



U.S. Nuclear Regulatory Commission Office of Nuclear Reactor Regulation NRR Temporary Staff Guidance

Temporary Staff Guidance No.: TSG-DORL-2020-XX

Temporary Staff Guidance Title: RISK-INFORMED PROCESS FOR
EVALUATIONS

Effective Date: MM DD, 2020

Approved By: Craig G. Erlanger

Date Approved: MM DD, 2020

Primary Contact: Name Name
301-415-xxxx
name.name@nrc.gov

Name Name
301-415-
xxxx
name.name@nrc.gov

Responsible Organization: NRR/DORL

ADAMS Accession No.: ML20XXXXXX

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Name Name
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Name.Name1@nrc.gov

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*by e-mail

OFFICE	NRR/DORL/LPLX/PM	NRR/DORL/LPLX/BC	OGC – NLO	NRR/DORL/D
NAME				CErlanger
DATE	/ /2020	/ /2020	/ /2020	/ /2020

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Temporary Staff Guidance – RIPE Related Exemption and License Amendment Requests

1. **OBJECTIVE**

This temporary staff guidance document provides Office of Nuclear Reactor Regulation (NRR) staff the framework for expedited processing of license amendments requests (LARs) and exemptions from 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 an LAR can be modeled using probabilistic risk assessment (PRA). These issues may be identified through inspections, corrective actions, or other licensee or regulatory processes.

The Division of Risk Assessment (DRA) is the only technical branch required for review of a RIPE submittal. The DRA review is expedited in that the RIPE process is based on the application of pre-existing risk-informed criteria that allow for an accelerated review and disposition of the submittal. An expedited Environmental (EnvCOE) review may also be required if the application does not clearly meet a categorical exclusion under 10 CFR 51.22(c).

This temporary staff guidance 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).

2. **BACKGROUND**

The RIPE expedited process is limited to licensees with a PRA model that was found acceptable to support 10 CFR 50.69, "Risk-informed Categorization and Treatment of Systems, Structures and Components of Nuclear Power Plants," and Technical Specification Task Force (TSTF) Traveler 505 "Risk Initiative 4b - Risk Informed Completion Times." Licensee's that have implemented NRC-approved applications to adopt 10 CFR 50.69 and TSTF-505 can leverage their PRA models to perform safety impact characterizations using the RIPE process and request licensing actions with the expectation that the NRC would use a streamlined review process if the issue is characterized as having a minimal safety impact. For the RIPE process, all of 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 contributes less than 1% of total CDF and LERF.
- The issue has no safety impact or minimal safety impact.
- Cumulative risk is acceptable.

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If the safety impact cannot be characterized as minimal, then the licensee may still submit the issue to the NRC for review, but the submittal does not qualify for the NRC streamlined RIPE review process.

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

- Actions needed to address inspection findings.
- Resolution of non-compliance 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.

The RIPE expedited process may not be used for the following:

- Any immediate actions necessary for continued safe operation (e.g., to support an NRC finding of adequate protection, to restore compliance with a Technical Specification; to resolve an environmental compliance issue with an adverse effect on public health and safety; or to 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 or changes to emergency planning programs).

3. **EXEMPTIONS: LIC-103 REVISION 2 BASIC REQUIREMENTS REPLACEMENTS OR SUPPLEMENTS**

3.1 **Work Planning (Replacement for LIC-103, Rev. 2 Basic Requirement 4.1)**

When a Licensing Project Manager (PM) receives the RIPE exemption request from a licensee, the PM will initiate a new project in the Reactor Program System (RPS). The PM should title the project as “[Plant Name] – [RIPE] Part XX Exemption.”

Note:

For the PM’s awareness, when submitting documents, the licensee is expected to follow Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1007, “Communications,” 10 CFR 50.4, “Written Communications,” 10 CFR 55.5, “Communications,” and 10 CFR 73.4, “Communications.”

