U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation

NRR Temporary Staff Guidance

Temporary Staff Guidance No.:	**TSG-DORL-2021-01 Revision 2**
Temporary Staff Guidance Title:	**RISK-INFORMED PROCESS FOR EVALUATIONS**
Effective Date:	May 10, 2022
Approved By:	Bo Pham
Date Approved:	May 10, 2022
Primary Contact:	**W. Orders** **301-415-3329** **William.Orders@nrc.gov** **A. Zoulis** **301-415-1209** **Antonios.Zoulis@nrc.gov**
Responsible Organization:	**NRR/DORL**
ADAMS Accession No.:	**ML22088A136**

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Summary: This revision includes guidance for applying the RIPE process to license amendment requests involving changes to the Technical Specifications.

ADAMS Accession No. ML22088A136 ***by e-mail**

OFFICE	NRR/DORL/LPL4/PM*	NRR/DORL/LPL4/LA*	NRR/DORL/LPL4/BC*
NAME	SLingam	PBlechman	JDixon-Herrity
DATE	3/20/2022	3/30/2022	4/20/2022
OFFICE	OGC-NLO*	NRR/DORL/D*	
NAME	CKreuzberger/RHarper	BPham (GSuber for)	
DATE	5/3/2022	5/10/2022	

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1. OBJECTIVE

This temporary staff guidance (TSG) document provides the Office of Nuclear Reactor Regulation (NRR) staff the framework for streamlined processing of license amendment requests (LARs) and exemptions from U.S. Nuclear Regulatory Commission (NRC) requirements that are submitted under the Risk-Informed Process for Evaluations (RIPE). Use of this guidance is limited to issues for which the safety impact associated with an issue addressed by an exemption request, or a LAR can be modeled and shown to be minimal using probabilistic risk assessment (PRA). These issues could be identified through inspections, corrective actions, or other licensee or regulatory processes.

NRR's Division of Risk Assessment (DRA) is the lead technical division required to provide evaluation input for a RIPE submittal. The NRC's review is streamlined in that RIPE is based on the application of pre-existing risk-informed criteria that allow for review and disposition of the submittal with minimal resources.

This TSG provides the NRR staff with expectations and flexibilities that replace or supplement the routine exemption and LAR review processes described in NRR Office Instructions LIC-103, "Exemptions from NRC Regulations" (Section 3 of this TSG), and LIC-101, "License Amendment Review Procedures" (Section 4 of this TSG), for requests that meet the RIPE requirements.

2. BACKGROUND

By memorandum dated January 5, 2021, the Office of Nuclear Reactor Regulation established a new process for addressing very low safety significance issues that are within the licensing basis of a plant (ADAMS Accession No. ML20261H428). The new process, referred to as RIPE, is the implementation of Recommendation 5 from the low safety significance issue resolution working group (ADAMS Accession No. ML21006A324). RIPE is available to licensees that have a technically acceptable PRA and have established an Integrated Decision-Making Panel (IDP). For the purposes of RIPE, having a technically acceptable PRA must be demonstrated by having an approved and implemented license amendment for Technical Specifications Task Force (TSTF) Traveler TSTF-505, "Provide Risk Informed Extended Completion Times – RITSTF [Risk-Informed TSTF] Initiative 4b"[1] or TSTF-425 "Relocate Surveillance Frequencies to Licensee Control-RITSTF Initiative 5b." For the purposes of RIPE, an IDP may be established by having an approved and implemented 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," amendment or by establishing 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).

[1] NRC has approved some licensee programs for risk-informed initiatives consistent with NEI 06-09, "Risk-Informed Technical Specifications Initiative 4b, Risk-Managed Technical Specifications (RMTS) Guidelines" and NEI 04-10, "Risk-Informed Technical Specifications Initiative 5b, Risk-Informed Method for Control of Surveillance Frequencies," which can be used in lieu of TSTF-505 or TSTF-425, respectively, for RIPE. Any references in this TSG to TSTF-505 and TSTF-425 also include NEI 06-09 and NEI 04-10, respectively.

Licensees that have implemented an NRC-approved amendment to adopt TSTF-505 or TSTF-425 and have established an IDP can leverage these initiatives to perform safety impact characterizations using RIPE and request licensing actions with the expectation that the NRC will use a streamlined review process if the issue is characterized as having a minimal safety impact.

RIPE was originally developed for licensees that have an approved and implemented TSTF-505 license amendment. Licensees that use an approved and implemented TSTF-425 license amendment to demonstrate PRA technical acceptability may use the RIPE process to characterize the safety impact of proposed changes by supplementing their submittal with additional information relative to PRA technical acceptability. Specifically, licensees that rely on their TSTF-425 program for PRA technical acceptability must:

- Justify that the issue being analyzed is limited to internal events or identify which additional previously NRC-approved applications address any relevant external hazards (e.g., internal fires, seismic, etc.) beyond internal events. If the issue involves a hazard that is not covered by a previously approved NRC application, the licensee may not use this process.

- If the issue involves an external hazard covered by a previously approved NRC application, justify that the associated PRA does not have any applicable open facts and observations (F&Os).

- Provide technical justification for the exclusion of external hazards not applicable to the exemption or amendment request.

