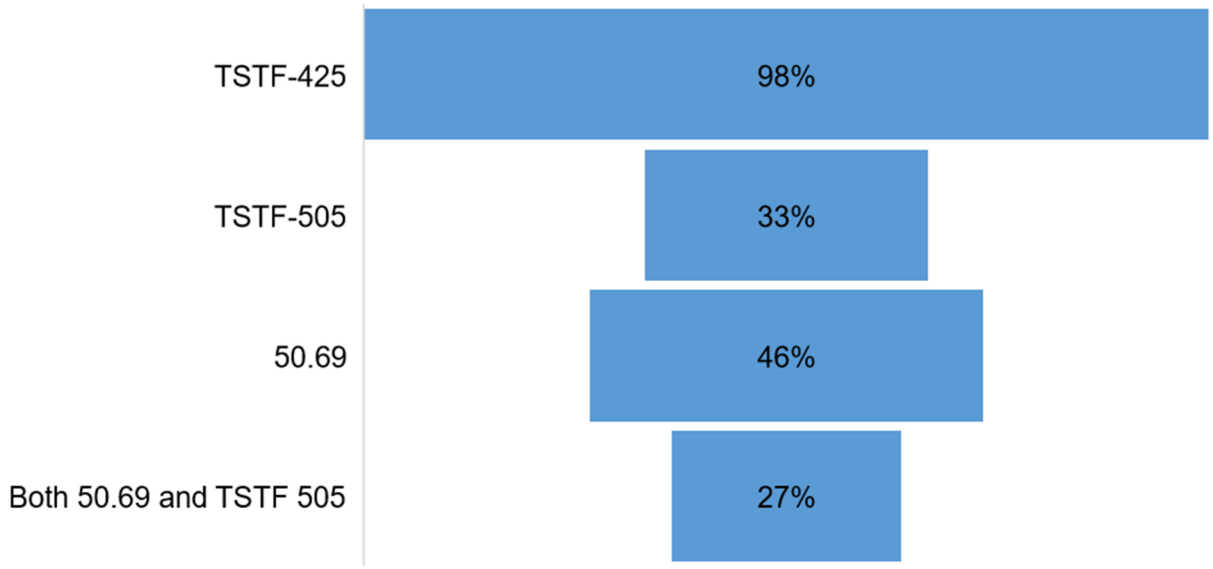
RIPE builds on existing industry guidance that NEI provided as part of the NRC staff's initiative to prioritize regulatory issues, known as the Risk Prioritization Initiative. The NRC staff observed several demonstration pilots of this guidance, "Summary of the NRC Staff Observations on the Nuclear Energy Institute Demonstration Pilots for Prioritization and Scheduling Implementation," dated October 2014 (ADAMS Accession No. ML14302A269).

Internal and External Feedback

The LSSIR Rec 5 working group engaged in extensive outreach with both internal and external stakeholders. Regional and NRR staff comments focused on how the process would be integrated into current regulatory processes and what issues would qualify for RIPE. Any issues for which the safety impact cannot be assessed directly using PRA such as fuel changes, changes to emergency planning programs, or security related changes, would not qualify for RIPE. In addition, RIPE is not intended to impact the inspection or oversight function of the NRC. Rather, RIPE is intended to address streamlined NRC staff review of exemption or license amendment requests that concern LSS issues. These issues may be NRC- or licensee-identified compliance issues or issues identified through other regulatory or licensee processes. Finally, the working group received feedback associated with non-DRA technical staff review of RIPE submittals. In response to that feedback, the RIPE review process was revised to include non-DRA technical staff as part of the acceptance review of a RIPE submittal. The purpose of this review would be to determine if unique aspects of the submittal warrant additional evaluation by non-DRA technical staff.

Because many licensees have not adopted both 10 CFR 50.69 and TSTF-505, industry feedback focused on making RIPE available to a broader number of licensees. Figure 1 below illustrates the number of licensees that have adopted various risk-initiatives and the percentage of licensees that have adopted both 10 CFR 50.69 and TSTF-505.

Figure 1 Percent of Licensees with Risk-Informed Initiatives Completed or Under Review



For example, industry proposed allowing licensees that have only adopted TSTF-425, "Relocate Surveillance Frequencies to Licensee Control-RITSTF Initiative 5b," to be able to use RIPE. TSTF-425 requires a PRA and an IDP.

