



UNITED STATES
NUCLEAR REGULATORY COMMISSION
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MEMORANDUM TO: Andrea D. Veil, Director
Office of Nuclear Reactor Regulation

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SUBJECT: EXPANSION OF RISK-INFORMED PROCESS FOR EVALUATIONS
(LOW SAFETY SIGNIFICANCE ISSUE RESOLUTION
RECOMMENDATION 5)

Purpose

The purpose of this memorandum is to inform you of the expansion to the Risk-Informed Process for Evaluation (RIPE) that was proposed to the former Director of the Office of Nuclear Reactor Regulation (NRR) on January 5, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20261H475), and subsequently approved on January 7, 2021 (ADAMS Accession No. ML21006A324). As you are aware, RIPE is a process for addressing very low safety significance issues that are within the licensing basis of a plant and require resolution. RIPE implements Recommendation 5 from the low safety significance resolution (LSSIR) working group effort that the former NRR Director endorsed in a memorandum dated February 7, 2020 (ADAMS Accession No. ML20022A032). The expanded RIPE process has not changed substantively and continues to meet the same process constraints and attributes that were identified in the initial issuance. It continues to leverage previous risk-informed approaches, which allow for a more efficient review of submittals in addressing very low safety significant issues, and thereby enabling both the NRC and licensee resources to better focus on safety significant issues. The Expansion of RIPE continues to enable the efficient and predictable review of licensing actions for very low safety significant issues consistent with the NRC's Principles of Good Regulation.

Background

Risk-informed and performance-based approaches provide for greater focus on regulatory issues of higher safety significance, enable more efficient use of agency resources, and reduce unnecessary regulatory burden. Approaches that 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, support implementation of this higher

risk-informed and performance-based objective. RIPE supports this by establishing a process that leverages current regulations and risk initiatives to allow for a streamlined NRC review process of plant-specific exemption requests or license amendment requests. The initial issuance of the RIPE process was designed for licensees that have a robust probabilistic risk assessment (PRA) and integrated decision-making panel (IDP), that support a fully risk-informed assessment of the very low safety significant issue from both a quantitative and qualitative standpoint. To implement RIPE, licensees must have adopted:

- Technical Specifications Task Force (TSTF) Traveler TSTF-505, “Provide Risk Informed Extended Completion Times – RITSTF [Risk-Informed TSTF] Initiative 4b” (or Nuclear Energy Institute (NEI) 06-09, “Risk-Informed Technical Specifications Initiative 4b, Risk Managed Technical Specifications (RMTS) Guidelines”), and
- either Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.69, “Risk-informed categorization and treatment of structures, systems and components for nuclear power plants” or a RIPE IDP, as documented in NEI guidance, “NEI Guidelines for the Implementation of the Risk-Informed Process for Evaluations Integrated Decision-Making Panel” (ADAMS Accession No. ML20245E147).

The initial issuance of RIPE was supported by the following two documents that provided guidance to support the assessment of the issue, and corresponding guidance to govern the staff’s review of the RIPE submittal:

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

During the development and issuance of the RIPE process, the NRC received feedback from industry, suggesting that the NRC consider allowing licensees that have only adopted TSTF-425 (or NEI 04-10, “Risk-Informed Technical Specifications Initiative 5b, Risk-Informed Method for Control of Surveillance Frequencies”), to be able to use RIPE. The working group’s concern with this proposal was that there are varying degrees of PRA scope under TSTF-425. Similar to TSTF-505, TSTF-425 is a broad scope licensing process that requires review of all applicable hazards and open facts and observations (F&Os). TSTF-425 reached a peak in industry adoption during a phase when the Standard was changing for internal events and internal fires. Therefore, many licensees did not have external hazards PRAs at that time. Also, when most of these TSTF-425 reviews were completed, the peer review process did not have a mechanism to close out F&Os, without getting another full or focused-scope peer review. This left many F&Os and other risk-informed amendments unresolved for TSTF-425, until the F&O closure process was accepted by the NRC. Therefore, staff was not confident that licensee PRAs under TSTF-425 would allow for the same efficiencies in RIPE as in TSTF-505 PRAs. The Recommendation 5 working group suggested that industry could leverage the industry’s F&O closure process, which would resolve the main source of PRA scope and F&O discrepancies through independent industry teams. Notwithstanding these concerns, and as discussed in the previous January 2021 memo to the former NRR Director, the working group committed to continue to work with industry to evaluate this proposal.

Expansion of RIPE

On January 26, 2021, NEI and industry met with the NRC staff to discuss the proposal for expanding RIPE to include licensees that have approved TSTF-425 applications. This interaction was principally aimed at addressing the previous NRC feedback regarding the technical acceptability of the TSTF-425 PRAs, including issues such as unresolved F&Os and the lack of an external events PRA (including internal fires). Meeting minutes are available in ADAMS at Accession No. ML21028A118. The NEI proposal described 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. 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. In short, the proposal appeared to be structured and aligned with the RIPE attributes, in terms of the PRA aspect of the process. Accordingly, following that meeting, a second meeting was held on February 25, 2021, at which time the NRC staff provided its feedback on the industry proposal. Meeting minutes are available in ADAMS at Accession No. ML21061A320. The NRC's general feedback was that the industry proposal for including TSTF-425 within RIPE appeared reasonable with specific feedback provided on the meeting slides (refer to ADAMS Accession No. ML21050A203). At the end of this meeting, NEI indicated that it would develop industry guidance for RIPE that would include TSTF-425, considering the feedback from the two public meetings.