- Describe any open F&Os from the internal events PRA, including an assessment of the relevance, or lack thereof, of the F&O to the decision being sought. In order to support a streamlined NRC review, licensees should make every effort to close F&Os in advance, typically via the finding closure process.

- Describe the maintenance process of the PRA model, including any updates, peer reviews, and independent assessments performed since the PRA was reviewed as part of an approved licensing action by the NRC.

For RIPE, all the following must apply in order to characterize an issue as having a minimal safety impact:

- The issue contributes less than 1×10^{-7}/year to core damage frequency (CDF).

- The issue contributes less than 1×10^{-8}/year to large early release frequency (LERF).

- The issue has no safety impact or minimal safety impact in accordance with "Guidelines for Characterizing the Safety Impact of Issues," Revision 2 (ADAMS Accession No. ML22088A135).

- Cumulative risk is assessed based on plant-specific CDF and LERF. Cumulative risk is acceptable for the purposes of this guidance if baseline risk remains less than

1×10^{-4}/year for CDF and less than 1×10^{-5}/year for LERF once the impact of the proposed change is incorporated into baseline risk.

If the safety impact cannot be characterized as minimal, then the submittal does not qualify for the NRC streamlined RIPE review. The NRC, however, may still review the LAR or exemption request through its normal process (i.e., not using the streamlined RIPE review).

Examples of issues for which this process may be used include, but are not limited to, the following:

- Actions needed to address inspection findings.
- Resolution of issues identified through other regulatory or licensee processes.
- Responses to orders requiring changes or modifications to the plant.
- Generic issues requiring changes or modifications to the plant.

RIPE may not be used for the following:

- Any immediate actions necessary for continued safe operation (e.g., to restore compliance with a technical specification (TS) or remove a threat to personnel safety).

- Any immediate repairs necessary for continued power production (e.g., replacing a damaged main transformer).

- Any issues for which the safety impact cannot be directly assessed using PRA (e.g., fuel changes, changes to emergency planning programs, or changes to security).

3. EXEMPTIONS: LIC-103 BASIC REQUIREMENTS, REPLACEMENTS, OR SUPPLEMENTS

3.1. Work Planning (Supplement to LIC-103, Basic Requirement 4.1, "Exemption Processing")

When a Division of Operating Reactor Licensing (DORL) project manager (PM) receives the RIPE exemption request from a licensee, the PM should initiate a new project in the reactor program system (RPS). The PM should title the project as "[Plant Name] – RIPE Part XX Exemption."

A RIPE exemption submittal is limited to issues for which the safety impact associated with an issue addressed by an exemption request can be modeled directly or with surrogates using PRA to show that there is no or a minimal impact on safety. The licensee's streamlined exemption technical justification is a risk-related justification that leverages previous NRC evaluations and approvals regarding the plant's adoption of a 10 CFR 50.69 IDP or equivalent, and TSTF-505 or TSTF-425 license amendments. Therefore, one of DRA's PRA branches will be assigned to review a RIPE exemption request and will provide an evaluation input. The DORL PM should also assign other technical and environmental branches depending on the subject matter of the request; those branches will be assigned initially to determine if there is no technical

objection in applying the RIPE process. No technical objection means that the technical branch has no objection to applying RIPE for the request without additional review in the branch's respective technical area. This review entails reviewing the request to ensure that the concerns related to the branch's technical area have been considered by the IDP. Any technical objections identified by the branch must be supported by a sound regulatory basis that challenges the safety impact characterization.

See Tables 3.1 and 3.2 in Section 3.2 for the creation of the schedule milestones.

3.2. RIPE Applicability Review (Supplement to LIC-103, Section 4.2, "Review Request for Completeness and Acceptability")

A RIPE exemption applicability review includes both an acceptance review in accordance with LIC-109, "Acceptance Review Procedures," as well as the staff determination that there is no technical objection to applying the RIPE process for the submittal, with the additions and exceptions noted below.

The DRA reviewer is responsible for performing the acceptance review. Any additional reviewers are responsible for performing a no technical objection review. The no technical objection review includes determining whether the licensee's assumptions in the submitted analysis are reasonable, whether the licensee has used an appropriate methodology, whether the licensee fully considered the technical aspects of the issue under consideration to support the IDP's determination, and whether the screening questions were answered acceptably by the licensee's IDP. See Section 3.3.5 for more details.

In addition to the completeness and acceptability items listed in LIC-103, Section 4.2, the PM and DRA staff involved in the review should determine if an exemption is eligible for a streamlined review using the criteria in Section 2 of the TSG by ensuring the following elements are included:

- The application clearly meets a categorical exclusion under 10 CFR 51.22(c).
- The issue that qualifies the exemption request for the RIPE streamlined process is well defined.
- The RIPE submittal confirms that the plant has implemented an NRC approved TSTF-505 or TSTF-425 risk-informed license amendment and has completed all associated license conditions.
- If the RIPE submittal relies on a TSTF-425 license amendment to demonstrate PRA acceptability, the submittal includes the following additional information:
    - Description of PRA model changes and peer review history since implementation of TSTF-425.
    - Description of independent assessment reviews.

  - Description of all open F&Os, including a discussion about whether they are applicable to the submittal.
  - Description of key assumptions and sources of uncertainty.
  - Explanation of external hazard applicability, including
    - Discussion of non-applicable external hazards.
    - Discussion of applicable external hazards, including the previously NRC-approved application that reviewed the PRA model for the applicable external hazard, and any changes, peer reviews, and open F&O discussions for that model.