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For the PM's awareness, the licensee is expected to submit a RIPE related exemption request using one of two methods below. Methods (1) and (2) are routine except for the addition of the wording in the comment field or the subject line:

- (1) in PDF format through the Electronic Information Exchange (EIE), along with an e-mail to the plant's Licensing PM. When submitting through EIE, include "EXPEDITE" in the Comment field.
- (2) as an attachment in PDF format to an e-mail addressed to the Document Processing Center (DocProcessing.Center@nrc.gov) and the plant's Licensing PM. The Subject line of the e-mail should include "EXPEDITE – RIPE Part XX Exemption Request."

Whichever method is used, as always, the licensee is expected to ensure that the PDF is in compliance with PDF settings per "Guidance for Electronic Submissions to the NRC" (ADAMS Accession No. ML13031A056) so that it can be promptly added to ADAMS. Documents that do not meet the E-submissions-rule guidance document criteria cannot be promptly processed into ADAMS. The Document Control Desk will address non-conforming documents with the Licensing PM, who will work with the licensee to resolve the issue and obtain a submittal that can be processed into ADAMS.

3.2 Review Request for Completeness for Expedited Review (Supplement for LIC-103, Rev. 2 Basic Requirement 4.2)

A RIPE submittal is limited to issues for which the safety impact associated with an issue addressed by an exemption request can be modeled directly or through the use of surrogates using PRA. The exemption technical justification provided by the licensee is a risk-related justification that leverages previous NRC evaluations and approvals regarding the plant's adoption of 50.69 and TSTF-505 license amendments. Therefore, DRA will be the only technical branch assigned for review of a RIPE exemption request. Environmental (EnvCOE) review may also be required if the application does not clearly meet a categorical exclusion under 10 CFR 51.22(c). However, it is expected that the nature of a RIPE application will be such that an expedited Environmental review can be completed if required. If the exemption request application requires the assignment of additional technical branches, then the application is not eligible for expedited review under the RIPE process.

Acceptance review in accordance with LIC-109, "Acceptance Review Procedures," will be followed for RIPE exemption requests; however, because of the predetermined content and structure of an expedited RIPE exemption request, the acceptance review steps may also be expedited. If

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the DORL PM or DRA (and EnvCOE, if required) technical reviewer acceptance review determines that the RIPE exemption request does not contain the information necessary to qualify as a RIPE submittal, or that an information insufficiency requiring a supplement is required, then the exemption request will not be dispositioned under the expedited RIPE process. Should this occur, the DORL PM will notify the licensee that the exemption request will continue to be processed under a normal NRC review schedule.

The acceptance review for a RIPE submittal will follow the tasks and expedited milestone schedule below, assuming the submittal meets the criteria in the previous paragraph and is acceptable for review:

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

	ACCEPTANCE REVIEW MILESTONES	SCHEDULE
1	PM creates project in the NRR workload management tool	T = 0
2	PM review for information sufficiency	< T = 14 days (2 weeks)
3	Technical staff provide results of technical sufficiency review to PM	< T = 14 days (2 weeks)
4	PM notify licensee or applicant (e.g., via call, e-mail or letter) that RIPE exemption request is acceptable	< T = 21 days (3 weeks)
5	PM records the date of acceptance in the NRR workload management tool	< T = 21 days (3 weeks)

In addition to the completeness and acceptability items listed in LIC-103, Rev. 2, Section 4.2, the following elements must be included in a RIPE exemption request:

- The issue that qualifies the exemption request as eligible for the RIPE expedited process is well defined.
- The RIPE submittal confirms that the plant has implemented an NRC approved TSTF-505 risk-informed technical specification amendment and has completed all license conditions of the associated safety evaluation.
- The RIPE submittal confirms that the plant has implemented an NRC approved amendment to adopt 10 CFR 50.69 and has completed all license conditions of the associated safety evaluation.
- The RIPE submittal includes the results of the integrated decision-making panel's (IDP's) review of the issue addressed in the submittal.
- The RIPE submittal states that the issue addressed in the request:
 - contributes less than 1×10^{-7} /year to CDF;
 - contributes less than 1×10^{-8} /year to LERF;
 - contributes less than 1% of total CDF and LERF;

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- has no safety impact or minimal safety impact;
- results in a cumulative risk that is acceptable.