On March 22, 2021, 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" (ADAMS Accession No. ML21103A325), to the NRC staff for its consideration and feedback. The staff reviewed the NEI guidance and held several additional outreach sessions with internal staff from the Division of Operating Reactor Licensing (DORL) (March 24 and 25, 2021) and Division of Risk Assessment (DRA) (March 18, 23, and 31, 2021) to discuss the expansion of RIPE and obtain feedback. While the feedback was generally supportive of the RIPE process from the perspective that RIPE supports more efficient reviews for these very low safety significant issues, the staff was concerned that the level of review would increase for these TSTF-425-based RIPE submittals, such that it would no longer fit the streamlined RIPE process. The increased review could raise issues and aspects of the TSTF-425 PRA that were never reviewed in depth, when originally approved, such as key assumptions, uncertainties, and unresolved F&Os. Based on its review and these sessions, the staff provided the following feedback to NEI on April 13, 2021 (ADAMS Accession No. ML21103A325):

1. The document should include more guidance for determining the applicability of external events to the issue.
2. There should be guidance for keeping PRA up to date when using TSTF-425 for a RIPE submittal.
3. With the addition of TSTF-425, there should be guidance and direction to the IDP to discuss the key assumptions and sources of uncertainty associated with the TSTF-425 PRA.
4. The guidance should include a reference to the F&O closure process.
5. The description for the calculation of the risk change should be revised to accommodate the two general scenarios for RIPE submittals (i.e., one where the very low safety

significant issue is out of compliance with the licensing basis, the other where the very low safety significant issue is not presently out of compliance with the licensing basis).

6. There should be guidance for defining what constitutes a “surrogate.”
7. References to NRC participation in a Generic Assessment Expert Team should be removed.

Based on this feedback, NEI revised the expanded RIPE guidance in NEI 21-01, and by letter dated April 29, 2021 (ADAMS Accession No. ML21120A056), issued NEI 21-01 to its members. NEI did not provide the NRC with a public copy of the revised guidance.

Path Forward

As discussed above, the NRC staff reviewed the revised NEI 21-01 document and concluded that this guidance addressed the NRC’s feedback prior to its issuance by NEI on April 29, 2021, and that it is sufficient to support RIPE submittals. However, since NEI was not willing to make the guidance document publicly available to support TSTF-425 RIPE requests, the staff developed a revision (i.e., Revision 1) to its safety characterization guidance. The new revision expands the initial safety characterization guidance to accommodate TSTF-425 RIPE submittals and includes guidance that is consistent with NRC’s feedback provided to NEI on the draft of NEI 21-01.

The staff recognizes that RIPE submittals using TSTF-425 PRAs will likely require additional review resources, when compared to TSTF-505 based RIPE submittals and may in a few cases include requests for additional information. In light of this, the associated and supporting Temporary Staff Guidance document was revised to accommodate for the additional review that may be required for TSTF-425 based RIPE submittals.

As a result, for licensees to use the expanded RIPE process, the following must be met:

- adopt TSTF-505 (or NEI 06-09), or TSTF-425 “Relocate Surveillance Frequencies to Licensee Control-RITSTF Initiative 5b” and
- adopt either 10 CFR 50.69 or a RIPE IDP, as documented in NEI guidance, “NEI Guidelines for the Implementation of the Risk-Informed Process for Evaluations Integrated Decision-Making Panel.”

Licensees choosing to submit RIPE requests should use the NRC’s, “Guidelines for Characterizing the Safety Impact of Issues,” Revision 1 (ADAMS Accession No. ML21180A014), or non-public NEI 21-01. The NRC staff will review these submittals using the guidance in TSG-DORL-2021-01, Revision 1 (ADAMS Accession No. ML21180A013).

Guidance and Training

To date, there have been no RIPE submittals. The working group will assist the DORL licensing project managers in NRR as licensees send RIPE submittals to the NRC. Once RIPE has been exercised, the guidance can be further refined based on that review experience. The working group will then 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 following the review of several RIPE submittals, but no later than 18 months following the date of this memorandum.

OMB Review

The revised NRC Guidance document (Enclosure 1) will be under Office of Management and Budget (OMB) review, as required by the Congressional Review Act. OMB's review is expected to take 30-90 days, so we anticipate issuance of the guidance as a publicly available document between August to October of this year.

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

Enclosures:

1. Guidelines for Characterizing the Safety
Impact of Issues, Revision 1
(ADAMS Accession No. ML21180A014)
2. Revised Temporary Staff Guidance
TSG-DORL-2021-01, Revision 1, "Expanded
Risk-Informed Process for Evaluations"
(ADAMS Accession No. ML21180A013).

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ADAMS Accession Nos.:

Package ML21180A011

Memorandum: ML21180A012

Enclosure 1: ML21180A014

Enclosure 2: ML21180A013

***via e-mail**

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