- The RIPE submittal includes a description of surrogates used in the application.

- The RIPE submittal confirms that the plant has implemented an NRC approved amendment to adopt the 10 CFR 50.69 IDP, or equivalent, and has completed all associated license conditions.

- The RIPE submittal includes the results of the IDP's review of the issue addressed in the submittal.

- The RIPE submittal states that the issue has no or minimal safety impact (i.e., risk-informed considering both qualitative and quantitative risk), meaning the following are addressed in the request:

  - The issue contributes less than 1×10^{-7}/year to CDF.
  - The issue contributes less than 1×10^{-8}/year to LERF.
  - The issue has no or minimal safety impact in accordance with "Guidelines for Characterizing the Safety Impact of Issues."
  - Cumulative risk is assessed on a plant-specific basis, to be less than 1×10^{-4}/year for CDF and less than 1×10^{-5}/year for LERF once the impact of the proposed change is incorporated into baseline risk.

As described in Section 2 of this TSG, RIPE may not be used to support immediate actions or repairs.

If the involved staff have a technical objection and believe that the exemption request does not contain the information necessary to qualify as a RIPE submittal (with branch chief approval), that more information through a supplement is required, or that the application is non-acceptable, then the acceptance review results will either be non-acceptable or non-acceptable with an opportunity to supplement, and the LIC-109 process should be followed. If the licensee responds with a supplement that is acceptable for review but still does not qualify for a streamlined review under RIPE, then the PM should notify the licensee that the request will continue to be processed under a normal NRC review schedule, and the PM in consultation with the Integrated Program Management and Beyond Design Basis Branch (LPMB) (if required) should revise the Enterprise Project Identifier (EPID) title by removing "RIPE" from it.

The acceptance review for a RIPE submittal should follow the tasks and streamlined milestone schedule below, assuming the submittal meets the criteria for a streamlined review and is acceptable for review:

Table 3.1, "Acceptance Review Milestones for a RIPE Exemption"

	ACCEPTANCE REVIEW MILESTONES	SCHEDULE
1	PM creates project in the NRR workload management tool	T* = 0
2	PM reviews submittal for information sufficiency	< T = 14 days (2 weeks)
3	Technical staff determines if there is any technical objection in applying the RIPE process and provides recommendation to PM	< T = 14 days (2 weeks)
4	PM notifies licensee or applicant (e.g., via call, e-mail, or letter) that the submittal meets the criteria for a streamlined review and is acceptable for review under the RIPE process	< T = 21 days (3 weeks)
5	PM records the date of acceptance review notification in the NRR workload management tool	< T = 21 days (3 weeks)

* T = Time from date when RIPE exemption request is declared an Official Agency Record in ADAMS (in calendar days and weeks).

If the submittal was not acceptable for review or had to be supplemented, then the milestone schedules per LIC-109 should be followed. The predetermined content and structure of a RIPE exemption request that has been determined to contain the RIPE-related items described above should be planned with a streamlined schedule as shown in Table 3.2 (in calendar days and weeks), assuming the application is acceptable for review.

The work schedule described in Table 3.2 allows for an approximate 90-day review of RIPE exemption requests. This schedule does not accommodate the issuance and licensee response to requests for additional information (RAIs); however, this schedule may be able to accommodate the request for confirmation of information (RCI) process for certain issues. The streamlined RIPE review is predicated on the issue being justified as having minimal or no safety impact with the RIPE limitations and having review elements clearly and completely addressed in the submittal. Should an RAI be required (intended to be a rare situation), and the PM determines it could be supported on an expedited schedule, the case and need should be reviewed and approved by the DORL Division Director prior to proceeding with the review under RIPE. If this is approved, the milestones in Table 3.2, may not be appropriate. If this occurs, the PM in consultation with LPMB (if required) should notify the licensee and develop new work schedule milestones.

Table 3.2, "Project Milestones for a RIPE Exemption without RAIs"

	TECHNICAL REVIEW AND PROCESSING MILESTONES	SCHEDULE*
1	DRA exemption review input provided to PM	< T = 49 days (7 weeks)
2	PM provides exemption package to OGC for NLO	< T = 63 days (9 weeks)
3	OGC provides NLO response to PM	< T = 77 days (11 weeks)
4	NRC completes its review of exemption (DORL Division Director (or delegate) to sign)	< T = 91 days (13 weeks)

*continued from the schedule in Table 3.1, assuming the submittal was acceptable for review.

3.3. Technical Review (Supplement to LIC-103, Basic Requirement 4.5, "Technical Review of the Proposed Exemption")

3.3.1. Implementation of an IDP

The DRA technical reviewer should confirm that the licensee has implemented an IDP consistent with risk-informed initiative 10 CFR 50.69 or equivalent, as discussed in Section 2 of this TSG. The DRA technical reviewer should also confirm that the IDP evaluation results, including a summary of the basis for each decision, is documented in the exemption request. For more information on an IDP and/or Generic Assessment Expert Team (GAET) see the "Guidelines for Characterizing the Safety Impact of Issues." A GAET could be used to inform the IDP but is not required. If a GAET was used to inform the IDP, the reviewer should confirm that the licensee dispositioned any considerations identified by the GAET and explained how they apply to the plant. The reviewer should also confirm that the licensee provided a basis for any plant-specific departures from the GAET assessment.