With respect to the TSTF-425 PRA, the LSSIR Rec 5 working group noted that there are varying degrees of PRA acceptability under TSTF-425. When most of the industry had reviews completed for TSTF-425, the peer review process did not have a mechanism to close out facts and observations (F&Os). Thus, many F&Os were left unresolved for TSTF-425 and other risk-informed amendments until the F&O closure process was accepted by the NRC. Therefore, staff were not confident that licensees PRAs under TSTF-425 were of same level of quality as TSTF-505 PRAs. Some LSSIR Rec 5 working group members suggested industry could leverage the industry's F&O closure process, which would resolve the main source of PRA modeling discrepancies through independent industry teams. The LSSIR Rec 5 working group intends to continue to work with industry to evaluate this proposal, and is developing recommendations that would enable the PRA technical acceptability required to ensure the issue in question is LSS and, as such, possibly streamline the review by NRR staff. These recommendations will be part of a follow-on effort.

With respect to use of the TSTF-425 IDP in lieu of a 10 CFR 50.69 IDP, the LSSIR Rec 5 working group noted that the level of management engagement on a TSTF-425 IDP was not equivalent to the 10 CFR 50.69 IDP. Specifically, the TSTF-425 IDP builds on the Maintenance Rule Expert Panel with the addition of the surveillance frequency coordinator, while the 10 CFR 50.69 IDP includes a diverse group of licensee senior managers and subject matter

experts. Industry acknowledged those concerns and provided guidance for the composition and structure of a new RIPE IDP (ADAMS Accession No. ML20245E157). The LSSIR Rec 5 working group concluded that, for the purpose of qualifying for RIPE only, licensees can use the industry suggested RIPE IDP in lieu of a 10 CFR 50.69 IDP. However, the RIPE IDP cannot be applied in lieu of a 10 CFR 50.69 IDP for any other purpose (e.g., the RIPE IDP cannot be used for a 10 CFR 50.69 application).

In summary, after evaluating the industry's proposal, the LSSIR Rec 5 working group concluded that an important element of RIPE is that the issue under consideration be capable of quantification by a PRA and shown to be of very low risk. The working group concluded that if an issue contributes less than 1 x 10 7/year to core damage frequency and less than 1 × 10-8/year to large early release frequency this quantitative criteria would be met. When the working group engaged with other staff members in NRR to solicit feedback (e.g., through townhalls with project managers, technical staff, and branch chiefs), this very low safety impact in conjunction with the level of PRA acceptability required in a TSTF-505 application, and use of either a 10 CFR 50.69 IDP or RIPE IDP, provides confidence that the streamlined review process under RIPE is appropriate and commensurate with the safety significance of the issue.

Another proposal from the LSSIR Rec 5 working group was to consider folding the streamlined review process under RIPE into NRR Office Instruction LIC-206, "Integrated Risk-Informed Decision-Making for Licensing Reviews" (ADAMS Accession No. ML19263A645), which provides guidance on leveraging integrated review teams for the review of various types of license amendments using risk insights where appropriate to determine the level and extent of staff review. Recognizing that LIC-206 still requires a deterministic review, any future incorporation of RIPE within LIC-206 would need to account for this difference.

Path Forward

The LSSIR Rec 5 working group evaluated the feedback from internal and external stakeholders and recommends moving forward with the initial trial approach for RIPE, which leverages risk informed initiatives TSTF-505 and the 10 CFR 50.69 IDP. As noted above, after evaluating the RIPE IDP proposal provided by industry, the LSSIR Rec 5 working group also recommends that licensees be allowed to use the RIPE IDP in lieu of a 10 CFR 50.69 IDP only for the purpose of qualifying for RIPE (i.e., the RIPE IDP is not equivalent to the 10 CFR 50.69 IDP for any other purpose and cannot be applied in lieu of a 50.69 IDP for the implementation of 10 CFR 50.69).

The LSSIR Rec 5 working group will continue to consider how licensees using a TSTF-425 PRA could use a streamlined review process in light of the LSS of these issues. As previously mentioned, industry could leverage the F&O closure process to enhance the technical acceptability of the TSTF-425 PRA, and the LSSIR Rec 5 working group will also explore incorporating RIPE into LIC-206 for these LSS issues as a future activity.

Guidance and Training

As previously mentioned, the documents supporting RIPE are in the enclosures to this memorandum. NRR staff can begin processing RIPE requests on a trial basis. The LSSIR Rec 5 working group will assist the Division of Operating Reactor Licensing project managers in NRR as licensees send RIPE submittals to the NRC. Once RIPE has been exercised and the guidance further refined, the working group will formalize the guidance in the appropriate NRR

office instructions and regulatory guides. The working group recommends that NRR conduct a self-assessment of the RIPE process within one year following implementation of RIPE.

If you have any questions, please contact either Antonios Zoulis at (301) 415-1209 or Antonios.Zoulis@nrc.gov or Tim Reed at (301) 415-1462 or Timothy.Reed@nrc.gov.

Enclosures:
1. Guidelines for Characterizing the Safety Impact of Issues (ADAMS Accession No. ML20261H462)
2. Temporary Staff Guidance TSG-DORL-2021-01, “Risk-Informed Process for Evaluations” (ADAMS Accession No. ML20261H473)

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