3.3 Work Schedule (Replacement for LIC-103, Rev. 1 Basic Requirement 4.4)

The predetermined content and structure of a RIPE exemption request that has been determined to contain the RIPE-related items described above will be *planned* with an expedited schedule as follows (in calendar days and weeks):

	TECHNICAL REVIEW AND PROCESSING MILESTONES	SCHEDULE (continued from AR Milestones above)
1	DRA SE input / draft exemption provided to PM	49 days (7 weeks)
2	EnvCOE provide environmental review to PM (if required)	49 days (7 weeks)
3	PM provides exemption package to OGC	63 days (9 weeks)
4	OGC provides NLO to PM	77 days (11 weeks)
5	NRC grants exemption if acceptable	91 days (13 weeks)

The work schedule described above 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). The expedited RIPE process is predicated on the issue being justified as having minimal or no safety impact with the RIPE limitations and review elements clearly and completely addressed in the submittal. Should the technical review process determine that an RAI is required, the submittal cannot be dispositioned under the RIPE expedited process and the normal work schedule milestones will be applied. The DORL PM will notify the licensee if this occurs.

As described in Section 2.0 of this TSG, the RIPE process may not be used to support immediate actions or repairs. Therefore, verbal exemption approvals will not be completed using RIPE.

3.4 Technical Review of the Proposed Exemption (Supplement for LIC-103, Rev. 2 Basic Requirement 4.7)

3.4.1 Implementation of amendments to adopt 10 CFR 50.69 and TSTF-505

The RIPE expedited process can only be used by and for licensees that have implemented NRC-approved amendments for risk-informed

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initiatives 10 CFR 50.69 and TSTF-505. The RIPE process builds on the licensee's expanded use of PRA models for making day-to-day decisions and benefit from the use of IDPs that were constituted as part of implementation of 10 CFR 50.69. Licensees need to have implemented the IDP process and completed any license conditions associated with implementation of 10 CFR 50.69 and TSTF-505 to use this process, but do not need to have characterized any systems, structures, or components in accordance with 10 CFR 50.69.

Confirm that the IDP evaluation results, including a summary of the basis for each decision is documented in the RIPE exemption request. In particular, the assessment of any considerations identified by an industry or NRC generic assessment expert team (GAET) and how they apply to the plant and a basis for any plant-specific departures from the GAET assessment should be noted. The level of documentation should be such that a sufficient basis is provided 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 GAET, IDP and the licensee's subject matter expert must be clearly stated.

3.4.2 Use of acceptable/approved PRA model

Only those licensees with an acceptable PRA model can leverage their PRA models to perform quantitative risk assessments to support using this process, if all of the following conditions apply:

- The issue is completely within the scope of the licensee's PRA model or can be bounded using surrogates.
- The licensee has implemented risk-informed initiatives 10 CFR 50.69 and TSTF-505 and has completed all license conditions of the associated safety evaluation.
- The licensee's PRA model was found acceptable to support approvals of 10 CFR 50.69 and TSTF-505 applications by the NRC.
- The issue is within the scope of the portion(s) of the PRA model that was found acceptable by the NRC.

The plant-specific PRA must include the capability to assess CDF and LERF and the risk evaluation must 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., low power and shutdown).

3.4.3 Evaluation of PRA Results

Confirm that the change in CDF and LERF were calculated as the difference in the risk to the plant with the existing non-compliance and to the plant if it were fully compliant. The risk analysis may not include any credit for proposed risk management actions or other activities implemented to reduce the risk impact associated with the issue. The risk analysis must 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 must include an evaluation of the impact on internal events risk, as well as the impact on any relevant external events.

The PRA results will 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, and
- the issue contributes less than 1×10^{-8} /year to LERF, and
- the issue contributes less than 1% of total CDF and LERF (consistent with RG 1.174).