The level of documentation should be such that the licensee provides a sufficient basis for a knowledgeable individual to independently review the information and reach the same conclusion. The basis for any engineering judgment and the logic used in the assessment should be documented to the extent practicable and to a degree commensurate with the safety impact and complexity of the issue. The items considered by the IDP, GAET (if used), and the licensee's subject matter expert should be clearly stated.

3.3.2. Use of Acceptable/Approved PRA Model

In order to expedite the review, the DRA technical reviewer should confirm that the licensee has a technically acceptable PRA model in order to leverage its PRA models to perform quantitative risk assessments in support of this process. To do so, the DRA technical reviewer should confirm each of the following conditions apply:

- The issue is completely within the scope of the licensee's PRA model or can be bounded using surrogates and is within the scope of the portion(s) of the PRA model that was found acceptable by the NRC.

- The licensee has implemented risk-informed initiative TSTF-505 or TSTF-425 and has completed all associated license conditions.

- The licensee's PRA model was found acceptable to support a TSTF-505 or TSTF-425 license amendment by the NRC.

- If the RIPE submittal relies on a TSTF-425 license amendment to demonstrate PRA acceptability, the DRA technical reviewer should review the following additional information:

    - PRA model changes and peer review history since implementation of TSTF-425.
    - Independent assessment reviews.
    - All open F&Os.
    - Key assumptions and sources of uncertainty.
    - External hazard applicability, including
        - Discussion of non-applicable external hazards.
        - Discussion of applicable external hazards, including the previously NRC-approved application that reviewed the PRA model for the applicable external hazards, and any changes, peer reviews, and open F&O discussions for that model.

The plant-specific PRA should include the capability to assess CDF and LERF, and the risk evaluation should include a quantified assessment of all significant sources of risk (i.e., external events, internal flooding, and fires) that can be impacted by the issue being assessed. Where PRA models are not available, the licensee may perform conservative or bounding analyses to quantify the risk impact (e.g., external events, low power and shutdown).

3.3.3. Evaluation of PRA Results

The DRA technical reviewer should confirm that the licensee calculated the changes in CDF and LERF as the difference between plant risk with and without the proposed change. For compliance issues, the change in risk is the difference between risk if the plant were fully compliant with its licensing basis and risk with the plant in the non-compliant configuration requested in the submittal. For licensee-identified issues that do not involve a compliance issue, the change in risk is the difference between risk with the plant in the current configuration and with the plant in the configuration requested in the submittal. The risk analysis may not include any credit for proposed risk management actions (RMAs) or other activities implemented to reduce the risk impact associated with the issue. The risk analysis should document any assumptions made when performing the risk evaluation, whether any parts of the issue were outside the scope of the licensee's PRA, and whether any surrogates were used to account for the impact of the issue. The final quantitative

risk analysis should include an evaluation of the impact on internal events risk, as well as the impact on any relevant external events.

The PRA results should be compared to the relative change in risk of the licensee's overall CDF and LERF. An issue is not risk-significant (i.e., minimal or less than minimal) if all of the following apply:

- The issue contributes less than 1×10^{-7}/year to CDF.
- The issue contributes less than 1×10^{-8}/year to LERF.
- Cumulative risk is assessed on a plant-specific basis to be less than 1×10^{-4}/year for CDF and less than 1×10^{-5}/year for LERF once the impact of the proposed change is incorporated into baseline risk.

If the risk results are less than the criteria above, the issue is considered to have a minimal impact on safety.

3.3.4. Assessment of the Need for Risk Management Actions

Although RMAs should not be given credit in the risk analysis, the use of RMAs can lower risk when the risk is found to be minimal. If the issue assessed in the RIPE exemption request was determined to have no safety impact, then RMAs are not required, but are encouraged. However, if the issue was determined to have a minimal impact on safety, then RMAs should be considered to offset the risk increase due to the issue.

RMAs are typically associated with managing configuration risk when equipment is out of service or for temporary changes. However, in the case of a RIPE application, the proposed change will become the permanent plant configuration if the exemption request is approved. Therefore, only long-term actions to reduce risk associated with the new configuration should be considered, such as permanent procedure changes or simple plant modifications. For example, if an automatic interlock is defeated permanently, procedure changes to verify proper manual operation of the equipment may be appropriate to reduce the risk associated with removal of the automatic interlock.

3.3.5. Additional Considerations

Ensure the issue is well-defined: Confirm that the specific issue is appropriately defined and articulated in order to illustrate the safety impact due to the issue.

Realism so as to not bias the assessment: The level of realism and analyses will vary depending on the issue, but in order to avoid bias, realistic analysis is the objective. The licensee's assessment should include sensitivity analyses to address the key assumptions and sources of uncertainty that are driving the results. The key assumptions, details, and results of the sensitivity studies should be documented for

consideration by the IDP (or GAET, if used). If the risk impact is exceedingly small, or clearly large, then a bounding evaluation may suffice.

Uncertainty considerations: Sensitivity analyses should be performed, commensurate with the impact of the issue, to address any key assumptions and sources of uncertainty that may influence the results. The key assumptions, details, and results of the sensitivity studies should be documented for consideration by the IDP (or GAET, if used).

Evaluation of the overall nature of the risk impact of a potential action: Both beneficial and adverse effects should be considered (e.g., replacing a small pump with a large pump could reduce the available margin of an emergency diesel generator, or closing and depowering pressurizer power operated relief valve block valves to prevent spurious operation could reduce effectiveness of feed and bleed operations).

Identifying the extent of the impact: The specific intended impact of the issue, as well as other related or indirect effects, should be addressed (e.g., diverse and flexible coping strategies (FLEX) provides mitigation for more than external hazards even though that is its fundamental intended purpose). In other words, one specific issue could impact the specific function under consideration as well as multiple other separate plant functions. This could include both positive and negative impacts that may not be immediately evident if the impacts of the issue are considered independently.

3.4. Emergency Plans (Replacement for LIC-103, Basic Requirement 4.7, "Exemptions that Result in a Decrease in Effectiveness of the Emergency Plan")

RIPE is not applicable to any issues for which the safety impact cannot be directly assessed using PRA. Therefore, exemption requests related to the emergency plans should not be considered under the RIPE streamlined review process.

3.5. Design Certification Rule (Replacement for LIC-103, Basic Requirement 4.8, "Exemptions Referencing a Design Certification Rule)

Section 52.63(b)(1) of 10 CFR allows a licensee who references a design certification rule to request an exemption from elements of the certification information. However, RIPE is only applicable to operating plants and should not be considered for review of exemptions for elements of design certification information.

3.6 Preparation of Exemption (Supplement to LIC-103, Basic Requirement 4.10, "Preparation of Work Products, Exemption Document")

In addition to verifying that special circumstances exist, Section III.A of the exemption should include defense-in-depth and safety margin conclusions assessed by the IDP as documented in the RIPE exemption request.

Section III.B of the exemption should include the RIPE safety evaluation (SE) input, including verification that TSTF 505 or TSTF-425 and 10 CFR 50.69 amendments (if used) have been approved and implemented at the plant and that all associated license conditions have been completed. In addition, if an alternate IDP is used, the SE should verify the IDP is equivalent to the 10 CFR 50.69 IDP and can be used to support the NRC's safety conclusion. Section III.B should also reflect that the issue described in the exemption request is within the scope of the licensee's PRA and that the risk impact was modeled using a technically acceptable model.

4. LICENSE AMENDMENT REQUESTS: LIC-101, APPENDIX B, "GUIDE FOR PROCESSING LICENSE AMENDMENTS FOR OPERATING REACTORS AND PLANTS TRANSITIONING TO DECOMMISSIONING"

4.1. Work Planning and Acceptance Review (Supplement to LIC-101, Appendix B, Section 2.0)

4.1.1. Initiate a New Project in the RPS (Supplement to LIC-101, Appendix B, Section 2.1)

When a PM receives the RIPE LAR from a licensee, the PM should initiate a new project in RPS. The PM should title the project as "[Plant Name] – RIPE LAR to [subject of LAR]."

A RIPE LAR submittal is limited to issues for which the safety impact associated with an issue addressed by a LAR can be modeled directly or with surrogates using PRA to show that there is no or a minimal impact on safety. The licensee's LAR technical justification is a risk-related justification that leverages previous NRC evaluations and approvals regarding the plant's adoption of a 10 CFR 50.69 IDP, or equivalent, and TSTF-505 or TSTF-425 license amendments. Therefore, one of DRA's PRA branches will be assigned to review a RIPE LAR and will provide an SE input. The DORL PM should also assign other technical and environmental branches depending on the subject matter of the request, but those branches will be assigned initially to determine if there is no technical objection in applying the RIPE process. No technical objection means that the technical branch has no objection to applying RIPE for the request without additional review in the branch's respective technical area. This review entails reviewing the request to ensure that the concerns related to the branch's technical area have been considered by the IDP. Any technical objections identified by the branch must be supported by a sound regulatory basis that challenges the safety impact characterization.

If the LAR includes changes to the Technical Specifications (TS), the Technical Specifications Branch should be included to give no technical objection and concurrence on the final package to verify the final version of the TS wording and formatting are correct.

See Tables 4.1 and 4.2 in Section 4.1.2 for the creation of the schedule milestones.

4.1.2 RIPE Applicability Review (Supplement to LIC-101, Appendix B, Section 2.3)

A RIPE LAR applicability review includes both an acceptance review in accordance with LIC-109, "Acceptance Review Procedures," as well as the staff determination that there is no technical objection to applying the RIPE process for the submittal, with the additions and exceptions noted below.

The DRA reviewer is responsible for performing the acceptance review. Any additional reviewers are responsible for performing a no technical objection review. The no technical objection review includes determining whether the licensee's assumptions in the submitted analysis are reasonable, whether the licensee has used an appropriate methodology, whether the licensee fully considered the technical aspects of the issue under consideration to support the IDP's determination, and whether the screening questions were answered acceptably by the licensee's IDP. See Section 4.3.5 for more details.