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

3.4.4 Assessment of the need for Risk Management Actions

If the issue assessed in the RIPE exemption request was determined to have no safety impact, then risk management actions (RMAs) are not required. However, if the issue was determined to have a minimal impact on safety, then RMAs must 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 non-compliances. However, in the case of a RIPE application, the non-compliance 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 need to 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.

3.4.5 Additional considerations

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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 license's assessment should include sensitivity analyses to address the key assumptions and sources of uncertainty that are driving the results. 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.

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.

3.5 Emergency Planning (Replacement for LIC-103, Rev. 2 Basic Requirement 4.9)

The RIPE process is not applicable to any issues for which the safety impact cannot be directly assessed using PRA. Therefore, exemption requests related to the emergency planning program will not be considered for NRC review under the RIPE expedited review process.

3.6 Design Certification Rule (Replacement for LIC-103, Rev. 2 Basic Requirement 4.10)

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

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information. However, the RIPE process is only applicable to operating plants and will not be considered for review of exemptions for elements of design certification information.

3.7 Preparation of Work Products (Supplement for LIC-103, Rev. 2 Basic Requirement 4.12)

In addition to verification that special circumstances exist, Section III.A of the exemption will 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 will include the RIPE safety evaluation input including verification that TSTF 505 and 10 CFR 50.69 amendments have been approved and implemented at the plant and that all associated license conditions have been completed. Section III.B will 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 the approved plant PRA.

4. License Amendment Requests: LIC-101, REVISION 6, APPENDIX B, REPLACEMENTS OR SUPPLEMENTS

4.1 Work Planning and Acceptance Review (Replacement for LIC-101, Rev. 6 Appendix B, Section 2.0)

When a Licensing Project Manager (PM) receives the RIPE LAR from a licensee, the PM will initiate a new project in the Reactor Program System (RPS). The PM should title the project as "[Plant Name] – [RIPE] License Amendment Request to XXXXX."

Note:

For the PM's awareness, when submitting documents, the licensee is expected to follow Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1007, "Communications," 10 CFR 50.4, "Written Communications," 10 CFR 55.5, "Communications," and 10 CFR 73.4, "Communications."

For the PM's awareness, the licensee is expected to submit a RIPE related exemption request using one of two methods below. Methods (1) and (2) are routine except for the addition of the wording in the comment field or the subject line:

- (1) in PDF format through the Electronic Information Exchange (EIE), along with an e-mail to the plant's Licensing PM. When submitting through EIE, include "EXPEDITE" in the Comment field.

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- (2) as an attachment in PDF format to an e-mail addressed to the Document Processing Center (DocProcessing.Center@nrc.gov) and the plant's Licensing PM. The Subject line of the e-mail should include "EXPEDITE – RIPE Part License Amendment Request to XXXX."

Whichever method is used, as always, the licensee is expected to ensure that the PDF is in compliance with PDF settings per "Guidance for Electronic Submissions to the NRC" (ADAMS Accession No. ML13031A056) so that it can be promptly added to ADAMS. Documents that do not meet the E-submissions-rule guidance document criteria cannot be promptly processed into ADAMS. The Document Control Desk will address non-conforming documents with the Licensing PM, who will work with the licensee to resolve the issue and obtain a submittal that can be processed into ADAMS.

A RIPE submittal is limited to issues for which the safety impact associated with an issue addressed by an LAR can be modeled using PRA. The LAR technical justification provided by the licensee is a risk-related justification that leverages previous NRC evaluations and approvals regarding the plant's adoption of 50.69 and TSTF-505 license amendments. Therefore, DRA will be the only technical branch assigned for review of a RIPE amendment. Environmental (EnvCOE) review may also be required if the application does not clearly meet a categorical exclusion under 10 CFR 51.22(c). However, it is expected that the nature of a RIPE application will be such that an expedited Environmental review can be completed if required. If the LAR requires the assignment of additional technical branches, then the application is not eligible for expedited review under the RIPE process.