In addition to the acceptance review elements described in LIC-101, Appendix B, Section 2.3, the PM and DRA staff involved in the review should determine if a LAR is eligible for a streamlined review using the criteria in Section 2 of the TSG by ensuring the following elements are included:

- The application clearly meets a categorical exclusion under 10 CFR 51.22(c).
- The issue that qualifies the LAR for the RIPE streamlined process is well defined.
- The RIPE submittal confirms that the plant has implemented an NRC approved TSTF-505 or TSTF-425 risk-informed license amendment and has completed all associated license conditions.
- If the RIPE submittal relies on a TSTF-425 license amendment to demonstrate PRA acceptability, the submittal includes the following additional information:
    - Description of PRA model changes and peer review history since implementation of TSTF-425.
    - Description of independent assessment reviews.

  - Description of all open F&Os, including a discussion about whether they are applicable to the submittal.
  - Description of key assumptions and sources of uncertainty.
  - Explanation of external hazard applicability, including:
    - Discussion of non-applicable external hazards.
    - Discussion of applicable external hazards, including the previously NRC-approved application that reviewed the PRA model for the applicable external hazard, and any changes, peer reviews, and open F&O discussions for that model.

- The RIPE submittal includes a description of surrogates used in the application.

- The RIPE submittal confirms that the plant has implemented an NRC approved amendment to adopt the 10 CFR 50.69 IDP, or equivalent, and has completed all associated license conditions.

- The RIPE submittal includes the results of the IDP's review of the issue addressed in the submittal.

- The RIPE submittal states that the issue has no or minimal safety impact (i.e., risk-informed considering both qualitative and quantitative risk), meaning the following are addressed in the request:

  - The issue contributes less than 1×10^{-7}/year to CDF.
  - The issue contributes less than 1×10^{-8}/year to LERF.
  - The issue has no or minimal safety impact in accordance with "Guidelines for Characterizing the Safety Impact of Issues."
  - Cumulative risk is assessed on a plant-specific basis to be less than 1×10^{-4}/year for CDF and less than 1×10^{-5}/year for LERF once the impact of the proposed change is incorporated into baseline risk.

As described in Section 2 of this TSG, RIPE may not be used to support immediate actions or repairs.

If the involved staff have a technical objection and believe that the LAR does not contain the information necessary to qualify as a RIPE submittal (with branch chief approval), that more information through a supplement is required, or that the application is non-acceptable, then the acceptance review results will either be non-acceptable or non-acceptable with an opportunity to supplement, and the LIC-109 process should be followed. If the licensee responds with a supplement that is acceptable for review but still does not qualify for a streamlined review under RIPE, then the PM should notify the licensee that the request will continue to be processed under a normal NRC review schedule, and the PM in consultation with LPMB (if required) should revise the Enterprise Project Identifier (EPID) title by removing "RIPE" from it.

The acceptance review for a RIPE submittal should follow the tasks and streamlined milestone schedule below, assuming the submittal meets the criteria for a streamlined review and is acceptable for review:

Table 4.1, "Acceptance Review Milestones for a RIPE LAR"

	ACCEPTANCE REVIEW MILESTONES	SCHEDULE
1	PM creates project in the NRR workload management tool	T* = 0
2	PM reviews submittal for information sufficiency	< T = 14 days (2 weeks)
3	Technical staff determines if there is any technical objection to applying the RIPE process and provides recommendation to PM	< T = 14 days (2 weeks)
4	PM notifies licensee or applicant (e.g., via call, e-mail or letter) that LAR meets the criteria for a streamlined review and is acceptable for review under the RIPE process	< T = 21 days (3 weeks)
5	PM records the date of acceptance review notification in the NRR workload management tool	< T = 21 days (3 weeks)

*T = Time from date when RIPE LAR is declared an Official Agency Record in ADAMS (in calendar days and weeks)

If the submittal was not acceptable for review or had to be supplemented, then the milestone schedules per LIC-109 would be followed. The predetermined content and structure of a RIPE LAR that has been determined to contain the RIPE-related items described above should be planned with a streamlined schedule as shown in Table 4.2 (in calendar days and weeks), assuming the application is acceptable for review.

The work schedule described in Table 4.2 allows for an approximate 140-day review of RIPE LARs. This schedule does not accommodate the issuance and licensee response to RAIs; however, the schedule may be able to accommodate the RCI process for certain issues. The streamlined RIPE LAR review is predicated on the issue being justified as having minimal or no safety impact as set forth in the RIPE limitations and having review elements clearly and completely addressed in the submittal. Should an RAI be required (intended to be a rare situation), and the PM determines it could be supported on an expedited schedule, the case and need should be reviewed and approved by the DORL Division Director prior to proceeding with the review under RIPE. If this is approved, the milestones in Table 4.2 below may not be appropriate. If this occurs, the PM in consultation with LPMB (if required) should notify the licensee and develop new work schedule milestones.

Table 4.2, "Project Milestones for RIPE LAR without RAIs"

	TECHNICAL REVIEW AND PROCESSING MILESTONES	SCHEDULE*
1	PM issues the notice of application in *Federal Register*	< 42 days (6 weeks)
2	DRA SE input provided to PM	< 70 days (10 weeks)
3	PM provides amendment package to OGC for NLO review	< 105 days (15 weeks)
4	OGC provides NLO response to PM	< 119 days (17 weeks)
5	NRC completes its review of the LAR	< 140 days (20 weeks)

* Continued from the schedule in Table 4.1, assuming the submittal was acceptable for review

4.2. Public Noticing (Replacement for LIC-101, Appendix B, Section 3.0, "Public Notification")

The PM should ensure that a 28-day notice is published in the *Federal Register*. However, the notice cannot be published before the acceptance review is complete. The notice may be published within 42 days (6 weeks) of the declaration of the LAR submittal as an official agency record in ADAMS to provide for the 30-day public comment period and 60-day period to request a hearing to facilitate a streamlined (i.e., approximately 140 days) RIPE review schedule for the LAR.

4.3. Safety Evaluation (Supplement to LIC-101, Appendix B, Section 4.0, "Safety Evaluation")

The RIPE SE input should document NRC's evaluation of defense-in-depth and safety margin conclusions assessed by the IDP, as documented in the RIPE LAR. The RIPE SE input should also include verification that TSTF-505 or TSTF-425 and 10 CFR 50.69 amendments (if used) have been approved and implemented at the plant and that all associated license conditions have been completed. In addition, if an alternate IDP is used, the SE should verify the IDP is equivalent to the 10 CFR 50.69 IDP and can be used to support the NRC's safety conclusion. Finally, the SE input should reflect that the issue described in the LAR is within the scope of the licensee's PRA and that the risk impact was modeled using the technically acceptable model.

4.3.1. Implementation of an IDP

The DRA technical reviewer should confirm that the licensee has implemented an IDP consistent with 10 CFR 50.69 or equivalent, as discussed in Section 2 of this TSG. The DRA technical reviewer should also confirm that the IDP evaluation results, including a summary of the basis for each decision, is documented in the LAR. For more information on an IDP (and/or GAET) see the "Guidelines for Characterizing the Safety Impact of Issues." A GAET could be used to inform the IDP but is not required. If a GAET was used to inform the IDP, the reviewer should

confirm that the licensee dispositioned any considerations identified by the GAET and explained how they apply to the plant. The reviewer should also confirm that the licensee provided a basis for any plant-specific departures from the GAET assessment.

The level of documentation should be such that the licensee provides a sufficient basis for a knowledgeable individual to independently review the information and reach the same conclusion. The basis for any engineering judgment and the logic used in the assessment should be documented to the extent practicable and to a degree commensurate with the safety impact and complexity of the issue. The items considered by the IDP, GAET (if used), and the licensee's subject matter expert should be clearly stated.

4.3.2. Use of Acceptable/Approved PRA Model

In order to expedite the review, the DRA technical reviewer should confirm that the licensee has a technically acceptable PRA model in order to leverage its PRA models to perform quantitative risk assessments in support of this process. To do so, the DRA technical reviewer should confirm each of the following conditions apply:

- The issue is completely within the scope of the licensee's PRA model or can be bounded using surrogates and is within the scope of the portion(s) of the PRA model that was found acceptable by the NRC.

- The licensee has implemented risk-informed initiative TSTF-505 or TSTF-425 and has completed all associated license conditions.

- The licensee's PRA model was found acceptable to support a TSTF-505 or TSTF-425 license amendment by the NRC.

- If the RIPE submittal relies on a TSTF-425 license amendment to demonstrate PRA acceptability, the DRA technical reviewer should review the following additional information:

    - PRA model changes and peer review history since implementation of TSTF-425.
    - Independent assessment reviews.
    - All open F&Os.
    - Key assumptions and sources of uncertainty.
    - External hazard applicability, including
        - Discussion of non-applicable external hazards.
        - Discussion of applicable external hazards, including the previously NRC-approved application that reviewed the PRA model for the applicable external hazards, and any changes, peer reviews, and open F&O discussions for that model.

The plant-specific PRA should include the capability to assess CDF and LERF, and the risk evaluation should include a quantified assessment of

all significant sources of risk (i.e., external events, internal flooding, and fires) that can be impacted by the issue being assessed. Where PRA models are not available, conservative or bounding analyses may be performed to quantify the risk impact (e.g., external events, low power and shutdown).

4.3.3. Evaluation of PRA Results

The DRA technical reviewer should confirm that the licensee calculated the changes in CDF and LERF as the difference between plant risk with and without the proposed change. For compliance issues, the change in risk is the difference between risk if the plant were fully compliant with its licensing basis, and risk with the plant in the non-compliant configuration requested in the submittal. For licensee-identified issues that do not involve a compliance issue, the change in risk is the difference between risk with the plant in the current configuration and with the plant in the configuration requested in the submittal. The risk analysis may not include any credit for proposed RMAs or other activities implemented to reduce the risk impact associated with the issue. The risk analysis should document any assumptions made when performing the risk evaluation, whether any parts of the issue were outside the scope of the licensee's PRA, and whether any surrogates were used to account for the impact of the issue. The final quantitative risk analysis should include an evaluation of the impact on internal events risk, as well as the impact on any relevant external events.

The PRA results should be compared to the relative change in risk of the licensee's overall CDF and LERF. An issue is not risk-significant (i.e., minimal or less than minimal) if all of the following apply:

- The issue contributes less than 1×10^{-7}/year to CDF.
- The issue contributes less than 1×10^{-8}/year to LERF.
- Cumulative risk is assessed on a plant-specific basis to be less than 1×10^{-4}/year for CDF and less than 1×10^{-5}/year for LERF once the impact of the proposed change is incorporated into baseline risk.