Acceptance review in accordance with LIC-109, "Acceptance Review Procedures," will be followed for RIPE LARs; however, because of the predetermined content and structure of an expedited RIPE LAR, the acceptance review steps may also be expedited. If the DORL PM or DRA (and EnvCOE, if required) technical reviewer acceptance review determines that the RIPE LAR does not contain the information necessary to qualify as a RIPE submittal, or that an information insufficiency requiring a supplement is required, then the LAR will not be dispositioned under the expedited RIPE process. Should this occur, the DORL PM will notify the licensee that the LAR will continue to be processed under a normal NRC review schedule.

The acceptance review for a RIPE submittal will follow the tasks and expedited milestone schedule below, assuming the submittal meets the criteria in the previous paragraph and is acceptable for review:

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

	ACCEPTANCE REVIEW MILESTONES	SCHEDULE
1	PM creates project in the NRR workload management tool	T = 0
2	PM review for information sufficiency	< T = 14 days (2 weeks)
3	Technical staff provide results of technical sufficiency review to PM	< T = 14 days (2 weeks)
4	PM notify licensee or applicant (e.g., via call, e-mail or letter) that RIPE LAR is acceptable	< T = 21 days (3 weeks)
5	PM records the date of acceptance in the NRR workload management tool	< T = 21 days (3 weeks)

In addition to the acceptance review elements described in LIC-101, Rev. 5, Appendix B, Section 2.3, the following elements must be included in a RIPE LAR:

- The issue that qualifies the LAR as eligible for the RIPE expedited process is well defined.
- The RIPE submittal confirms that the plant has implemented an NRC approved TSTF-505 risk-informed technical specification amendment and has completed all license conditions of the associated safety evaluation.
- The RIPE submittal confirms that the plant has implemented an NRC approved amendment to adopt 10 CFR 50.69 and has completed all license conditions of the associated safety evaluation.
- The RIPE submittal includes IDP information regarding the issue addressed in the submittal.
- The RIPE submittal states that the issue addressed in the request:
 - contributes less than 1×10^{-7} /year to CDF;
 - contributes less than 1×10^{-8} /year to LERF;
 - contributes less than 1% of total CDF and LERF;
 - has no safety impact or minimal safety impact;
 - results in a cumulative risk that is acceptable.

4.2 Public Noticing (Replacement for LIC-101, Rev. 6 Appendix B, Section 3.0)

A bi-weekly federal register notice (BWN) per Section 3.1 of LIC-101, Rev. 6, Appendix B, will be submitted to the DORL bi-weekly notice coordinator. However, the BWN cannot be issued before the acceptance review is complete. The notice may be provided to the DORL BWN coordinator 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 an expedited (i.e.,

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approximately 140-days) RIPE review schedule for the LAR.

4.3 Safety Evaluation (Supplement for LIC-101, Rev. 6 Appendix B, Section 4.0)

As described in Section 4.1 of this TSG, DRA, and potentially EnvCOE, will be the only technical branches assigned for review of a RIPE amendment. Specific guidance related to the DRA review is provided in Section 4.6 below.

4.4 SE Planning and Control (Supplement for LIC-101, Rev. 6 Appendix B, Section 4.1)

The predetermined content and structure of a RIPE LAR that has been determined to contain the RIPE-related items described above will be *planned* with an expedited schedule as follows (in calendar days and weeks):

	TECHNICAL REVIEW AND PROCESSING MILESTONES	SCHEDULE (from submittal availability in ADAMS)
1	PM provide BWN to DORL BWN coordinator for issuance in <i>Federal Register</i>	42 days (6 weeks)
2	DRA SE input provided to PM	70 days (10 weeks)
3	EnvCOE provide environmental review to PM (if required)	70 days (10 weeks)
4	PM provides amendment package to OGC	105 days (15 weeks)
5	OGC provides NLO to PM	119 days (17 weeks)
6	PM issues amendment	140 days (20 weeks)

4.5 Requests for Additional Information (Replacement for LIC-101, Rev. 6 Appendix B, Section 4.3)

The work schedule described above allows for an approximate 140-day expedited review of RIPE LARs. This schedule does not accommodate the issuance and licensee response to Requests for Additional Information (RAIs). The expedited RIPE process is predicated on the issue being justified as having minimal or no safety impact with the RIPE limitations and review elements clearly and completely addressed in the submittal. Should the technical review process determine that an RAI is required, the submittal cannot be dispositioned under the RIPE expedited process, and the NRC's normal work schedule milestones will be applied. The DORL PM will notify the licensee if this occurs.