If the risk results are less than the criteria above, the issue is considered to have a minimal impact on safety.

4.3.4. Assessment of the Need for Risk Management Actions

Although RMAs should not be given credit in the risk analysis, the use of RMAs can lower risk when the risk is found to be minimal. If the issue assessed in the RIPE LAR was determined to have no safety impact, then RMAs are not required, but are encouraged. However, if the issue was determined to have a minimal impact on safety, then RMAs should be considered to offset the risk increase due to the issue.

RMAs are typically associated with managing configuration risk when equipment is out of service or for temporary changes. However, in the case of a RIPE application, the proposed change will become the permanent plant configuration if the LAR is approved. Therefore, only long-term actions to reduce risk associated with the new configuration should be considered, such as permanent procedure changes or simple plant modifications. For example, if an automatic interlock is defeated permanently, procedure changes to verify proper manual operation of the equipment may be appropriate to reduce the risk associated with removal of the automatic interlock.

4.3.5. Additional Considerations

Ensure the issue is well-defined: Confirm that the specific issue is appropriately defined and articulated in order to illustrate the safety impact due to the issue.

Realism so as to not bias the assessments: The level of realism and analyses will vary depending on the issue, but in order to avoid bias, realistic analysis is the objective. The license's assessment should include sensitivity analyses to address the key assumptions and sources of uncertainty that are driving the results. The key assumptions, details, and results of the sensitivity studies should be documented for consideration by the IDP (or GAET, if used). If the risk impact is exceedingly small, or clearly large, then a bounding evaluation may suffice.

Uncertainty considerations: Sensitivity analysis should be performed, commensurate with the impact of the issue, to address any key assumptions and sources of uncertainty that may influence the results. The key assumptions, details, and results of the sensitivity studies should be documented for consideration by the IDP (or GAET, if used).

Evaluation of the overall nature of the risk impact of a potential action: Both beneficial and adverse effects should be considered (e.g., replacing a small pump with a large pump could reduce the available margin of an emergency diesel generator, or closing and depowering pressurizer power operated relief valve block valves to prevent spurious operation could reduce effectiveness of feed and bleed operations).

Identifying the extent of the impact: The specific intended impact of the issue, as well as other related or indirect effects, should be addressed (e.g., FLEX provides mitigation for more than external hazards even though that is its fundamental intended purpose). In other words, one specific issue could impact the specific function under consideration as well as multiple other separate plant functions. This could include both positive and negative impacts that may not be immediately evident if the impacts of the issue are considered independently.

4.4. Emergency Plans (Replacement for LIC-101, Appendix B, Section 9.0, "Amendments for Emergency Plan Changes")

RIPE is not applicable to any issues for which the safety impact cannot be directly assessed using PRA. Therefore, LARs related to the emergency plans should not be considered for NRC review under the RIPE streamlined LAR review process.

4.5 Security-Related Amendments (Supplement to LIC-101, Appendix B)

RIPE is not applicable to any issues for which the safety impact cannot be directly assessed using PRA. Therefore, LARs related to the security program should not be considered for NRC review under the RIPE streamlined LAR review process.

4.6 Fuel Related Documents

RIPE is not applicable to issues related to changes in reactor fuel that cannot be directly assessed using PRA. Therefore, LARs related to the fuel changes should not be considered for NRC review under the RIPE streamlined LAR review process.

4.7 Technical Specification Amendments

The RIPE process is based on a licensee's implementation of a TSTF-505 or a TSTF-425 TS change amendment, as approved by the NRC. Approval of TSTF-505 or TSTF-425 ensures that the NRC staff has reviewed and approved a plant's PRA model as being appropriate for the RIPE review process.

A RIPE LAR involving the TSs should demonstrate that the PRA considerations described above justify that a probabilistic safety assessment shows that the requested change to the TSs is not significant to public health and safety.

If the LAR includes changes to TS, the Technical Specifications Branch should be included to give no technical objection and concurrence on the final package to verify the final version of the TS wording and formatting are correct.

5. PAPERWORK REDUCTION ACT

5.1 Paperwork Reduction Act

This document references voluntary guidance for implementing the mandatory information collections in 10 CFR Part 50 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget (OMB), under control number 3150-0011. Send comments regarding this information collection to the FOIA, Library, and Information Collections Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0011), Office of Management and Budget, Washington, DC 20503.

5.2 Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

Enclosure:
1. Appendix A: Change History

Appendix A - Change History

TSG Change History - Page 1 of 1			
Date	**Description of Changes**	**Method Used to Announce & Distribute**	**Training**
1/5/21	This is the initial issuance of TSG-DORL-2021-01 for using RIPE	E-mail to NRR staff	Recommended reading for DORL PMs and technical staff supporting license amendments and exemptions
6/30/21	Revised TSG to include guidance for applying RIPE for licensees with an NRC-approved TSTF-425, “Relocate Surveillance Frequencies to Licensee Control-RITSTF Initiative 5b,” license amendment	E-mail to NRR staff	Recommended reading for DORL PMs and technical staff supporting license amendments and exemptions
5/10/22	Revised TSG to include application of RIPE LAR reviews to TS changes.	E-mail to NRR staff	Recommended reading for DORL PMs and technical staff supporting license amendments and exemptions