4.6 Safety Evaluation (Replacement for LIC-101, Rev. 6 Appendix B, Section 7.0)

The SE input will assess defense-in-depth and safety margin conclusions assessed by the IDP as documented in the RIPE LAR. The RIPE SE input will also include verification that TSTF 505 and 10 CFR 50.69 amendments have been approved and implemented at the plant and that all associated license conditions have been completed. Finally, the SE input will 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 approved plant PRA.

4.6.1 Implementation of amendments to adopt 10 CFR 50.69 and TSTF-505

The RIPE expedited process can only be used by and for licensees that have implemented NRC-approved amendments for risk-informed initiatives 10 CFR 50.69 and TSTF-505. The RIPE process builds on the licensee's expanded use of PRA models for making day-to-day decisions and benefit from the use of IDPs that were constituted as part of implementation of 10 CFR 50.69. Licensees need to have implemented the IDP process and completed any license conditions associated with implementation of 10 CFR 50.69 and TSTF-505 to use this process, but do not need to have characterized any systems, structures, or components in accordance with 10 CFR 50.69.

Confirm that the IDP evaluation results, including a summary of the basis for each decision is documented in the RIPE exemption request. In particular, the assessment of any considerations identified by an industry or NRC generic assessment expert team (GAET) and how they apply to the plant and a basis for any plant-specific departures from the GAET assessment should be noted. The level of documentation should be such that a sufficient basis is provided 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 GAET, IDP, and the licensee's subject matter expert must be clearly stated.

4.6.2 Use of acceptable/approved PRA model

Only those licensees with an acceptable PRA model can leverage their PRA models to perform quantitative risk assessments to support using this process, if all of the following conditions apply:

- The issue is completely within the scope of the licensee's PRA model or can be bounded using surrogates.

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- The licensee has implemented risk-informed initiatives 10 CFR 50.69 and TSTF-505 and has completed all license conditions of the associated safety evaluation.
- The licensee's PRA model was found acceptable to support approvals of 10 CFR 50.69 and TSTF-505 applications by the NRC.
- The issue is within the scope of the portion(s) of the PRA model that was found acceptable by the NRC.

The plant-specific PRA must include the capability to assess CDF and LERF and the risk evaluation must 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., low power and shutdown).

4.6.3 Evaluation of PRA Results

Confirm that the change in CDF and LERF were calculated as the difference in the risk to the plant with the existing non-compliance and to the plant if it were fully compliant. The risk analysis may not include any credit for proposed risk management actions or other activities implemented to reduce the risk impact associated with the issue. The risk analysis must 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 must include an evaluation of the impact on internal events risk, as well as the impact on any relevant external events.

The PRA results will 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, and
- the issue contributes less than 1×10^{-8} /year to LERF, and
- the issue contributes less than 1% of total CDF and LERF (consistent with RG 1.174).

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

4.6.4 Assessment of the need for Risk Management Actions

If the issue assessed in the RIPE exemption request was determined to have no safety impact, then risk management actions (RMAs) are

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not required. However, if the issue was determined to have a minimal impact on safety, then RMAs must 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 non-compliances. However, in the case of a RIPE application, the non-compliance 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 need to 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.

4.6.5 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 license's assessment should include sensitivity analyses to address the key assumptions and sources of uncertainty that are driving the results. 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.

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

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considered independently.

**4.7 Emergency Planning (Replacement for LIC-101, Rev. 6
Appendix B, Section 9.0)**

The RIPE process is not applicable to any issues for which the safety impact cannot be directly assessed using PRA. Therefore, exemption requests related to the emergency planning program will not be considered for NRC review under the RIPE expedited LAR review process.